November 10, 2021

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA, INC.
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FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029

Dear Sir or Madam:

After our recent conference call on Tuesday October 12, 2021, with Eugene Chuang from the Center for Tobacco Products, where CTP has requested that PMTA and MRTP Annual Report requirements for Swedish Match USA, Inc's. ("Swedish Match", "our" or "we") General Snus products be combined to encompass one report submission, please accept this document to meet the report requirements as follows:

FDA's PMTA Marketing Orders, included as **Attachment A -** Periodic Report requirements under section 910(f) of the FD&C Act, Postmarket Annual Report.

FDA's MRTP Modified Risk Granted Orders, included as **Attachment B** – Risk Modification ("Granted Orders"), dated October 22, 2019.

Swedish Match acknowledges the obligation of the PMTA Marketing Orders, that beginning October 2016, FDA may determine whether continued marketing of the tobacco product is appropriate for the protection of public health, or whether there are or may be grounds for withdrawing or temporarily suspending the Marketing Order.

Swedish Match acknowledges the obligation per Appendix C, Section IV, of the Granted Modified Risk Orders, the requirement that on an annual basis the PMSS Protocols, a Description of the Implementation of all Advertising and Marketing Plans, Annual Age Verification/Youth Access Policies & Procedures Review, and Manufacturing Information must be submitted to FDA, as required under section 911(i)(2) of the FD&C Act.

Please note that due to inability to convert certain data/tables/information to Adobe format, and to allow data information to be viewed in a more legible manner, certain attachments/appendices are included as Excel documents (noted in bold print below) and can be located attached to this document (please see the "paperclip" icon on the left hand column of this filing to view the files).

As we have done for previous reports, Swedish Match will simultaneously submit media (.mp4) files as a separate independent transmission. This is due to the size of the media/video files and previous difficulty with the inability of Adobe format to link the media files to the final submission.

For recordkeeping purposes, Swedish Match provides the following information relative to the following STNs for the period November 2020 through October 2021:

1. **PM0000010 – PM0000017** *(*PM0000010, PM0000011, PM0000013 & PM0000015 are no longer in Market in the U.S.)*
2. **MR0000020 - MR0000022, MR0000024 - MR0000025, and MR0000027- MR0000029** *(*MR0000020 -MR0000021, MR0000024 & MR0000027 are no longer in Market in the U.S.)*

LIST OF GENERAL TOBACCO PRODUCT SUBMISSIONS – Current Marketing Status

Product Manufacturer	**Swedish Match USA, Inc.**
Product Category	**Smokeless Tobacco Products**
STN: Product Name	***PM0000010 & MR0000020: General Loose***
Product Sub-Category	Loose Snus
Package Type	Cardboard Can with Plastic Lid
Package Quantity	45.0 g
Characterizing Flavor	None
Marketing Status	***Out of Market - Effective 6/12/2017 was taken off the market.***
STN: Product Name	***PM0000011 & MR0000021: General Dry Mint Portion Original Mini***
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	6.0 g
Characterizing Flavor	Mint
Marketing Status	***Out of Market - Effective 12/31/2020 was taken off the market.***
STN: Product Name	**PM0000012 & MR0000022: General Portion Original Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	None
Marketing Status	**In Market.**
STN: Product Name	***PM0000013 & MR0000024: General Classic Blend Portion White Large – 12 ct***
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	10.8 g
Characterizing Flavor	None
Marketing Status	***Out of Market - effective 1/15/2016 was taken off the market.***
STN: Product Name	**PM0000014 & MR0000025: General Mint Portion White Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can

Package Quantity	24.0 g
Characterizing Flavor	Mint
Marketing Status	**In Market.**
STN: Product Name	***PM0000015 & MR0000027: General Nordic Mint Portion White Large – 12 ct***
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	10.8 g
Characterizing Flavor	Mint
Marketing Status	***Out of Market - effective 1/15/2016 was taken off the market.***
STN: Product Name	**PM0000016 & MR0000028: General Portion White Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	None
Marketing Status	**In Market.**
STN: Product Name	**PM0000017 & MR0000029: General Wintergreen Portion White Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	Wintergreen
Marketing Status	**In Market.**

Swedish Match submits that this submission and the information we are supplying in connection with this Report, are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact us.

Sincerely yours,

Gerard J. Roerty, Jr.

Vice President, General Counsel & Secretary

Package Quantity	24.0 g
Characterizing Flavor	Mint
Marketing Status	**In Market.**
STN: Product Name	***PM0000015 & MR0000027: General Nordic Mint Portion White Large – 12 ct***
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	10.8 g
Characterizing Flavor	Mint
Marketing Status	***Out of Market - effective 1/15/2016 was taken off the market.***
STN: Product Name	**PM0000016 & MR0000028: General Portion White Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	None
Marketing Status	**In Market.**
STN: Product Name	**PM0000017 & MR0000029: General Wintergreen Portion White Large**
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	Wintergreen
Marketing Status	**In Market.**

Swedish Match submits that this submission and the information we are supplying in connection with this Report, are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact us.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr.

Vice President, General Counsel & Secretary

Annual Report Attachments (Links located in Bookmarks)

Attachment A – PMTA Marketing Orders
Attachment B - Modified Risk Granted Orders dated 10/22/19
Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
    Attachment 1A.1 – General PMSS Sales
    Attachment 1A.2 – General PMSS Distribution Report **(Excel Attachment)**
Attachment 1B - Annual PMSS Adverse Experiences Report
Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health
    Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20
Attachment 2A - General Snus Analysis of Implementation of Marketing Plans
Attachment 3A- FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18
Attachment 3B (1-4) – Full Text Articles
    Attachment 3B.1 - XPaper_Morgan and Capella_ijerph-18-00576
    Attachment 3B.2 - XPaper_Smoker's Exposure to Perceived Modified Risks... (1)
    Attachment 3B.3 - XPaper_Wackowski_O_ (2021)_BMJTobControl
    Attachment 3B.4 - XPaper_Watten and Watten_11782218211027124
Attachment 4A - Annual Reporting Deviations Summary **(Excel Attachment)**

Document Appendices – Annual Post-Market Surveillance & Studies Report

Appendix 1C (1.1) - Descriptive Tables 1-4: General Snus Patterns of Use Study – Wave 2 Study Report **(Excel Attachment)**
Appendix 1C (1.2) - Study Questionnaire: General Snus Patterns of Use Study – Wave 2 Study Report
Appendix 1C (1.2a) - After Questionnaire General Snus PMSS Baseline Invite
Appendix 1C (1.3) - Protocol: General Snus Patterns of Use Study – Wave 2 Study Report
Appendix 1C (1.4) - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 2 Study Report
Appendix 1C (1.5) – Study Report: General Snus Patterns of Use Study – Wave 2 Study Report

Document Appendices – Analysis of Implementation of Marketing Plans

Appendix 2A (1) - General Snus Website – FULL: Marketing Plan
Appendix 2A (2) - General Snus Website - MRTP PAGES ONLY: Marketing Plan
Appendix 2A (3) - General Snus Advertising: Marketing Plan
Appendix 2A (4) - General Snus DM, EM, FB, POS, Pkg: Marketing Plan
Appendix 2A (5) - General Snus Digital Ad Domain List: Marketing Plan **(Excel Attachment)**
Appendix 2A (6) - General Snus Store List: Marketing Plan **(Excel Attachment)**
Appendix 2A (7) - General Snus Trade Advertising Plan: Marketing Plan
Appendix 2A (7.1) – General Snus Trade Media Advertising Plan **(Excel Attachment)**

Document Appendices – Summary of AFPPH Research Reports

Appendix 3A (1) – Consumer Insights Qualtrics Survey (October 2020)

Tables

Table 1.a. - Summary of publications not previously reported

Section 1 – Annual Post-Market Surveillance and Studies Report Summary

General Snus Use Behavior and Consumer Understanding and Perception – *[Common to both MRTP & PMTA Reports]*

See Appendix 3A (1) – Consumer Insights Qualtrics Survey (October 2020)

Sales and Distribution Reporting – *[Common to both MRTP & PMTA Reports]*

See Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting

See Attachment 1A.1 – PMSS Sales

See Attachment 1A.2 – PMSS Distribution Report **(Excel Attachment)**

Adverse Experiences Reporting - *[Common to both MRTP & PMTA Report]*

See Attachment 1B - Annual PMSS Adverse Experiences Report

Surveillance Consumer Perception Behavior & Health – *[MRTP Report Specific]*

See Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health

See Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20

- **Appendix 1C (1.1)** - Descriptive Tables 1-4: General Snus Patterns of Use Study – Wave 2 Study Report **(Excel Attachment)**
- **Appendix 1C (1.2)** - Study Questionnaire: General Snus Patterns of Use Study – Wave 2 Study Report
  - **Appendix 1C (1.2a)** - After Questionnaire General Snus PMSS Baseline Invite
- **Appendix 1C (1.3)** - Protocol: General Snus Patterns of Use Study – Wave 2 Study Report
- **Appendix 1C (1.4)** - Statistical Analysis Plan: Genera Snus Patterns of Use Study – Wave 2 Study Report
- **Appendix 1C (1.5)** – Report: General Snus Patterns of Use Study – Wave 2 Study Report

Section 2 - Advertising and Marketing Plans Annual Report

General Snus MRTP Marketing Support Plan – *[Common to both MRTP & PMTA Reports]*

See Attachment 2A - General Snus Analysis of Implementation of Marketing Plans

- Appendix 2A (1) - General Snus Website – FULL: Marketing Plan
- Appendix 2A (2) - General Snus Website - MRTP PAGES ONLY: Marketing Plan
- Appendix 2A (3) - General Snus Advertising: Marketing Plan
- Appendix 2A (4) - General Snus DM, EM, FB, POS, Pkg: Marketing Plan
- Appendix 2A (5) - General Snus Digital Ad Domain List: Marketing Plan **(Excel Attachment)**
- Appendix 2A (6) - General Snus Store List: Marketing Plan **(Excel Attachment)**
- Appendix 2A (7) - General Snus Trade Advertising Plan: Marketing Plan
- Appendix 2A (7.1) – General Snus Trade Media Advertising Plan **(Excel Attachment)**

Labeling Changes and Revised Full Color Printed Labeling Submission – *[PMTA Report Specific]*

In conjunction with this Report for the period October 1, 2020 – September 30, 2021, we are supplying copies of the revised top and side label final print proofs which include dimensions, Pantone color numbers, and legible text **(See Appendix 2A (4)** General Snus Packaging).

As this is the sixth annual report for this product, we are not required to submit actual physical labels for this product.

Section 3 – Annual Age Verification/Youth Access Procedures Review

Summary of Implementation & Effectiveness of Age-related Policies/Procedures - *[MRTP Report Specific]*

Swedish Match does not make any sales direct to consumers. Swedish Match focuses its efforts on responsible marketing practices. Information on Swedish Match's responsible marketing practices can be found in Section 2-Advertising and Marketing Plans Annual Report **(See Appendix 2A (3))**.

Section 4 - Manufacturing Information Annual Report

Manufacturing Facility Changes - *[Common to both MRTP & PMTA Reports]*

There has been no change to the manufacturing, facilities, or controls during the reporting period October 1, 2020 – September 30, 2021.

Manufacturing Deviations Relating to Characteristics of the Final Product – *[Common to both MRTP & PMTA Reports]*

Swedish Match is supplying a summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicated any deviation(s) that may affect the characteristics of the final product for the reporting period October 1, 2020 – September 30, 2021 (**See Attachment 4A -** Annual Reporting Deviations Summary) **(Excel Attachment)**. There were no manufacturing deviations for the reporting period for any of the General Snus products in market.

Section 5 – Summary – How the Tobacco Product Continues to be Appropriate for the Protection of the Public Health (AFPPH)

Ongoing Studies/Publications/Science Data – *[PMTA Report Specific]*

Swedish Match asserts this report for the period October 1, 2020 – September 30, 2021, contains appropriate scientific evidence and, to the extent possible, addresses the recommendations made by FDA in its June 1, 2018, correspondence (**See Attachment 3A-** FDA Recommendations Letter for PM0000011, PM0000012, PM0000014, PM0000016 and PM0000017). The attached research reports, containing information as requested by FDA, allow for a complete and substantive review of all General Snus products in market, and demonstrate that the tobacco product continues to be appropriate for the protection of public health.

The Post Market Surveillance & Studies Report mentioned above includes actual use behavior. This information can be found in **Attachment 1C** - Annual PMSS Surveillance Consumer Perception Behavior & Health.

For the reporting period October 1, 2020 – September 30, 2021, we provide the following research:

1. Qualtrics Survey (October 2020) **Appendix 3A (1)** - Consumer Insights Use Behavior Qualtrics Survey

The subsequent bullets summarize the attached research, specifically addressing the inclusions recommended by FDA in its June 1, 2018, correspondence:

- **Qualtrics Survey (October 2020): Appendix 3A (1):**
  - This complete study (n = 1,049) focuses on messages and ad concepts regarding General Snus. It does not include actual usage behavior.
  - Summary information by key demographic variables (e.g., tobacco use status, age, and

gender) is located in the "Demographics" slide **(See Attachment 3A (1).**

Swedish Match is supplying a summary of publications not previously reported (**See Table 1.a.**, below). Full text articles are available in **Attachment 3B (1-4)** - Full Text Articles. Swedish Match conducted a literature search of PubMed and Google Scholar using "snus" and "snus 2020" and "snus 2021"to access a general outline of peer reviewed Swedish snus-focused articles published in 2020 and 2021. Criteria for labeling articles as "not relevant" included articles not in English, articles using only U.S. snus (e.g., Camel Snus), and articles only mentioning snus in passing while not using snus in its research design. These "not relevant" articles are not attached.

Table 1.a. Summary of publications not previously reported

Item#	Publication Citation and Summary
1.	Morgan, J.C. and Cappella, J.N. (2021): **Harm Perceptions and Beliefs about Potential Modified Risk Tobacco Products**, International Journal of Environmental Research and Public Health, 18(2), 576, retrieved from https://doi.org/10.3390/ijerph18020576. • Research assessed MRTP risk perceptions and beliefs by adult tobacco consumers. Authors recruited 864 adult current and former smokers in August 2019 to assess perceptions of risk surrounding snus, heated tobacco, and e-cigarettes. • Participants read a paragraph describing the potential for the FDA to authorize MRTPs and a brief description of MRTPs. The most endorsed beliefs for each product were that they contained nicotine and that they were risky. • For snus, the beliefs that the product was not addictive and tasted good were associated with increased odds of intending to try snus.
2.	Wackowski, O. A., O'Conner, R.J., and Pearson, J.L. (2020): **Smokers' Exposure to Perceived Modified Risk Claims for E-Cigarettes, Snus, and Smokeless Tobacco in the United States**, Nicotine & Tobacco Research, ntaa159, retrieved from https://doi.org/10.1093/ntr/ntaa159. • Assessment of Wave 3 of the US-based Population Assessment of Tobacco and Health (PATH) study question which asks smokers if they had seen any e-cigarettes, snus, or other smokeless tobacco (SLT) products that claim to be "less harmful" in the past 12 months as well as their likelihood of using products with these claims in the next 30 days. • Results indicate that significantly fewer smokers saw snus (5.1%) or other SLT (5.6%) with "less harmful" claims compared with e-cigarettes (29.1%). The abstract states that for "each product, the prevalence of MRTP claim exposure was higher among smokers who perceived the product to be less harmful than smoking, who currently used the product, and who had higher rates of tobacco advertising exposure at the point of sale. • Among smokers who noticed products with "less harmful" claims, about one-quarter said they would use them in the future (24%–27%)."
3.	Wackowski, O.A., O'Conner, R.J., Diaz, D., Rashid, M., Lewis, M.J., Greene, K. (2021): **'95% less harmful'? Exploring reactions to quantitative modified risk claims for snus and e-cigarettes**, Tobacco Control, Epub ahead of print: 30 Sep 2021, retrieved from https://doi.org/10.1136/tobaccocontrol-2020-056303 • With limited research existing on reactions to quantitative MRTP messages, the study conducted 12 focus groups in the USA in 2019 with current smokers (ages 21–66) and young adult (ages 18–25) non-smokers (n=57). • Participants discussed messages stating that use of snus and vaping products have been estimated by scientists to be about 90% and 95% less harmful than smoking cigarettes, respectively. • Quantitative claims suggesting high levels of reduced risk when comparing e-cigarettes or smokeless tobacco/snus relative to cigarettes may be successful in gaining attention and being persuasive for some audiences, particularly, if from more credible sources.

4.	Watten R.G. and Watten, V.P. (2021): **Snus and Alcohol: Mutually Rewarding Effects in the Brain? A Matched Controlled Population Study**, Substance Abuse: Research and Treatment Volume 15: 1–9, retrieved from https://doi.org/10.1177/11782218211027124 • The research assessed the relationship between use of snus and alcohol in a matched controlled population study. The aim of the current study was to investigate alcohol consumption and drinking habits in a sample of users of snus compared to a sample of non-users matched on age and gender, including frequency of drinking in the weekdays, weekends, frequency of intoxication and frequency of excess drinking. • In the design, drinking habits and alcohol consumption in a group of users of snus (n=1043, mean age=35.20; n men=749, n women=294) were compared to a control group of non-users matched on age and gender (n=1043, mean age=35.65; n men=749, n women=294). • Users of snus had a higher frequency of drinking, higher frequency of intoxication, and showed more excess drinking.

Sales and Distribution Reporting – *[Common to both MRTP & PMTA Reports]*

Swedish Match is supplying a summary of sales and distribution data for the reporting period October 1, 2020 – September 30, 2021. This information includes total U.S. sales reported in dollars and units (i.e., number of cans), and volume (i.e., net weight multiplied by units) with breakdowns by US census region and retail markets and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops).

See Attachment 1A - Annual PMSS Sales & Distribution Reporting

Attachment 1A.1 – PMSS Sales

Attachment 1A.2 – PMSS Distribution Report **(Excel Attachment)**

Adverse Experiences Reporting - *[Common to both MRTP & PMTA Report]*

Swedish Match did not receive any reports of serious or unexpected adverse experiences, relative to General snus tobacco products in market for the reporting period October 1, 2020 – September 30, 2021. There have been no changes to the reference risk information.

We are supplying a summary of consumer contacts (all other reported adverse experiences) relative to General tobacco products in market for the reporting period October 1, 2020 – September 30, 2021. (**See Attachment 1B** - Annual PMSS Adverse Experiences Report)

Data on Current Product Users - *[PMTA Report Specific]*

Other than the research (provided above at **Attachment 3B (1-4)**) and sales and distribution data (provided above at **Attachments 1A.1 & 1A.2.**) supplied in attachments referenced above, there is no current product user data for the reporting period October 1, 2020 – September 30, 2021. Likewise, there has been no change in the intended target market for these products for the reporting period October 1, 2020 – September 30, 2021.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000010

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Loose
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
Tobacco Cut Size:[2]	(b)(4) [redacted]

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000010**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000010**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 05:58:03 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Loose Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000011

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Dry Mint Portion Original Mini
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
Portion Count:	20 pouches
Portion Mass:	300 mg
Portion Length:	28 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b)(4) [redacted]

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

---

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000011**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000011**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

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Center for Tobacco Products
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Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 05:59:58 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Dry Mint Portion Original Mini Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000012

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Portion Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	33 mm
Portion Width:	18 mm
Portion Thickness:	6 mm
Tobacco Cut Size:[2]	(b)(4) [redacted]

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

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[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instru.ctions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000012**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000012**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:00:57 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Portion Original Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000013

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Classic Blend Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b) (4) [redacted]

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000013**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000013**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
    b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
    c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
    d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
    e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
    a. A comparison of each change to what was described in the PMTA;
    b. The rationale for making each change; and
    c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
    a. The labeling should include all the panels, be presented in the actual size and color with legible text.
    b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:01:52 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Classic Blend Portion White Large - 12ct

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000014

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Mint Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b)(4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

---

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000014**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000014**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:03:46 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Mint Portion White Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000015

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Nordic Mint Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b)(4) [redacted]

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000015**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000015**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
    b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
    c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
    d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
    e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
    a. A comparison of each change to what was described in the PMTA;
    b. The rationale for making each change; and
    c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
    a. The labeling should include all the panels, be presented in the actual size and color with legible text.
    b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:04:40 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Nordic Mint Portion White Large - 12ct Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000016

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b)(4) [redacted]

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

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[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000016**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000016**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:05:34 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Portion White Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000017

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Wintergreen Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b)(4) [redacted]

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

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[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000017**.

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000017**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:06:25 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Wintergreen Portion White Large Labeling

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

October 22, 2019

MODIFIED RISK GRANTED ORDERS – –
RISK MODIFICATION

Swedish Match USA, Inc.
Attention: Gerard Roerty, Vice President, General
Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): MULTIPLE STNs, See Appendix A

Dear Mr. Roerty:

We completed review of your MRTPAs[1] and are issuing modified risk granted orders for the tobacco products identified in Appendix A.

Based on our review of your MRTPAs, we find that the modified risk tobacco products, as described in your applications and specified in Appendix A, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Therefore, we authorize the marketing of the modified risk tobacco products with the following modified risk information:

> "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

Under the provisions of section 911, you may introduce or deliver for introduction into interstate commerce the modified risk tobacco products, in accordance with these risk modification orders. These risk modification orders include requirements related to conditions of marketing under section 911(h) and postmarket surveillance and studies under section 911(i) as well as requests related to other record retention and reporting, as outlined in the attached appendices.

These orders expire 5 years from the issue date of this letter. If you wish to renew your orders, we recommend a request for renewal is received by FDA 360 days prior to the expiration date. Your renewal may cross-reference your MRTPAs that are subject to these orders.

The requirements in these risk modification orders are intended to help ensure that your modified risk tobacco products, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not

[1] Modified Risk Tobacco Product Applications (MRTPAs) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

currently use tobacco products. However, compliance with these requirements alone is not a guarantee that the modified risk tobacco products, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, particularly if, despite these measures, there is a significant increase in youth initiation or initiation by non-users. FDA will continue to monitor the marketing of your modified risk tobacco products and their impact on the population.

These orders authorizing the marketing of these modified risk tobacco products do not mean FDA "approved" the modified risk tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads, or would mislead consumers into believing, among other things, that the modified risk tobacco products specified in Appendix A are "approved" by FDA.[2] The modified risk tobacco products subject to these risk modification orders are subject to withdrawal as described in section 911(j).

We remind you that all regulated tobacco products, including the modified risk tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the modified risk tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[2] See Section 301(tt) of the FD&C Act.
[3] http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] https://www.fda.gov/industry/fda-esubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions regarding these orders, please contact Shireen Fotelargias, Regulatory Health Project Manager, at (240) 402-0435 or Shireen.Fotelargias@fda.hhs.gov.

If you have any questions regarding postmarket activities for the modified risk tobacco products subject of these orders, please contact Eugene Y Chuang, at (240) 402-9302 or Eugene.Chuang@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.10.22 08:58:56 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A- List of Tobacco Products That Are Subject of This Letter
Appendix B- Required Postmarket Surveillance and Studies
Appendix C- Advertising and Promotion Requirements
Appendix D- Recordkeeping and Retention
Appendix E- Manufacturing Information

Appendix A

List of Tobacco Products That Are Subject of This Letter

Common Attributes of MRTPAs	
Submission Date:	June 10, 2014
Receipt Date:	June 10, 2014
Product Manufacturer:	Swedish Match USA, Inc.
Product Category:	Smokeless Tobacco Products
Modified Risk Information:	Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
MR0000020: General Loose[7]	
Product Subcategory:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
MR0000021: General Dry Mint Portion Original Mini[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
MR0000022: General Portion Original Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000024: General Classic Blend Portion White Large – 12 ct[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
MR0000025: General Mint Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
MR0000027: General Nordic Mint Portion White Large – 12 ct[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint

[7] STN: Product Name (Brand/sub-brand or other commercial name used in commercial distribution)

MR0000028: General Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000029: General Wintergreen Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen

Appendix B

Required Postmarket Surveillance and Studies (PMSS)

Under Section 911(i)(1) of the FD&C Act, FDA must require postmarket surveillance and studies for any product for which an applicant received an order under 911(g)(1) in order to: "...determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product."

I. PMSS Content

MRTP Use Behavior and Consumer Understanding and Perception

After receiving authorization, the determination of whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole is likely to be driven by use behavior. Therefore, monitoring use of the eight General Snus products that are the subject of these applications in terms of uptake, dual use, and complete switching is required. In particular, your PMSS must assess the extent to which new MRTP users were non-users, smokers, or other tobacco product users before initiating the MRTPs and the extent to which new users of the MRTPs become exclusive users or dual users with cigarettes or other tobacco products over time. Relatedly, such surveillance must include an assessment of consumers' understanding of the claim and perceptions of the products. In particular, PMSS must assess the extent to which users of these products understand that, to reduce their risk of disease relative to smoking as described in the modified risk information, they must use General Snus exclusively. **To adequately assess these impacts, you must conduct PMSS that include assessing users' behavior and consumer understanding at multiple time points.**

In addition, FDA has determined that assessing the impact of your MRTP orders on uptake of the products requires surveillance of MRTP sales and distribution, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting MRTP sales and distribution in the U.S. by product, major metropolitan areas, and channels where the products are sold (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops). Your annual PMSS report must include:

- U.S. sales and distribution of the tobacco products by quarter since the granting of your modified risk granted orders (for the initial reporting period) or the previous reporting period (for all reports that follow), including, for each MRTPA STN, total U.S. sales and distribution reported in dollars and units, and broken down by major metropolitan areas, and channels where the products were distributed and sold during the reporting period (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops).
- A brief synthesis and summary of the sales and distribution data for the initial reporting period or the previous reporting period (for all reports that follow), including annual and quarterly growth rate (percent change) in total U.S. sales and distribution of the tobacco products for each MRTPA STN, post-MRTP authorization.

MRTP Use and Adverse Experiences

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole, your PMSS must include ongoing surveillance of all adverse experiences associated with the use of the MRTPs. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported adverse experiences for the tobacco products, which includes a listing of all adverse experiences during the reporting period and a cumulative list, including all serious and unexpected adverse experiences previously reported. The summary must be accompanied by an analysis of the reports and a statement of any changes to risk information related to the products including nature, frequency, and potential aggravating factors.

In addition, the PMTA orders for your General snus products, issued on November 10, 2015, require you to report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product within 15 calendar days after the report is received by you. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. We request that when submitting such reports, you reference both your PMTAs and you MRTPAs for these products. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT FOR STN(s) PM0000010-PM0000017 and MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029.**

For purposes of this reporting, *serious adverse experience* means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of this reporting, *unexpected adverse experience* means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA (including the results of human subject investigations) and other relevant sources of information, such as postmarket reports and studies;

- The expected natural progression of any underlying disease, disorder, or condition of the person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

Surveillance of New Research Study Findings the MRTPs and Consumer Perception, Behavior, or Health

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole, your PMSS must include surveillance of new research study information about the MRTPs and consumer perception, behavior, or health. In particular, your PMSS protocol must include procedures for monitoring and assessing findings both in your own studies (i.e., studies conducted by you or on your behalf) and in publications including any new scientific data (published or otherwise) regarding the MRTPs and consumer perception, behavior, or health. Your annual PMSS report must include:

- A summary of significant findings about the tobacco products from research studies conducted by you or on your behalf, whether or not such studies were specifically required under this order. A summary of significant findings in publications not previously reported and full copies of the articles. This must include any new scientific data (published or otherwise) on the MRTPs and consumer perception, behavior, or health.

II. Submitting PMSS Protocols and Reports

Within 30 days of receiving this notice, you must submit complete protocols for your PMSS as required under section 911(i)(2) of the FD&C Act. Label your submission clearly as a "PMSS Protocol," and reference your MRTPA Submission Tracking Numbers (STNs). If you have more than one protocol, submit each protocol as a separate submission. If applicable, each protocol should include the name(s) of the principal investigator(s) and materials that demonstrate the relevant professional credentials and training that qualify them to lead the study. Within 60 days of receipt of the protocol(s), FDA will determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol(s) will result in collection of the data or other information that FDA designates as necessary to protect public health, pursuant to section 911(i)(2) of the FD&C Act. FDA will notify you of and provide opportunities to address, any deficiency in the submission. If the PMSS protocol is amended subsequent to FDA approval, FDA must receive the amended protocol promptly. For protocol amendments that are administrative in nature (e.g., corrections in punctuation or titles), the amended protocol must be received by FDA within 30 days of the update. For protocol amendments that seek to modify the study design (including endpoints, sites, questionnaires, methodology, etc.) or other scientific parameters, you may not initiate the change until you receive FDA approval.

As part of the requirement to conduct PMSS, you must initiate and conduct your PMSS per timeframes established in your protocols and approved by FDA. Note that for PMSS that involve human subjects, the anticipated start date for each study must account for the time required for securing IRB approval, as needed. In addition to specifying the start date, your protocols must contain timelines for completion of major study milestones including, as applicable, the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. If you deviate from these timelines, we request that you report the deviation within 30 days to FDA.

Section 911(i) requires that the results of PMSS be submitted on an annual basis. These reports must be identified as "PMSS Report", and the MRTPA STNs should be referenced for each report. The PMSS Report must indicate the beginning and ending date of the period covered by the report and must include accomplishments since the last reporting period. For quantitative updates on studies in progress (e.g., participant accrual), reports should describe both interim (since the last reporting period) as well as cumulative (since study initiation) accomplishments. The PMSS Report describing studies in progress must describe the status of PMSS, including, as applicable the status of recruitment, data collection, and analysis; a summary of the study milestones achieved and any deviations from the agreed upon timelines in the protocol; a summary of protocol amendments; and a summary of any preliminary analyses conducted. Once a study is completed, the PMSS Report should include the complete final study report.

Appendix C
Advertising and Promotion Requirements

I. Recordkeeping and Retention

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to establish and maintain the following records:

- Records pertaining to the products' labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
  - Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information;
  - Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
  - Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
  - Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
  - Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/or promotional materials;
  - Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
    - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
    - Targeting of specific adult audiences by age-range(s), including young adult audiences, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
    - Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    - Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
    - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
    - Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products
  - Copies of all records pertaining to media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and

- Policies and procedures for real-time digital media monitoring to identify, correct, and prevent any delivery of advertising impressions to youth, ages 17 years and under, including documentation of such monitoring activities and implementation of corrective and preventive measures

II. Notifications

Under section 911(h)(5) of the FD&C Act these risk modification orders require that for the first six months after the date of your modified risk order you provide FDA a 30-day notification for all labeling, advertising, marketing, and/or promotional materials for which you plan on disseminating to the public. These notifications are not for pre-approval, but are required so that FDA can have timely access to your marketing plans and materials, and if needed, provide you advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of your products will benefit the health of the population as a whole. You may begin disseminating the materials 30 days after providing notification to FDA. This notification must be received by FDA **at least 30 days prior** to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. The notification must include:

- Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the products. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the text may be provided separately and referenced. Digital media, such as videos, must be submitted in a format that FDA is able to open and review.
- All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
  - Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans an media buys;
  - Target specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and psychographic characteristics that reflect your intended target audience(s), including how the target audience(s) are defined and the insights used to develop the target audience profile(s) and the source of such insights;
  - Restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
  - Use owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
  - Use partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
  - Conduct any consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated; and/or
  - Use public-relations outreach to create labeling for, advertise, market, and/or promote the products.

III. Periodic Reporting

Under sections 911(h)(5) of the FD&C Act, these orders require that you submit periodic reports every 6 months to FDA once during the month of June of each year and once during the month of December of each year, beginning June 2020. For the six-month reporting period, the report must include:

- A cover letter that includes the following text in your subject line: **PERIODIC REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029.** The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and reporting period.
- All final printed labeling (including all variations, such as those reflecting different required warnings) not previously submitted (e.g., if previously submitted under section 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), including the date the labeling was first disseminated and the date when the labeling was discontinued, and a description of all changes to the labeling. The labeling must include all the panels and be presented in the actual size and color with legible text. The labeling must include labels, inserts/onserts, instructions, and any other accompanying information or materials for the products.
- All final full-color advertising, marketing, and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers not previously submitted (e.g., if previously submitted under 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), along with the original date such materials were first disseminated and the date they were discontinued, and a description of all changes to the materials. The materials must be legible, include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text may be provided separately and clearly referenced. Digital media, such as videos must be submitted in a format that FDA is able to open and review.

IV. Annual Reporting

Under section 911(h)(5) of the FD&C Act, these risk modification orders require that you submit the following reports to FDA **on an annual basis**, beginning twelve months from the date of this order. For each twelve-month reporting period, these annual reports must include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans – whether conducted by you, on your behalf, or at your direction – by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:
  - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

- Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect the intended target audience(s), how the target audience(s) were defined and the insights used to develop the target audience profiles(s) and the source of such insights;
- Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
- Use of owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
- Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
- Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
- Use of public-relations outreach to create labeling for, advertise, market, and/or promote the products; including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel and by product.

- An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under), not previously submitted. This analysis should be verified against post-launch delivery-verification reports submitted to you from an accredited source.
- A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to youth, ages 17 and under, and including a summary of implementation of any corrective and preventive measures, not previously submitted.

V. Additional Conditions for Marketing

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to:

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in your **owned digital properties** (e.g., your company-owned, consumer-directed, product-branded website(s) and/or mobile applications) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare consumer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your products on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content-(e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such

labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product(s) running on another company's website; paid advertising for the product(s) running in social media; paid distribution of influencer content) – whether conducted by you, on your behalf, or at your direction:
  - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:
    - "First-party" age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and
    - "Second-party" age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.
    - "First-party" and "second-party" data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.
- Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to youth, ages 17 and under. Such monitoring also requires post-launch delivery verification reports be submitted to you from an accredited source.
- For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the products – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as "sponsored by [firm name]" in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the products, on your behalf, or at your direction.

The requirements above are intended to help ensure that your modified risk tobacco products, as actually used by consumers, will continue to benefit the health of the population as a whole. Limiting youth initiation of the products and, relatedly, youth exposure to advertising and marketing materials for the products are important factors in the population health benefit analysis. Accordingly, FDA also recommends limiting youth-exposure to any of the tobacco products' labeling, advertising, marketing, and/or promotion appearing in print media publications.

After receiving authorization, the determination of whether the eight modified risk General Snus products, as actually used by consumers, continue to benefit the health of the population as a whole

is likely to be driven by use behavior. An uptake in youth initiation and use of the products would have a significant negative impact on the population health benefit analysis. To help ensure that your products, as actually used by consumers, continue to benefit the health of the population as a whole, we strongly recommend that you take measures to limit youth initiation and use of the products, beyond limiting advertising and promotion as required in this order. For example, we strongly recommend you adopt the following measures related to all digital sales of your products:

- For any **digital sales** -- whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale of the products to individuals who are under the federal minimum legal age to purchase tobacco products.

Relatedly, we request that you submit the following information to CTP on an annual basis:

- A summary of the implementation and effectiveness of any policies and procedures regarding verification of the age and identity of purchasers of the products.
- A summary of the implementation and effectiveness of any policies and procedures regarding restrictions on youth access to the products.

We remind you that if FDA can no longer make the determination that your products, as actually used by consumers, will benefit the health of the population as a whole, FDA must withdraw the modified risk orders, after an opportunity for an informal hearing. See under section 911(j)(1) of the FD&C Act. Although adopting the measures above is not in itself a guarantee that the products will continue to benefit the health of the population as a whole, it is an important step in helping to ensure that there are no grounds for withdrawal of your orders.

Appendix D
Recordkeeping and Retention

The risk modification orders for your modified risk tobacco products are effective for 5 years from the issue date of the orders. If you wish to renew your orders, we recommend you submit a request for renewal 360 days prior to the end of your effective timeframe. In order to help ensure that your risk modification orders meet the standard for renewal and to help expedite the review of any renewal applications, we request that you establish and maintain the records listed below. The records should be retained for a period of not less than four years from the date of distribution of the last batch of the tobacco products listed in your orders under section 911(g)(1). The records should be legible, written in English, and upon request, available for inspection and copying by officers or employees duly designated by the Secretary. Please note that Appendices B and C require you to periodically submit some of these records to FDA (e.g., in PMSS reports and/or advertising and promotion-related reports). Additionally, we remind you that the PMTA orders for your General snus products issued on November 10, 2015, also require you to establish and maintain records, some of which overlap with the records listed below:

- The MRTPAs submitted prior to the orders
- Postmarket reports, as described in the Required PMSS Appendix, including adverse experience reports and all relevant documentation associated with the experience
- Records of all nonclinical or clinical studies, including:
  - Source data;
  - Study protocols (including statistical analysis plan);
  - Amendments showing the dates and reasons for any protocol revisions;
  - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
  - Informed consent forms;
  - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
  - Investigator financial disclosure statements;
  - Progress reports;
  - Monitoring reports;
  - Adverse experience reports;
  - Case report forms/subject diaries/medical records/laboratory reports;
  - Subject data line listings/observation records;
  - Test article accountability records;
  - Study results/protocol summaries/study reports; and
  - Certifications and amendments to certifications
- Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the products
- Records pertaining to the sale, distribution, or other disposition of the products, specifically:
  - A list of distributors and retailers of the products, including brick-and-mortar and digital[8];
  - Any available information (not to include personally identifiable information) about product purchases, such as purchasers' demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use);
  - Policies and procedures regarding verification of the age and identity of purchasers of the products; and

[8] For the purposes of this order, here and throughout the document, "digital" includes internet/online and mobile.

- Policies and procedures regarding restrictions on youth access to the products
- Health hazard analyses, if performed voluntarily or directed by FDA
- Records pertaining to any and all complaints associated with any of the products that you receive or of which you are aware

Appendix E

Manufacturing Information

The PMTA orders for your General Snus products, issued on November 10, 2015, require you to report to the FDA manufacturing information. We request that when submitting such reports, you reference both your PMTAs and you MRTPAs for these products. When cross-referencing, please provide the date of submission and location in the submission where the information is covered. When cross-referencing, please provide the date of submission and location in the submission where the information is covered.

For each twelve-month reporting period, the annual reports should include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A description of each change made to the manufacturing process, facilities, or controls during the reporting period including:
  - A comparison of each change to what was described in the MRTPAs;
  - The rationale for making each change; and
  - A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke or aerosol constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of the tobacco products and the basis for concluding that each manufacturing change did not result in any modification to the products.[9]
- A summary of all manufacturing deviations, investigations, and corrective and preventive actions, including, but not limited to, those deviations associated with processing, testing, packing, labeling, storage, holding, and distribution and indicate any deviation(s) that may affect the characteristics of the products. For additional information on manufacturing deviations, see below.

Manufacturing Deviations

You should promptly investigate all manufacturing deviations including, but not limited to, those associated with processing, testing, packing, labeling, storage, holding, and distribution. The PMTA orders for your General snus products, issued on November 10, 2015, require that, for products that have been distributed, if the deviation may negatively impact public health, you promptly identify and report that deviation to CTP. We request that when submitting such reports, you reference both your PMTAs and you MRTPAs for these products.

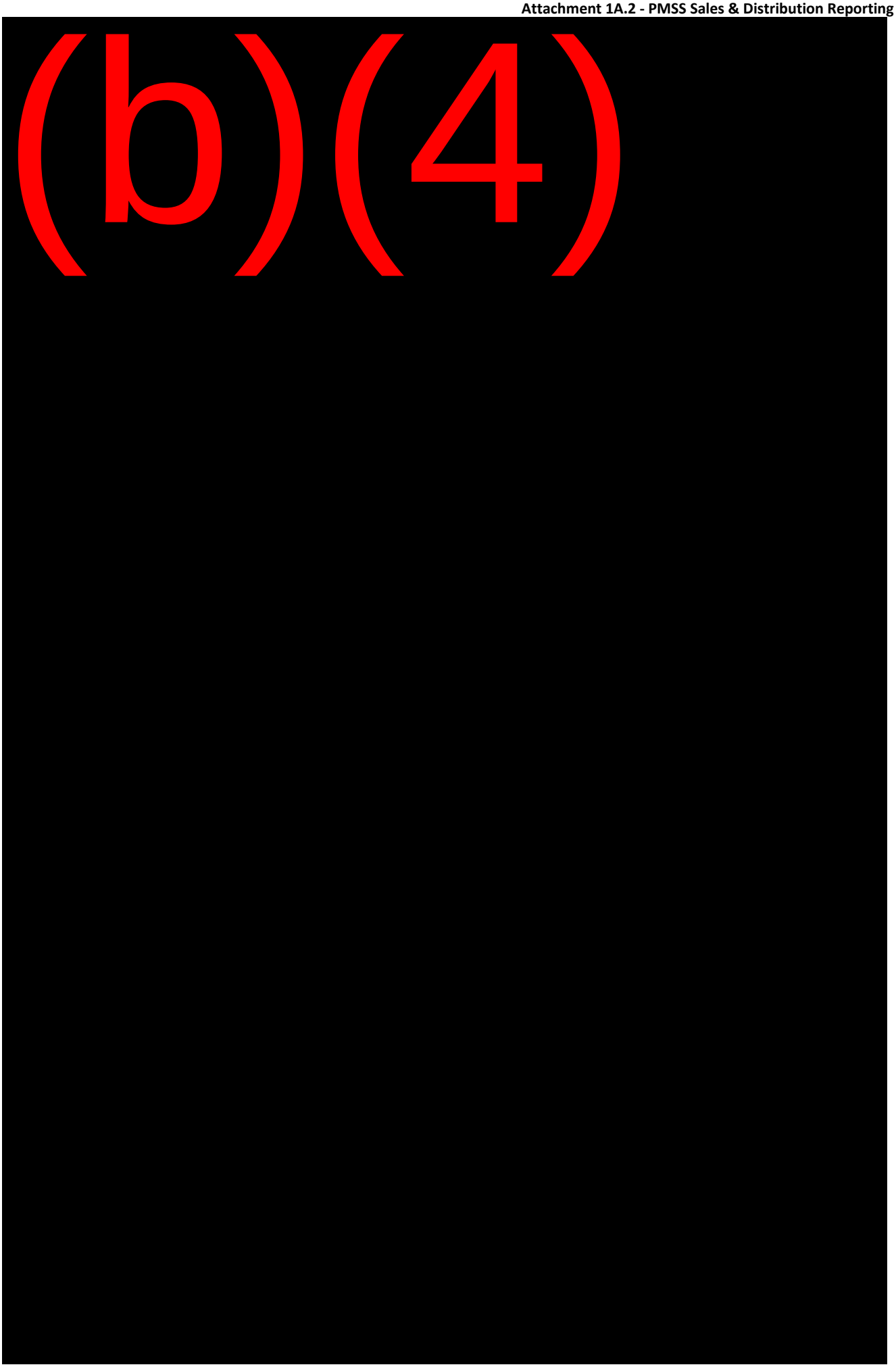
Discontinuation and Reintroduction

If you discontinue the manufacture, preparation, compounding, or processing for commercial distribution of these modified risk tobacco products and later decide to reintroduce the modified risk tobacco products into the market, please contact the Office of Compliance and Enforcement prior to reintroduction.

[9] We note that any modifications made to a tobacco product would render it a new tobacco product that would be subject to the premarket review requirements under section 910 of the FD&C Act.

			Unit Volume (1,000's)										*Dollar Sales ($1,000's)*									
			2020 Q4		2021 Q1		2021 Q2		2021 Q3		4 Quarters		2020 Q4		2021 Q1		2021 Q2		2021 Q3		4 Quarters	
FDA STN	UPC	Product Name	Sales	Chg v. Prior	Sales	Chg v. Prior	Sales	Chg v. Prior	Sales	Chg v. Prior	Total	Chg v. Prior	Sales	Chg v. Prior	Sales	Chg v. Prior	Sales	Chg v. Prior	Sales	Chg v. Prior	Total	Chg v. Prior
		Total General	[redacted]																			
MR0000020	6-09249-62053-8, 6-09249-62024-8, 6-09249-62000-2	General Loose																				
MR0000021	6-09249-66053-4, 6-09249-66024-4, 6-09249-66000-8	General Dry Mint Portion Original Mini																				
MR0000022	6-09249-60053-0, 6-09249-60024-0, 6-09249-60000-4	General Portion Original Large																				
MR0000025	6-09249-67053-3, 6-09249-67024-3, 6-09249-67000-7	General Mint Portion White Large																				
MR0000027	6-09249-68052-5, 6-09249-68022-8, 6-09249-68002-0	General Nordic Mint Portion White Large (12 ct																				
MR0000028	6-09249-61054-6, 6-09249-61024-9, 6-09249-61000-3	General Portion White Large																				
MR0000029	6-09249-64053-6, 6-09249-64024-6, 6-09249-64000-0	General Wintergreen Portion White Large																				
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Classic Blend Portion White Large (12 ct																				

(b)(4)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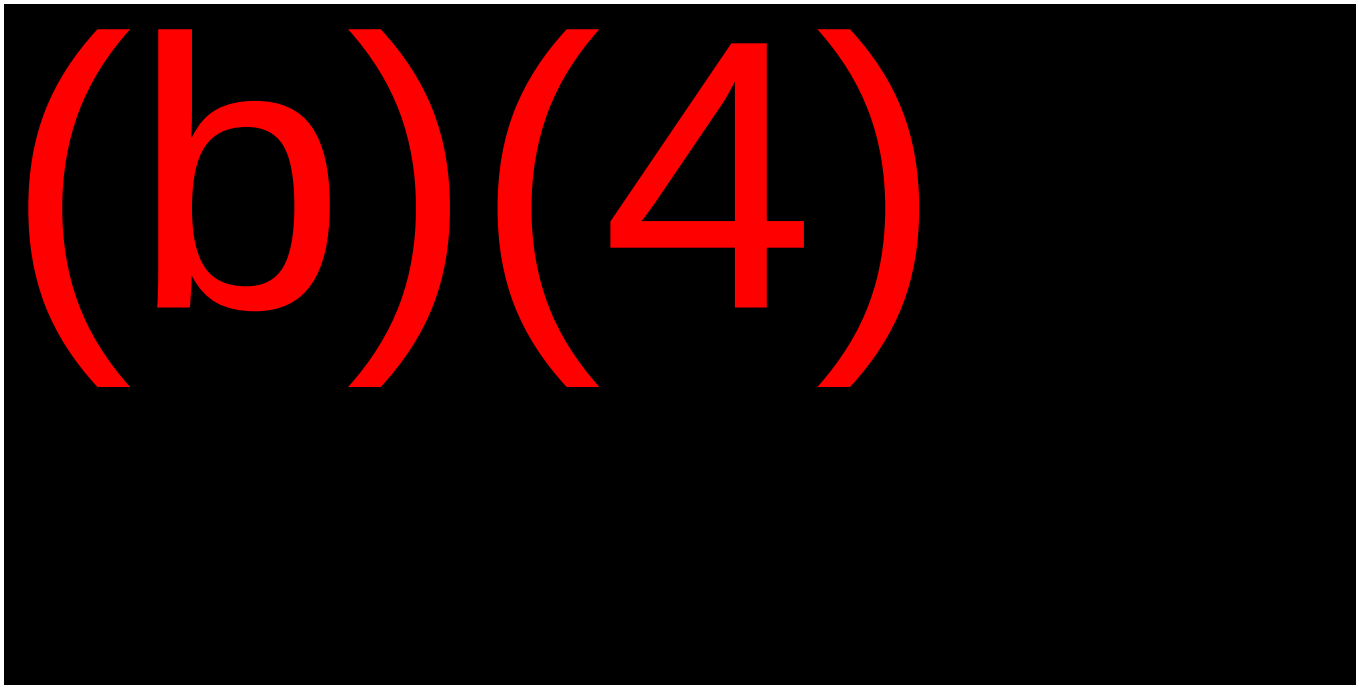

(b)(4)

Summary of Consumer Contacts (Adverse Experiences)

Product	General Portion Original Large
SKU Number	4880
FDA Tracking Number	PM0000012/MR0000022
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Complaint Description	Count	Importance
1	FLAVOR/AROMA	3	No serious and unexpected adverse experience.
2	FRESHNESS	1	No serious and unexpected adverse experience.
3	OTHER	1	No serious and unexpected adverse experience.
4	PACKAGING ISSUE	3	No serious and unexpected adverse experience.
5	POUCH RIPS/TEARS/OPENS	1	No serious and unexpected adverse experience.

Detail for Consumer Contacts (Adverse Experiences)

Product	General Portion Original Large
SKU Number	4880
FDA Tracking Number	PM0000012/MR0000022
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Case No.	Complaint Received	Complaint Description	Additional Information
1	00358075	2/4/2021	(b)(4)	
1	00360541	2/28/2021		
1	00355112	1/12/2021		
2	00378723	8/3/2021		
3	00345232	10/9/2020		
4	00384205	9/17/2021		
4	00368211	5/16/2021		
4	00362972	3/23/2021		
5	00364402	4/7/2021		

Summary of Consumer Contacts (Adverse Experiences)

Product	General Mint Portion Original Large
SKU Number	4752
FDA Tracking Number	PM0000014/MR0000025
Reporting Period	October 1, 2020 to September 30, 2021

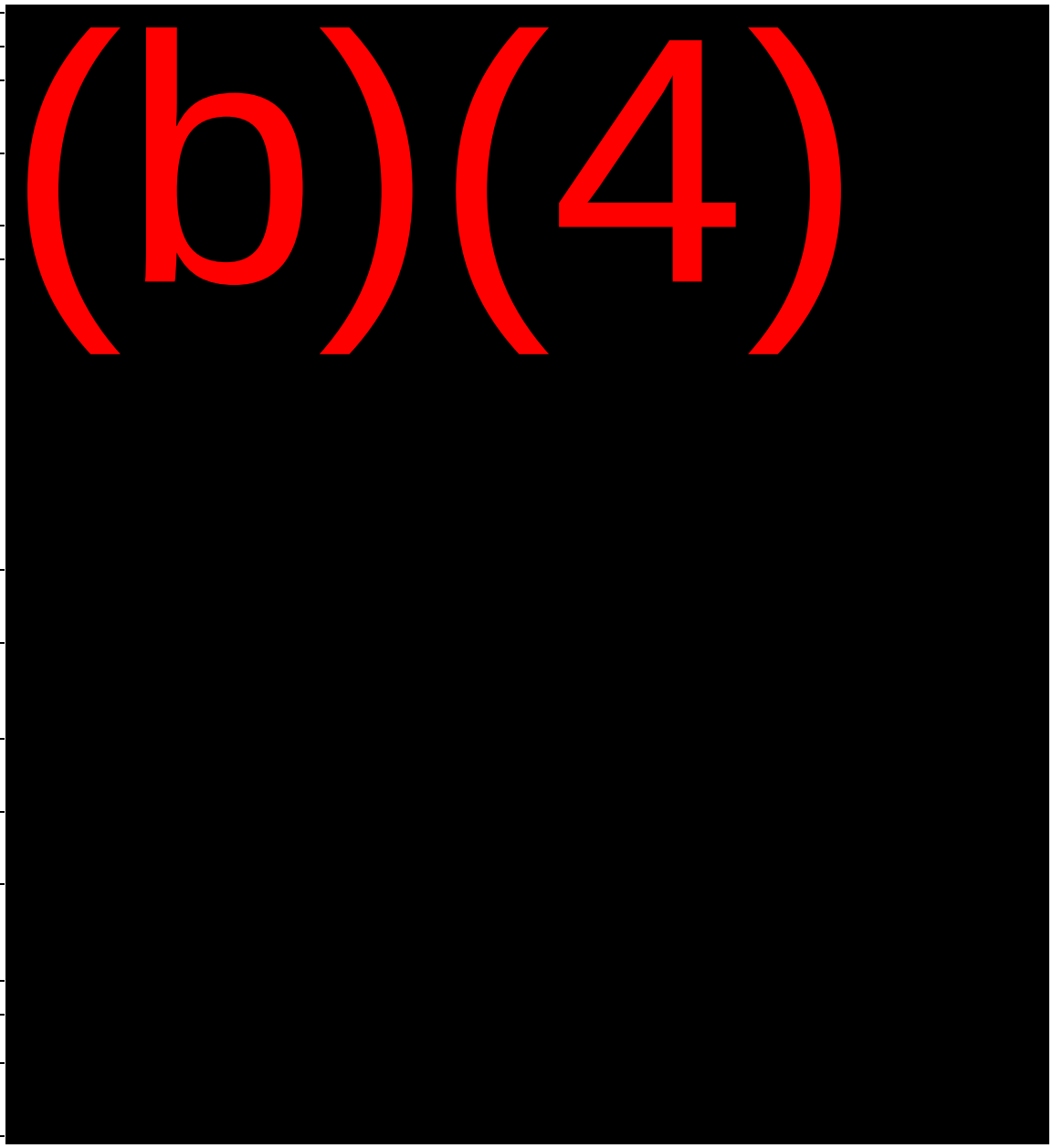
Item #	Complaint Description	Count	Importance
1	FLAVOR/AROMA	2	No serious and unexpected adverse experience.
2	FRESHNESS	2	No serious and unexpected adverse experience.
3	OTHER	6	No serious and unexpected adverse experience.
4	PACKAGING ISSUE	1	No serious and unexpected adverse experience.
5	POUCH RIPS/TEARS/OPENS	19	No serious and unexpected adverse experience.
6	WRONG PRODUCT	1	No serious and unexpected adverse experience.

Detail for Consumer Contacts (Adverse Experiences)

Product	General Mint Portion Original Large
SKU Number	4752
FDA Tracking Number	PM0000014/MR0000025
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Case No.	Complaint Received	Complaint Description	Additional Information
1	00359075	2/14/2021	(b)(4)	
1	00347654	11/3/2020		
2	00354255	1/4/2021		
2	00345056	10/7/2020		
3	00365846	4/22/2021		
3	00364987	4/13/2021		
3	00361232	3/7/2021		
3	00353107	12/23/2020		
3	00350631	11/30/2020		
3	00350029	11/24/2020		
4	00365606	4/20/2021		
5	00383679	9/14/2021		
5	00381854	8/30/2021		
5	00374766	6/28/2021		
5	00369069	5/23/2021		
5	00366302	4/28/2021		
5	00363652	3/30/2021		

5	00362932	3/23/2021
5	00362787	3/22/2021
5	00361708	3/10/2021
5	00360696	3/1/2021
5	00359060	2/14/2021
5	00354447	1/6/2021
5	00353045	12/23/2020
5	00352343	12/16/2020
5	00350359	11/27/2020
5	00349385	11/18/2020
5	00344978	10/6/2020
5	00346903	10/27/2020
5	00345516	10/13/2020
6	00360338	2/25/2021



Summary of Consumer Contacts (Adverse Experiences)

Product	General Portions White Large
SKU Number	4881
FDA Tracking Number	PM0000016/MR0000028
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Complaint Description	Count	Importance
1	FLAVOR/AROMA	1	No serious and unexpected adverse experience.
2	FRESHNESS	2	No serious and unexpected adverse experience.
3	OTHER	2	No serious and unexpected adverse experience.
4	PACKAGING ISSUE	2	No serious and unexpected adverse experience.
5	POUCH RIPS/TEARS/OPENS	7	No serious and unexpected adverse experience.
6	SHORT COUNT	1	No serious and unexpected adverse experience.

Detail for Consumer Contacts (Adverse Experiences)

Product	General Portions White Large
SKU Number	4881
FDA Tracking Number	PM0000016/MR0000028
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Case No.	Complaint Received	Complaint Description	Additional Information
1	00375600	7/5/2021	(b) (4)	
2	00369500	5/24/2021		
2	00353934	12/31/2020		
3	00355047	1/11/2021		
4	00345886	10/16/2020		
5	00384743	9/22/2021		
5	00379983	8/14/2021		
5	00379698	8/11/2021		
5	00377135	7/20/2021		
5	00370923	6/1/2021		
5	00369686	5/25/2021		
5	00364058	4/3/2021		
6	00351710	12/10/2020		

Summary of Consumer Contacts (Adverse Experiences)

Product	General Wintergreen Portion White Large
SKU Number	4882
FDA Tracking Number	PM0000017/MR0000029
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Complaint Description	Count	Importance
1	FRESHNESS	2	No serious and unexpected adverse experience.
2	MOLD	1	No serious and unexpected adverse experience.
3	OTHER	2	No serious and unexpected adverse experience.
4	POUCH RIPS/TEARS/OPENS	39	No serious and unexpected adverse experience.

Detail for Consumer Contacts (Adverse Experiences)

Product	General Wintergreen Portion White Large
SKU Number	4882
FDA Tracking Number	PM0000017/MR0000029
Reporting Period	October 1, 2020 to September 30, 2021

Item #	Case No.	Complaint Received	Complaint Description	Additional Information
1	00368279	5/17/2021	(b) (4)	
1	00366397	4/28/2021		
2	00362727	3/21/2021		
3	00362302	3/16/2021		
3	00347335	10/31/2020		
4	00382099	9/1/2021		
4	00378944	8/4/2021		
4	00378623	8/2/2021		
4	00379695	8/11/2021		
4	00379679	8/11/2021		
4	00375935	7/8/2021		
4	00378172	7/28/2021		
4	00377753	7/25/2021		
4	00372417	6/13/2021		

4	00368397	5/18/2021	(b) (4)
4	00368117	5/14/2021	
4	00367977	5/13/2021	
4	00361019	3/4/2021	
4	00363720	3/31/2021	
4	00363006	3/23/2021	
4	00362447	3/18/2021	
4	00360334	2/25/2021	
4	00358804	2/11/2021	

			(b) (4)
4	00357718	2/1/2021	
4	00357432	1/29/2021	
4	00357033	1/26/2021	
4	00356939	1/25/2021	
4	00356533	1/21/2021	
4	00356406	1/20/2021	
4	00355176	1/12/2021	
4	00354869	1/10/2021	
4	00354011	1/1/2021	
4	00353862	12/30/2020	
4	00353511	12/28/2020	
4	00352802	12/21/2020	
4	00350792	12/2/2020	
4	00352530	12/18/2020	
4	00352312	12/16/2020	
4	00351677	12/10/2020	
4	00349868	11/23/2020	

4	00348643	11/12/2020	(b) (4)
4	00345143	10/8/2020	
4	00344981	10/6/2020	
4	00344506	10/1/2020	

Postmarket Surveillance Consumer Perception Behavior & Health Study (PMSS) Annual Report

As part of the postmarket surveillance following FDA's granting a risk modification order for *General* Snus® on October 22, 2019, Kantar and Swedish Match developed a protocol and questionnaire for (b) (4) for *General* Snus®. After several interactions with FDA, Swedish Match was notified by FDA on April 16, 2020 **(See Attachment 1C.1)** that the protocols had been reviewed and that Swedish Match could proceed with the initiation of studies. (b) (4) has been completed and is being submitted as part of this annual report.

The overarching research questions within the studies are:

1. (b) (4)
2. (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4) and associated appendices.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

April 16, 2020

Swedish Match USA, Inc.
Attention: Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
FDA Submission Tracking Number (STN): TC0005410

Dear Mr. Roerty:

We completed review of your protocols for the proposed postmarket surveillance and studies (PMSS) submission for the tobacco products identified in Appendix A and do not have concerns. **You may proceed with initiation of the studies.**

Additionally, we have determined that the principal investigator proposed in your PMSS submission appears to have sufficient qualifications and experience to conduct such postmarket surveillance and studies, which are designed to collect data or other information as set forth in your October 22, 2019 Modified Risk Granted Order.

All regulated tobacco products, including the modified risk tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure that the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[1,2] using eSubmitter.[3] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[4]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[1] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[2] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[3] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter
[4] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions regarding postmarket activities for the tobacco products identified in Appendix A, please contact Eugene Chuang, at (240) 402-9302 or eugene.chuang@fda.hhs.gov.

Sincerely,

Lillian Ortega

Lillian Ortega
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement
Center for Tobacco Products

Enclosures:

Appendix A – List of Tobacco Products That Are Subject of This Letter
Appendix B – List of Amendments Received for Postmarket Surveillance and Studies

Appendix A

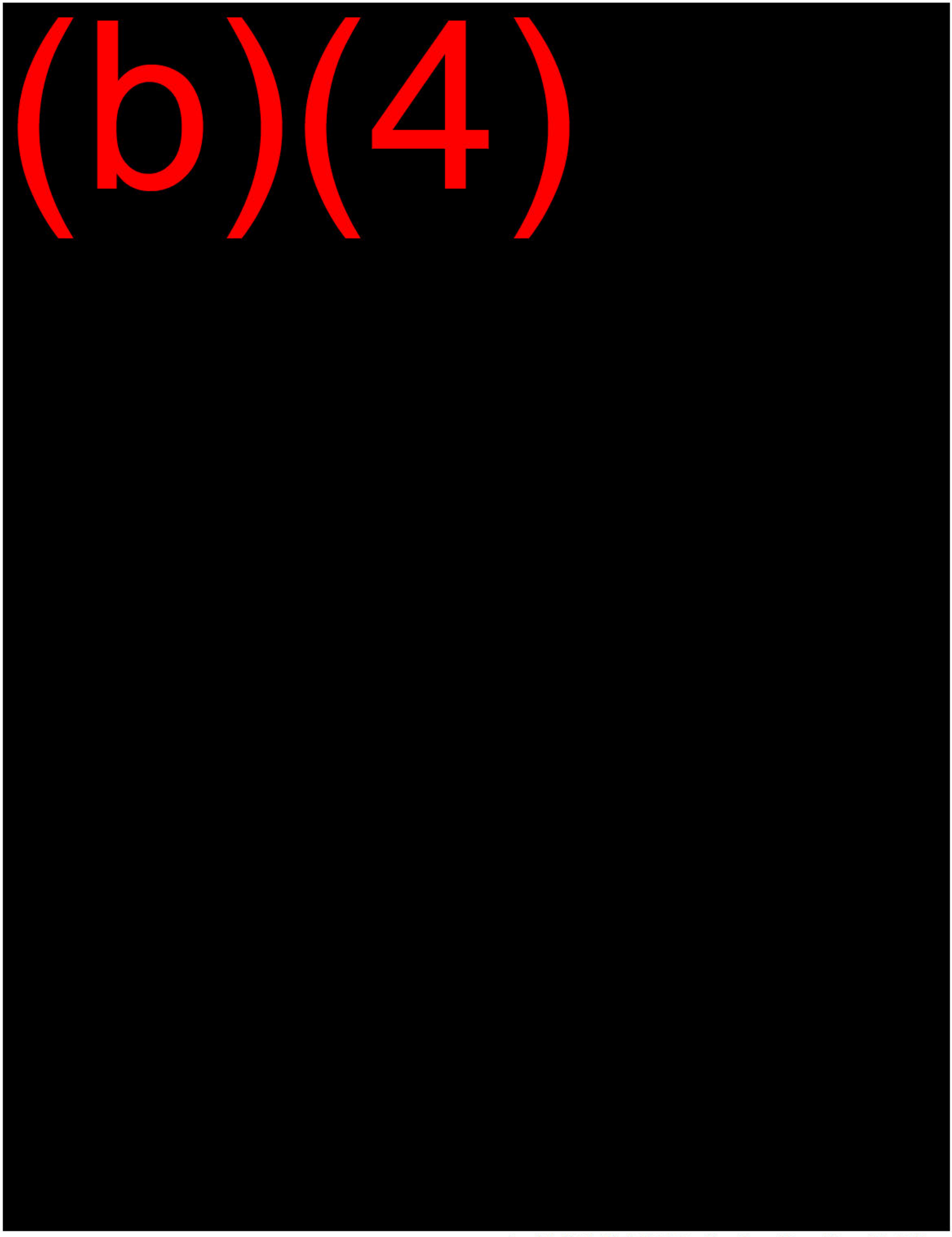
List of Tobacco Products That Are Subject of This Letter

Product STN	Tobacco Product Name	Date of Modified Risk Granted Order
MR0000020	General Loose	October 22, 2019
MR0000021	General Dry Mint Portion Original Mini	October 22, 2019
MR0000022	General Portion Original Large	October 22, 2019
MR0000024	General Classic Blend Portion White Large – 12 ct	October 22, 2019
MR0000025	General Mint Portion White Large	October 22, 2019
MR0000027	General Nordic Mint Portion White Large – 12 ct	October 22, 2019
MR0000028	General Portion White Large	October 22, 2019
MR0000029	General Wintergreen Portion White Large	October 22, 2019

Appendix B

List of Amendments Received for Postmarket Surveillance and Studies

Amendments Received	
Date of Submission:	February 18, 2020
Date of Receipt:	February 18, 2020
Reviewed:	Yes
Status:	Active
Brief Description:	Response to January 17, 2020 FDA Information Request Letter
Date of Submission:	April 1, 2020
Date of Receipt:	April 1, 2020
Reviewed:	Yes
Status:	Active
Brief Description:	Response to March 19, 2020 FDA Teleconference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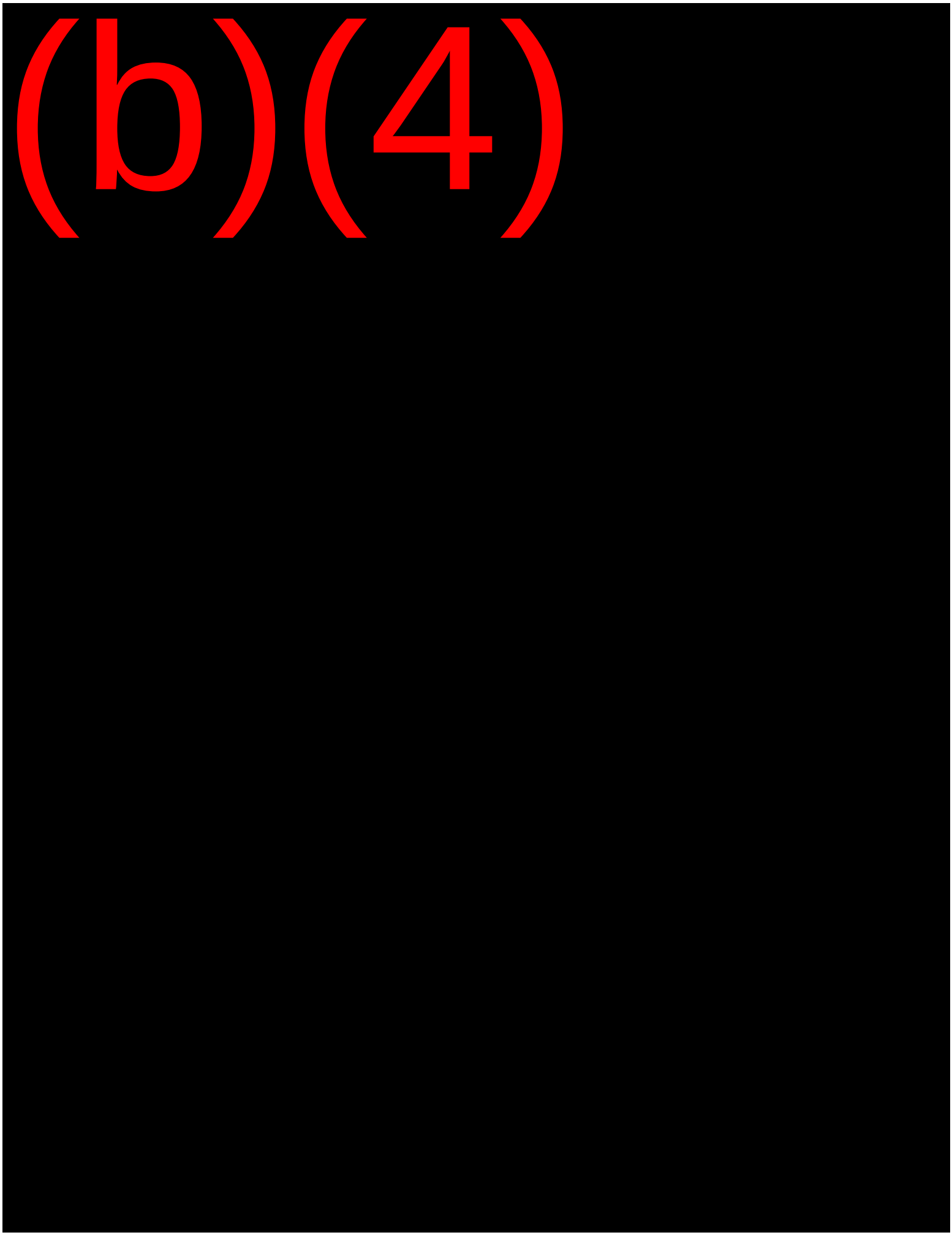
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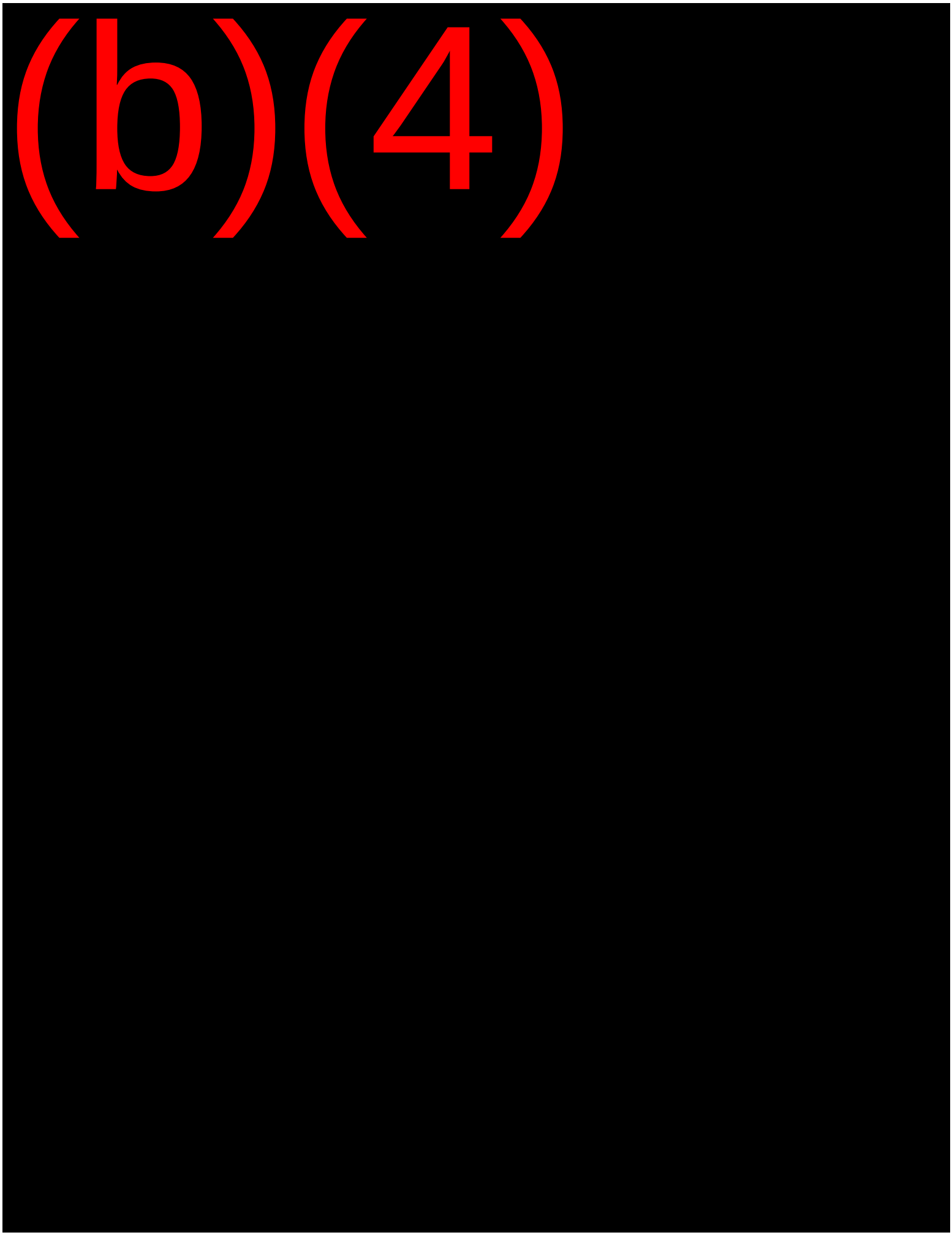
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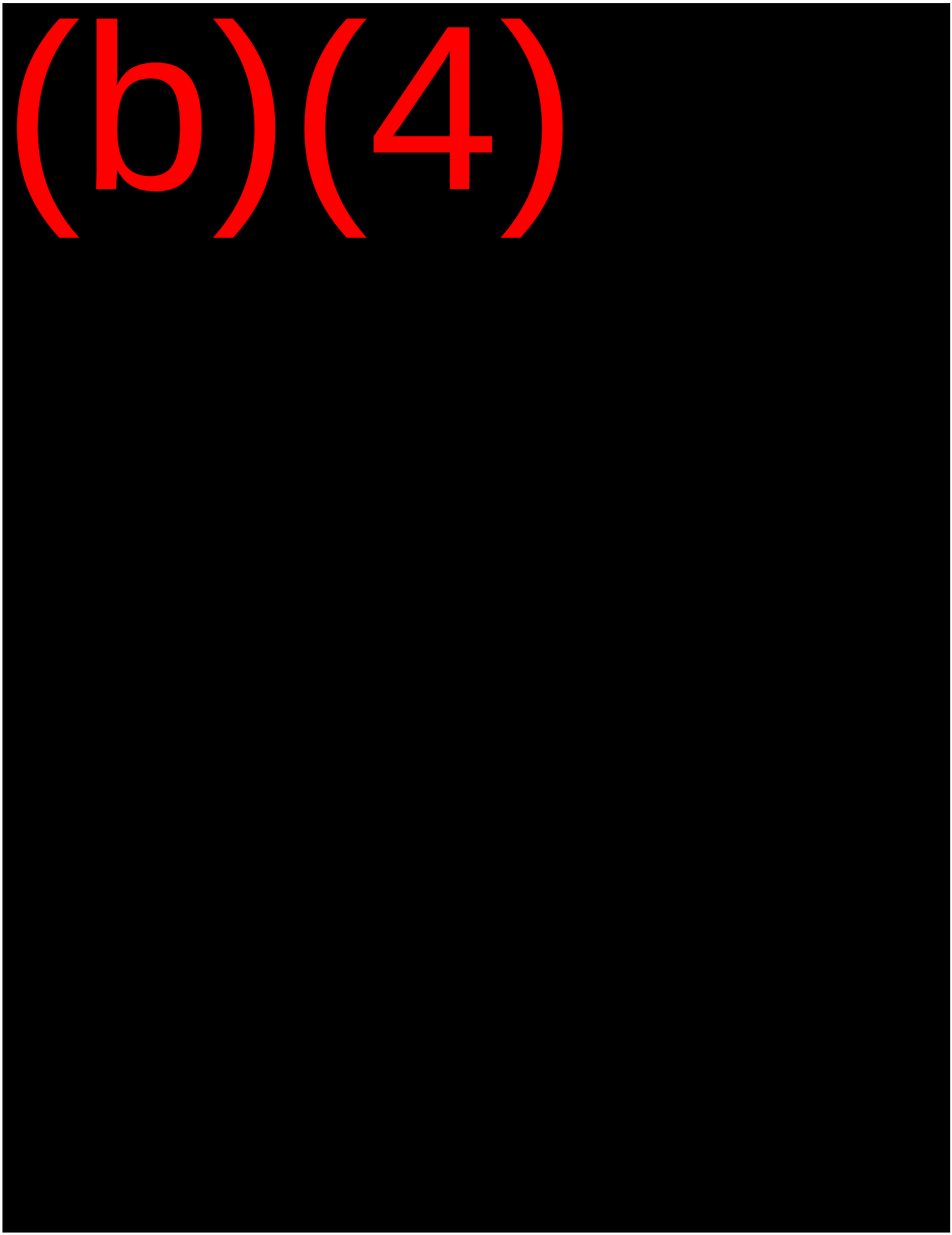
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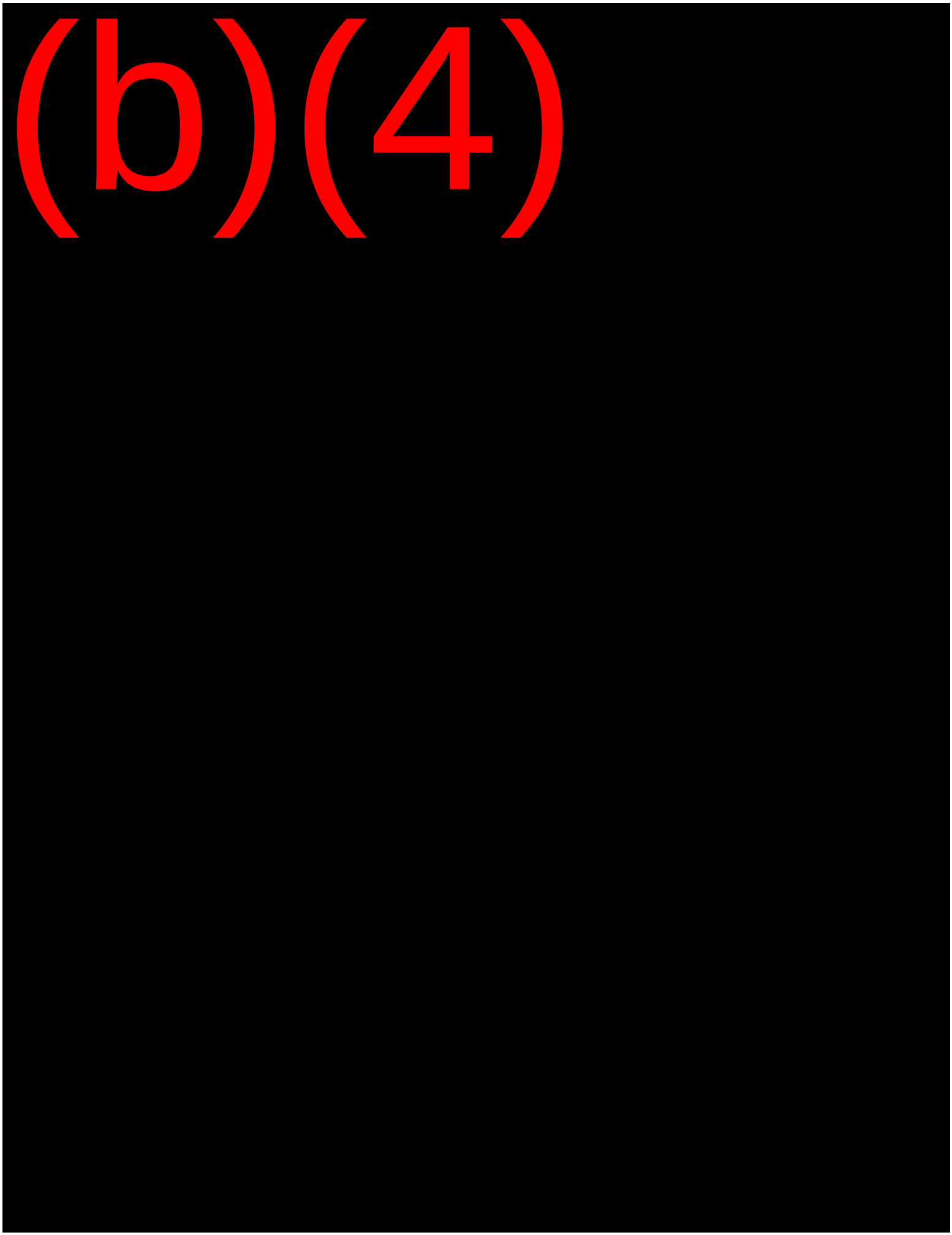
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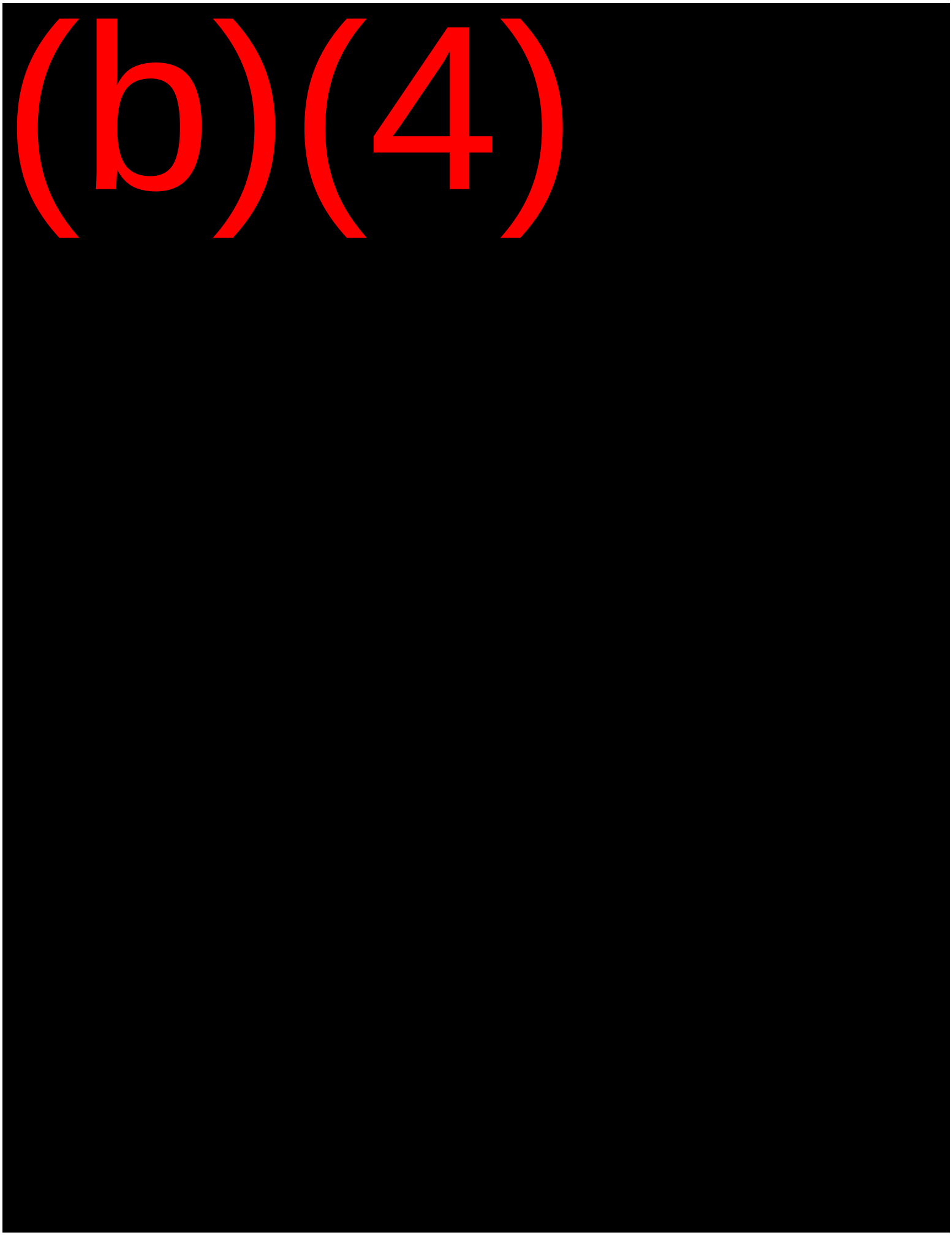
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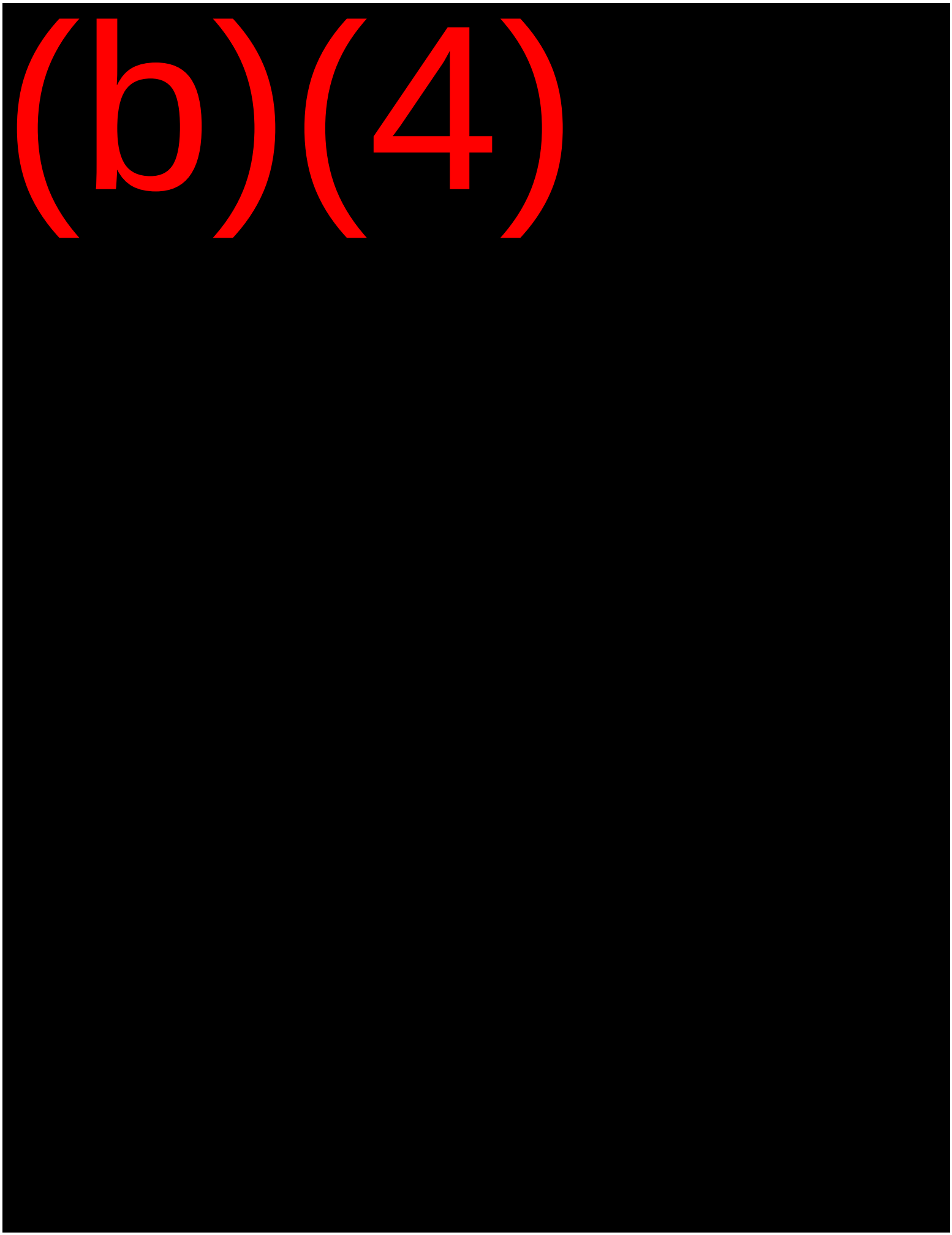
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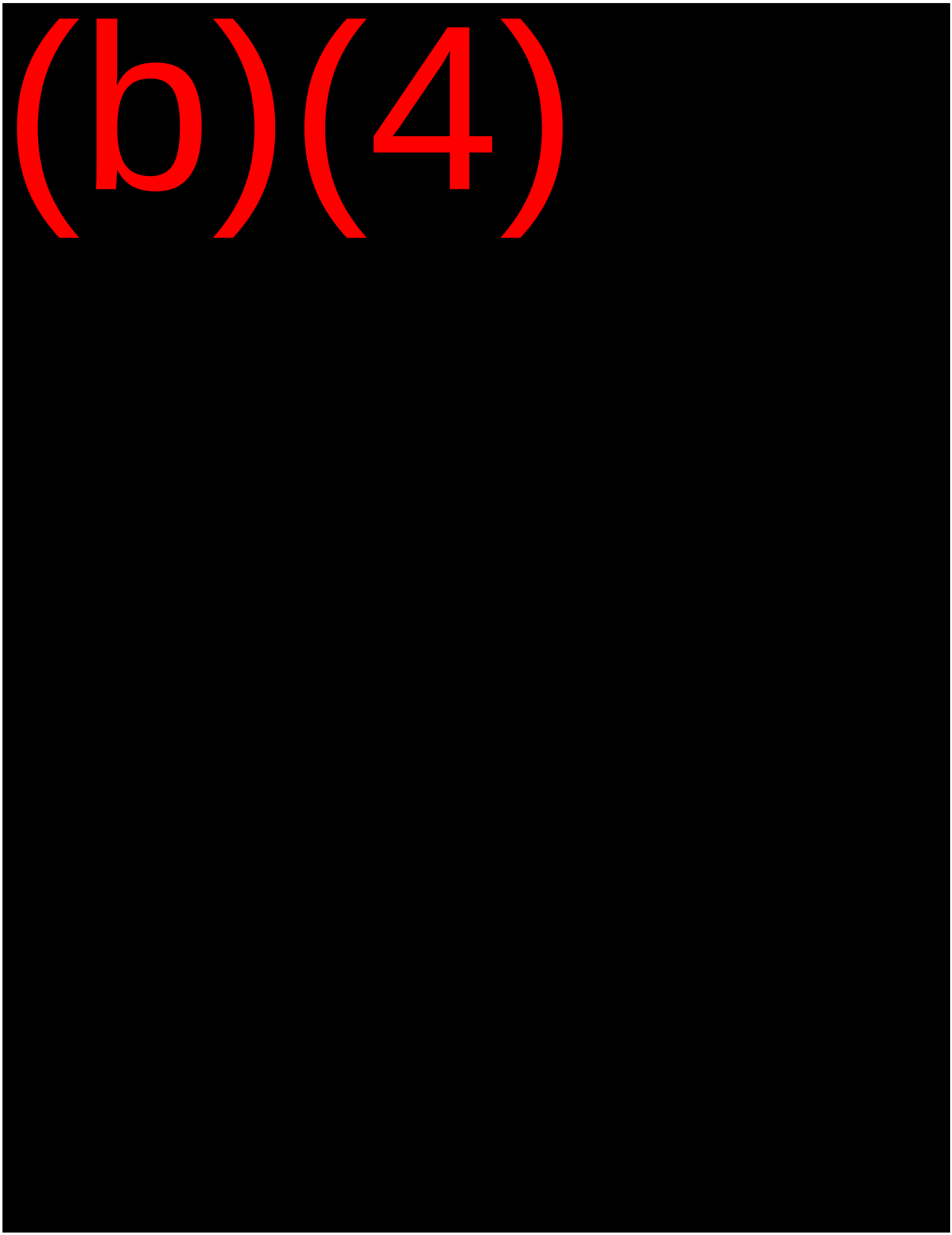
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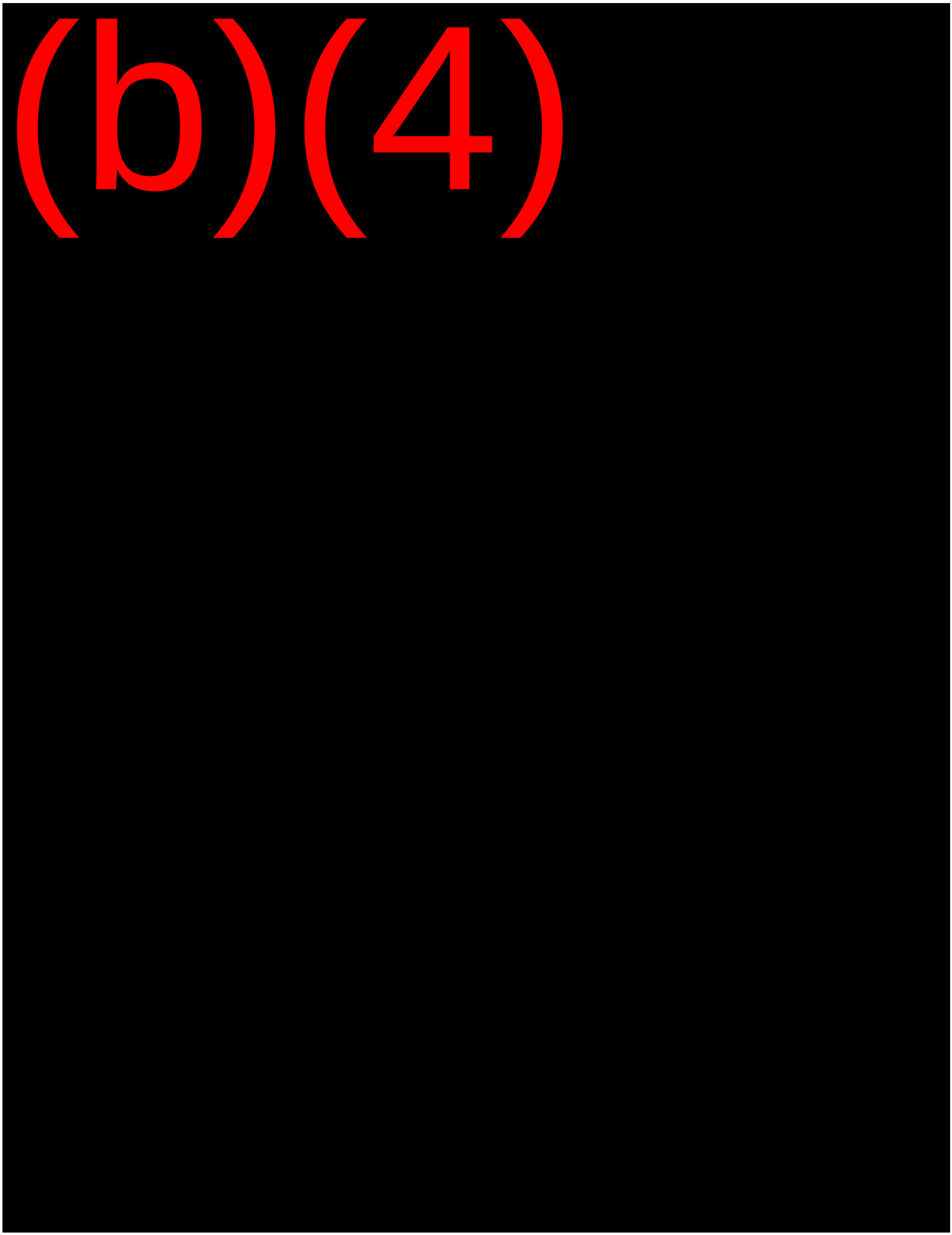
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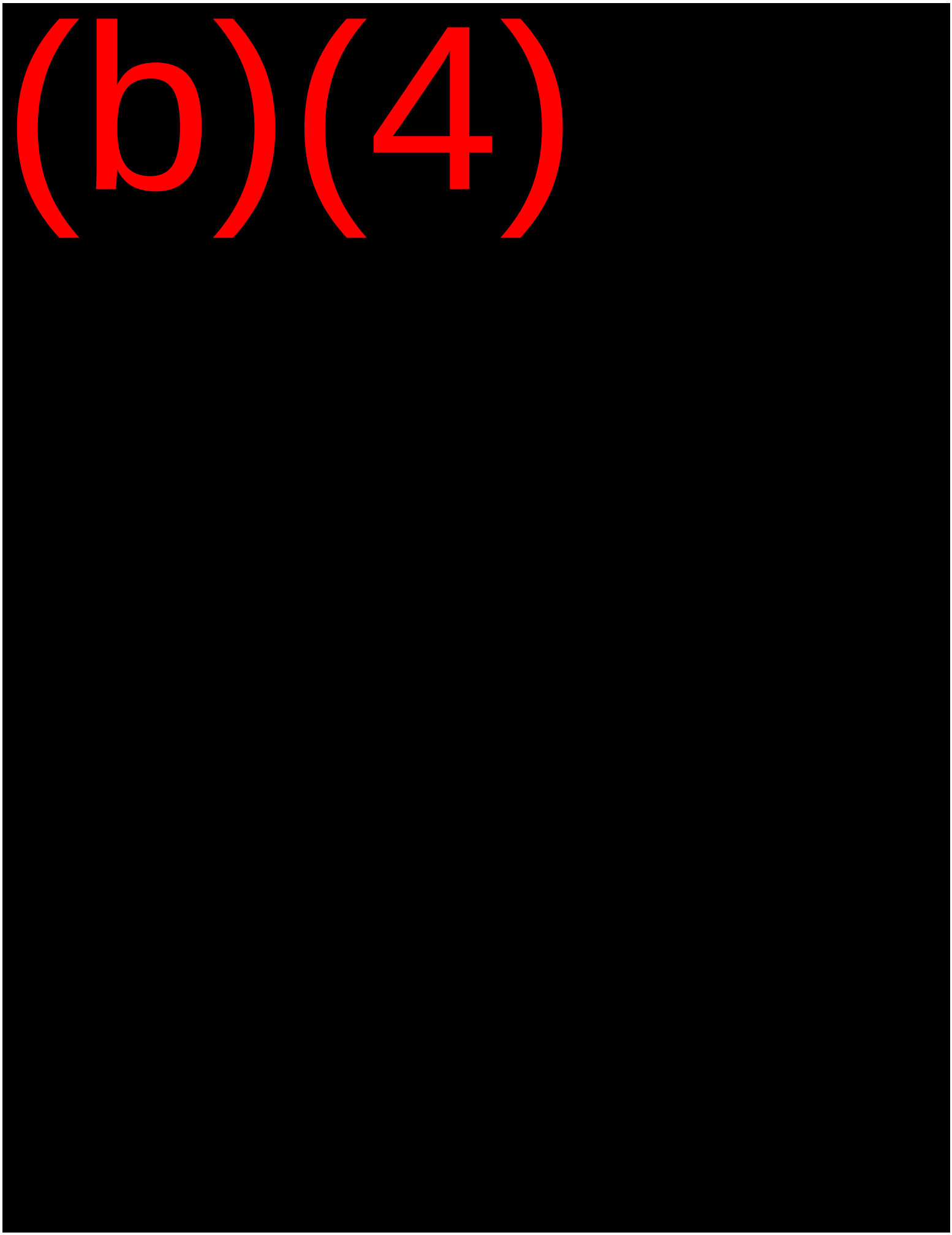
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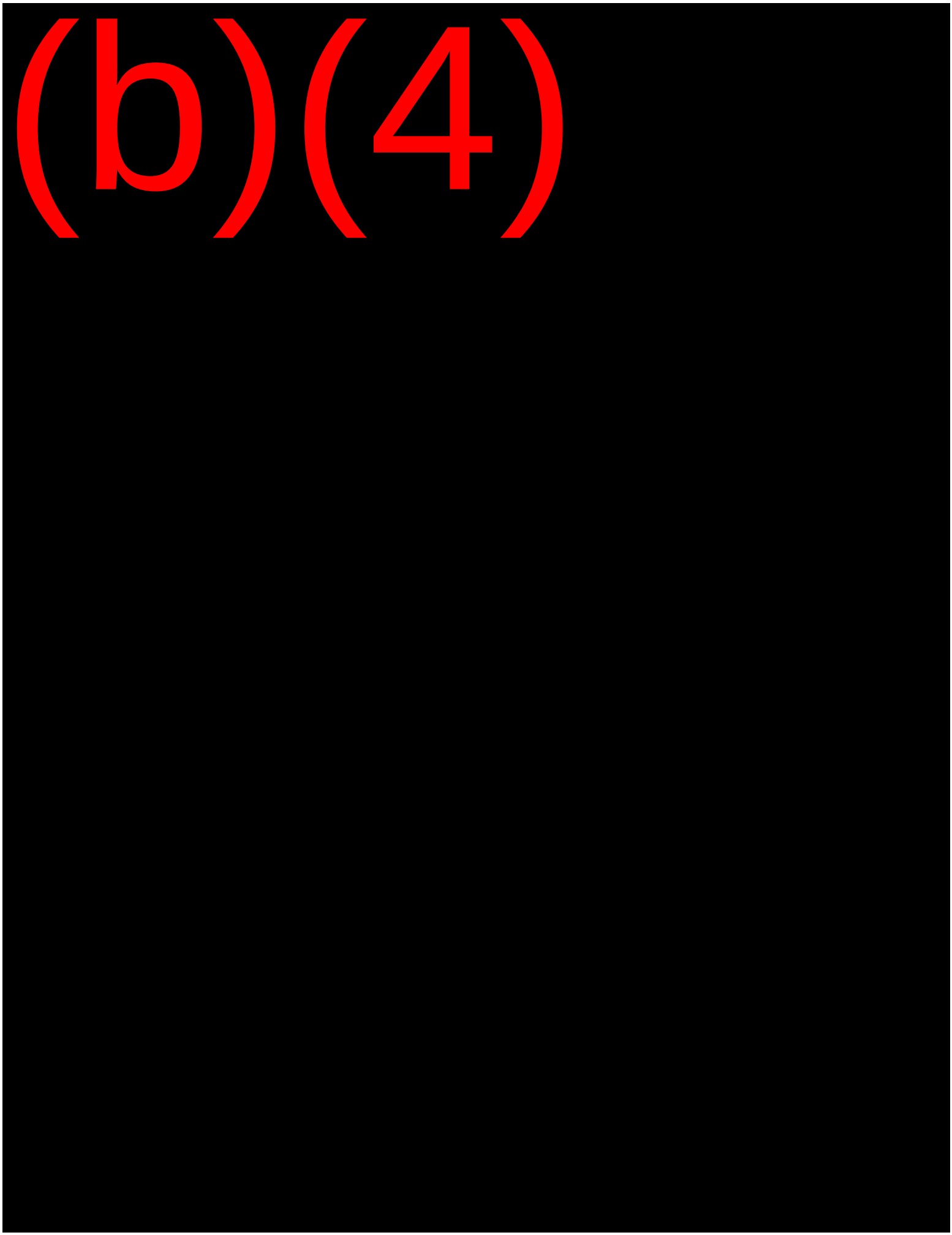
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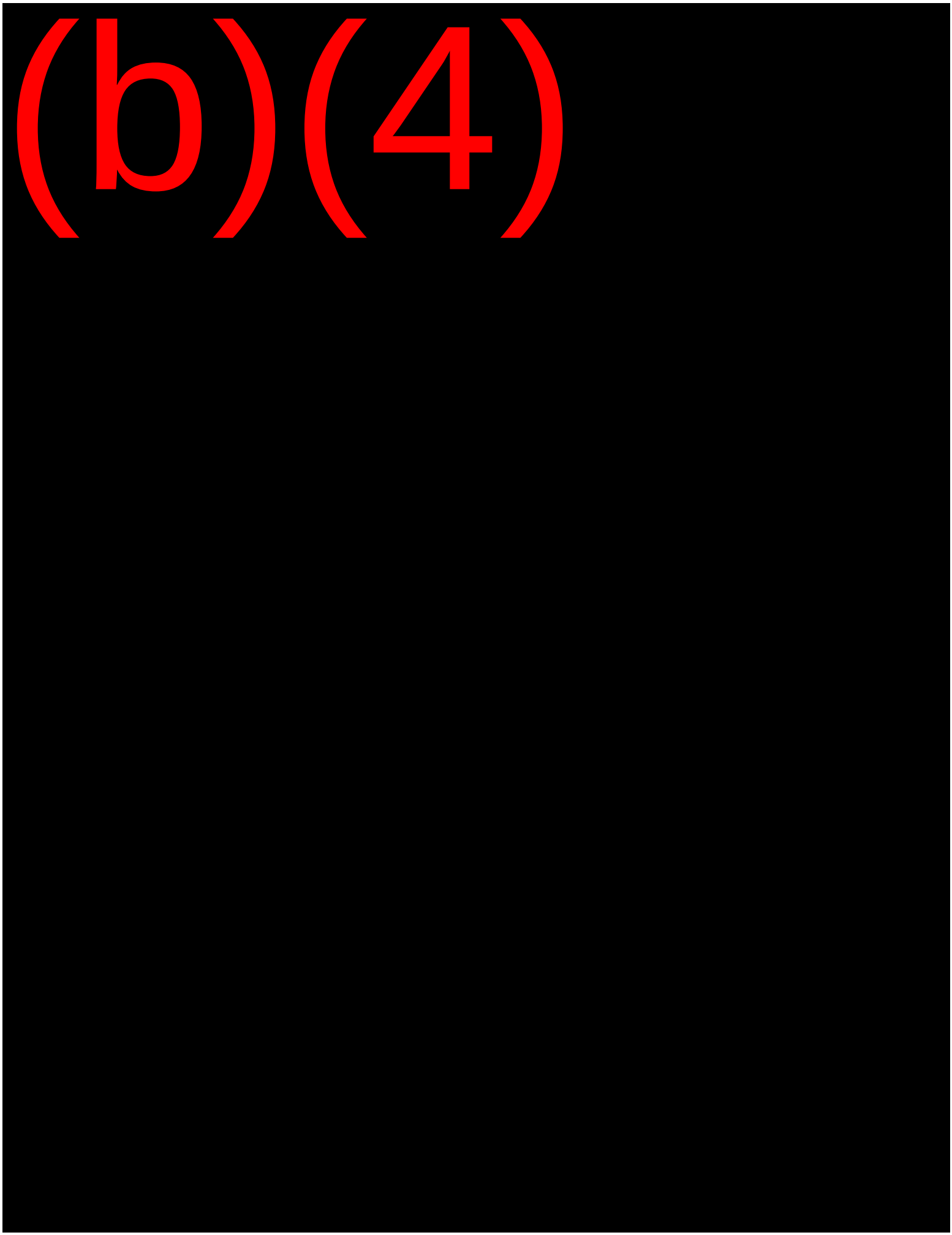
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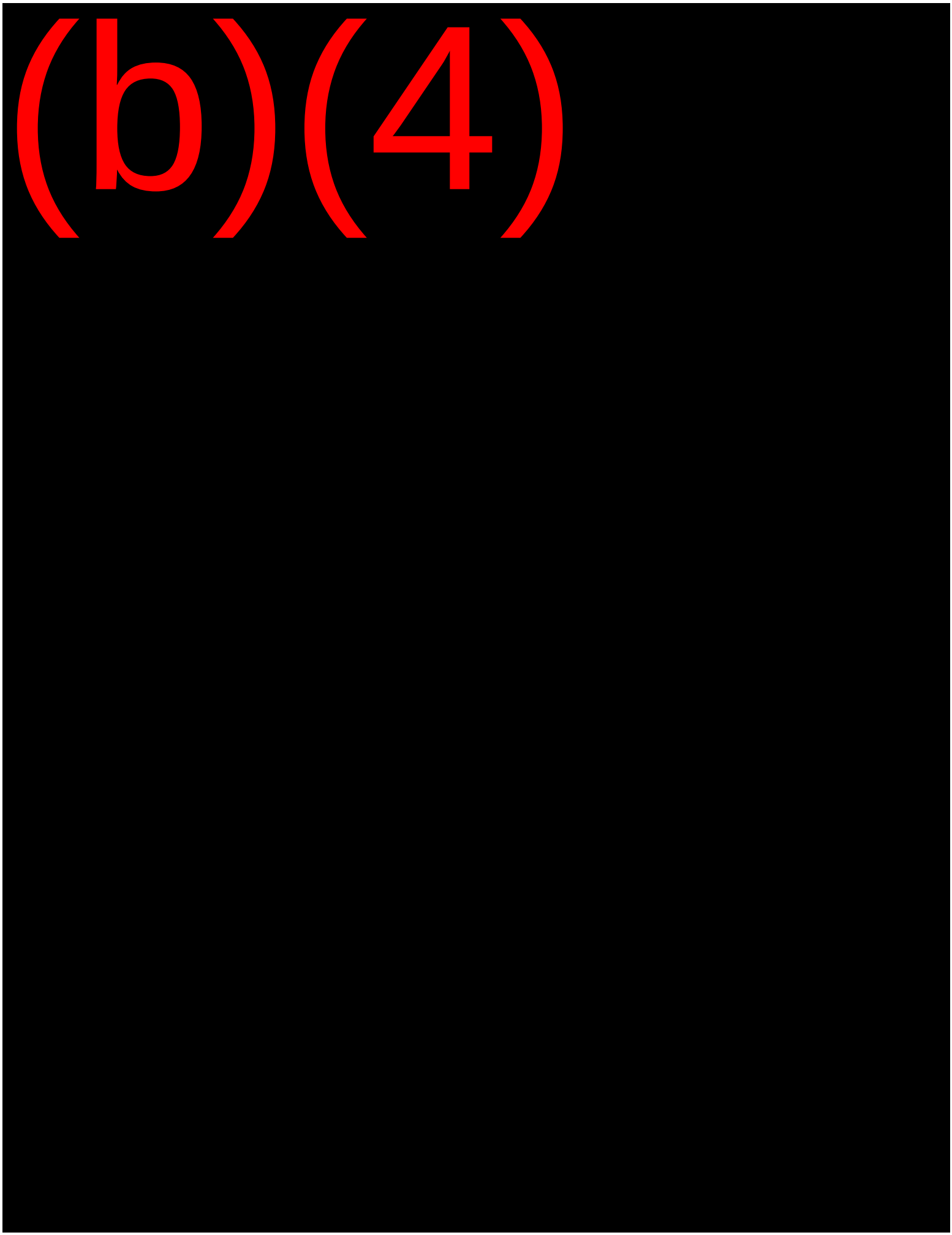
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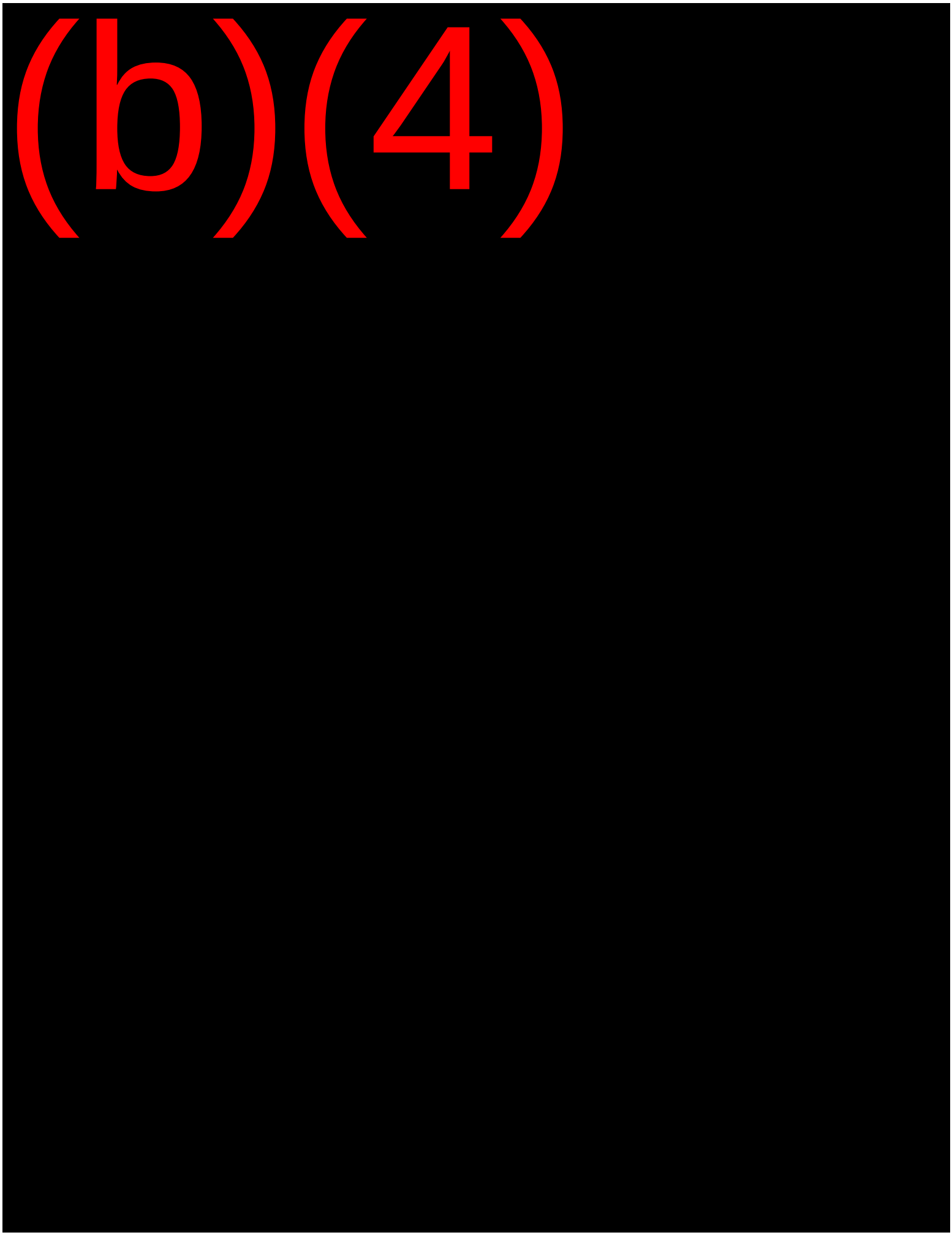
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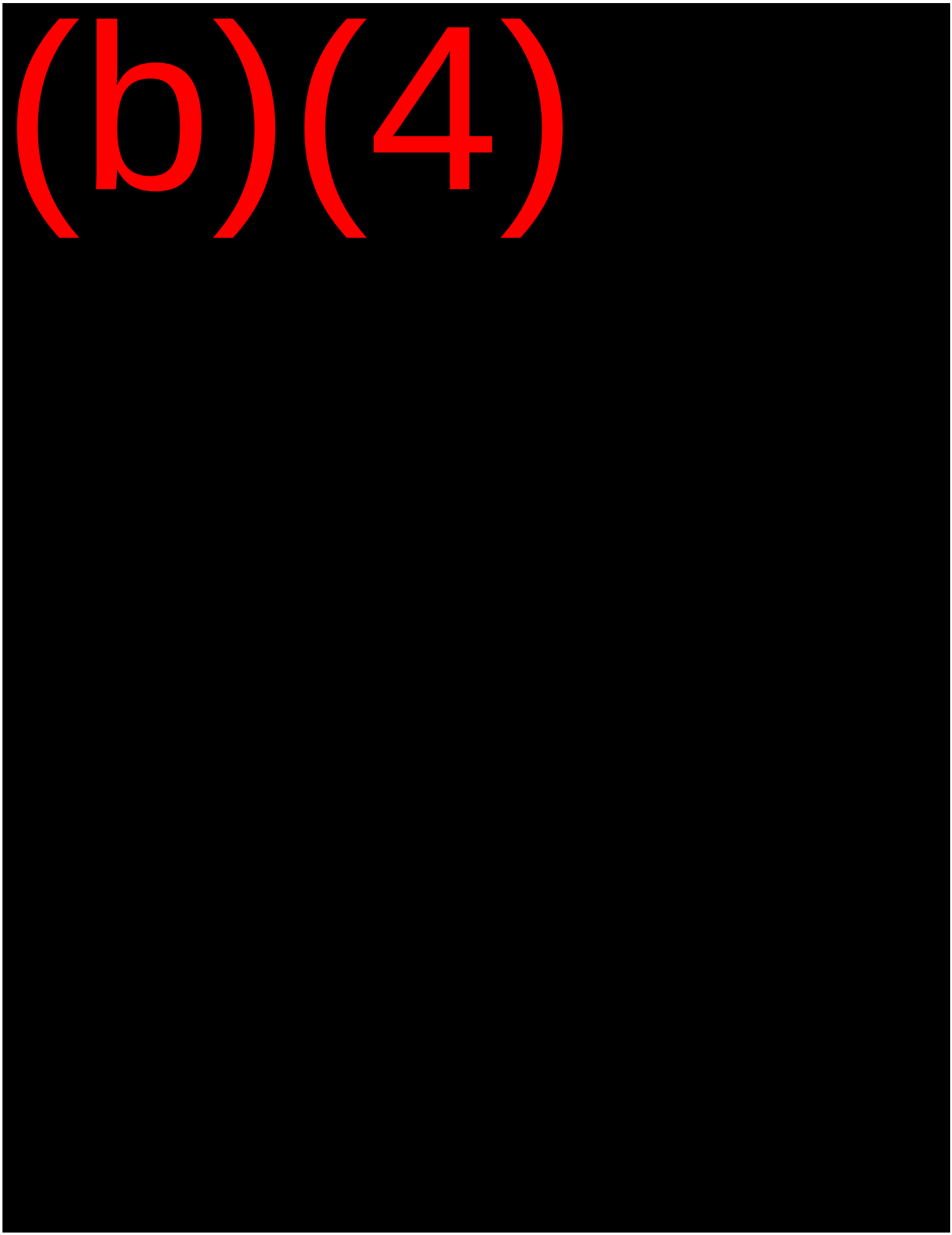
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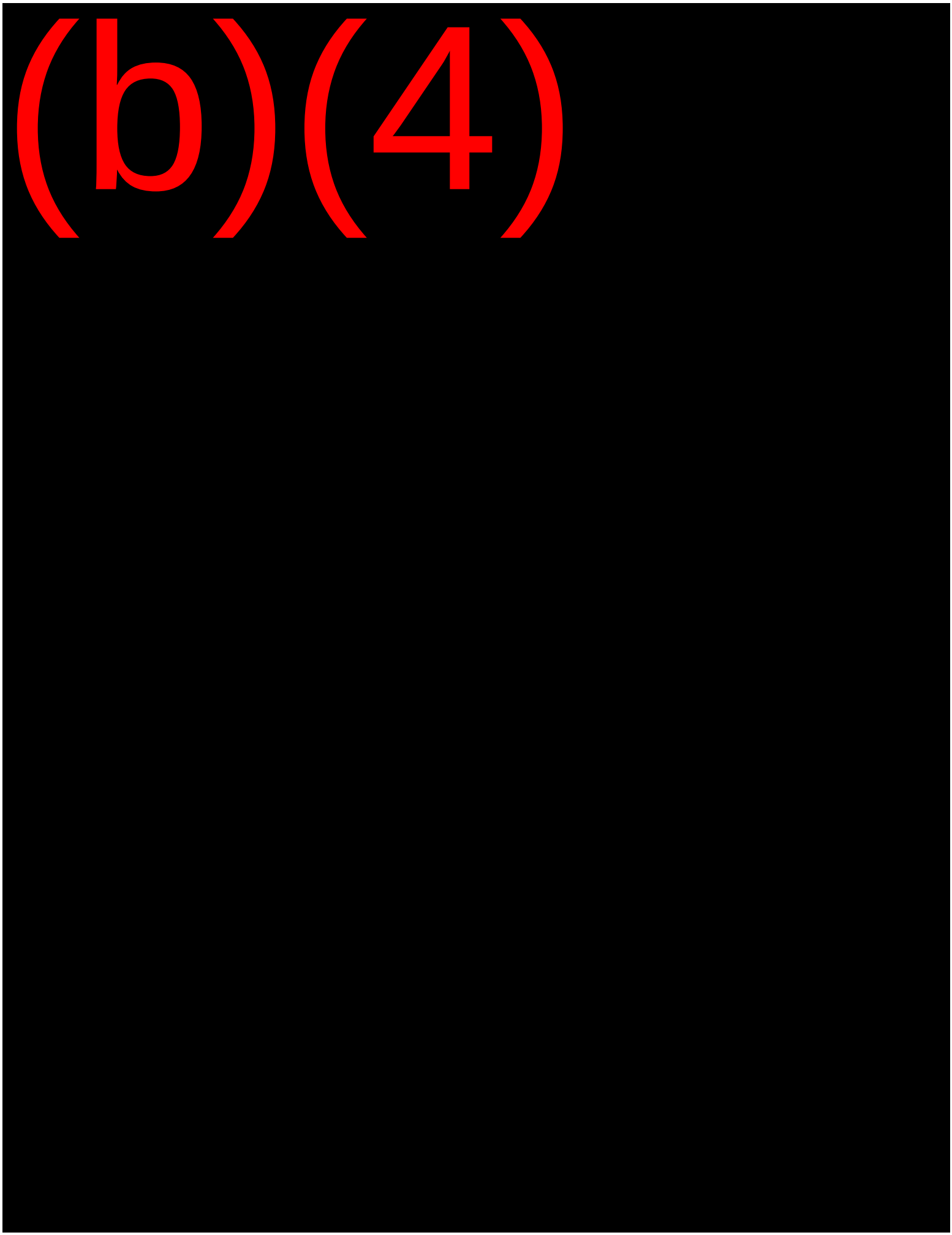
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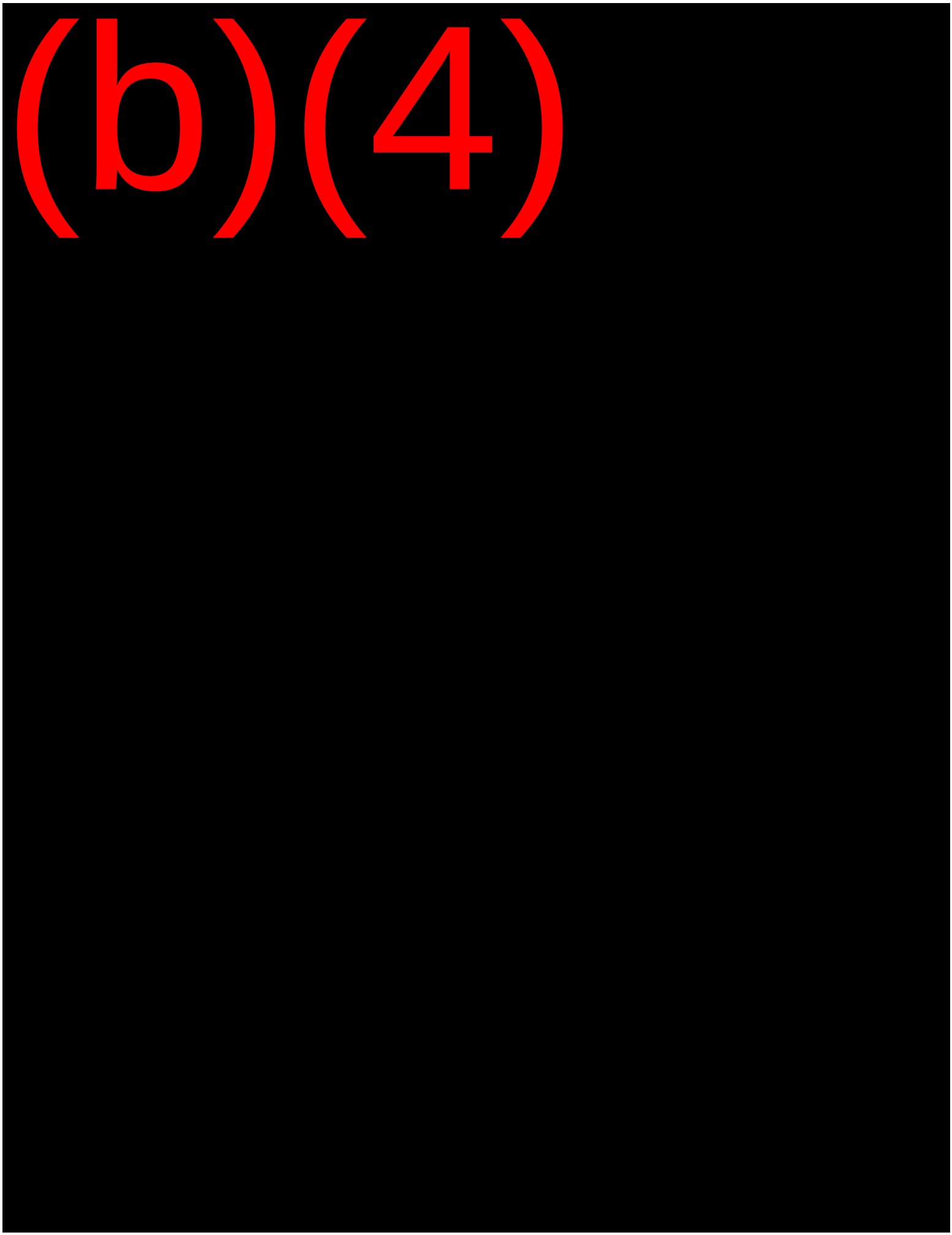
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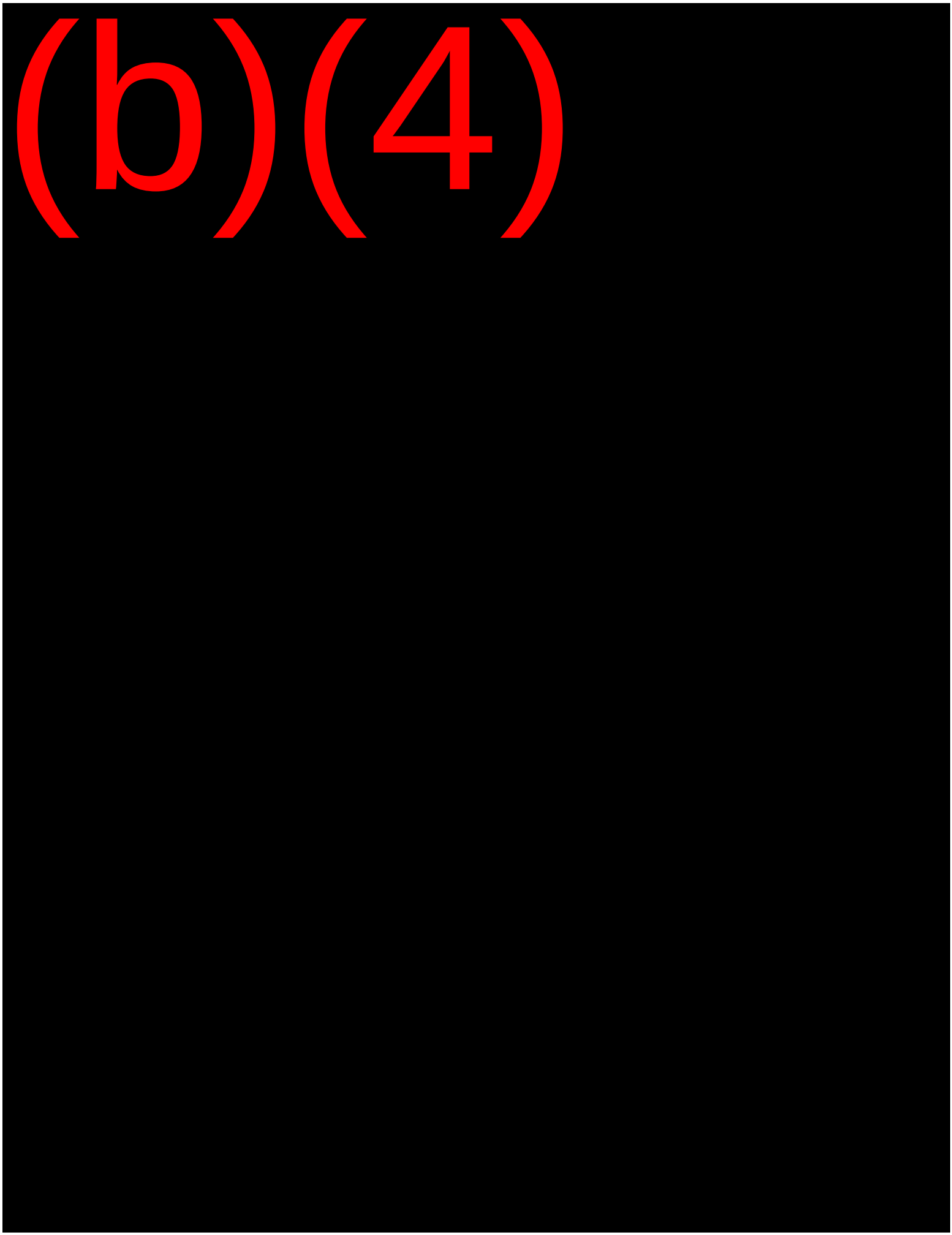
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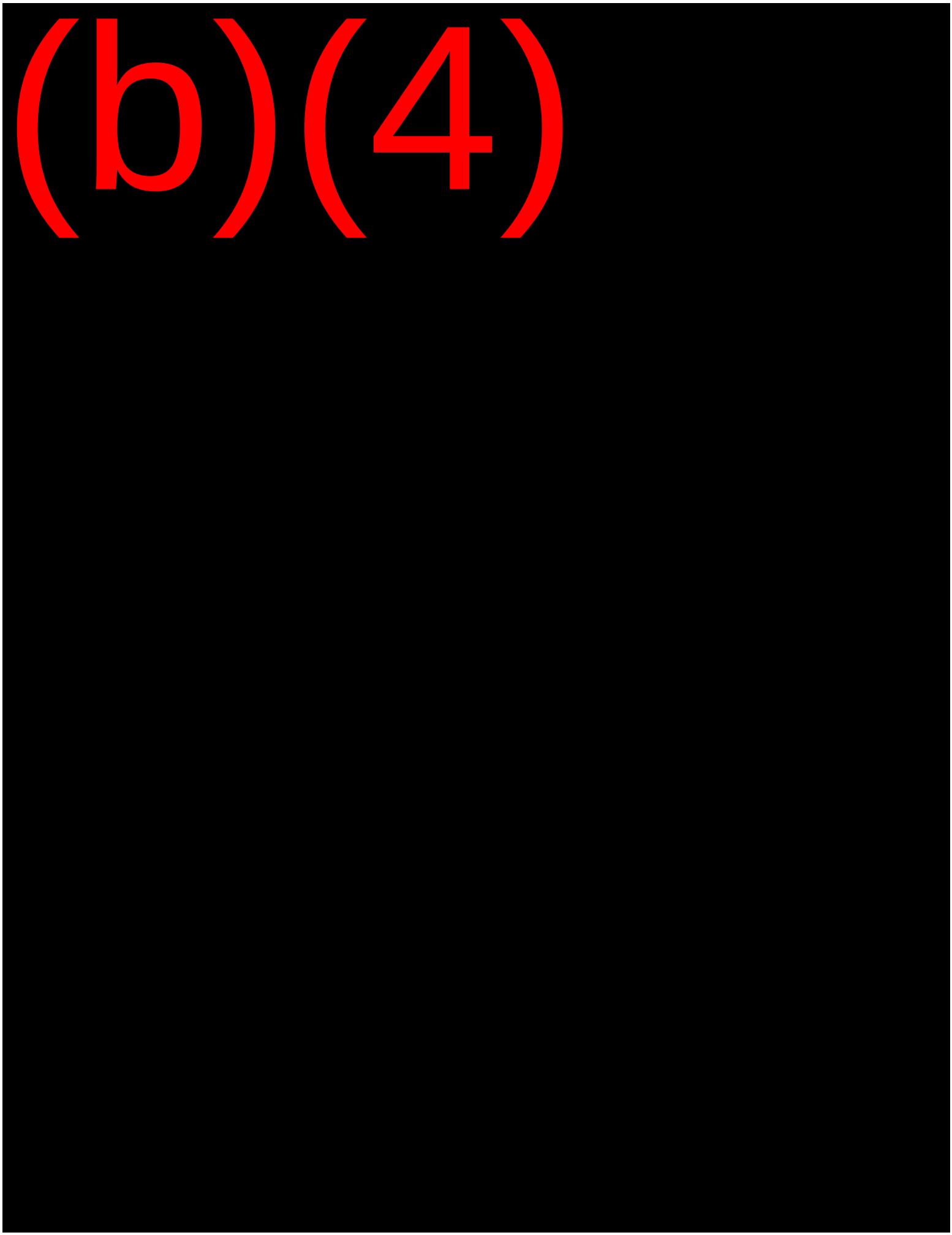
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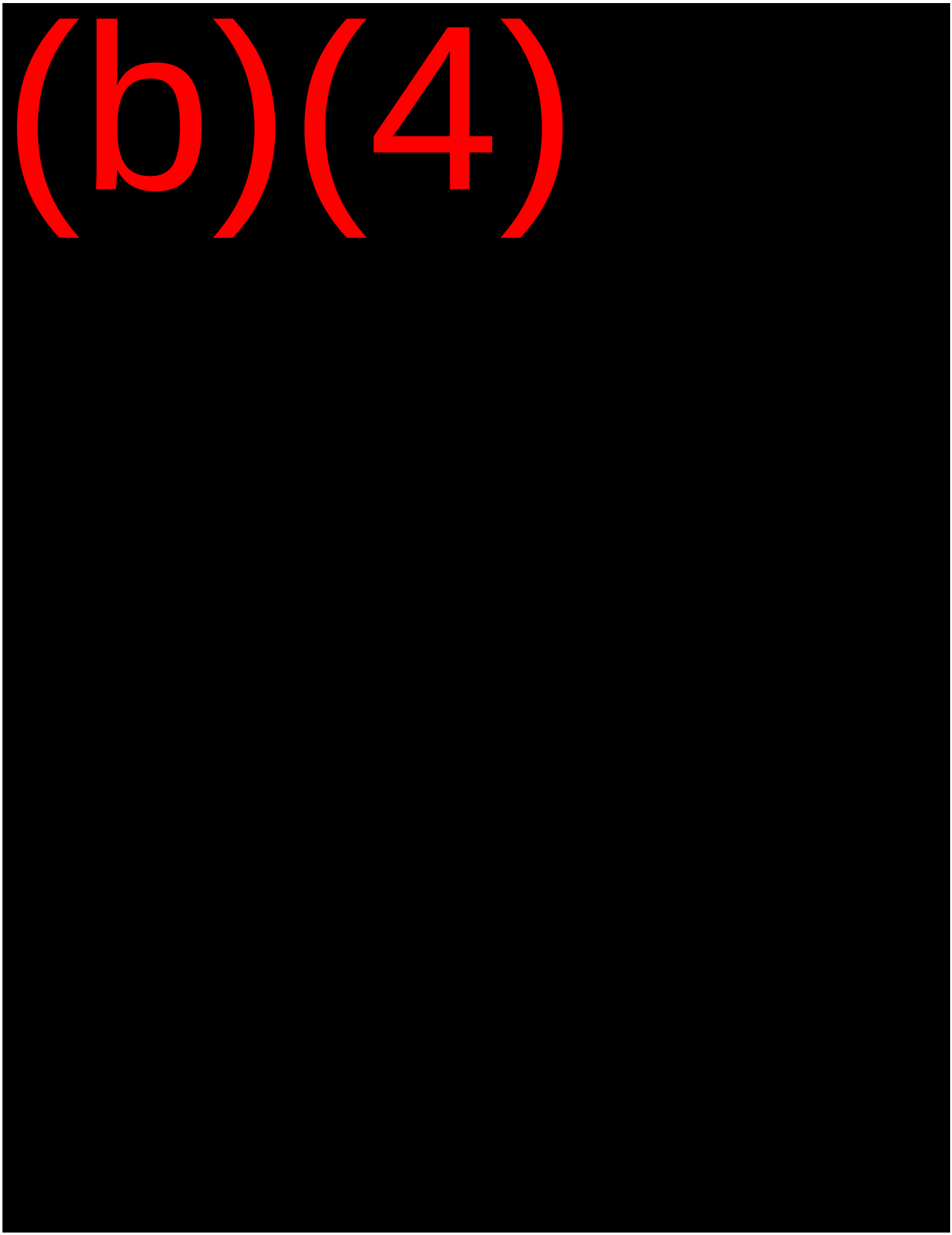
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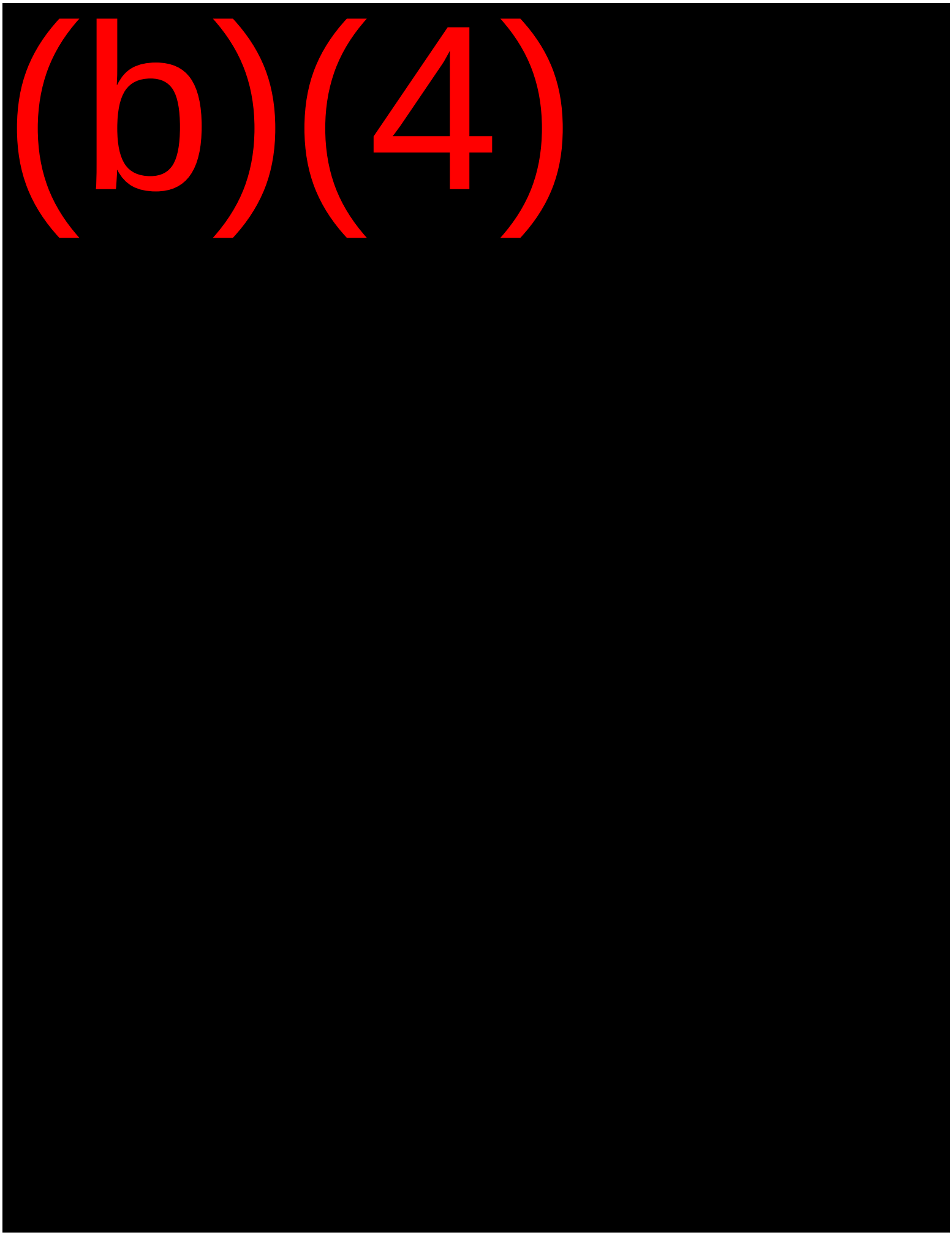
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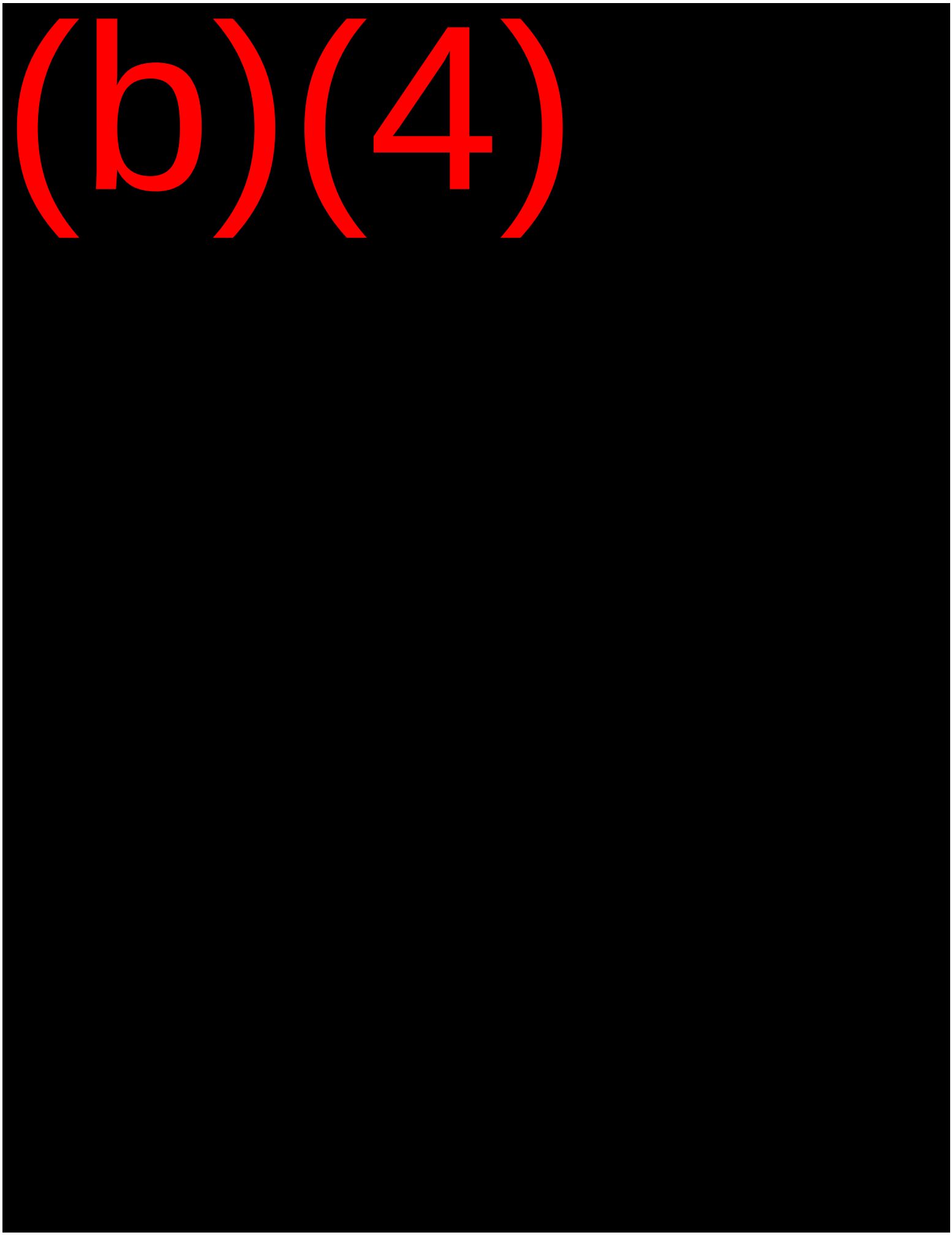
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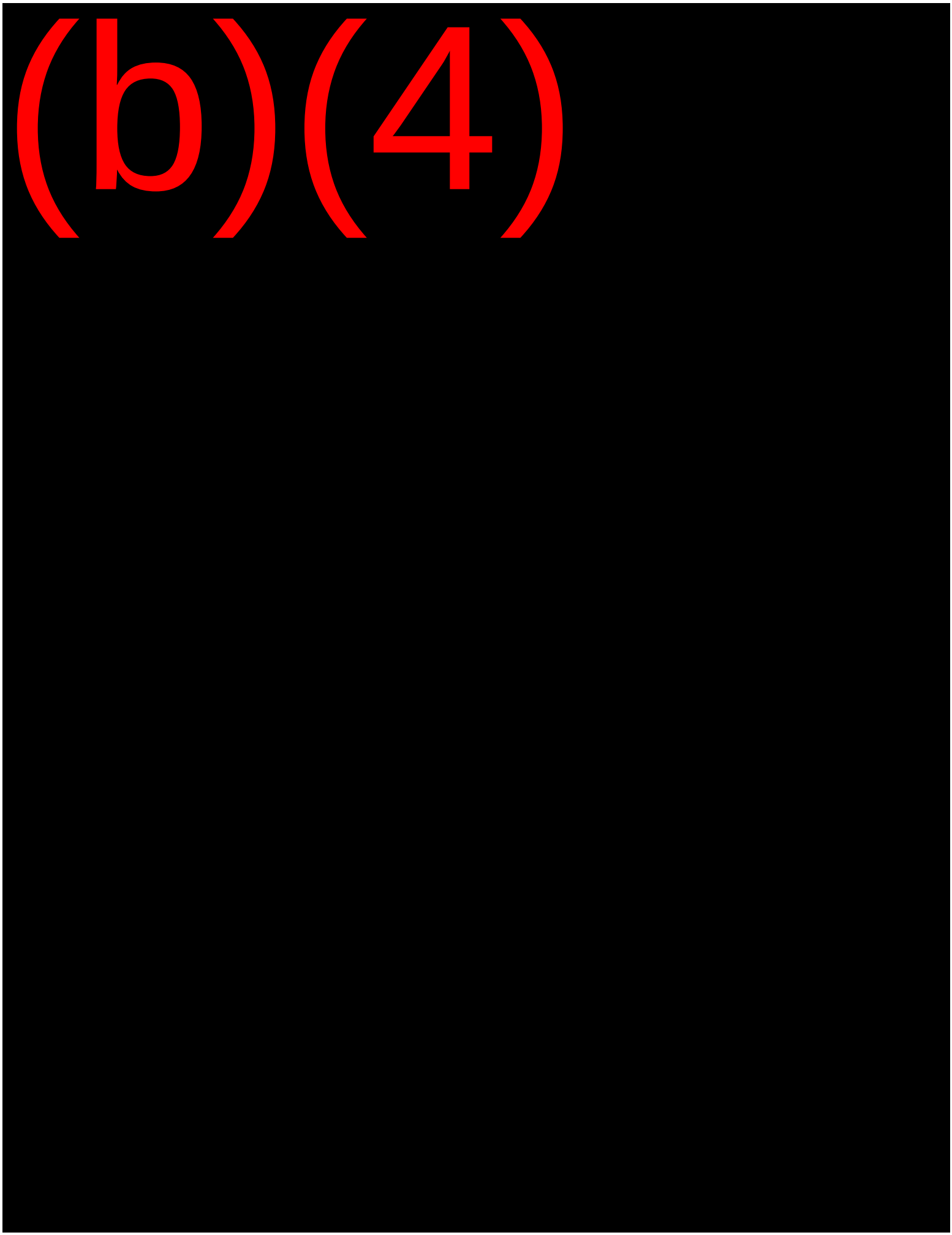
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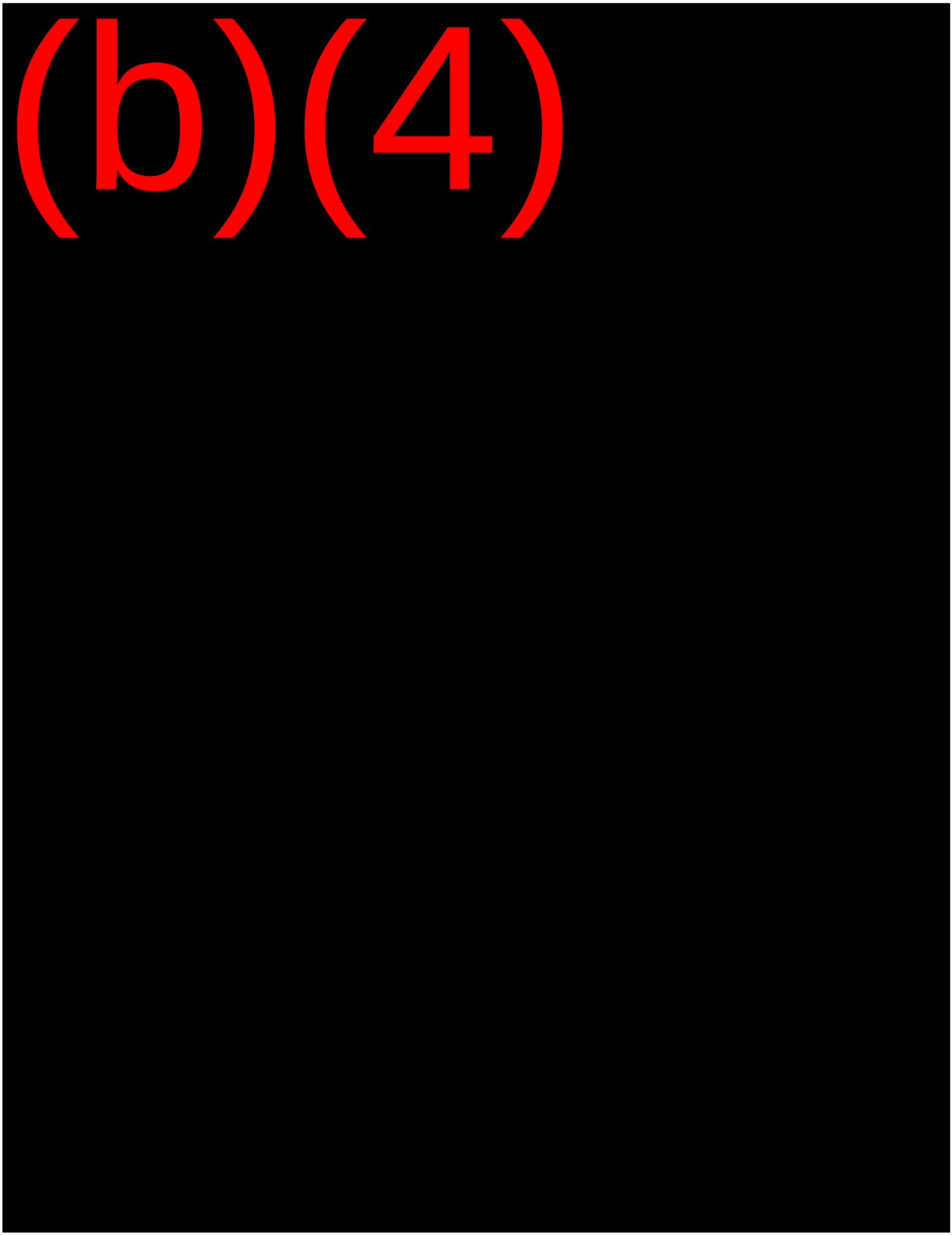
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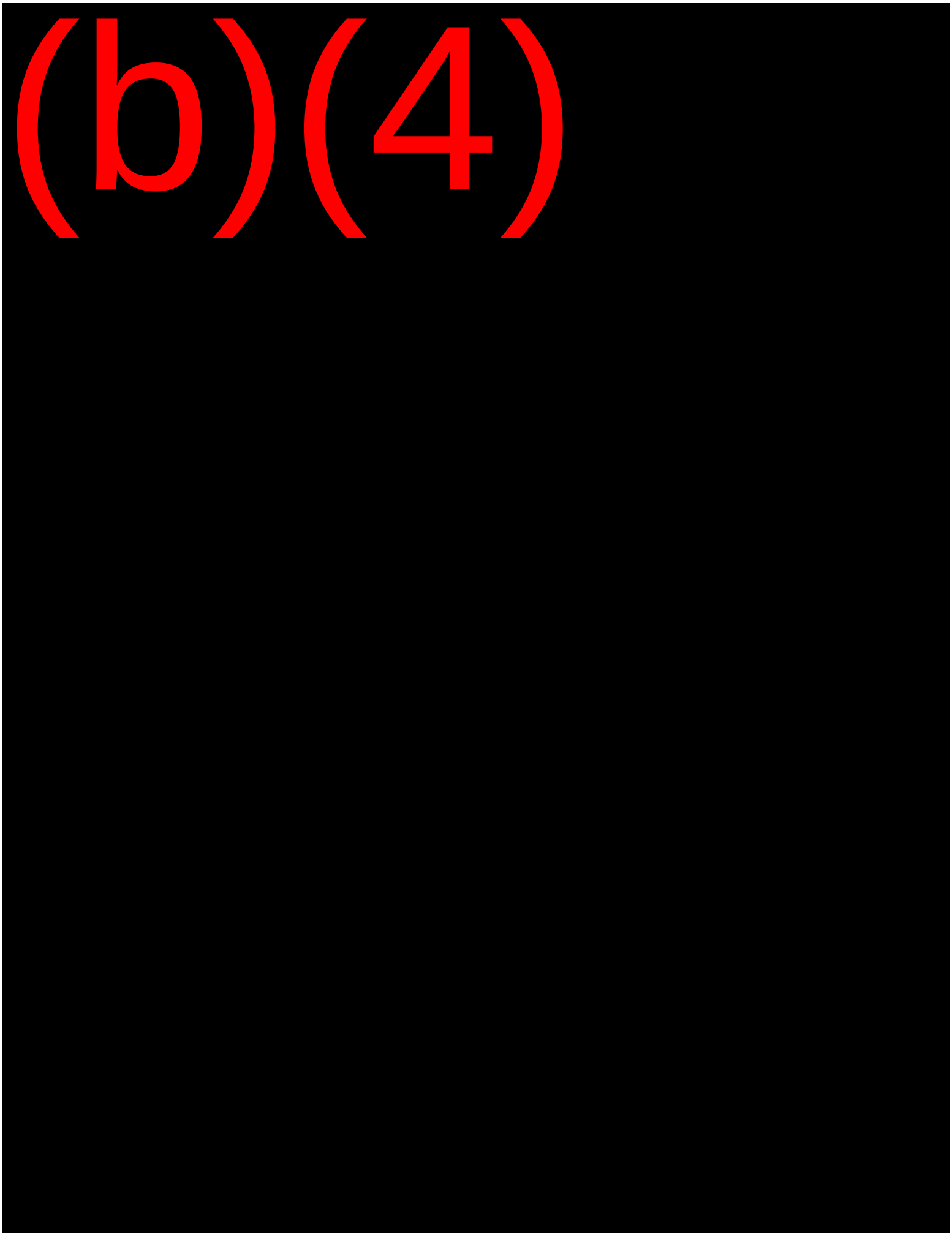
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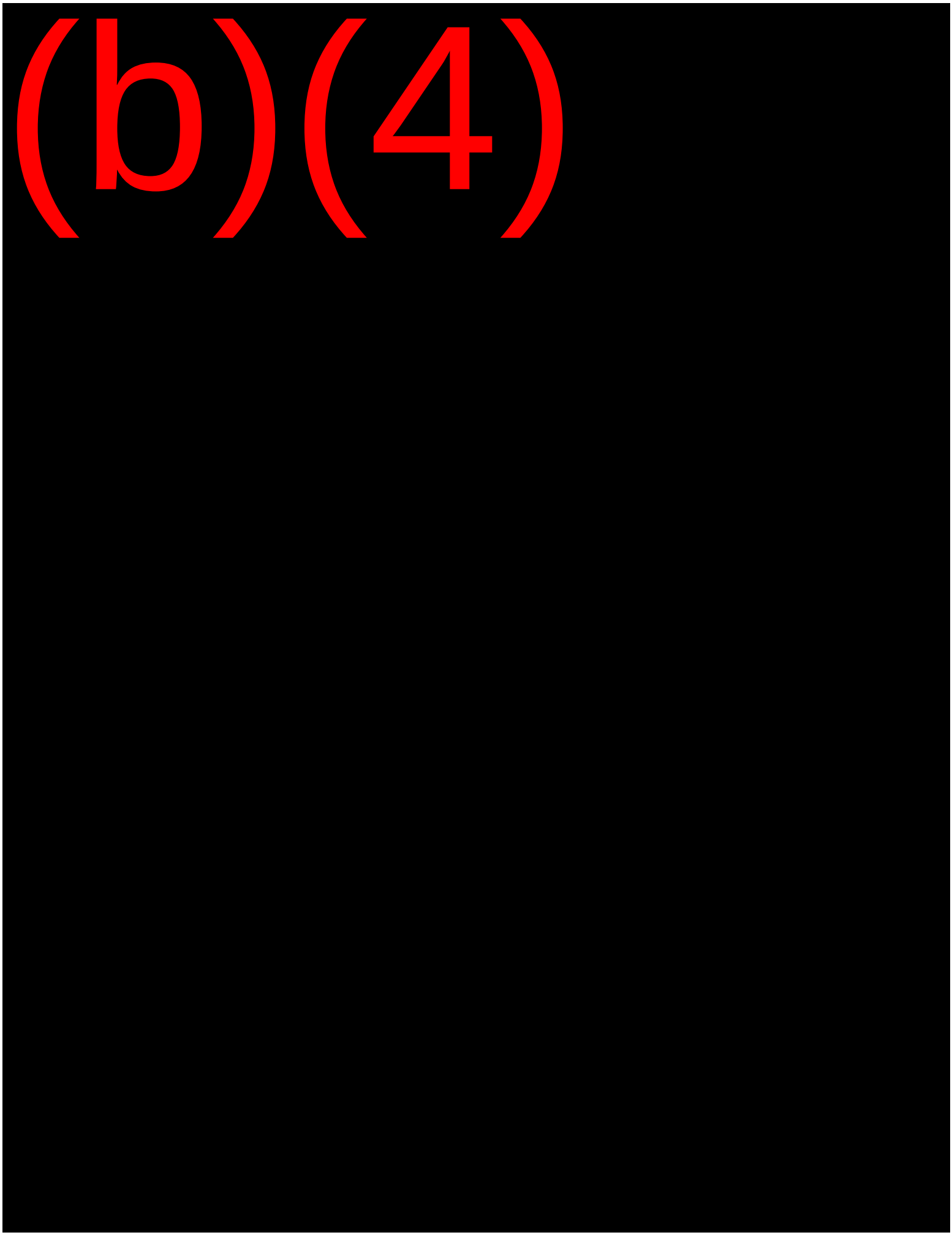
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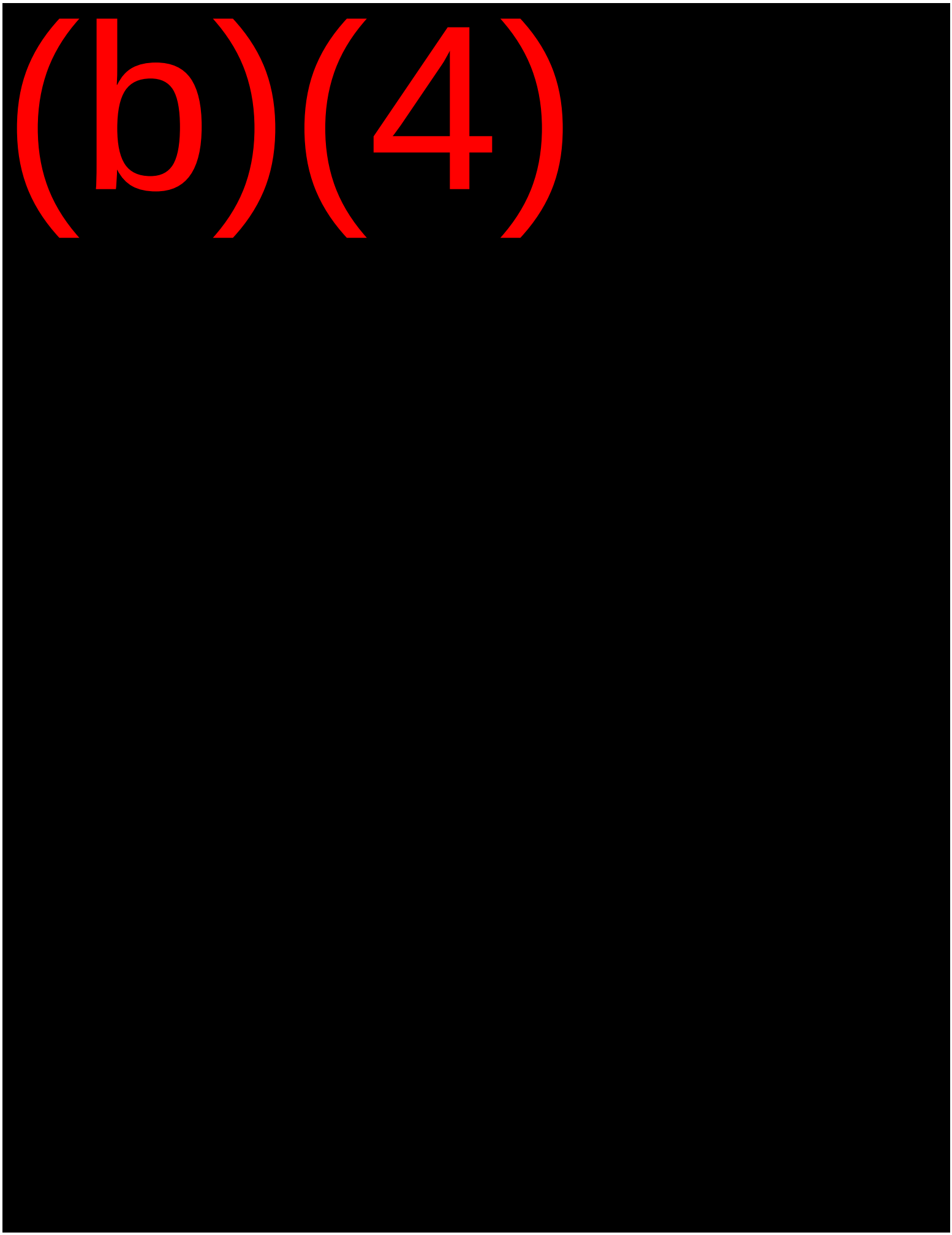
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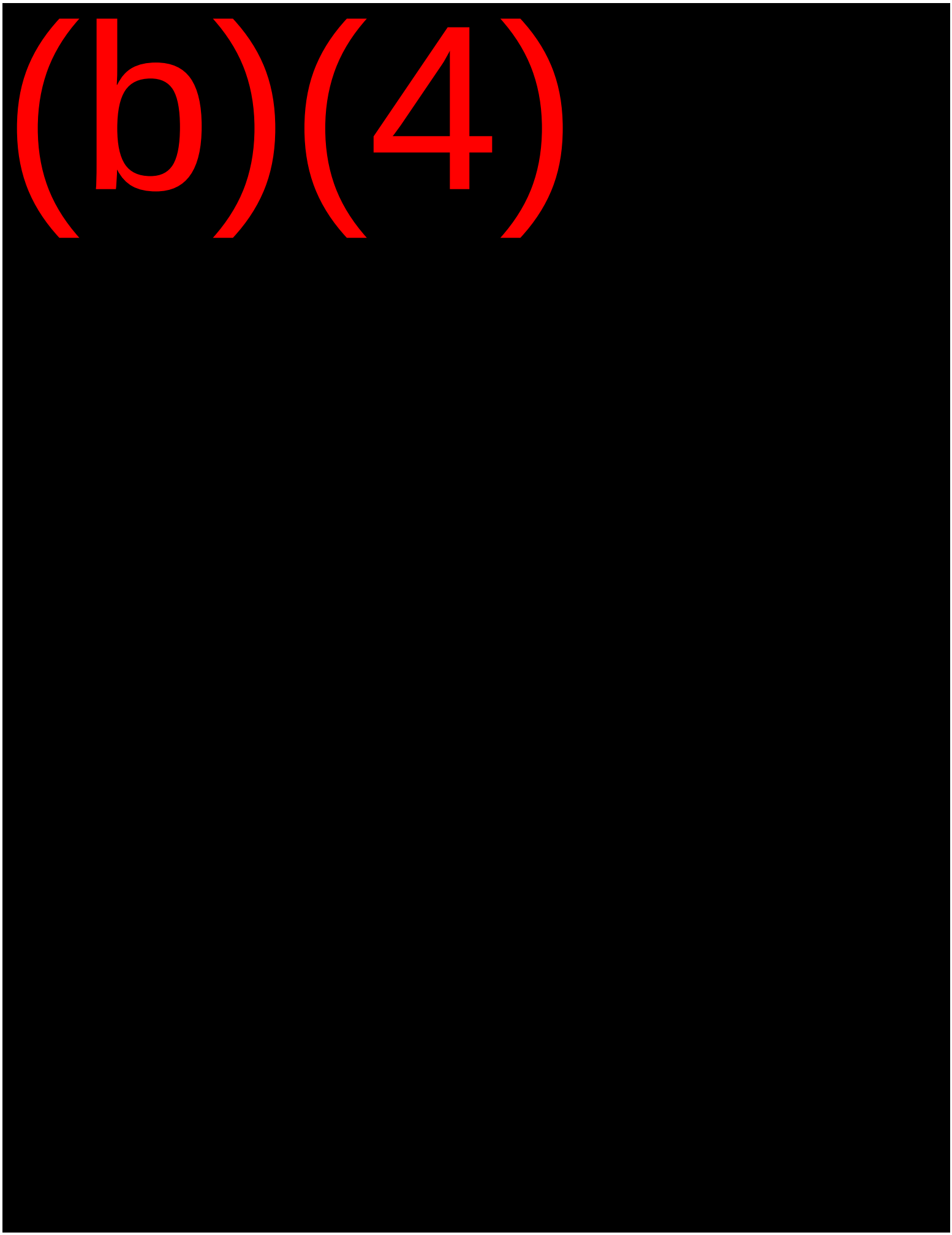
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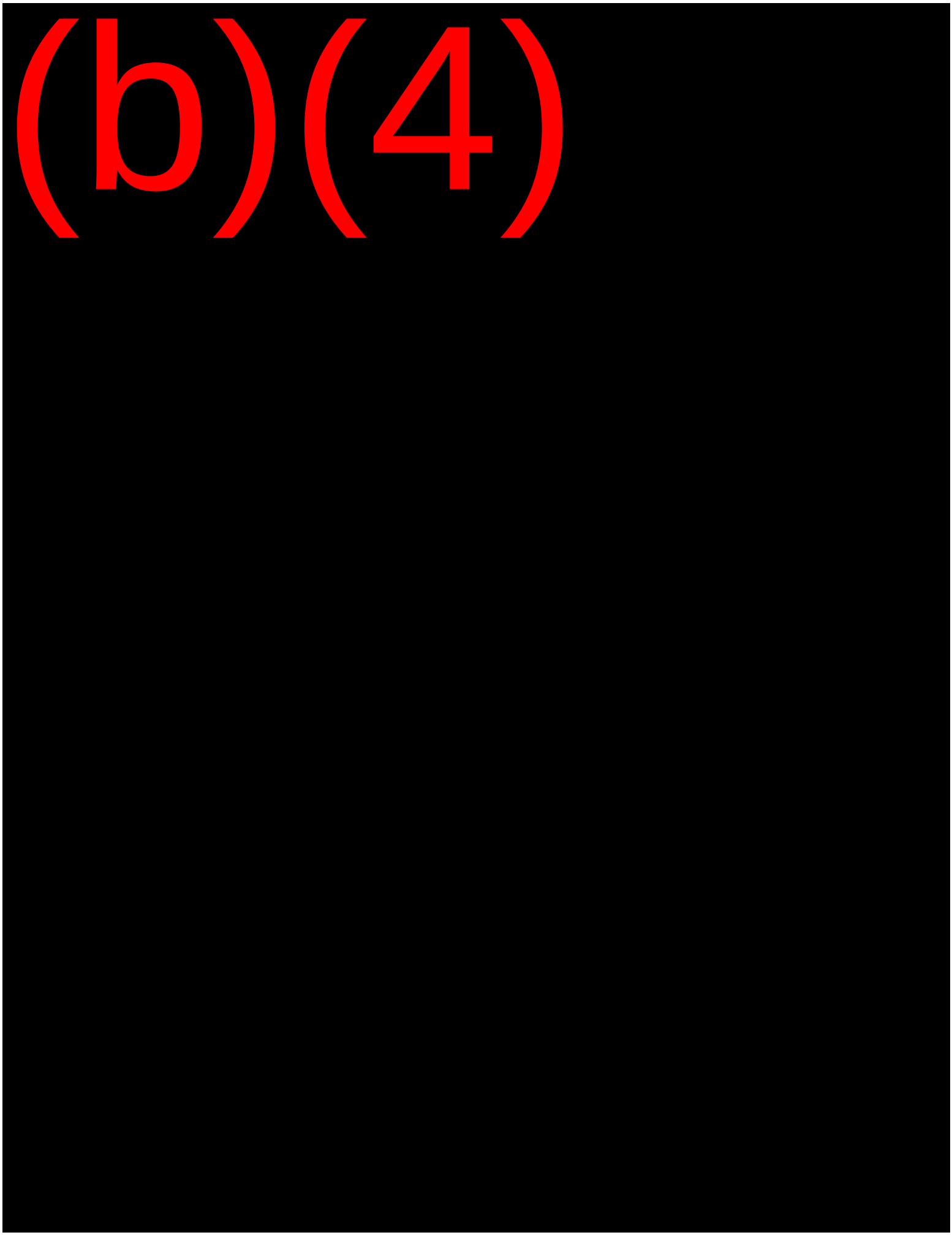
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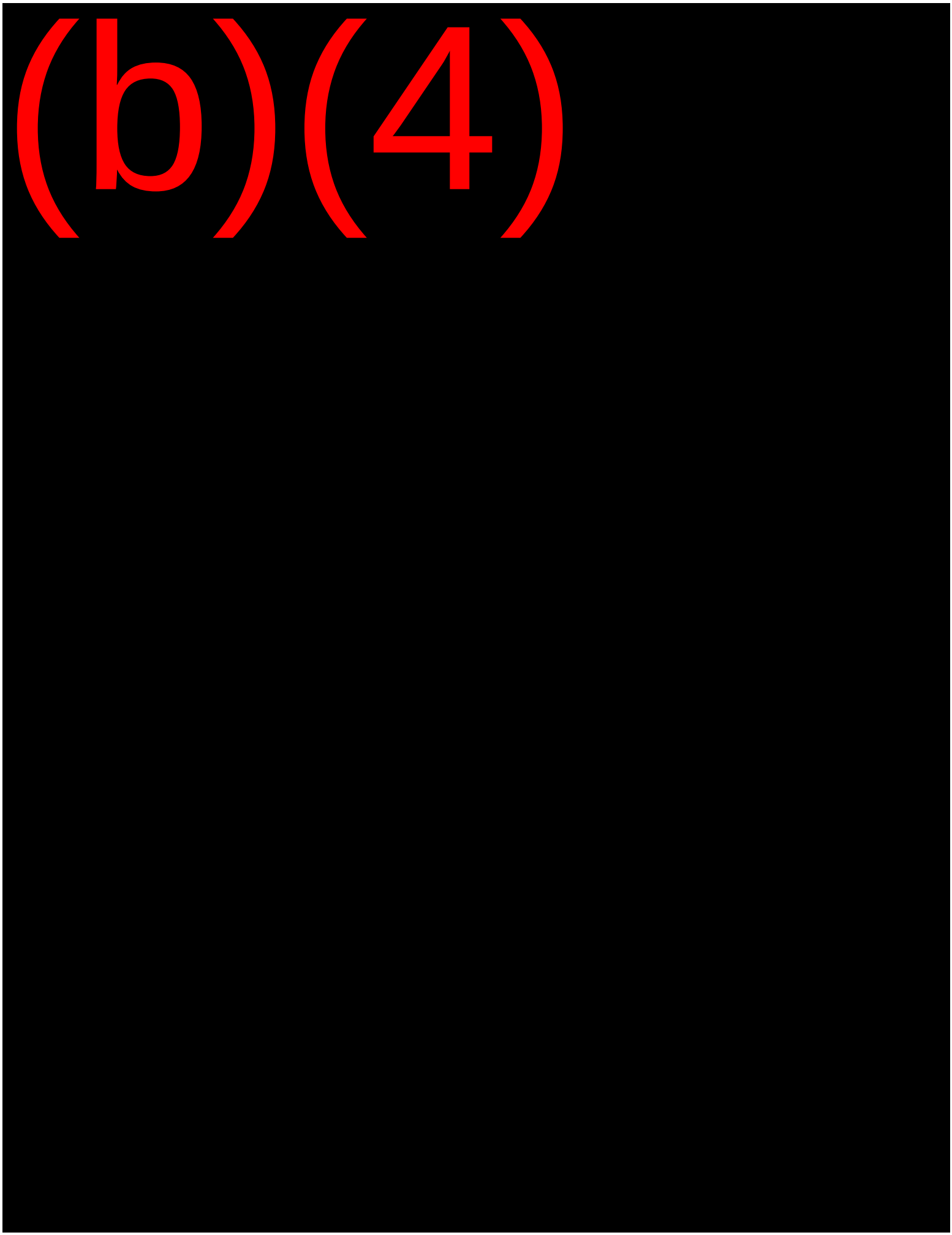
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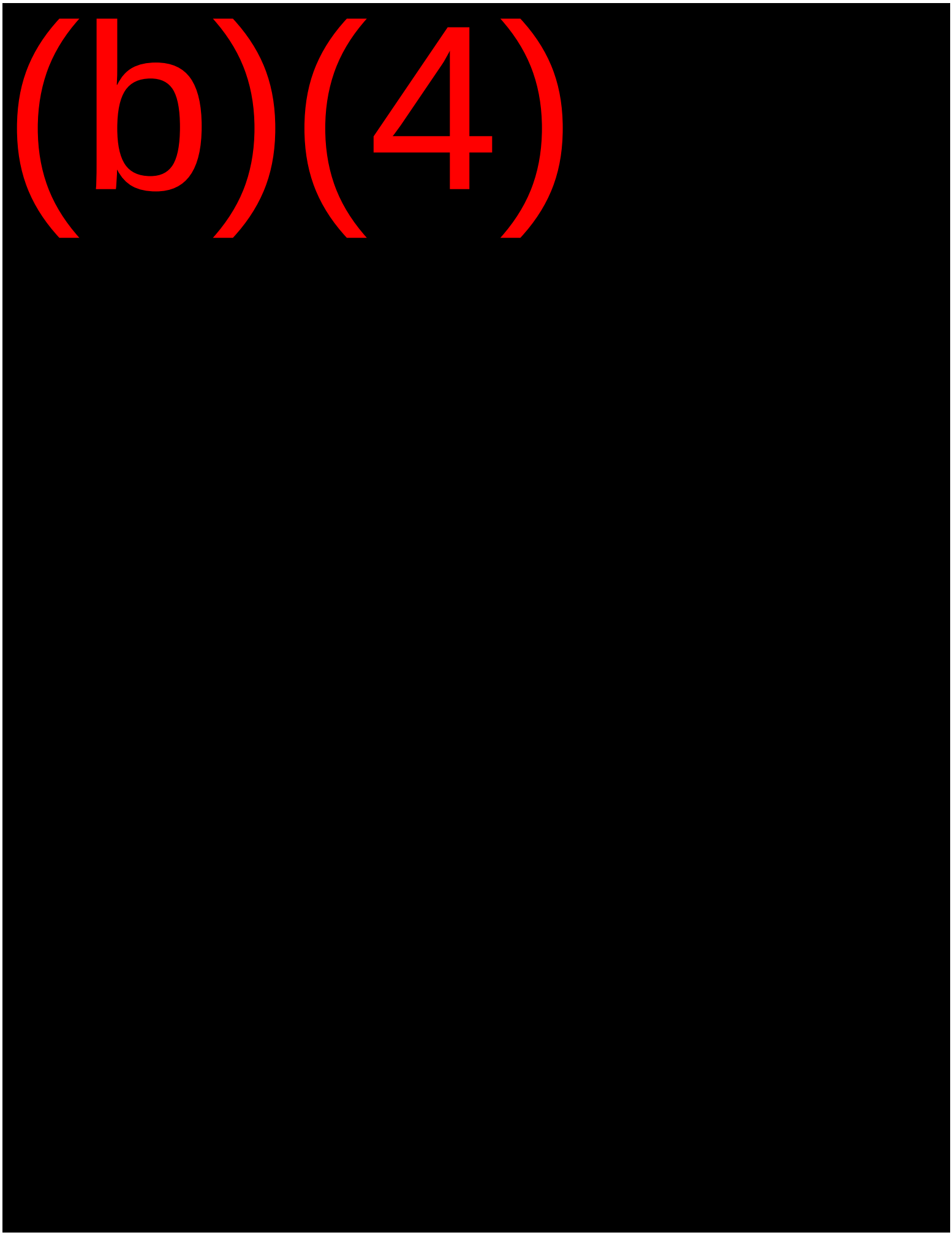
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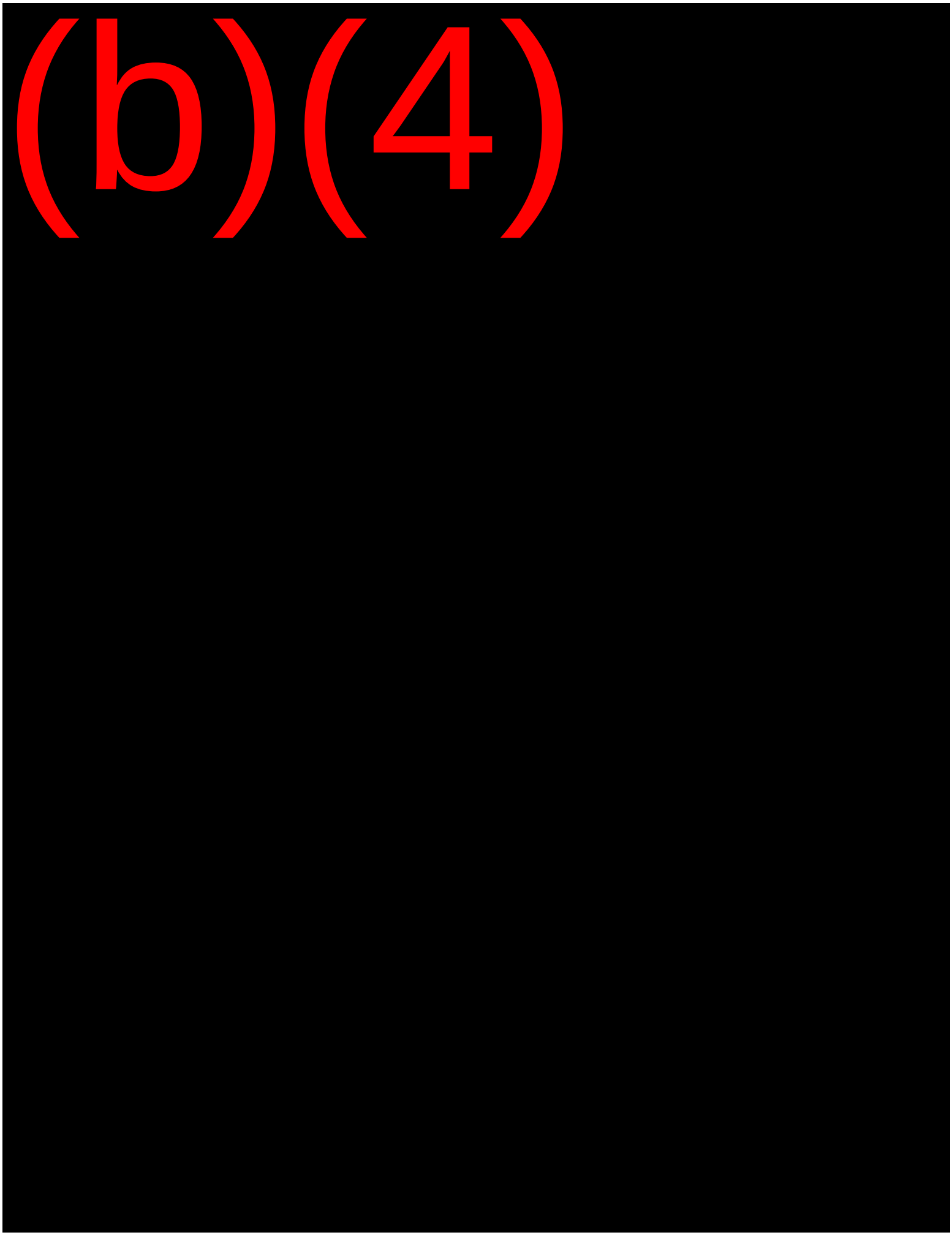
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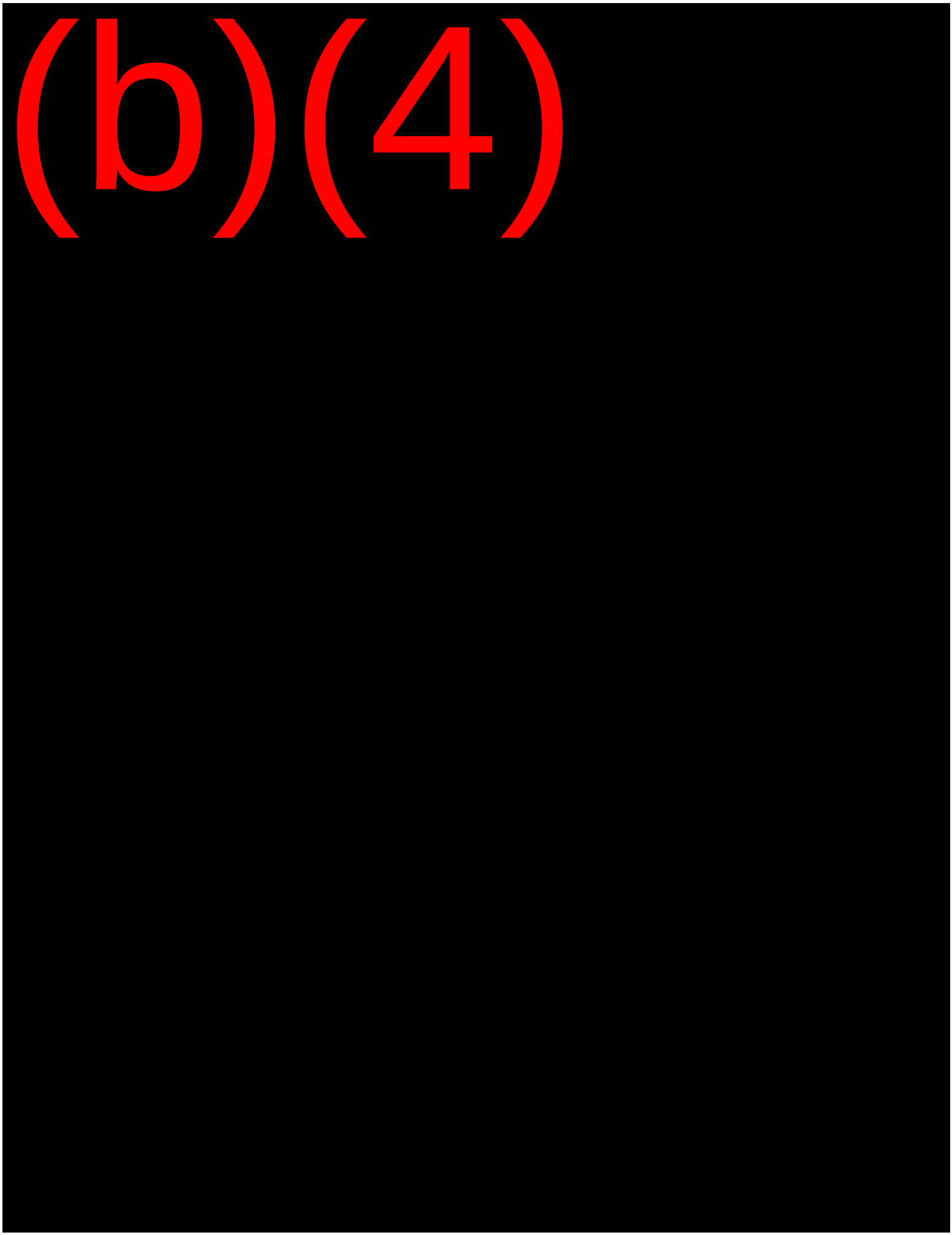
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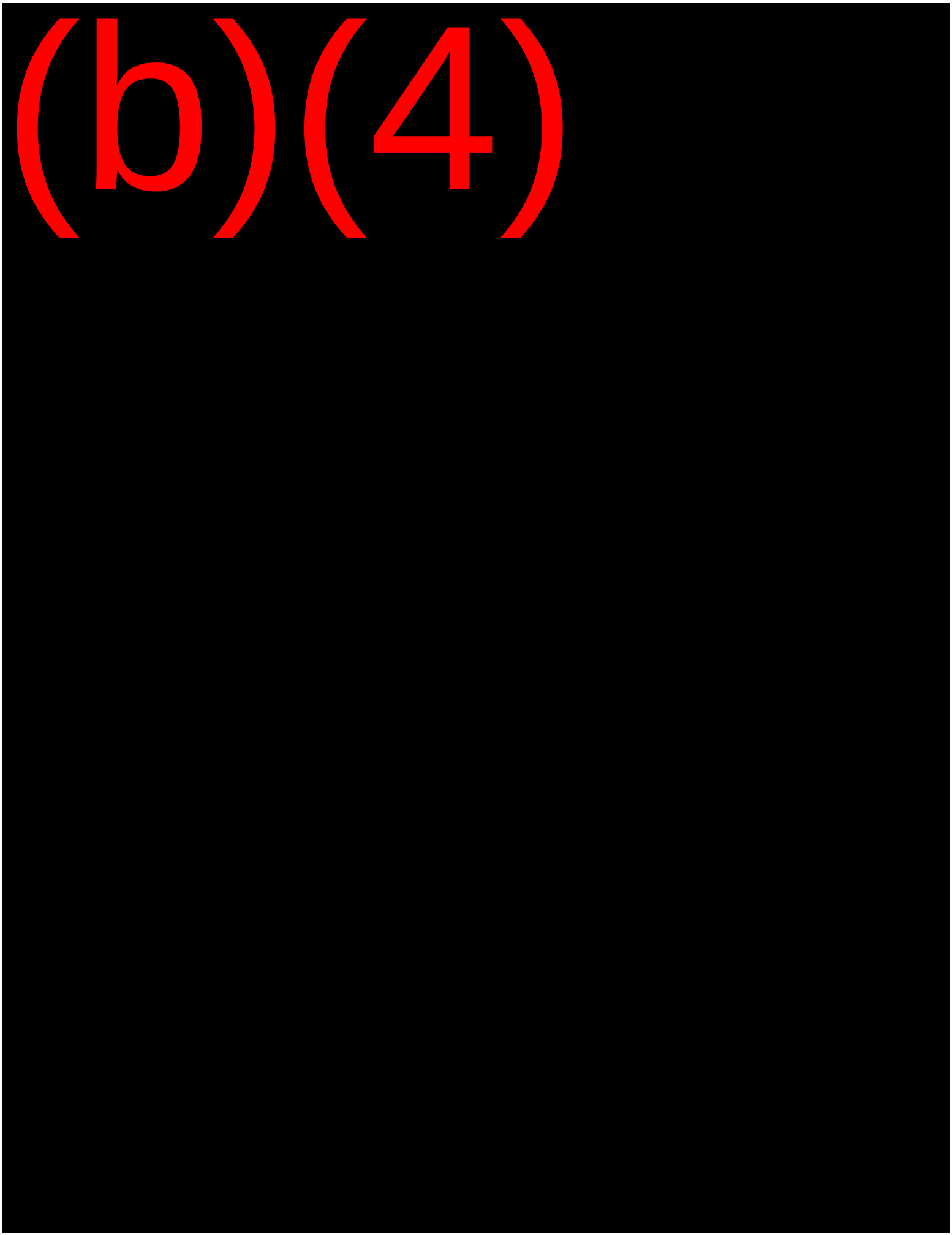
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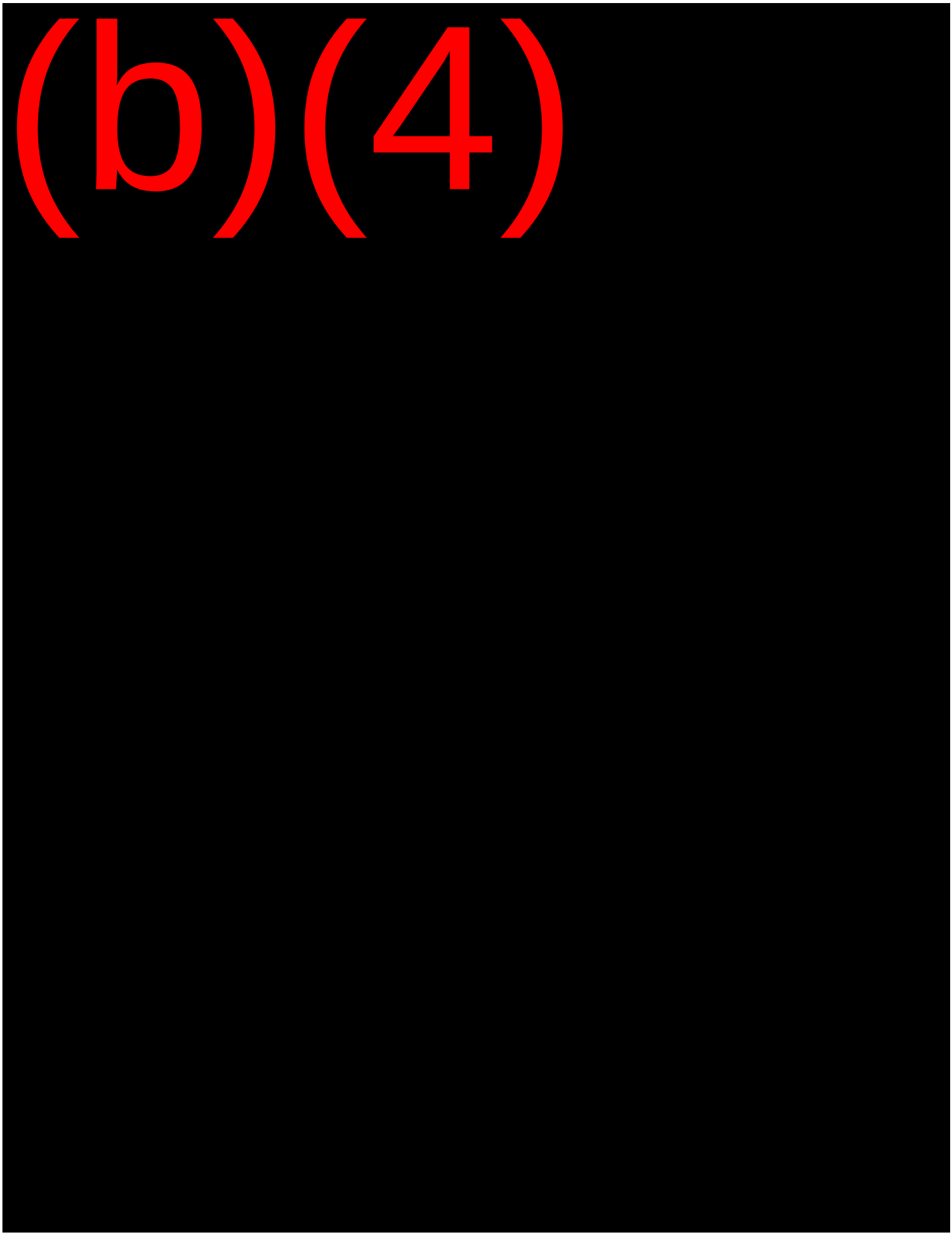
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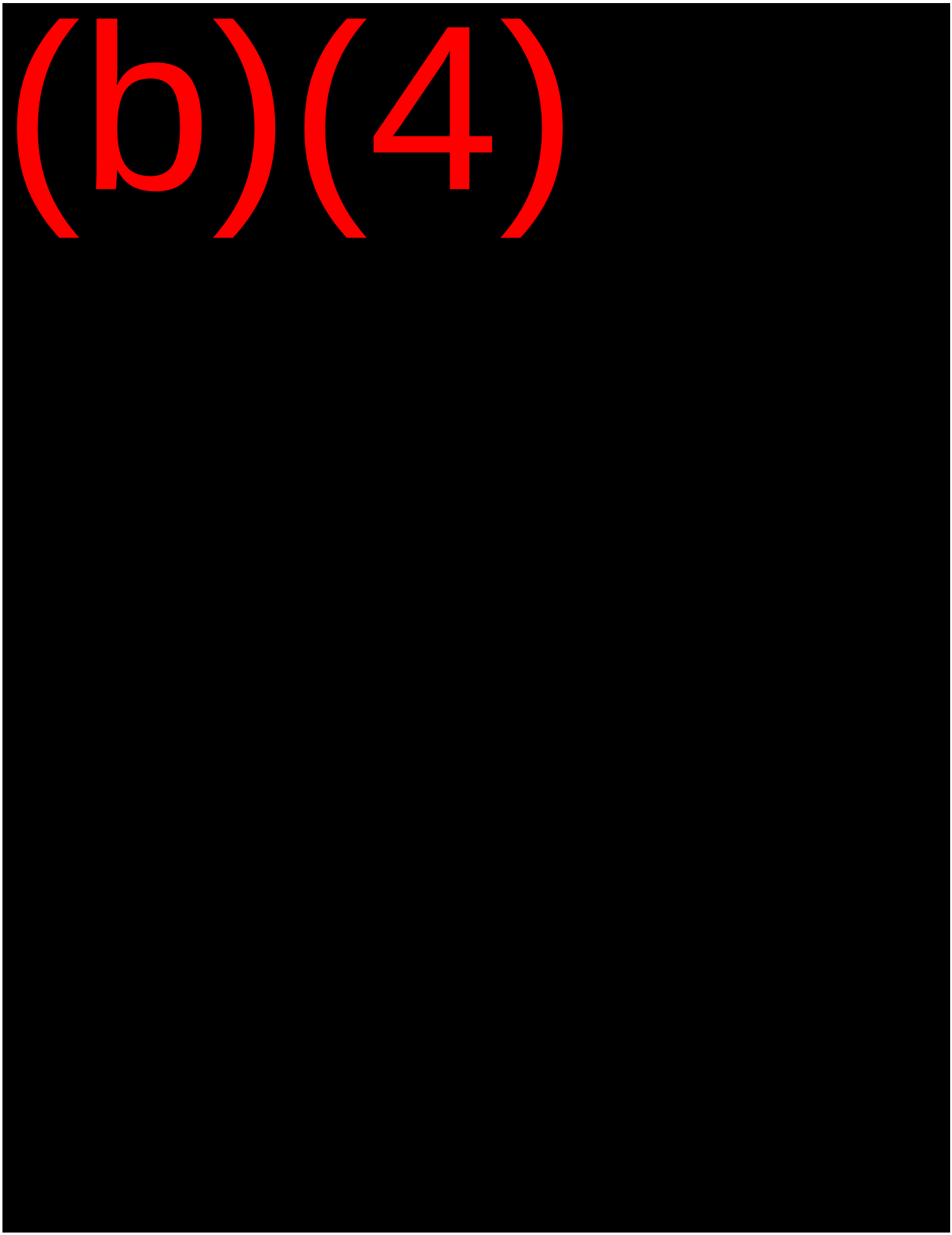
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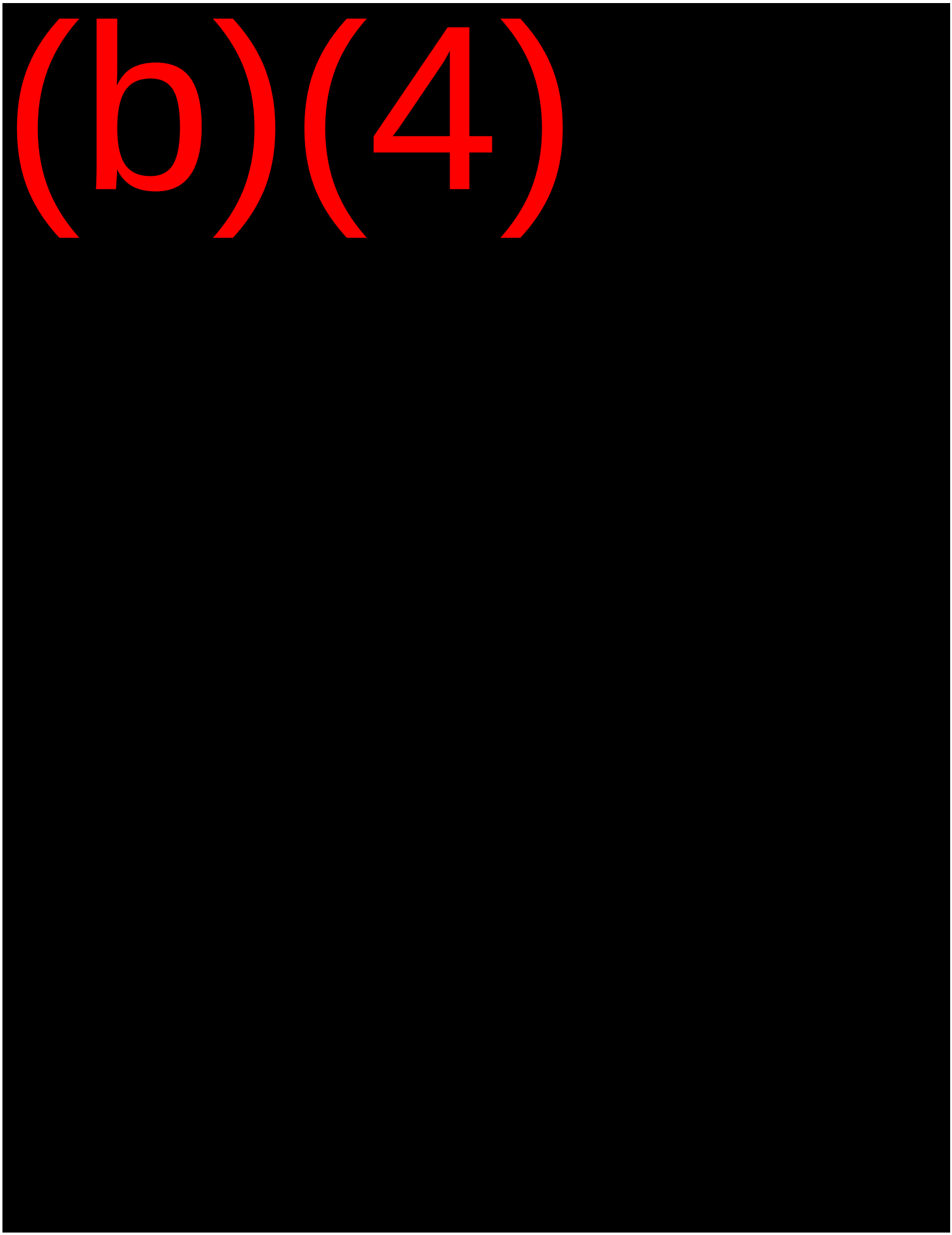
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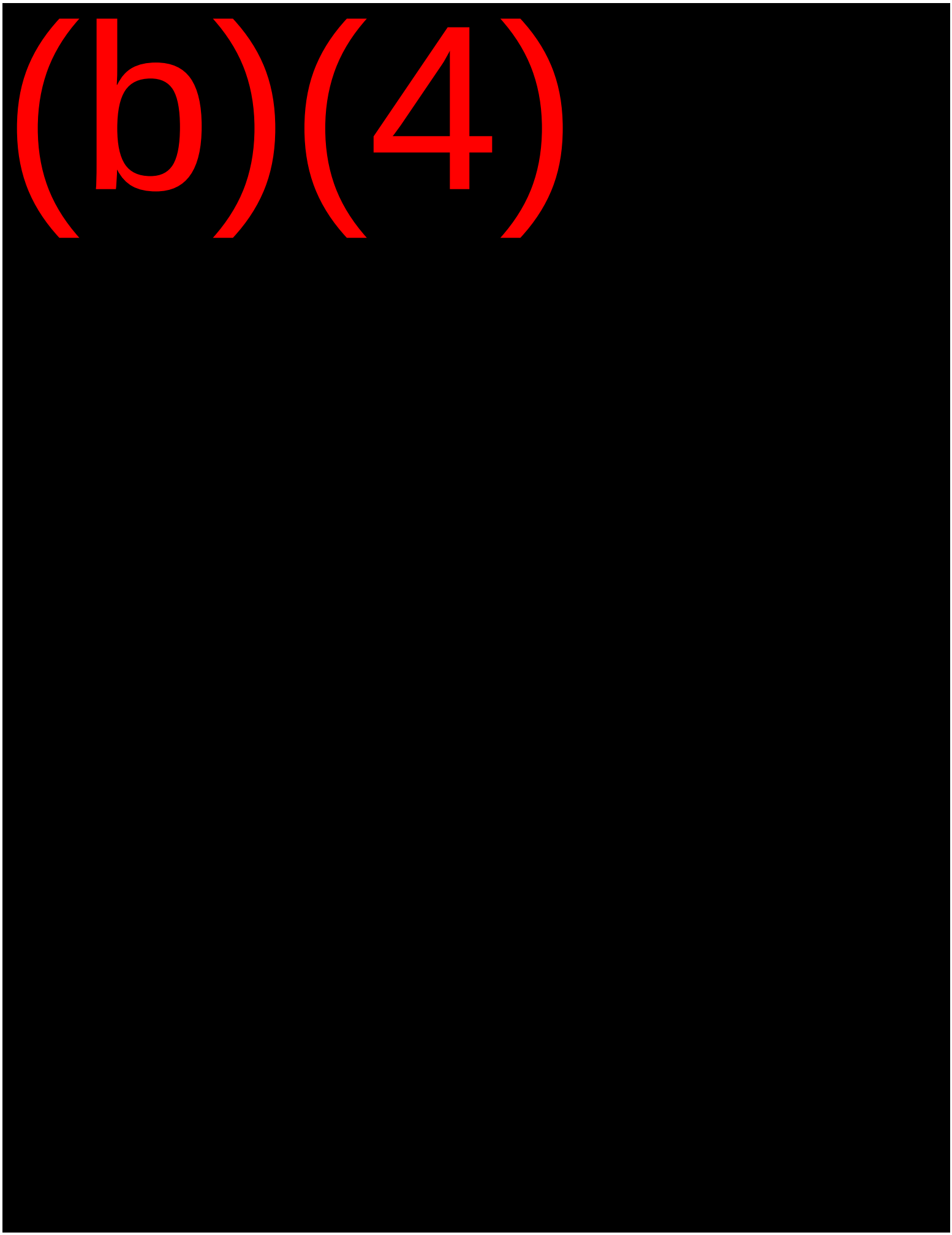
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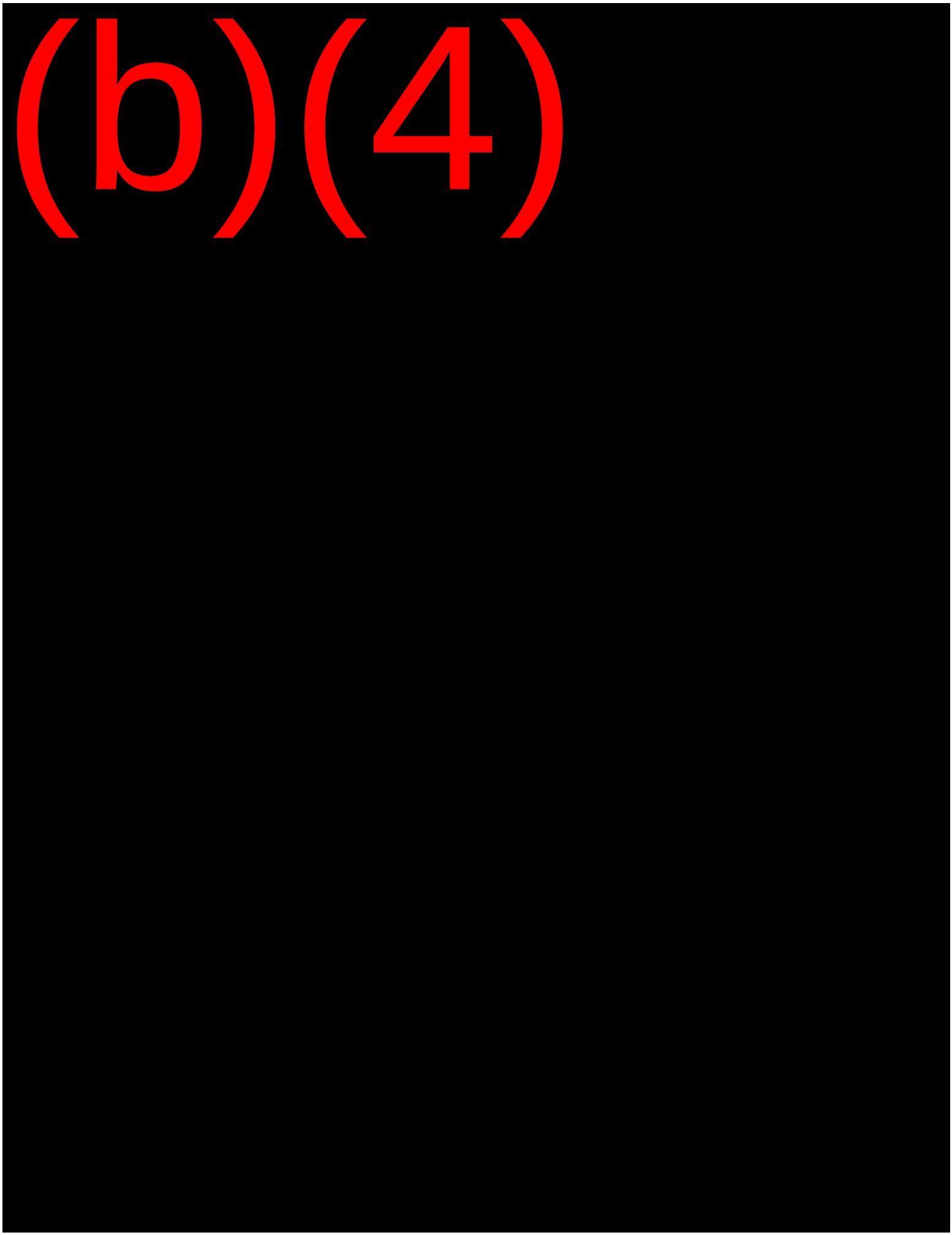
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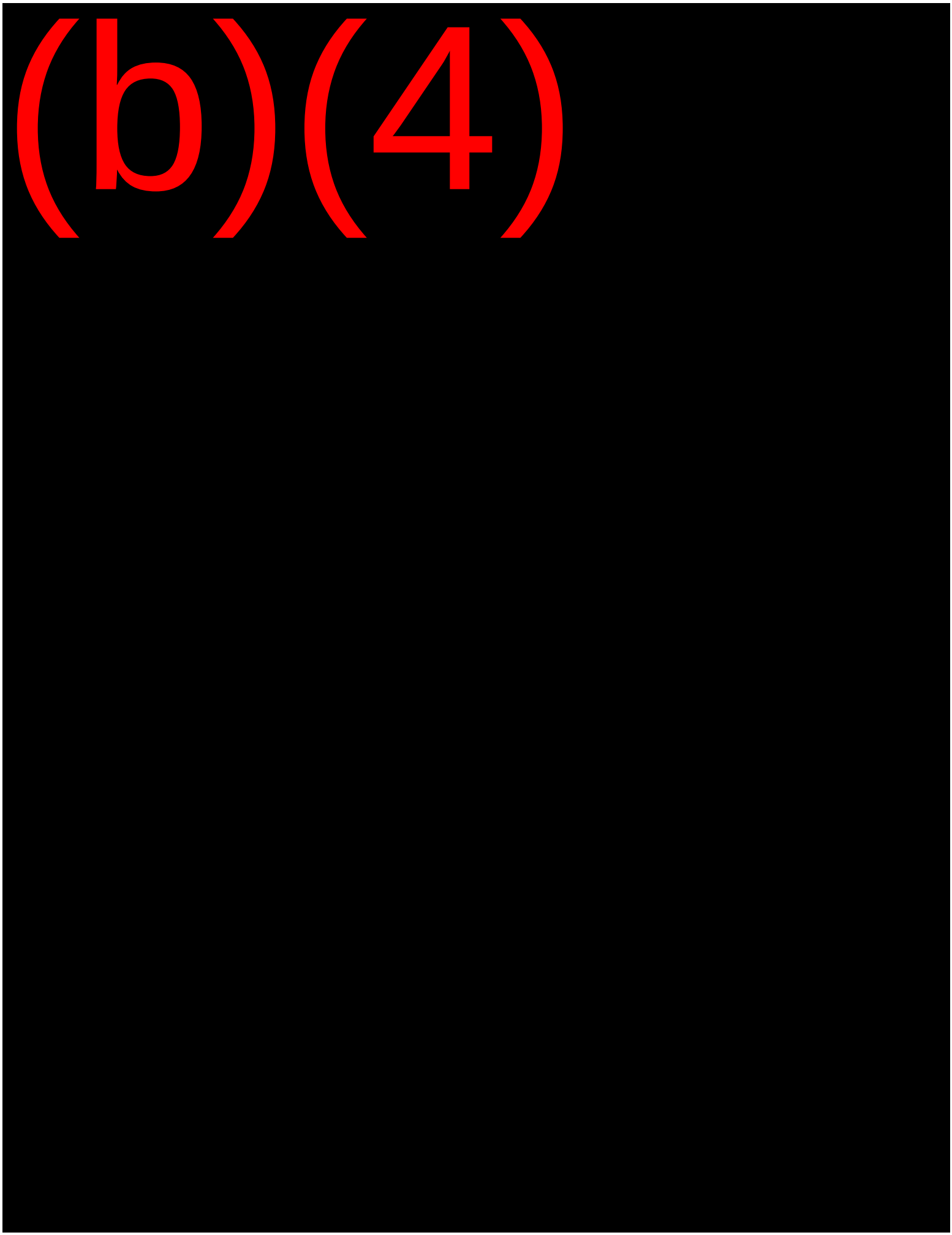
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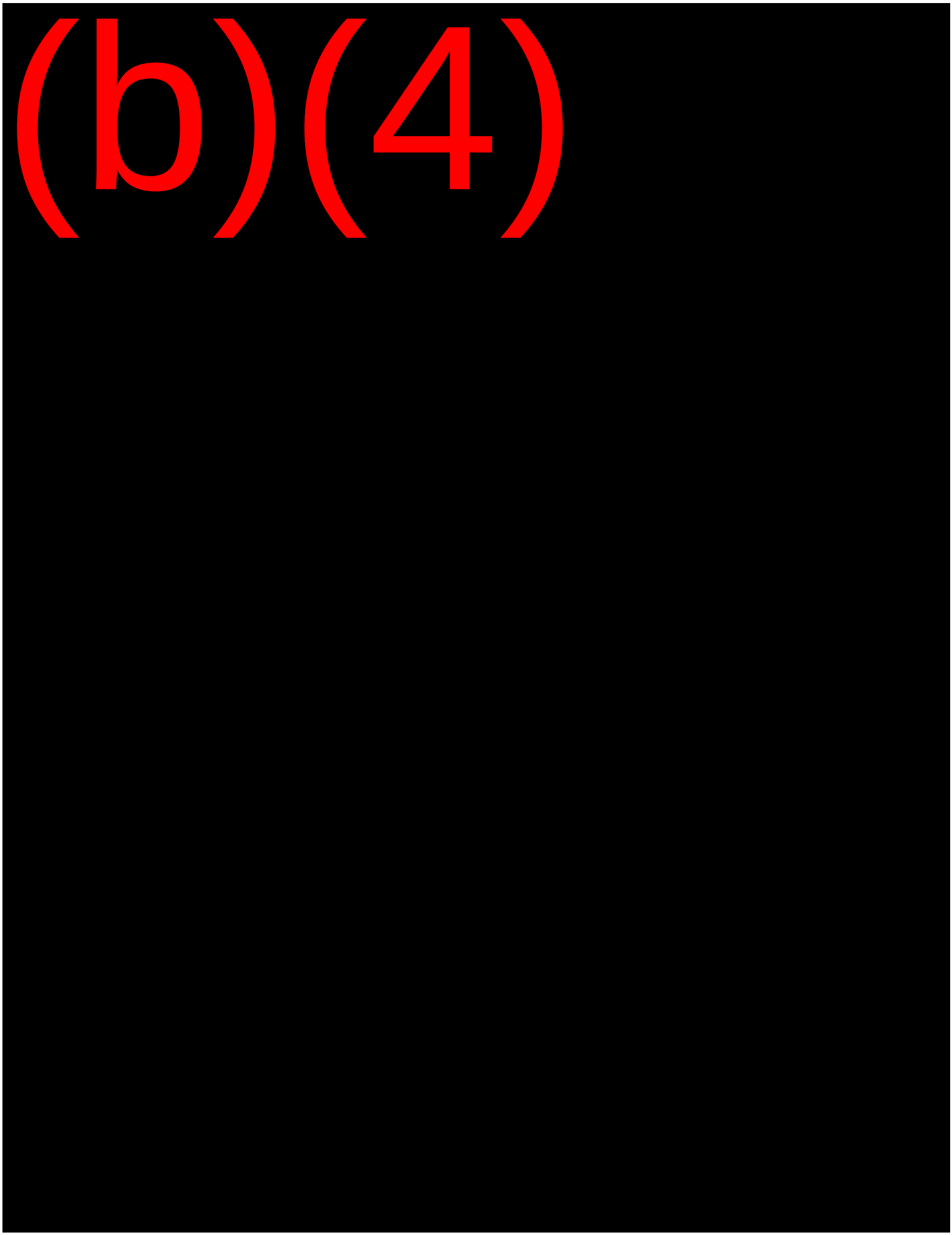
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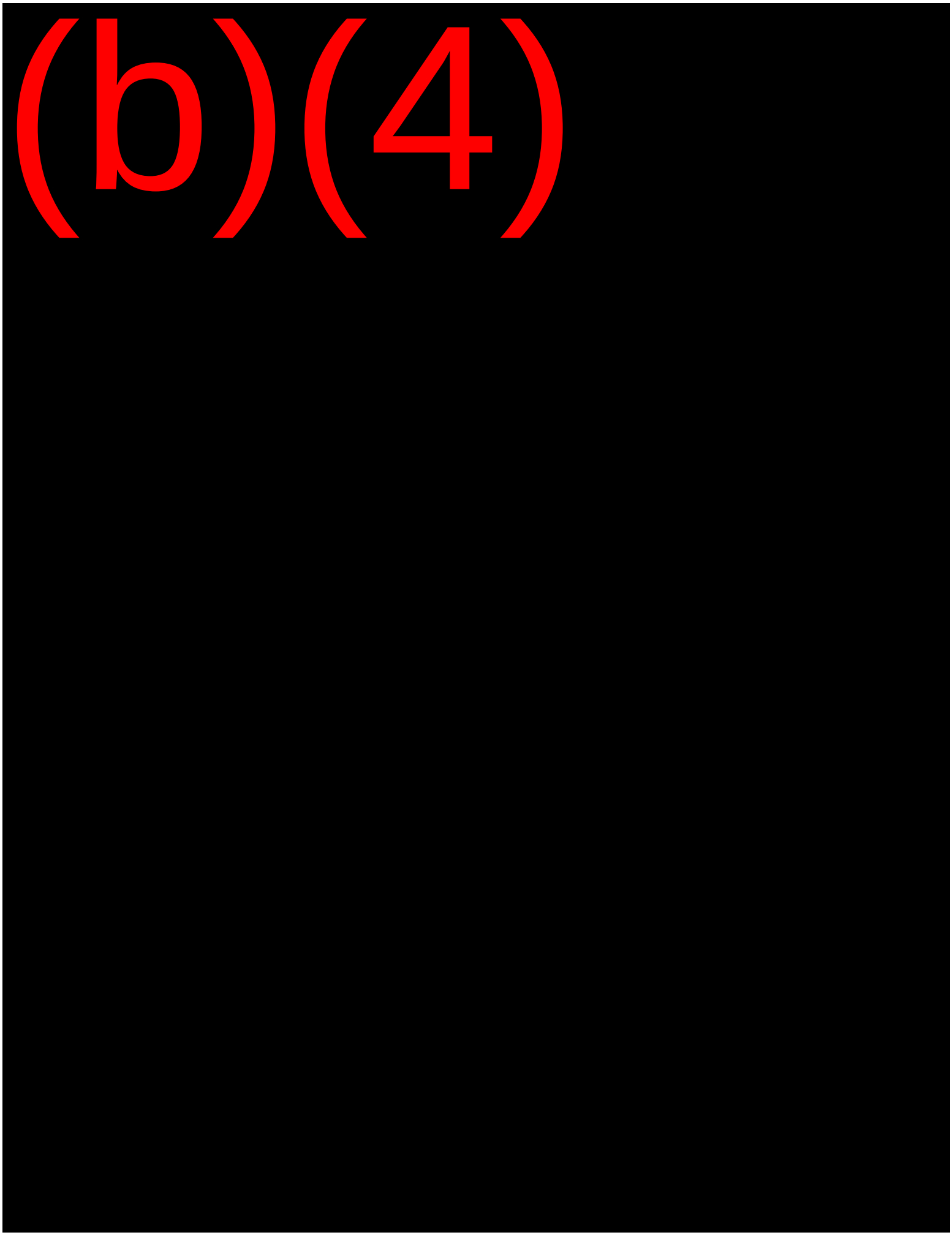
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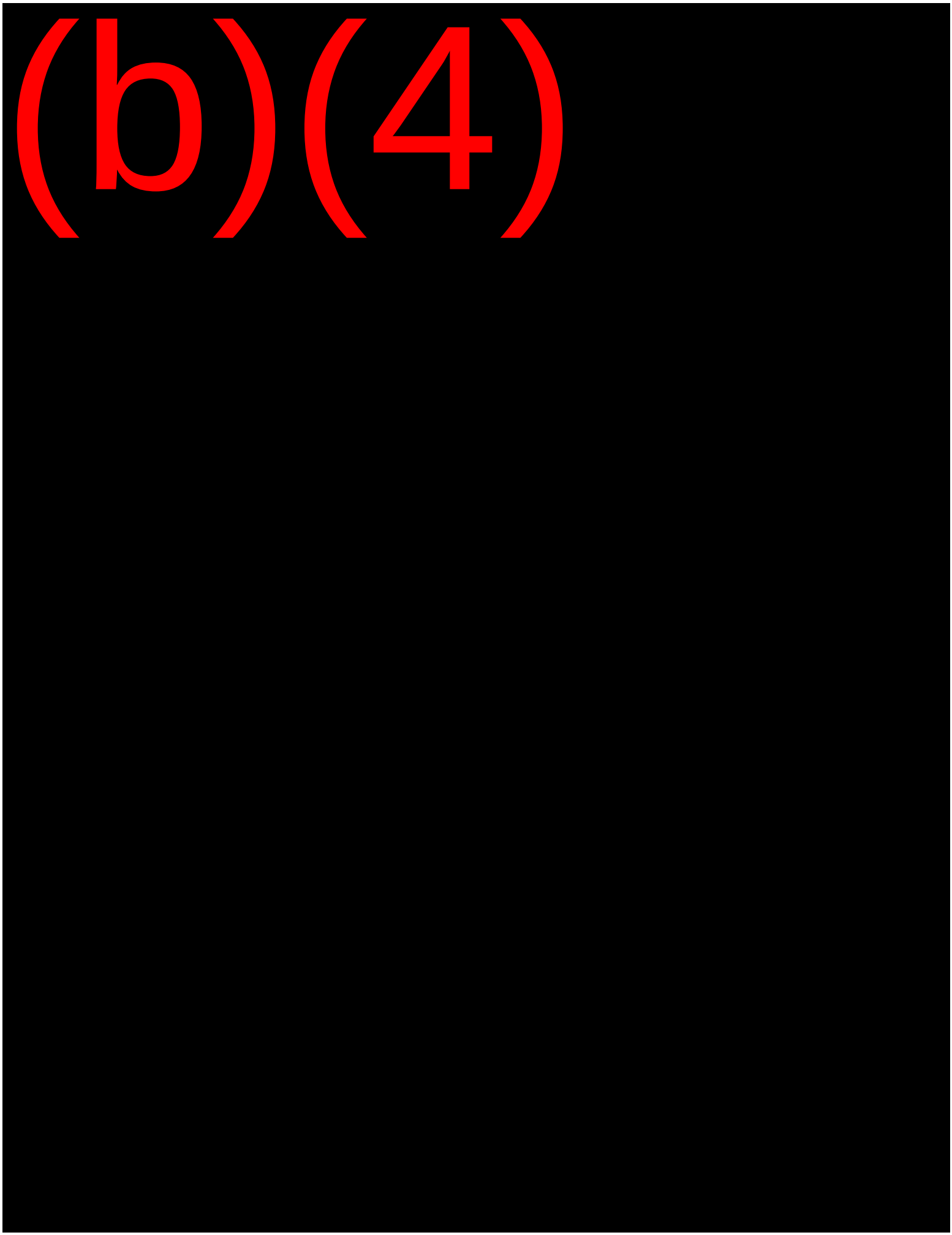
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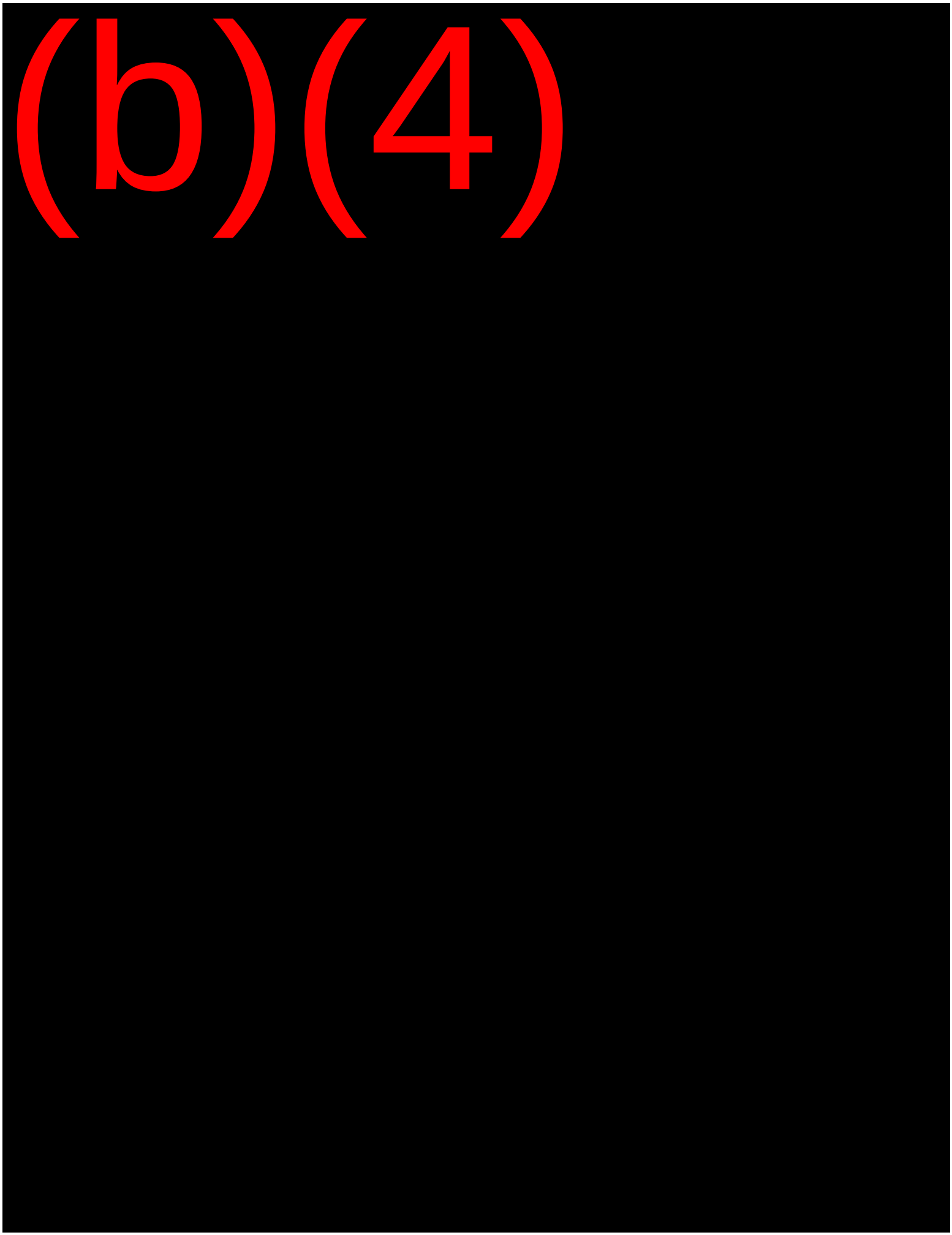
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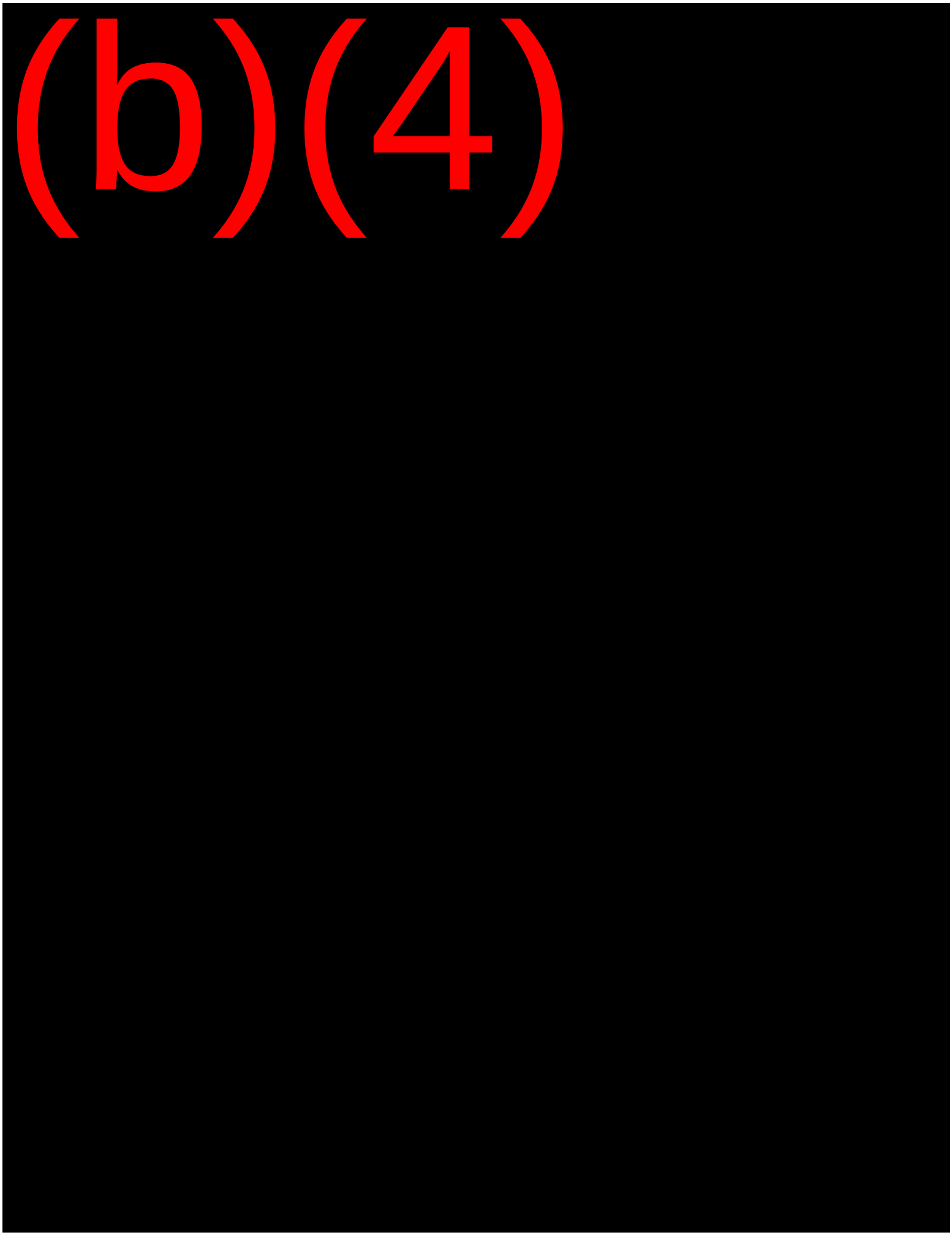
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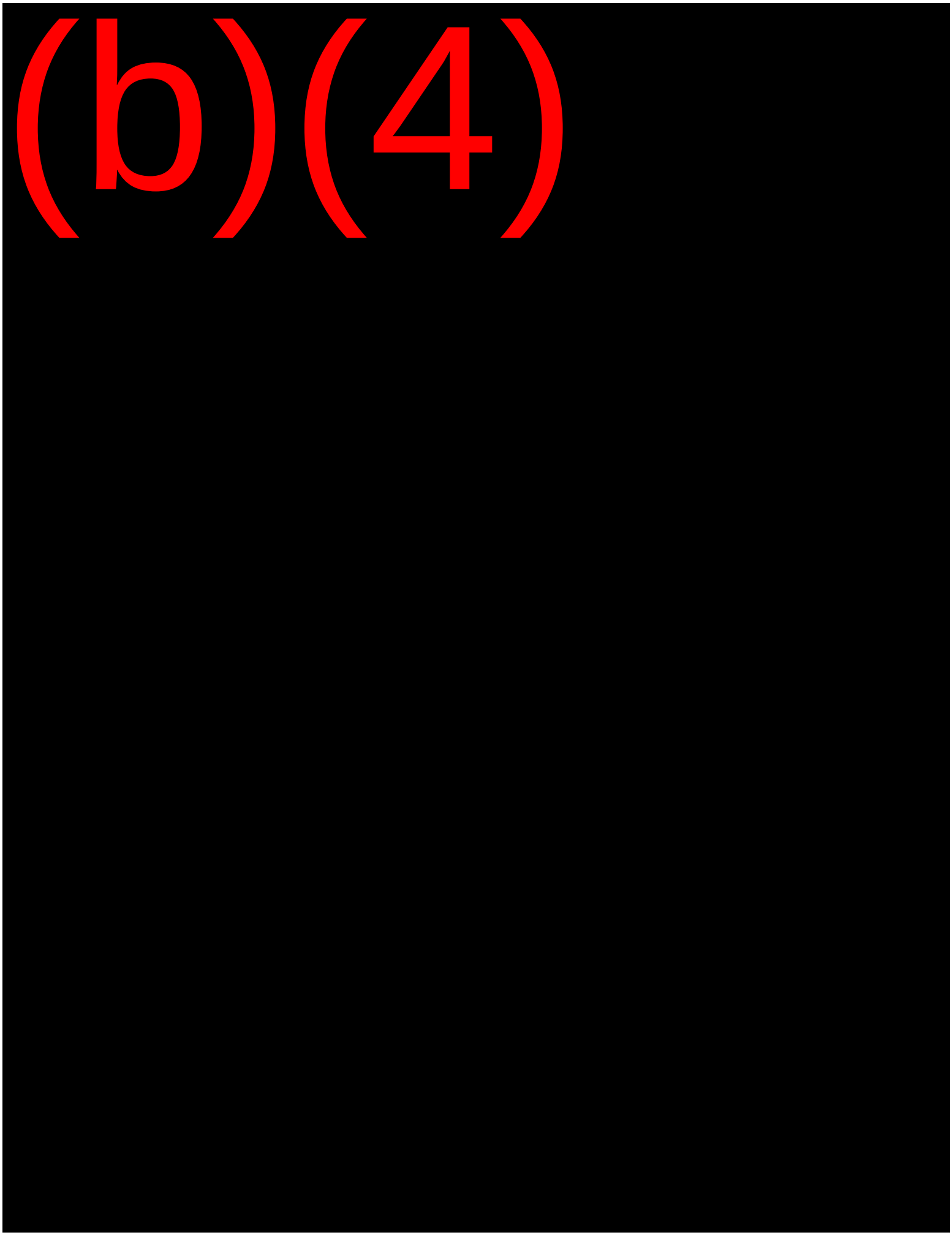
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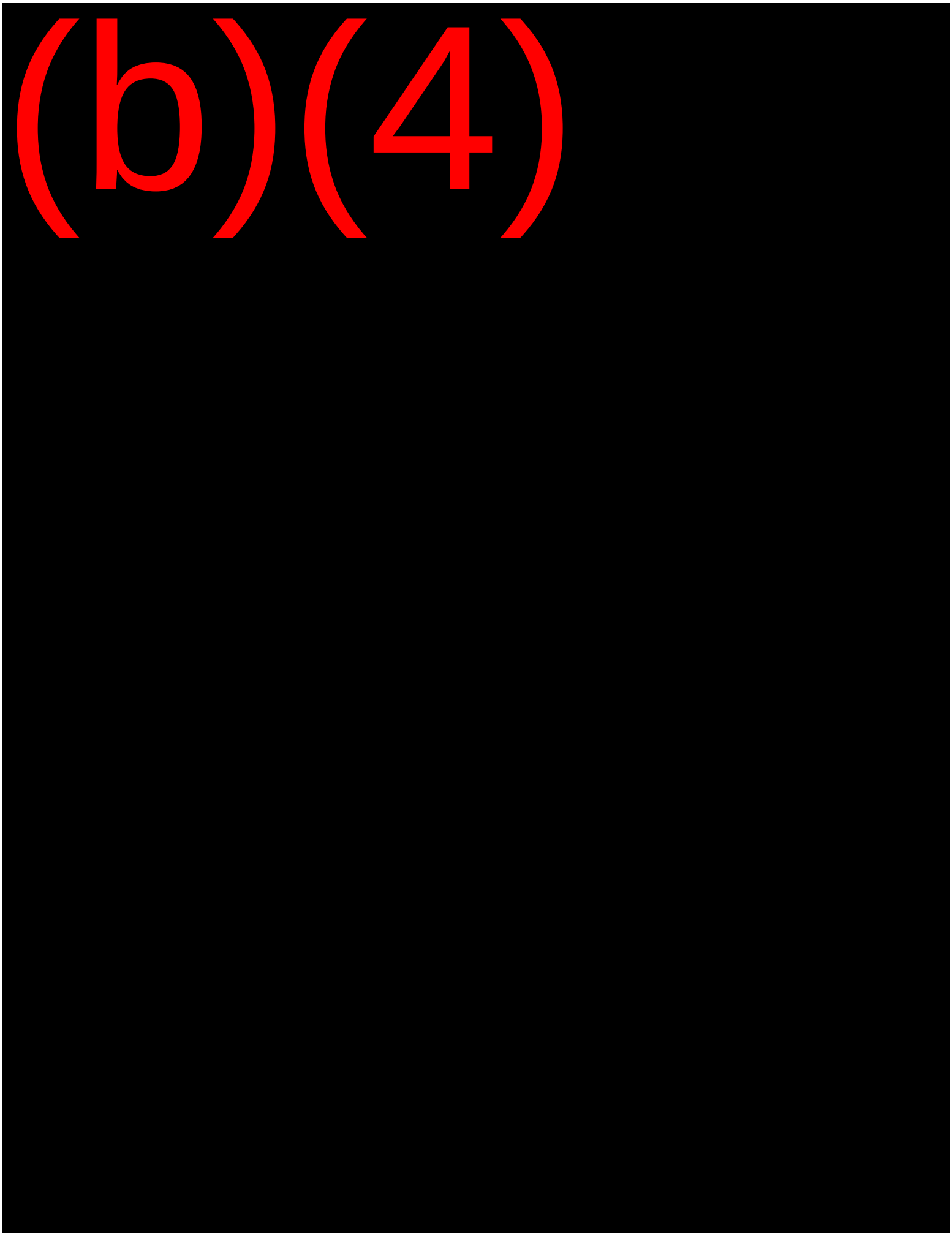
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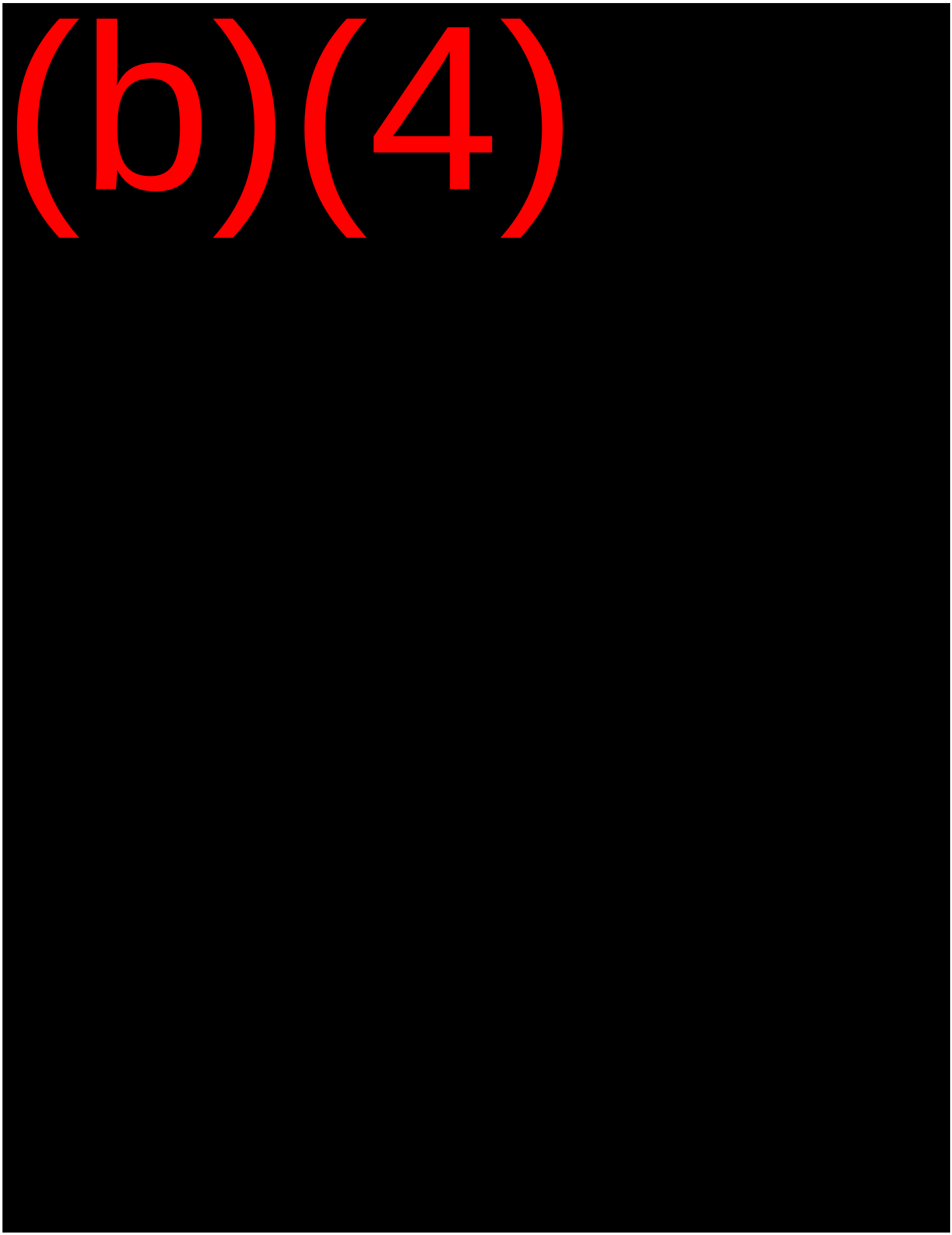
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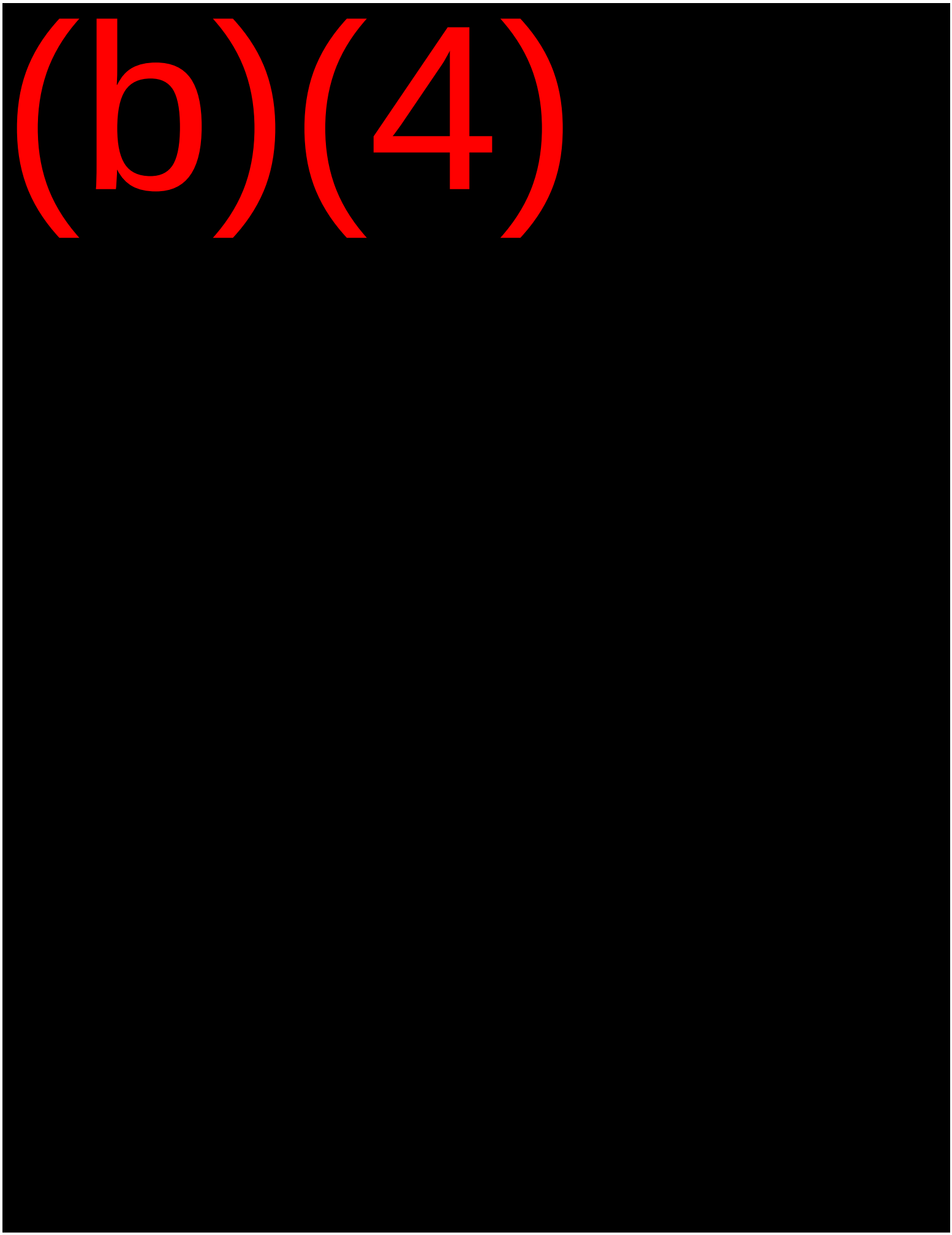
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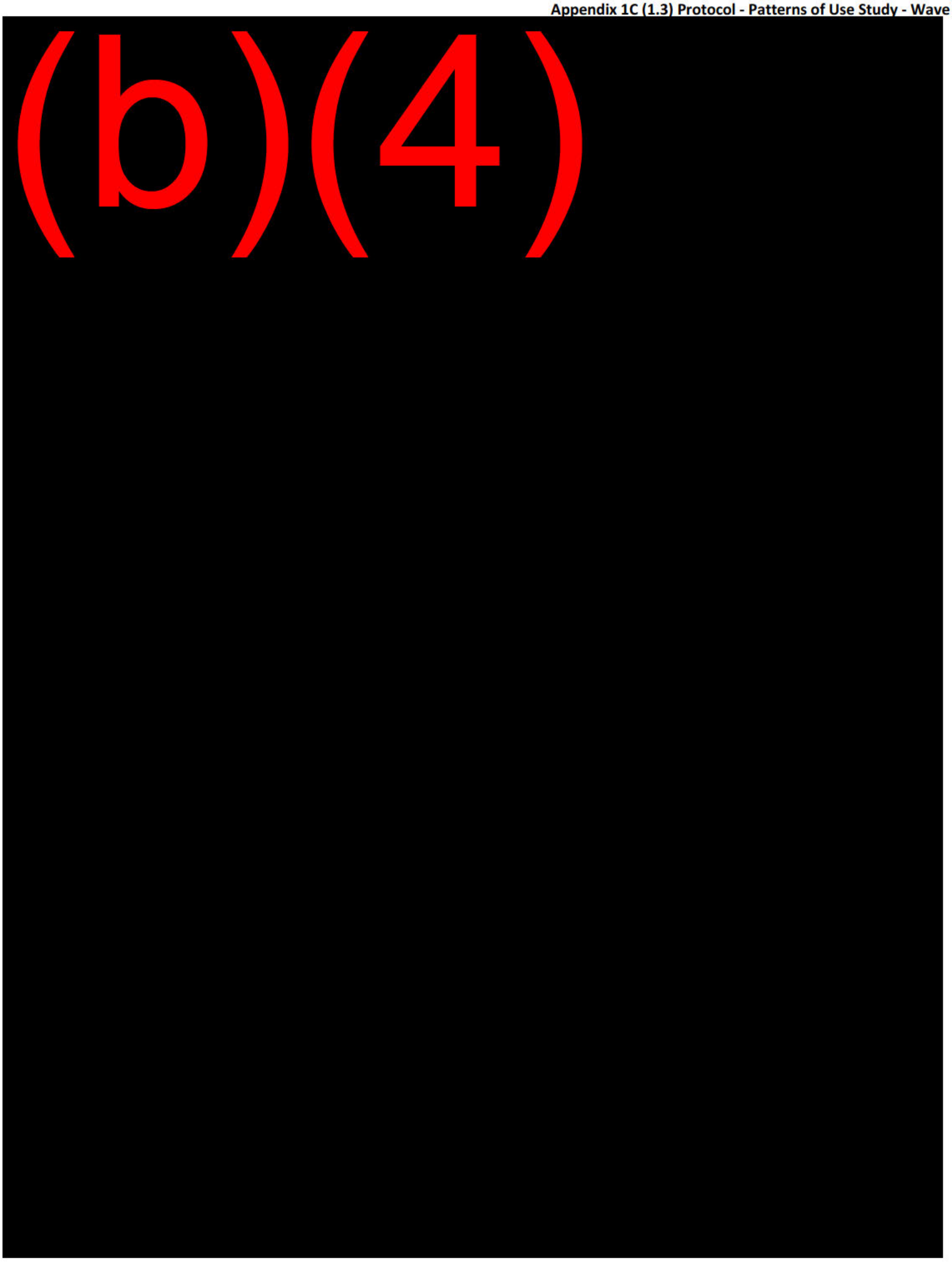
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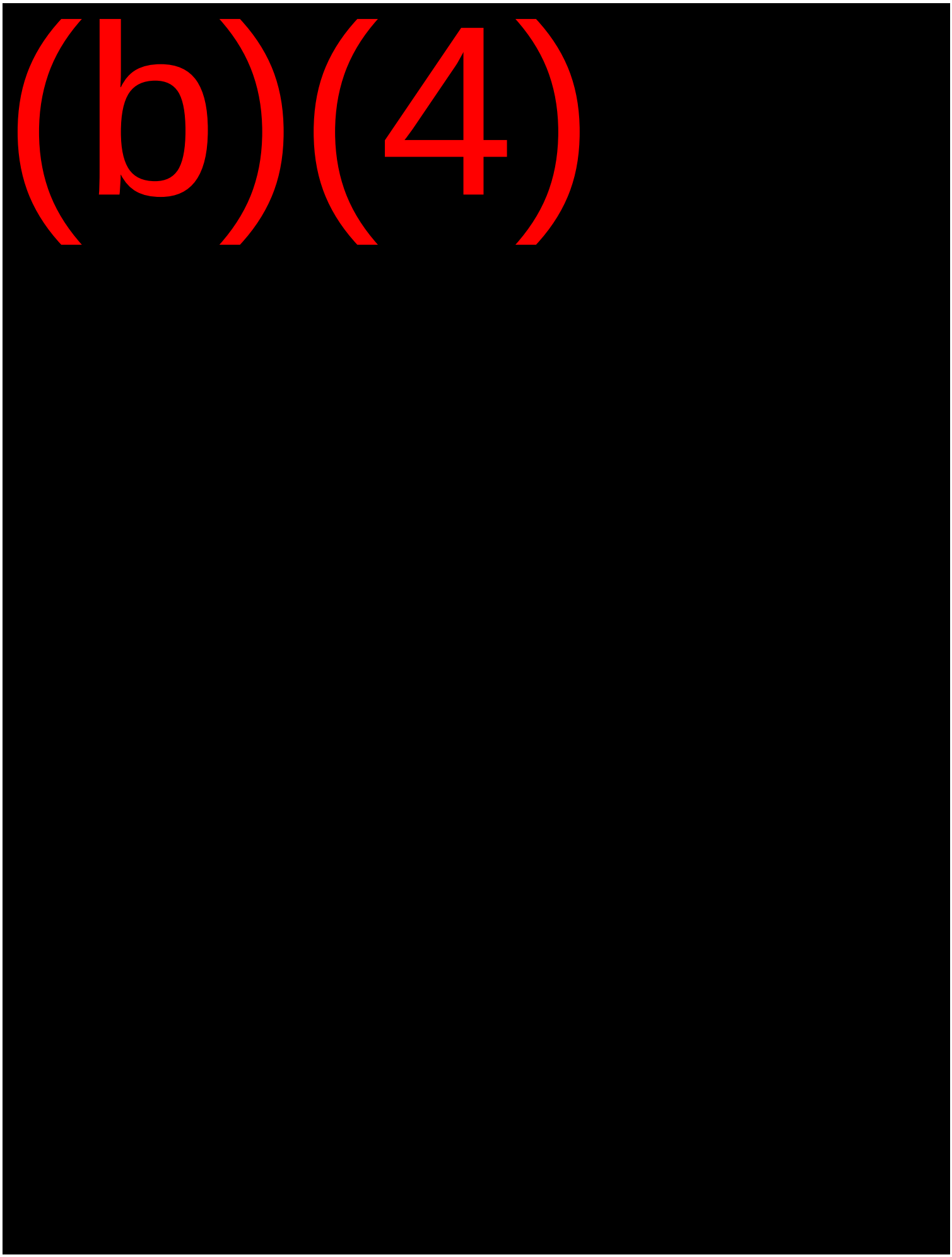
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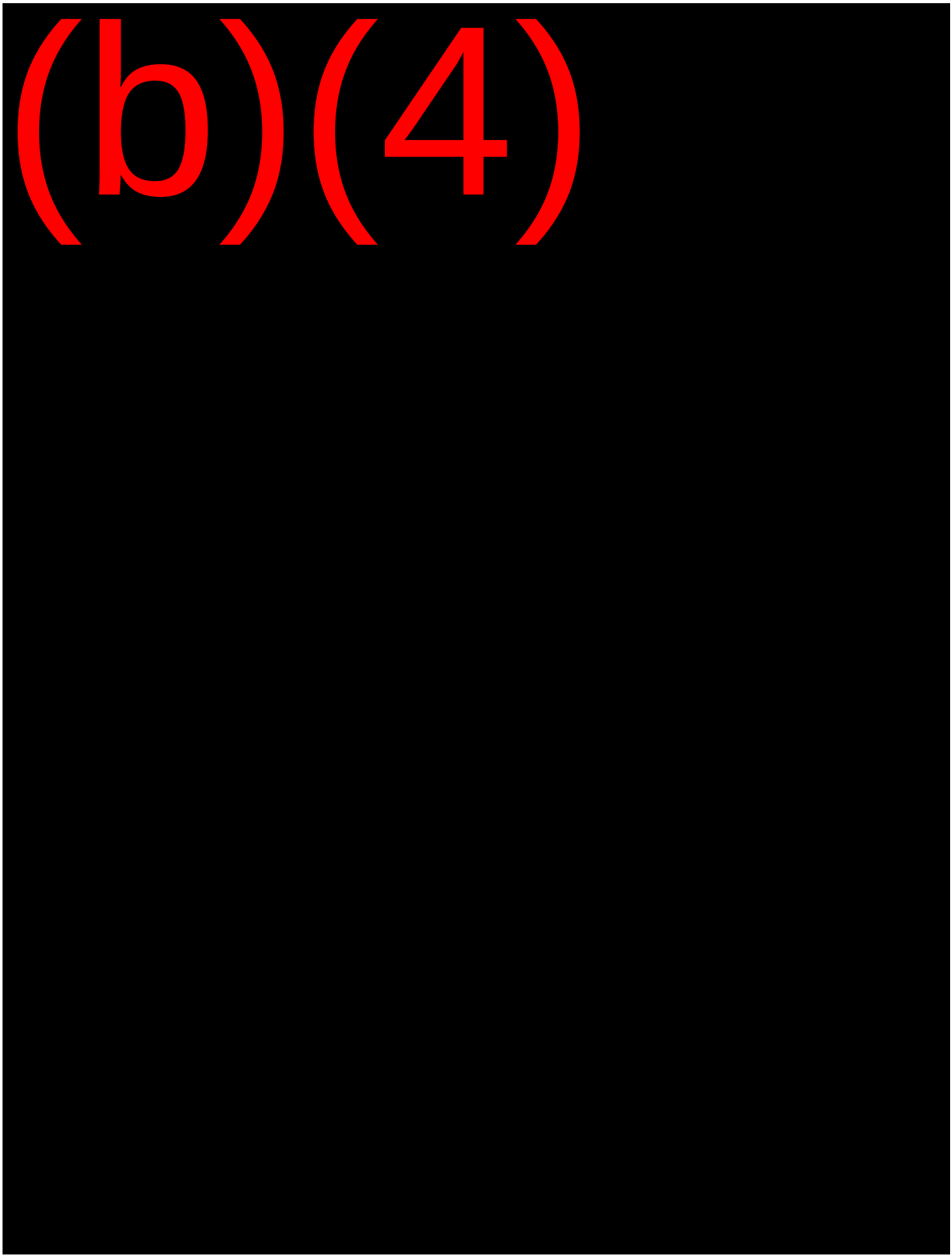
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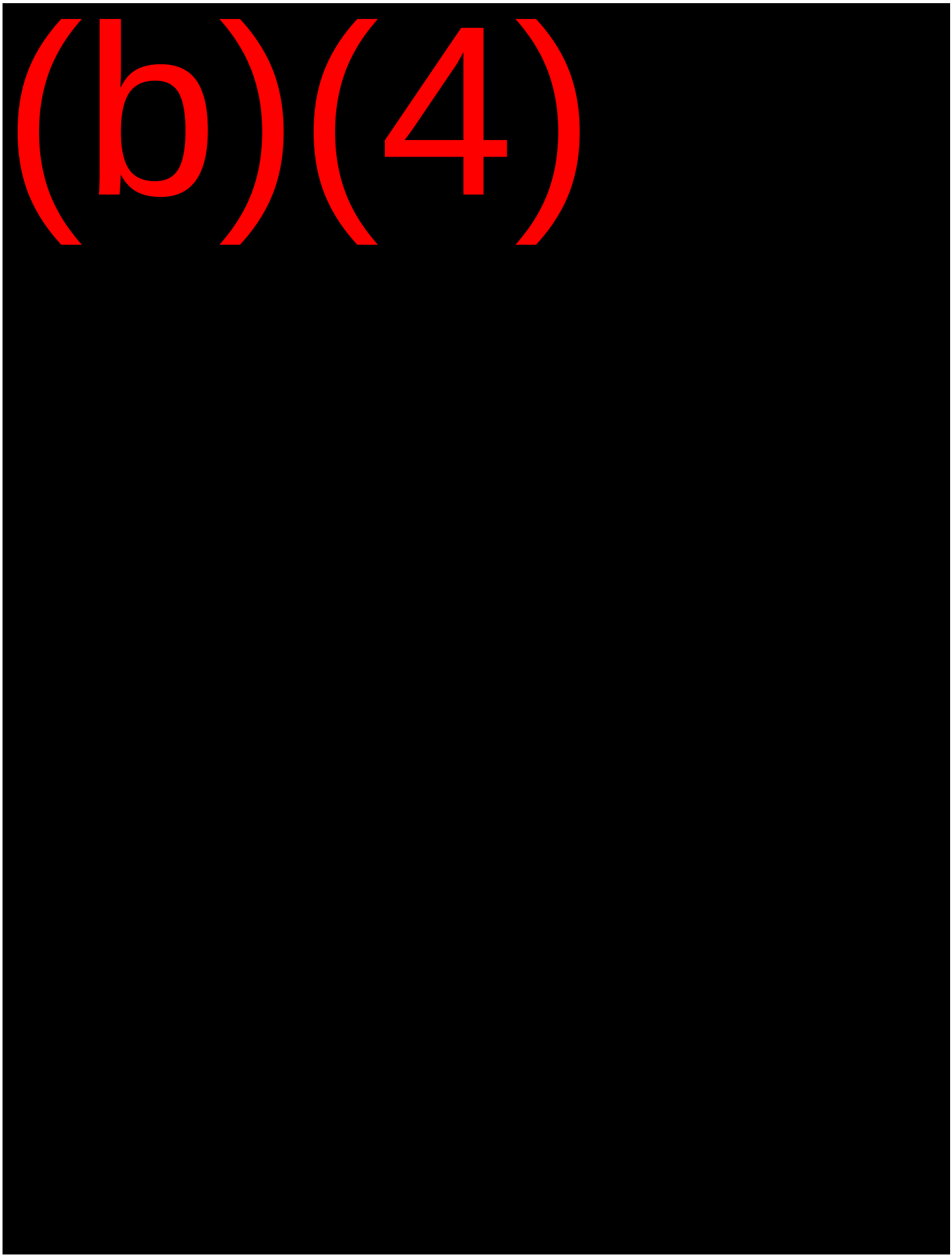
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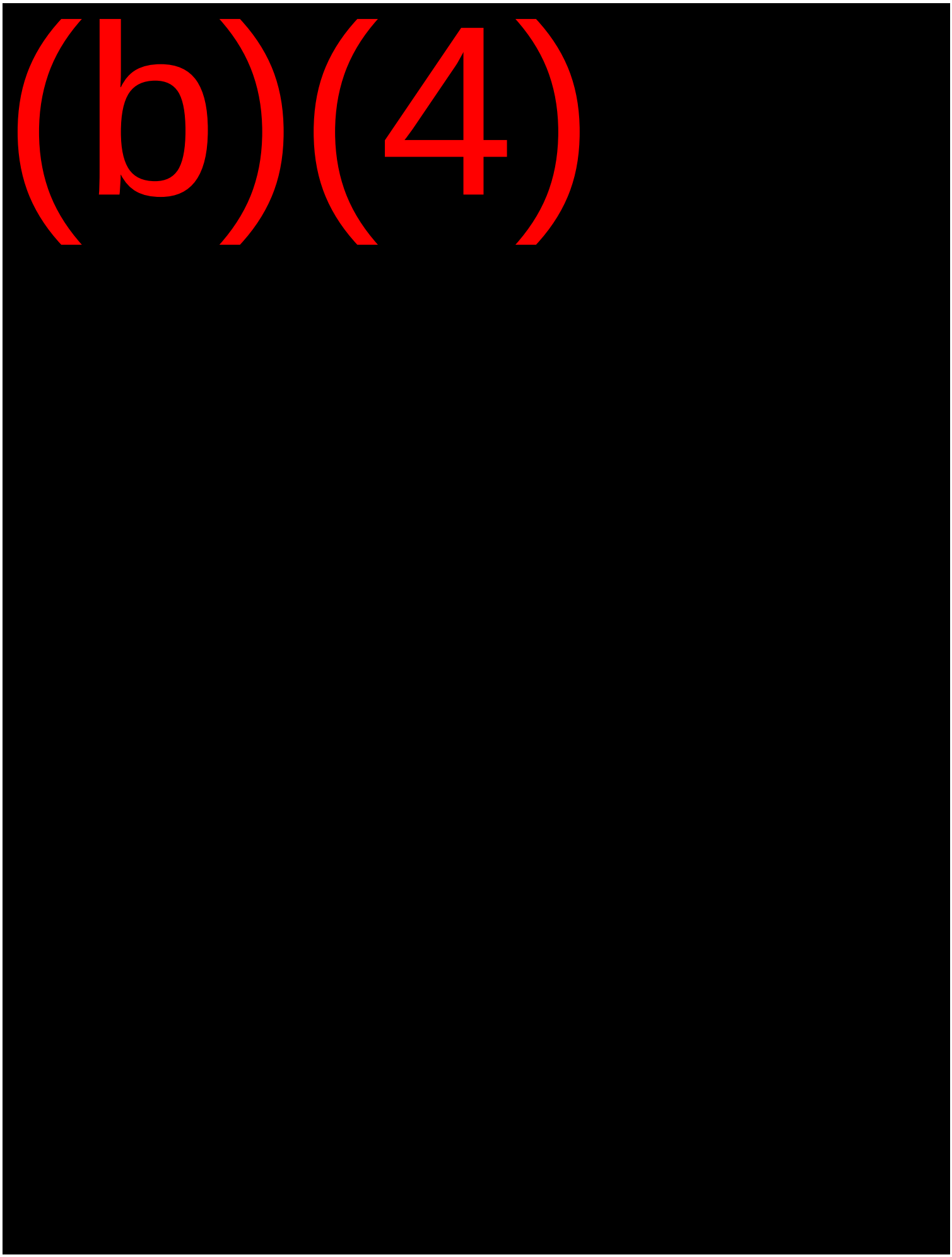
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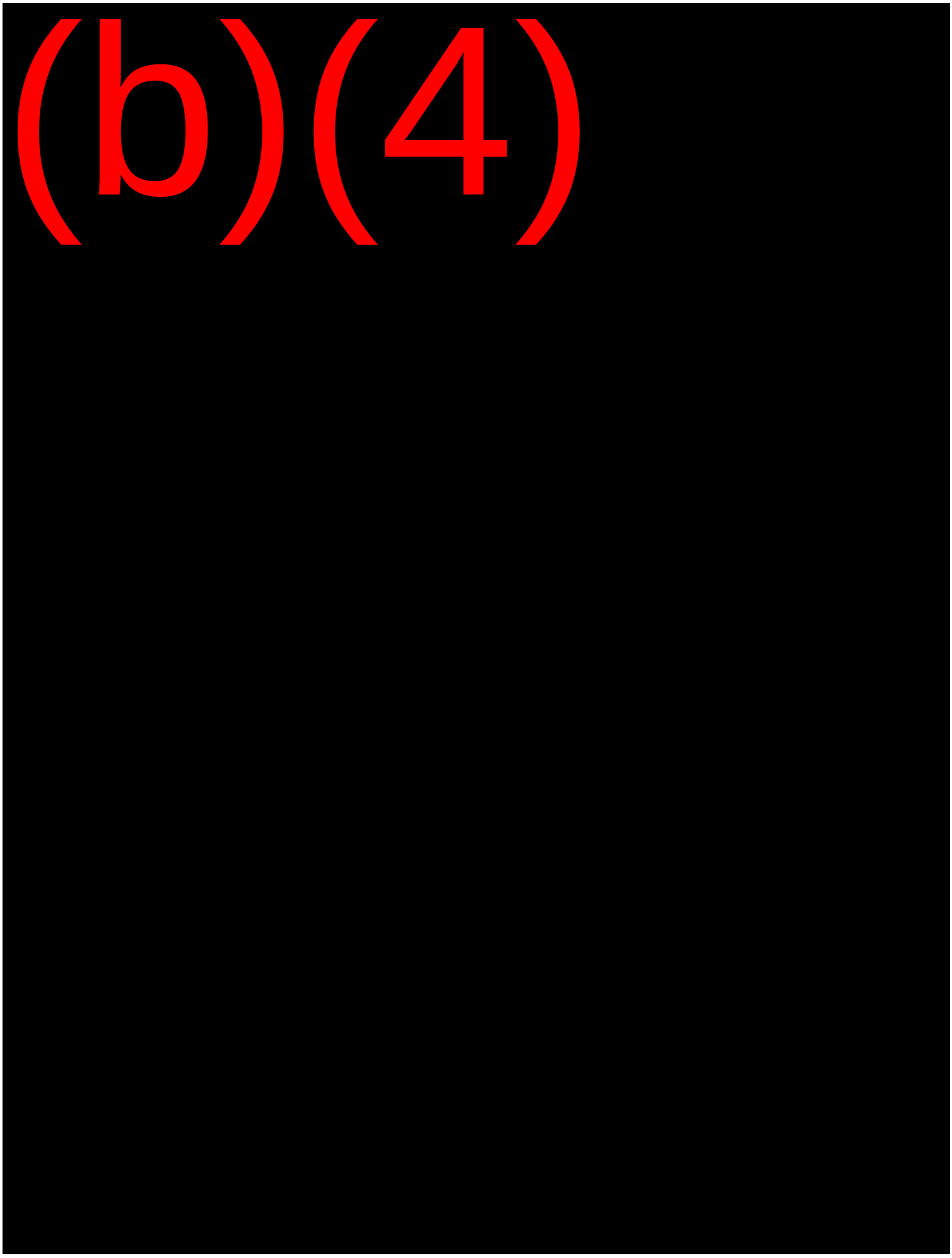
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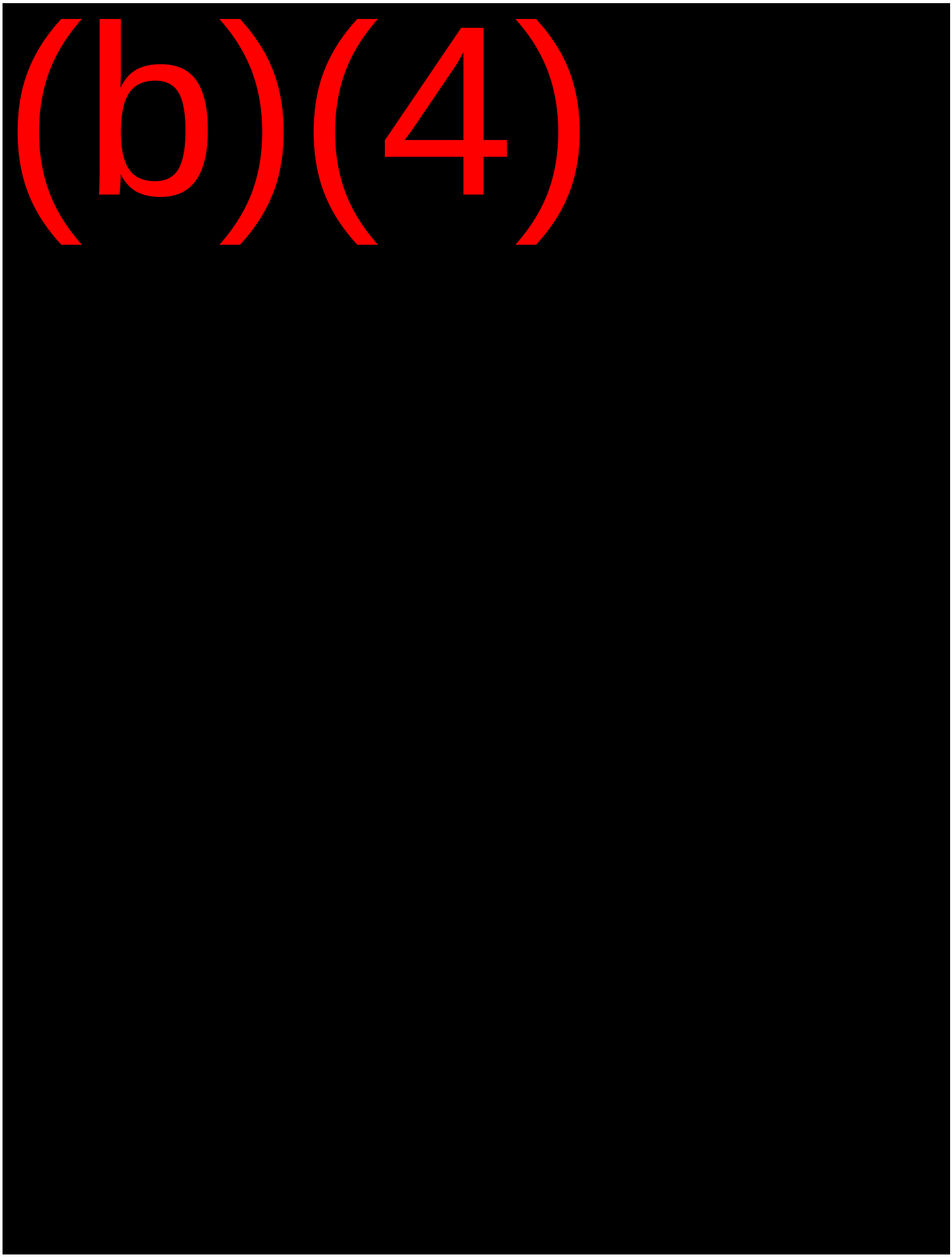
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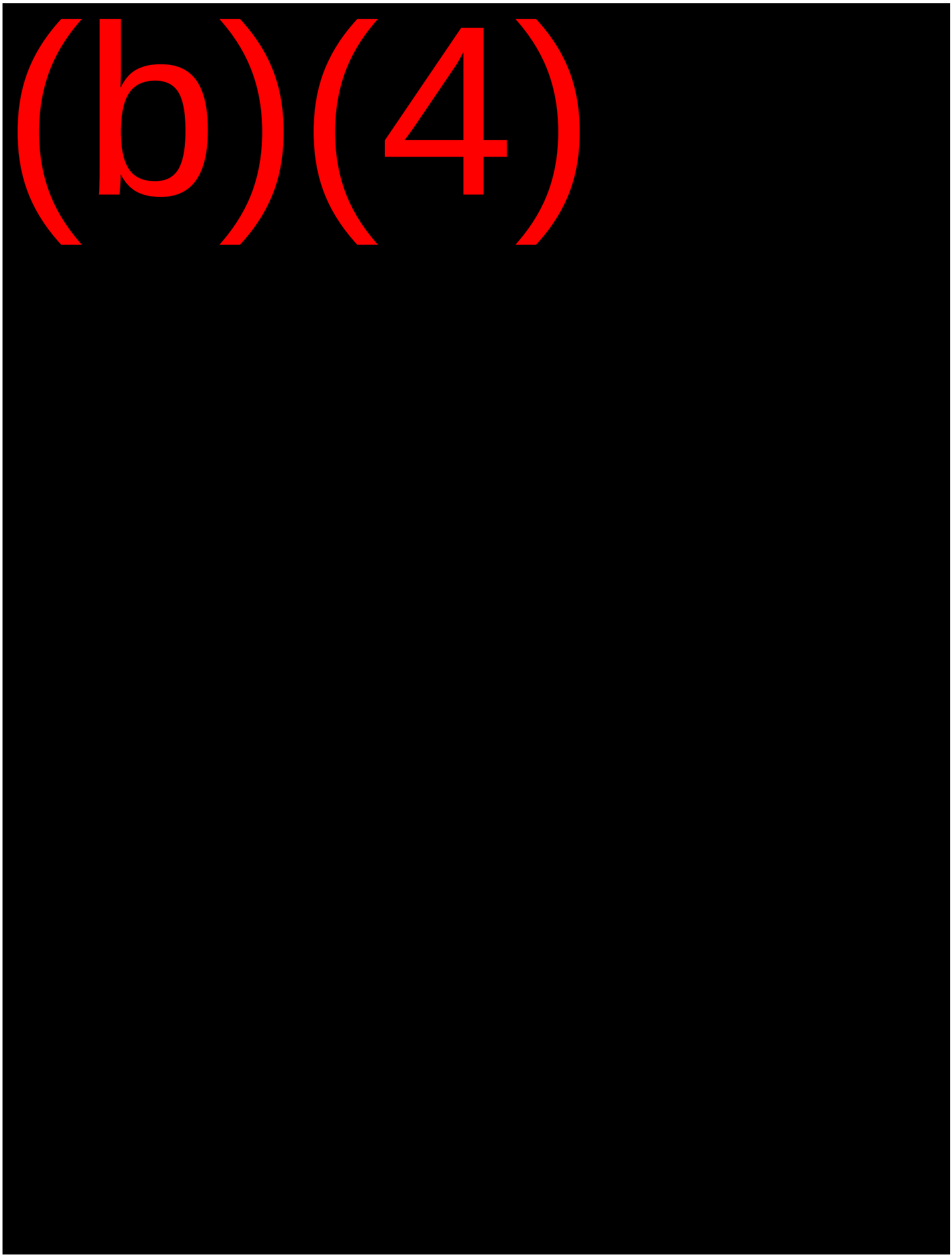
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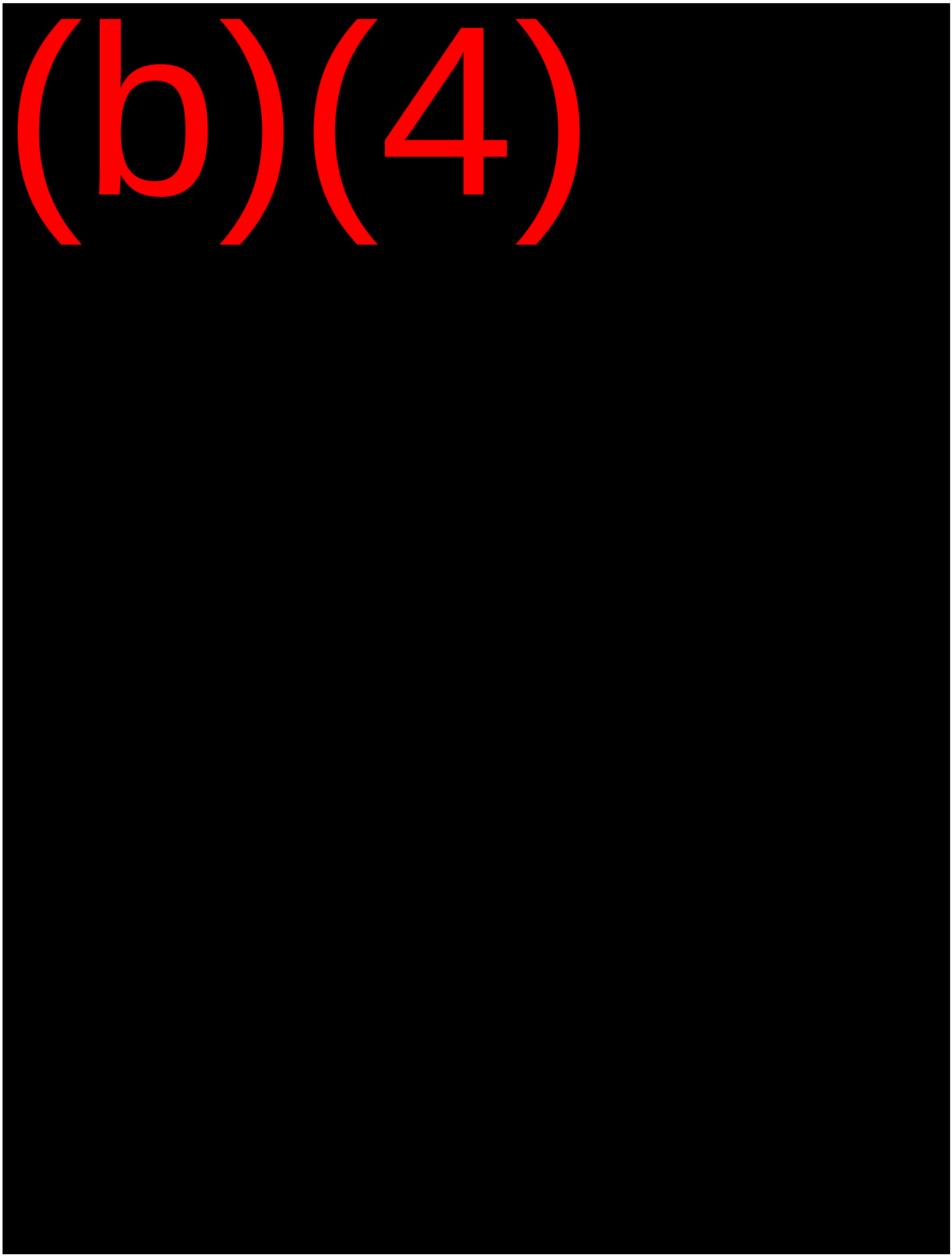
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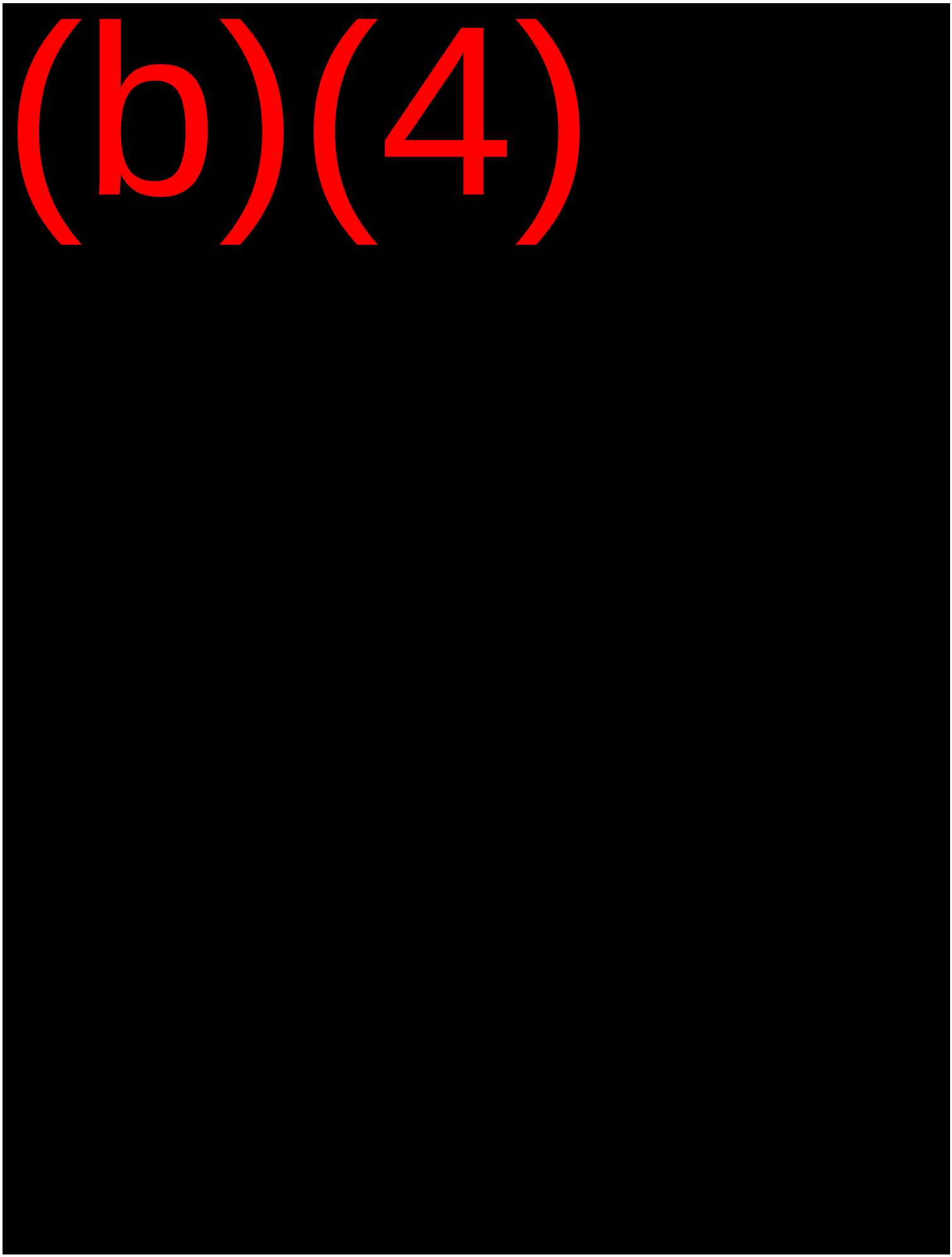
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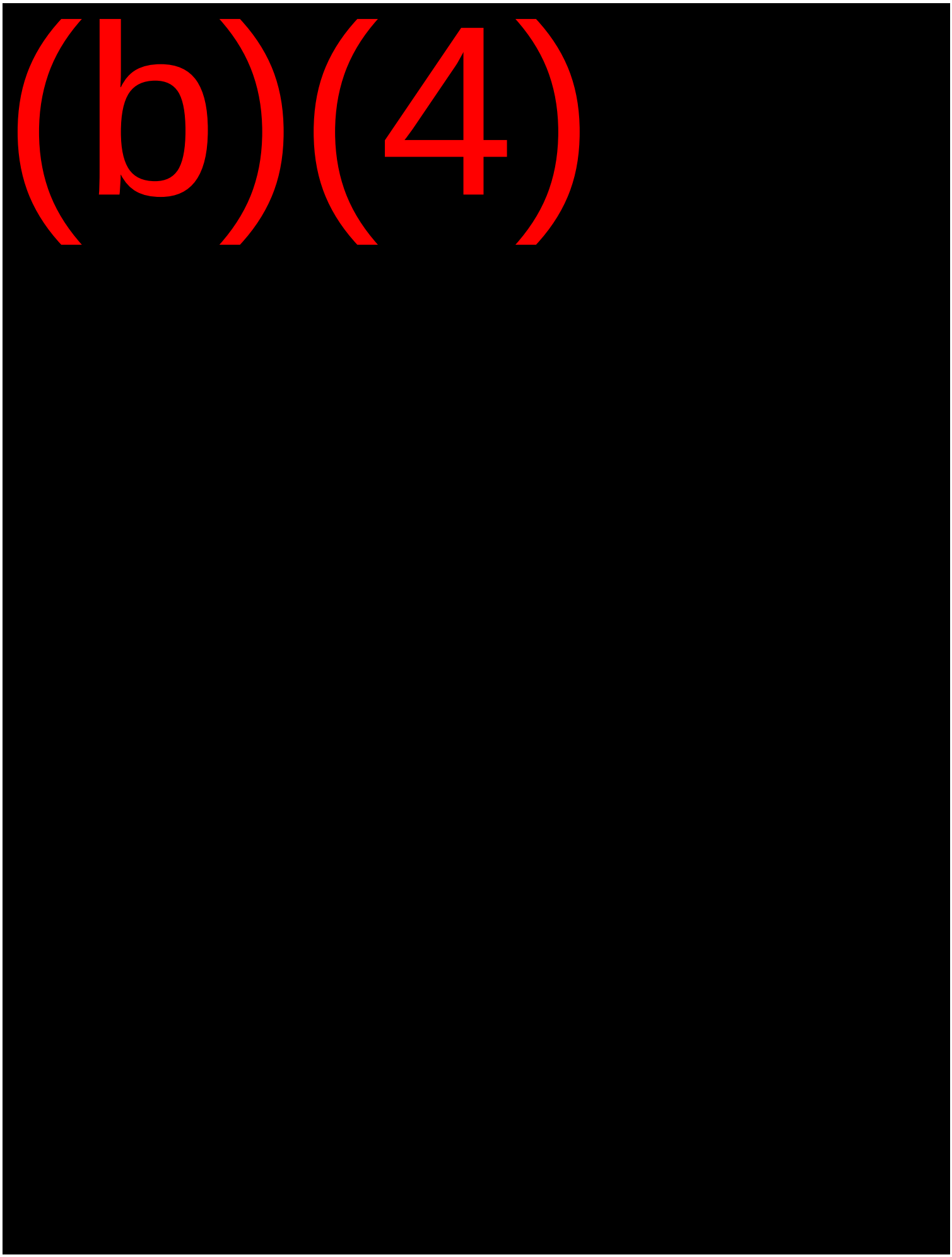
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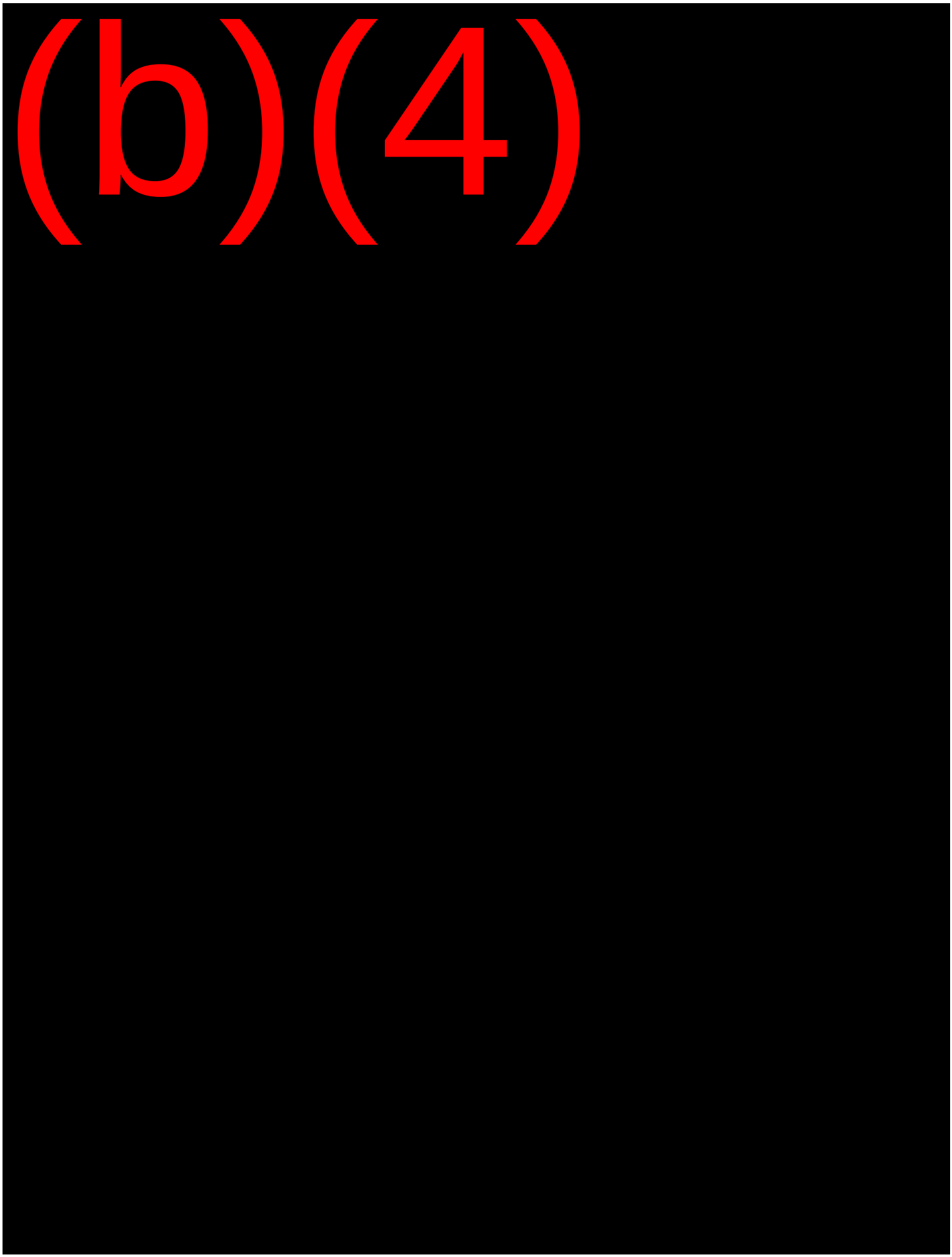
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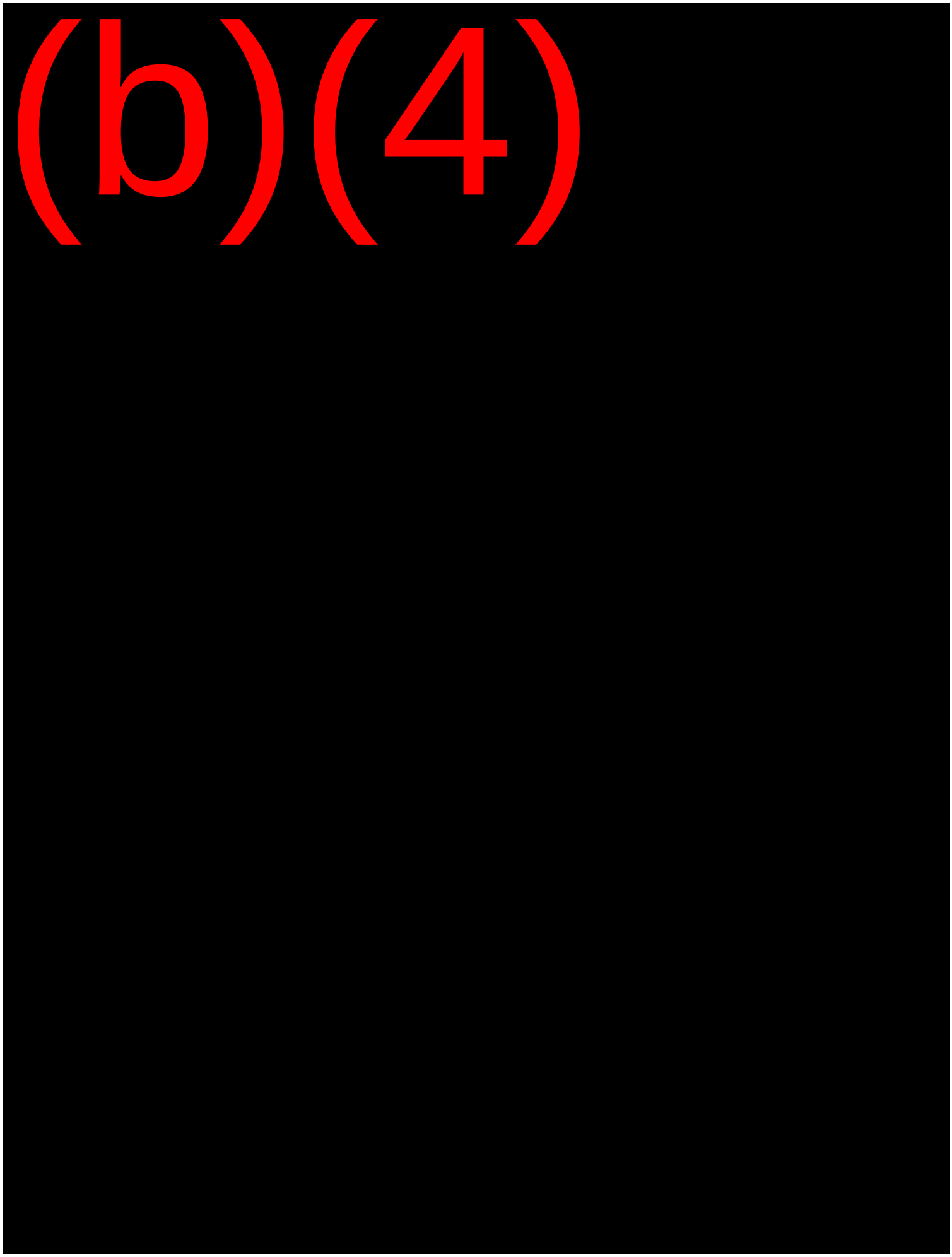
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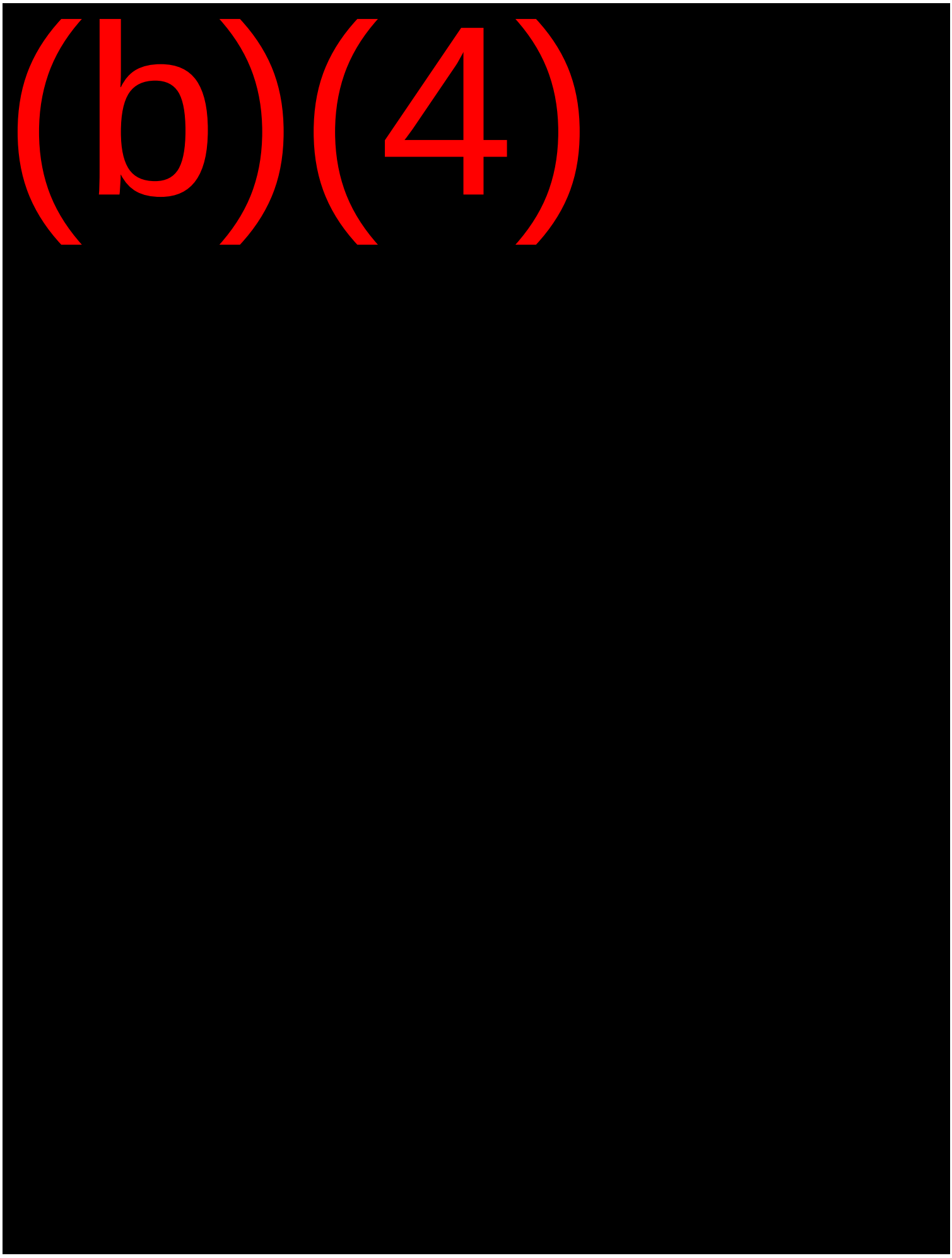
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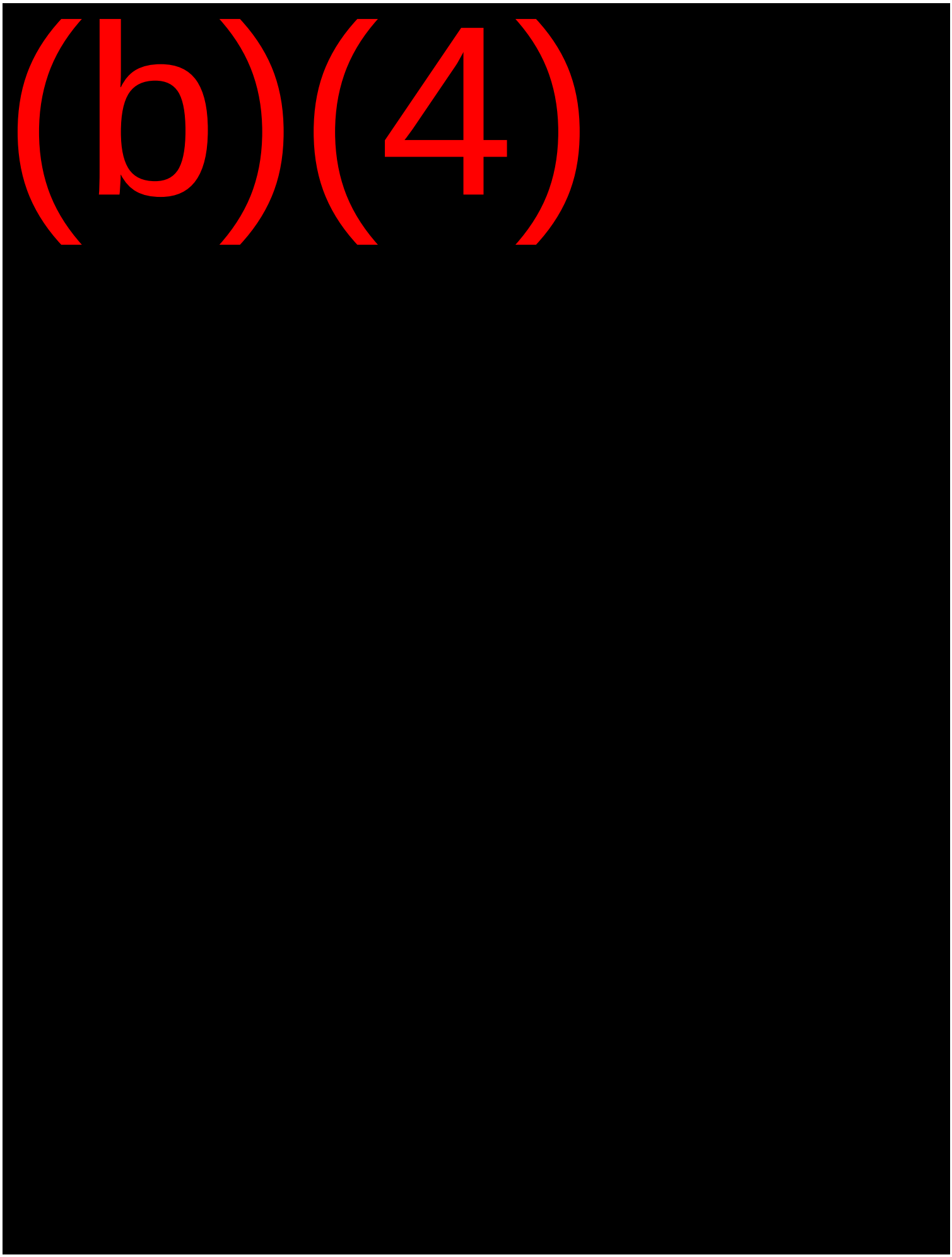
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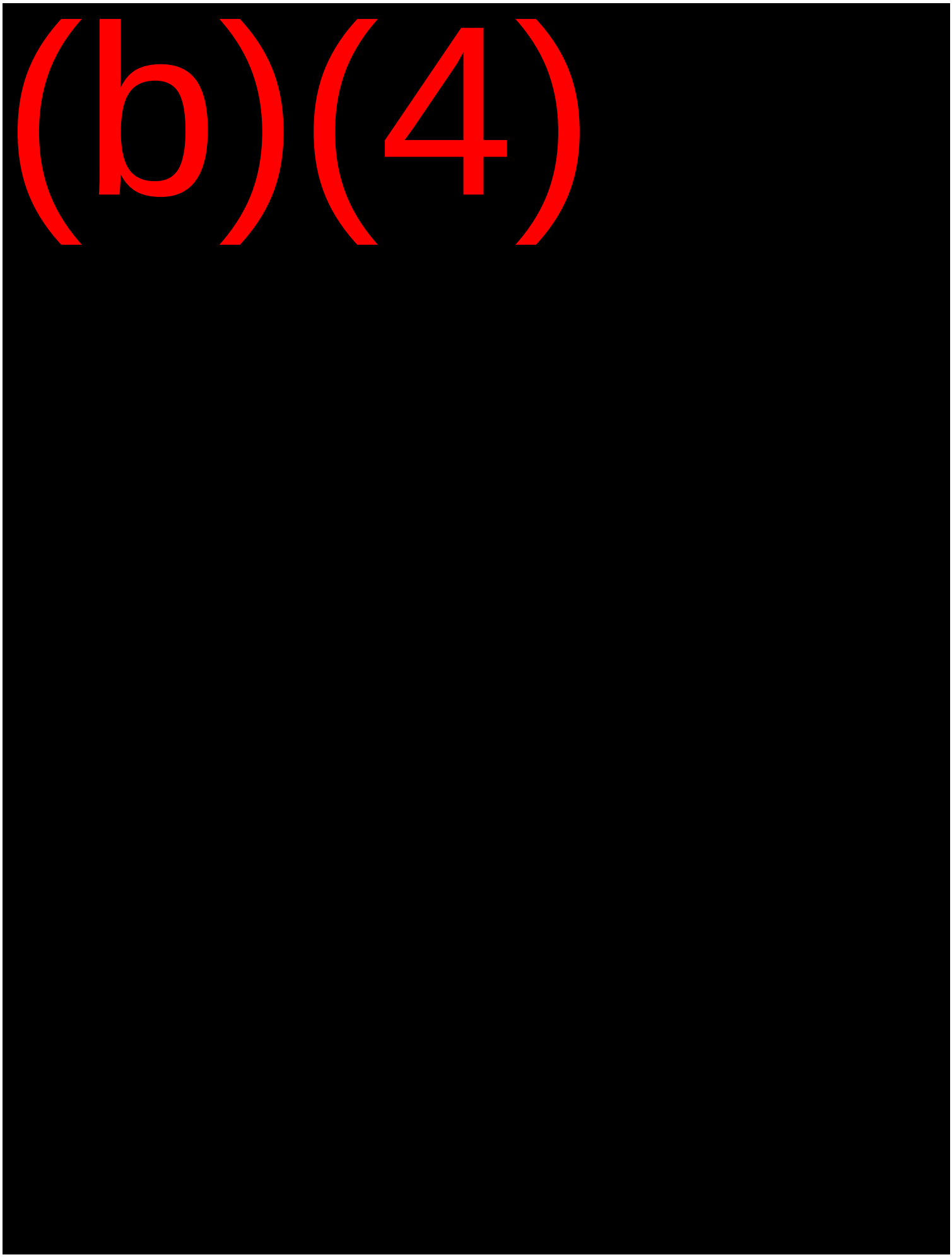
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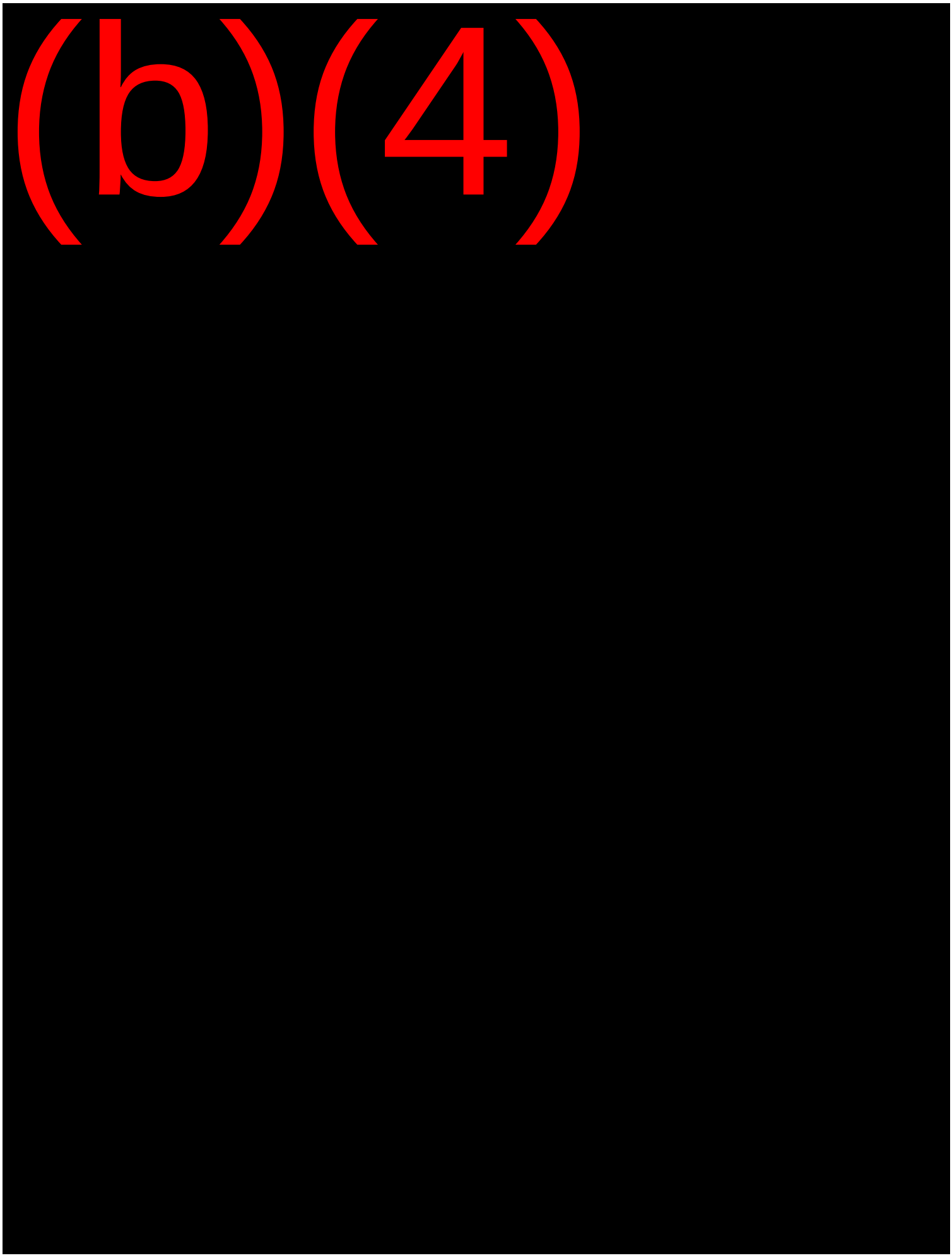
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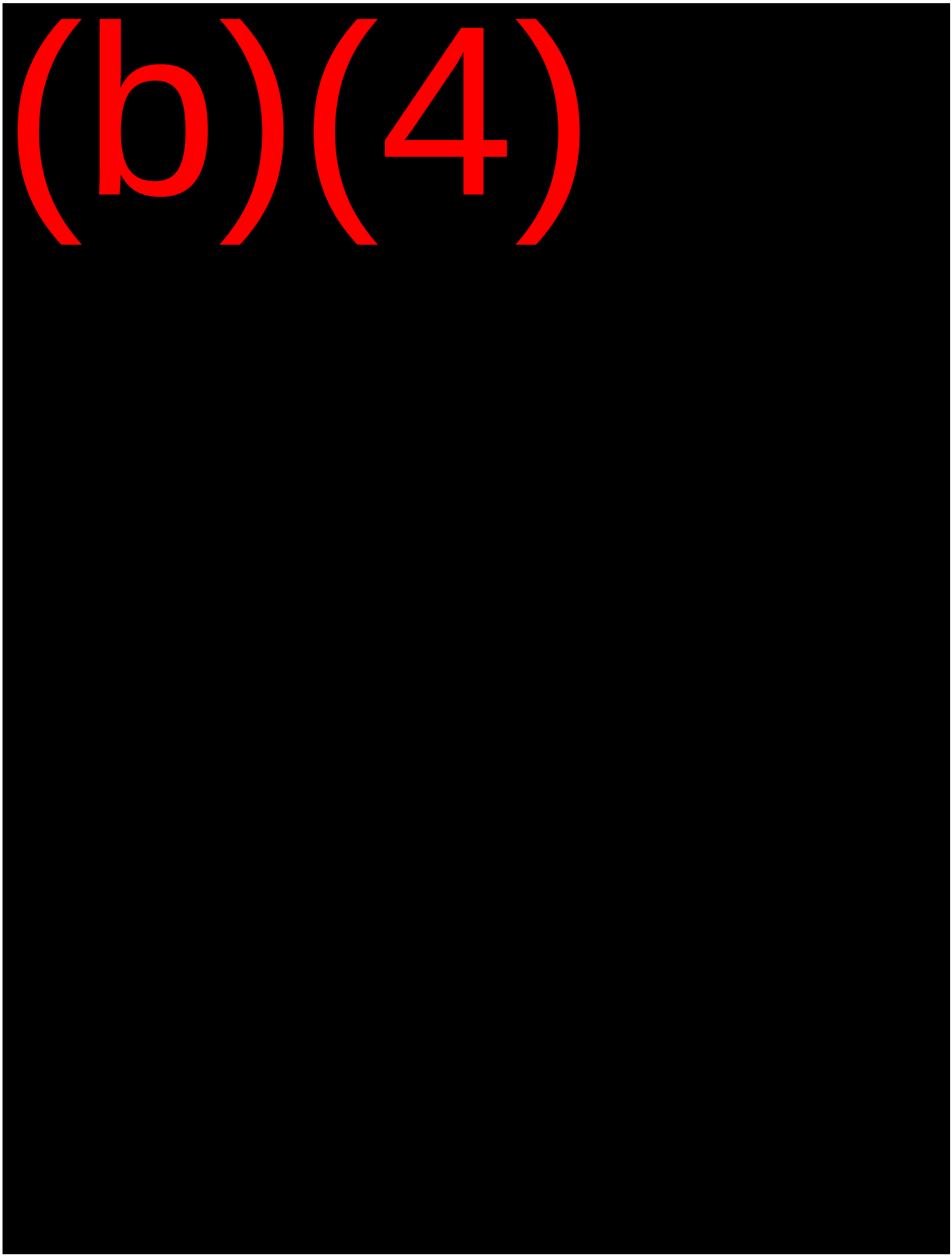
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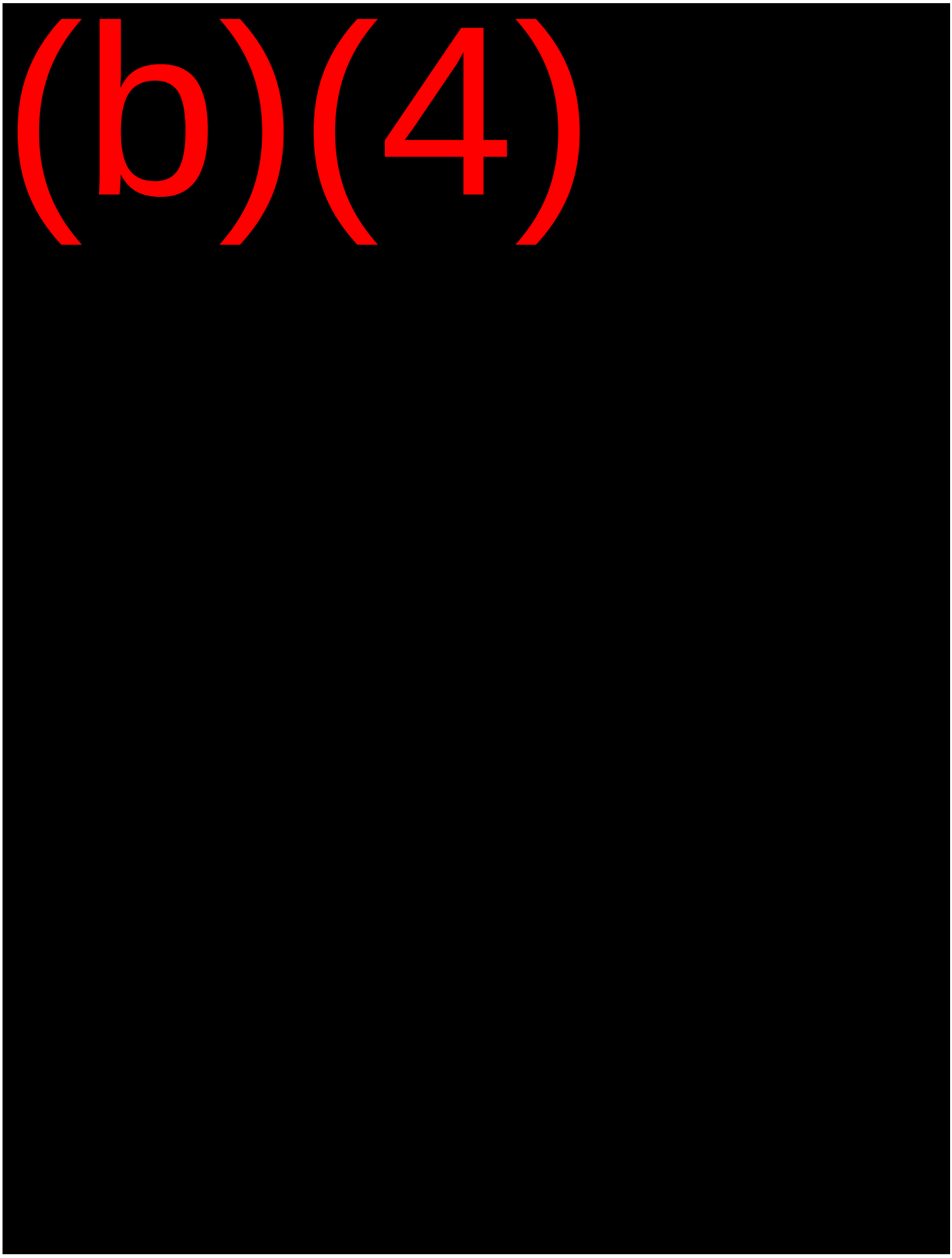
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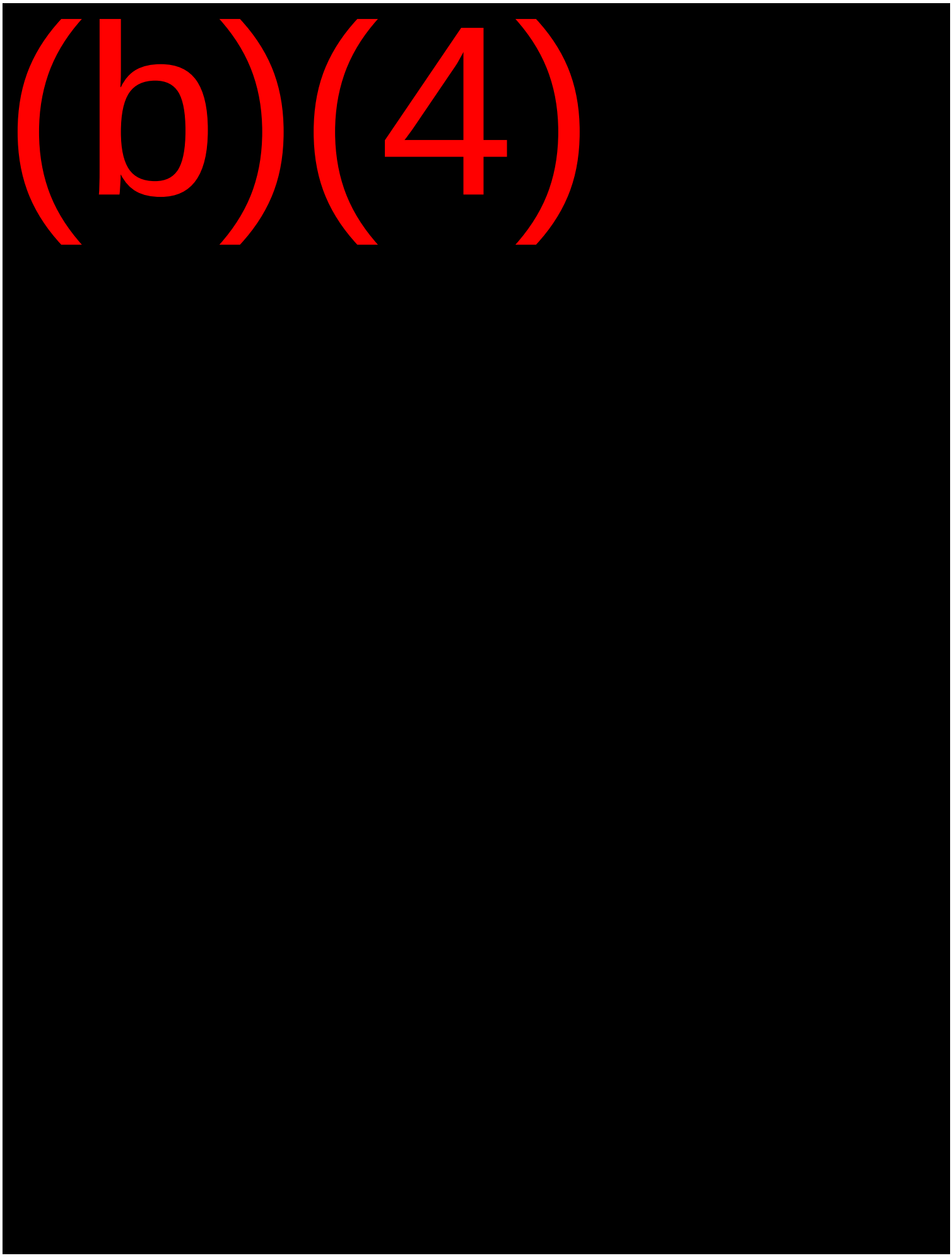
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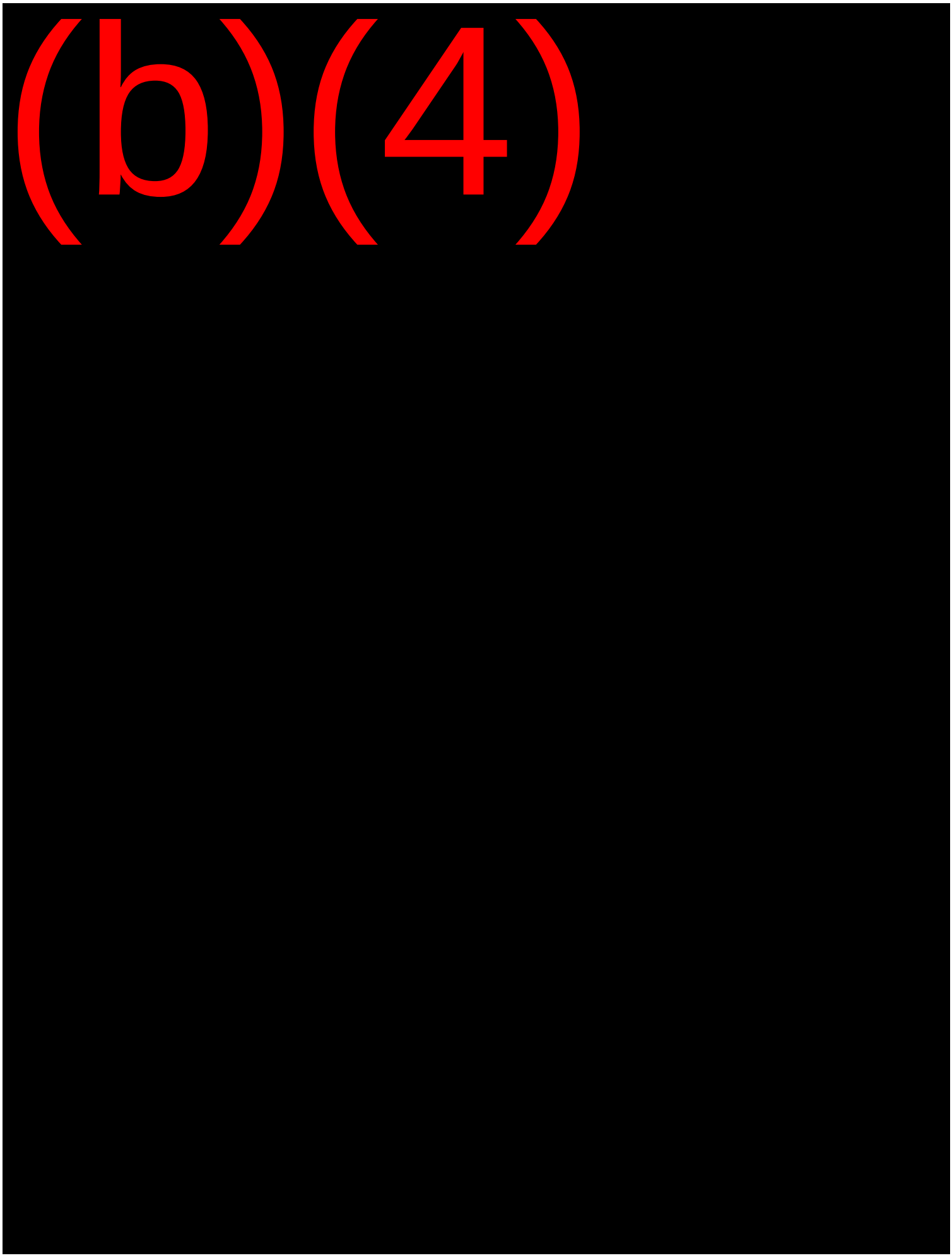
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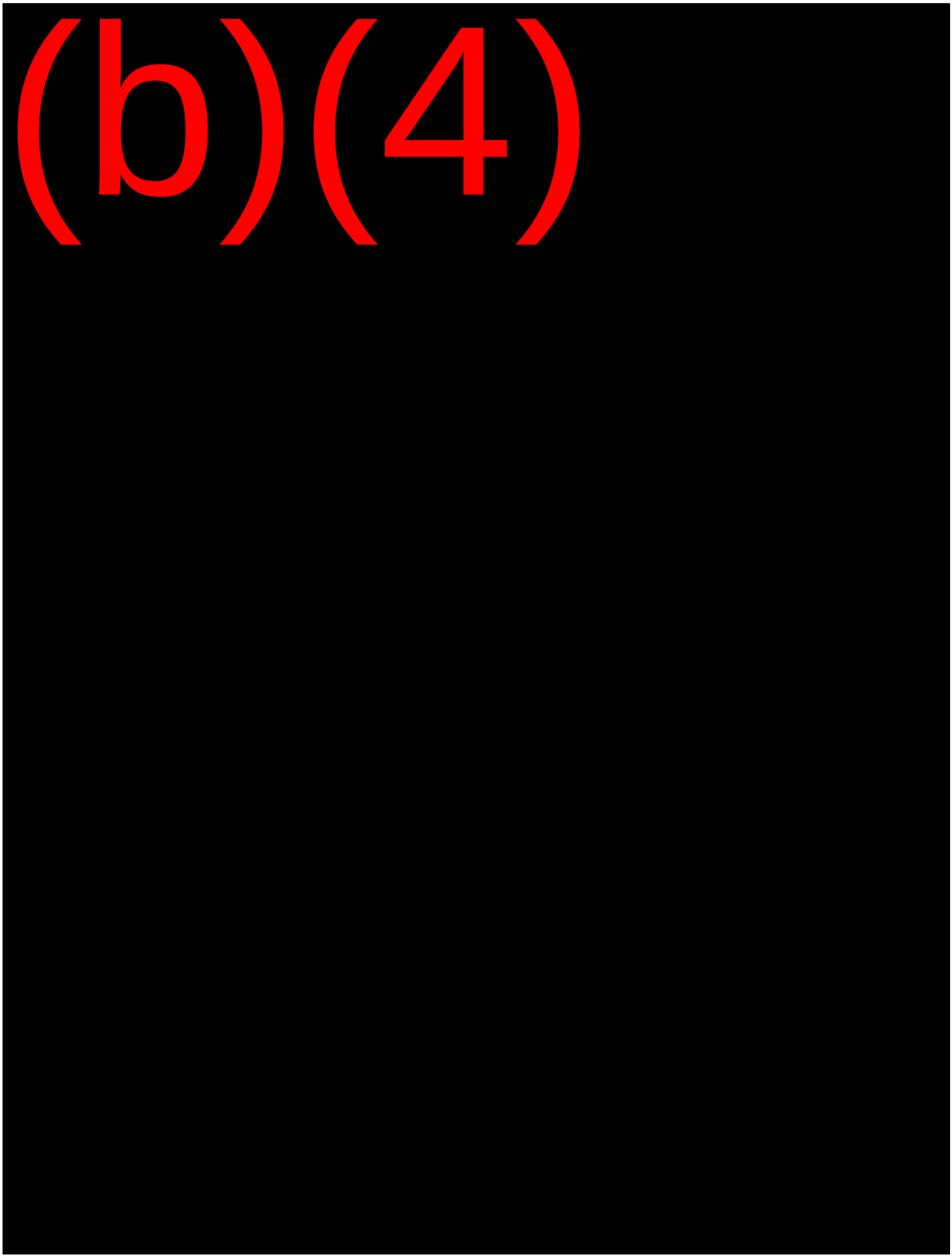
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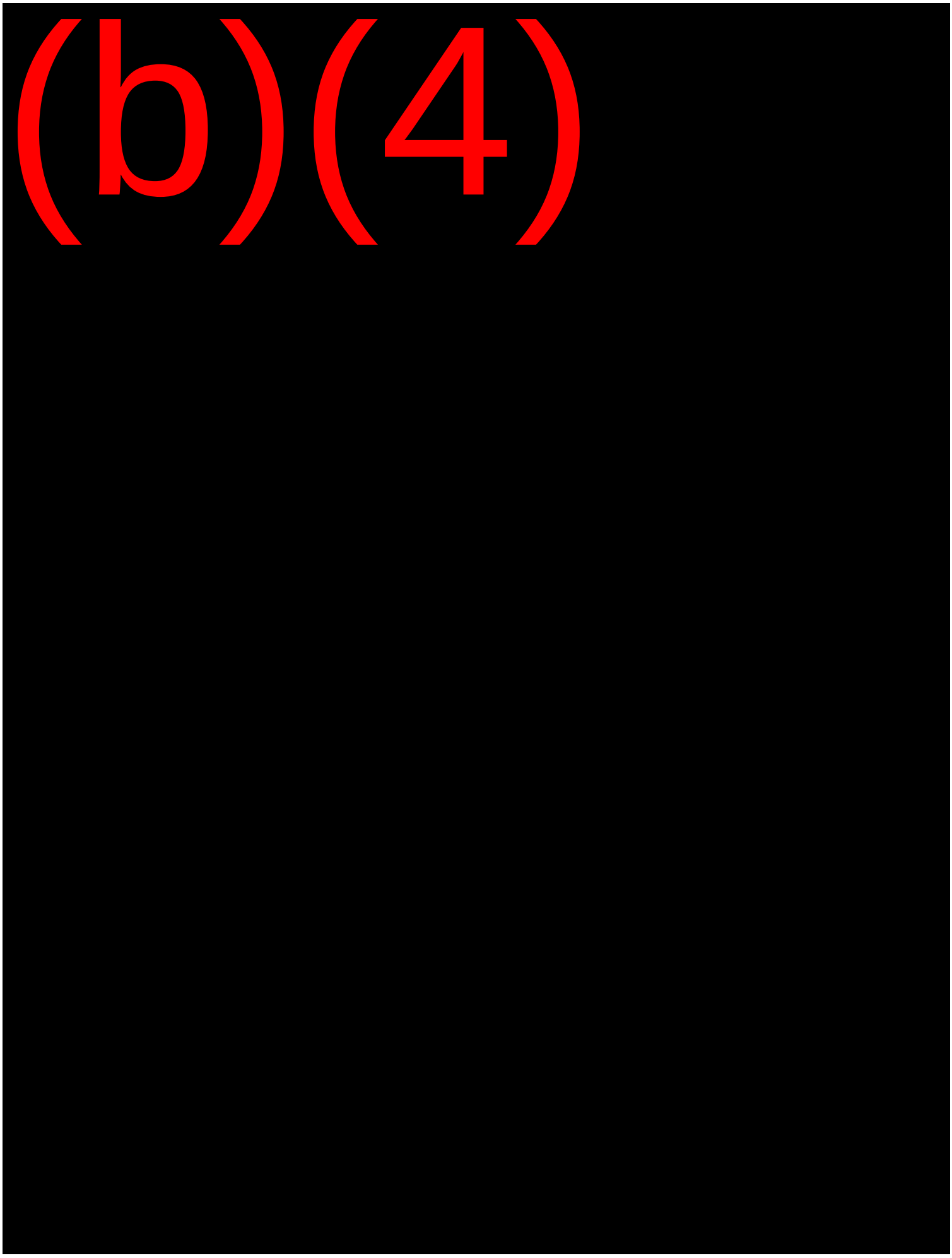
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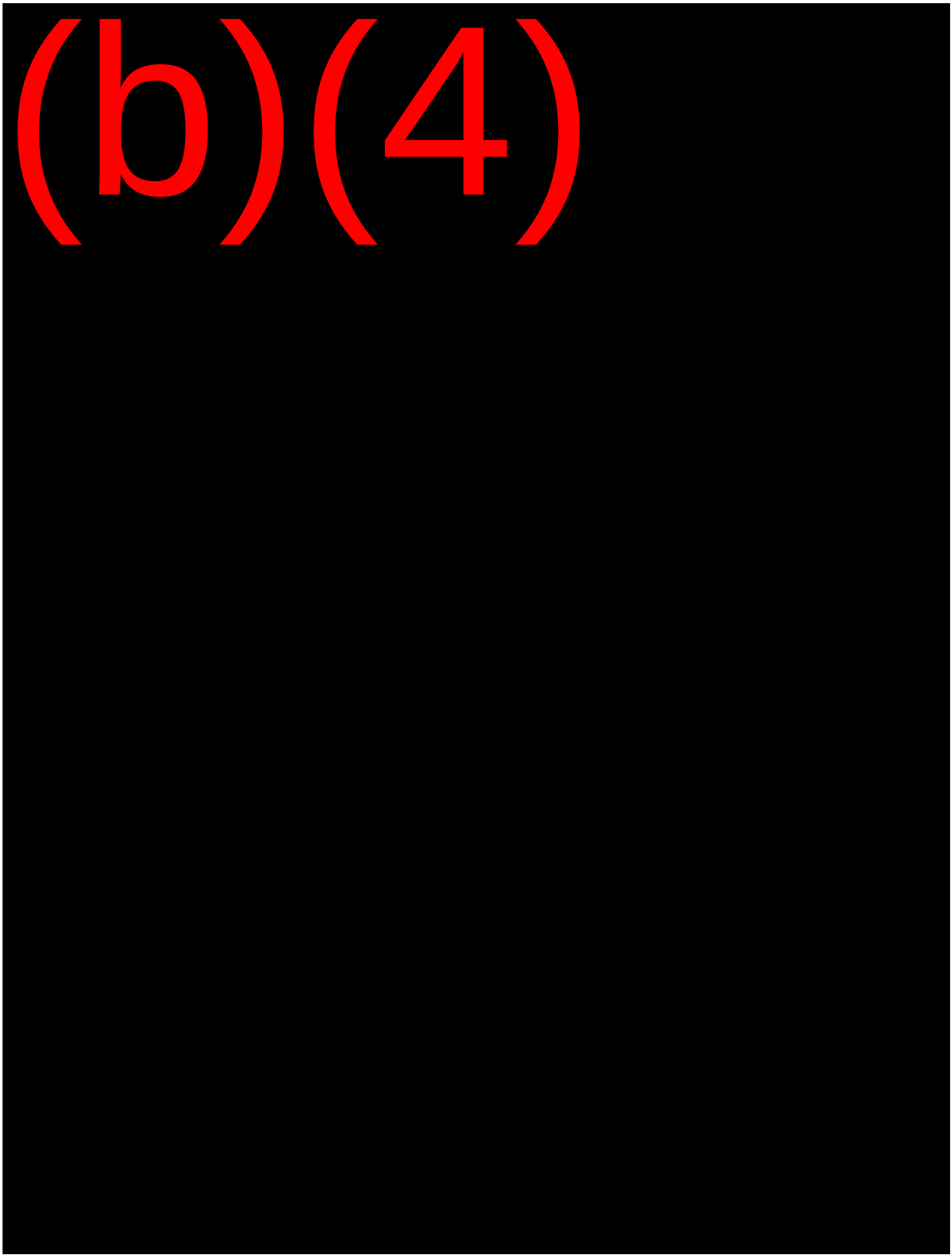
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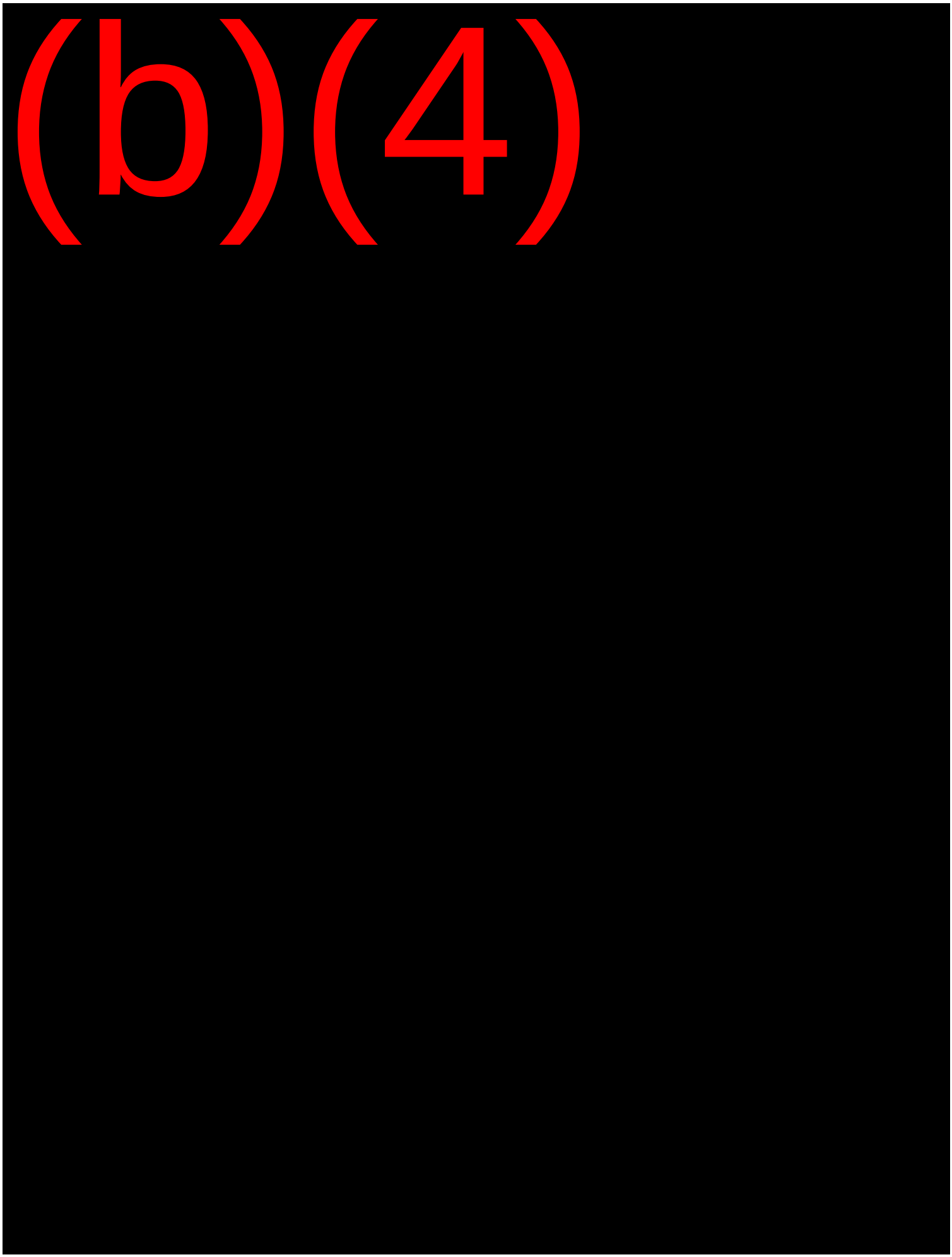
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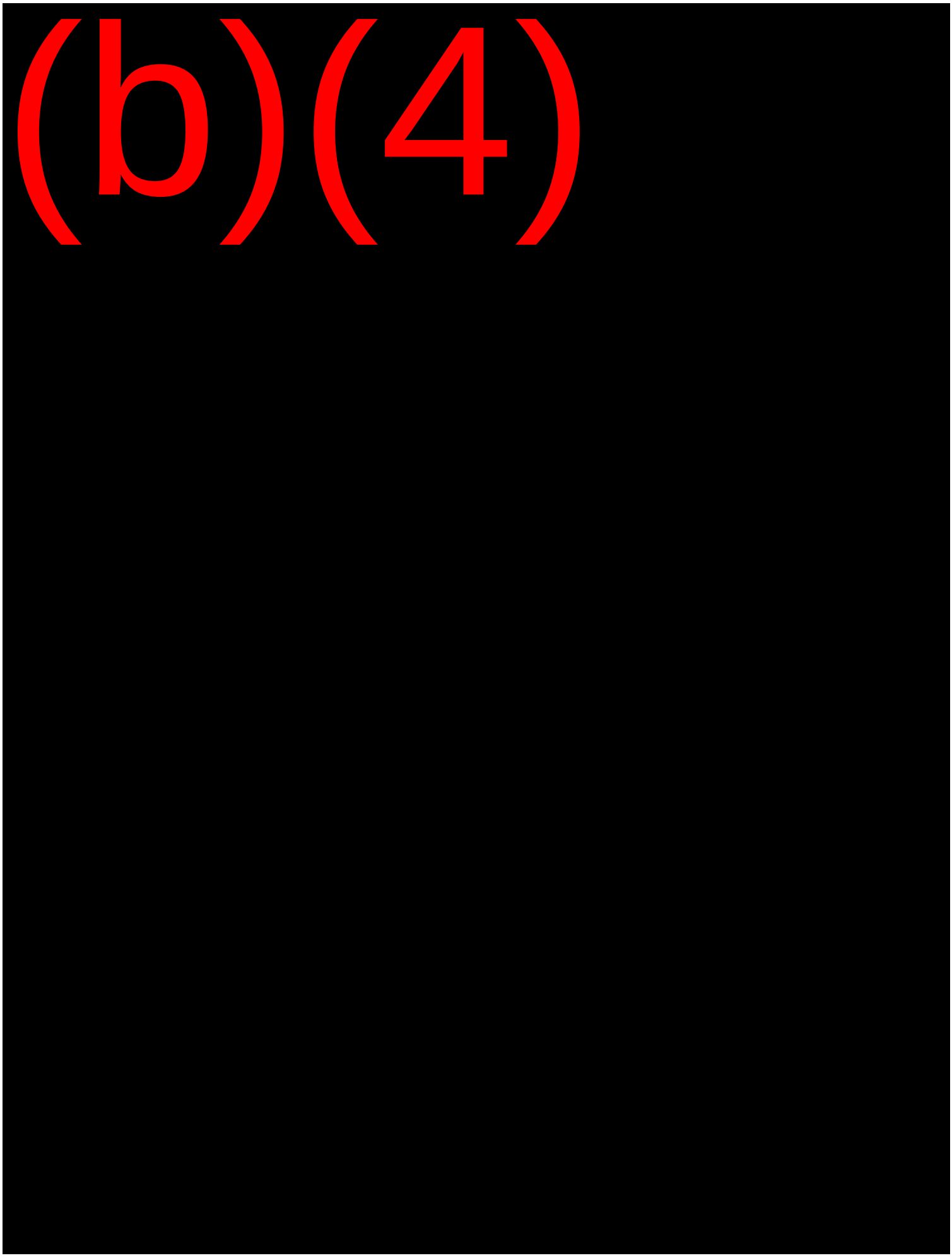
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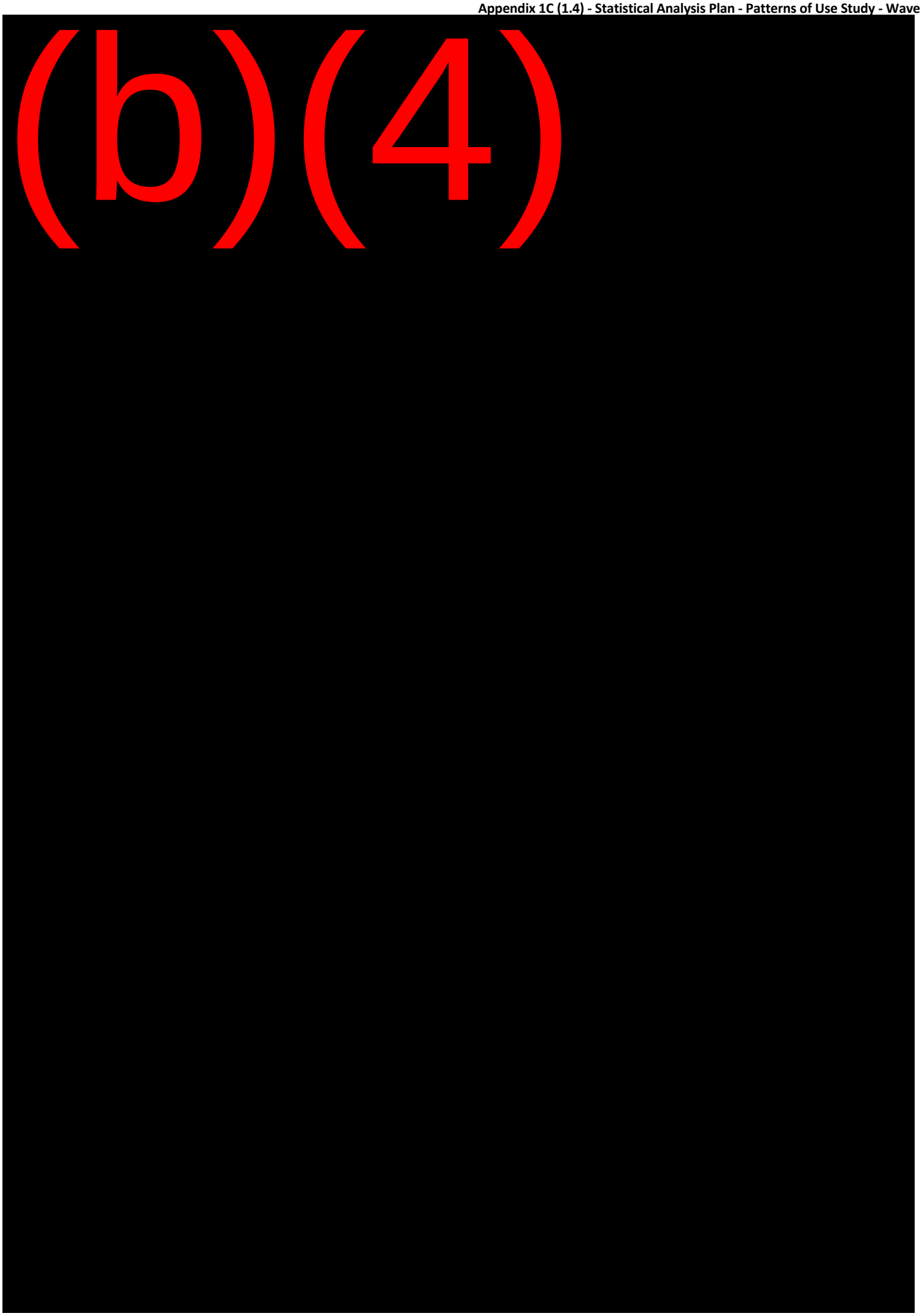
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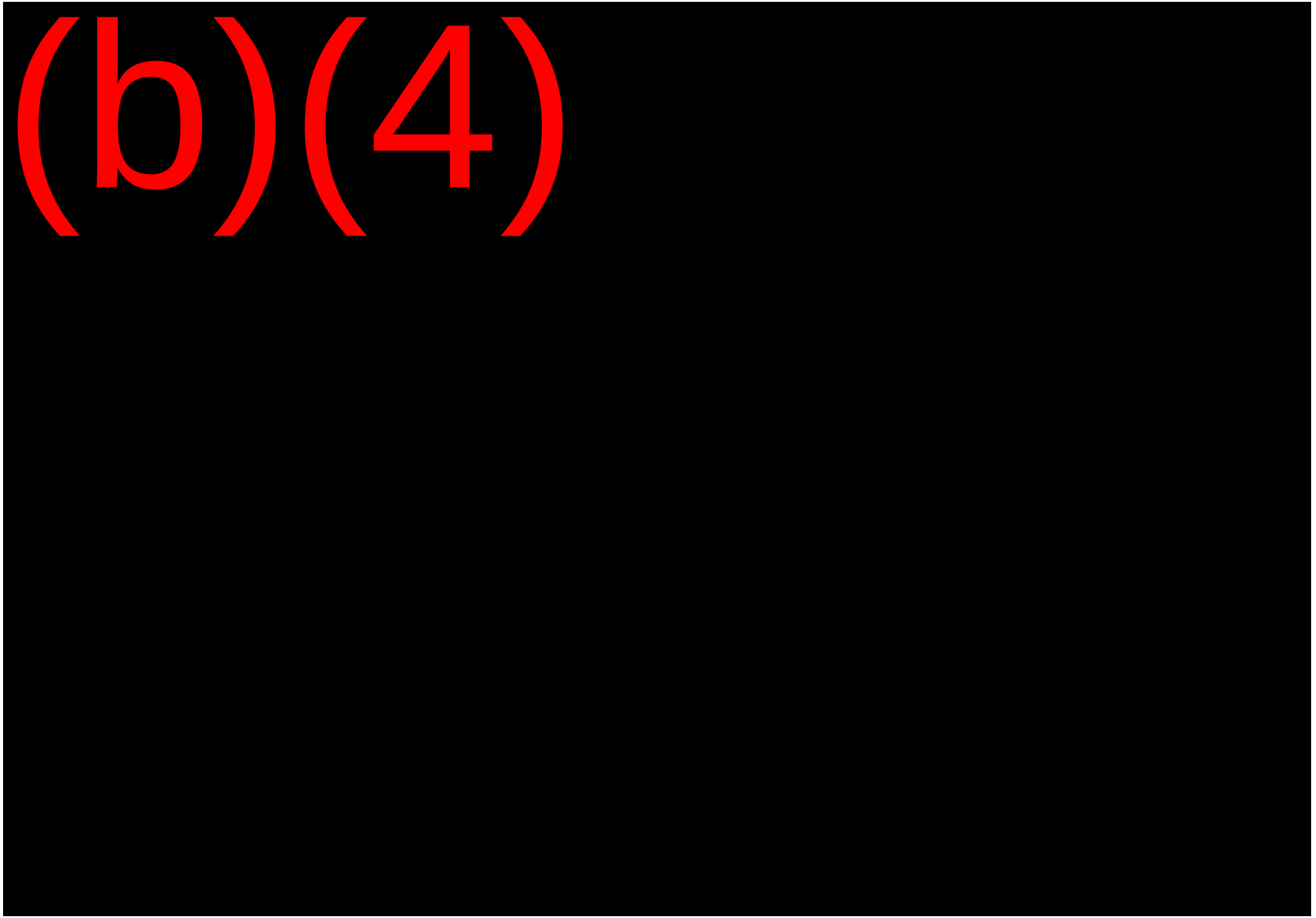
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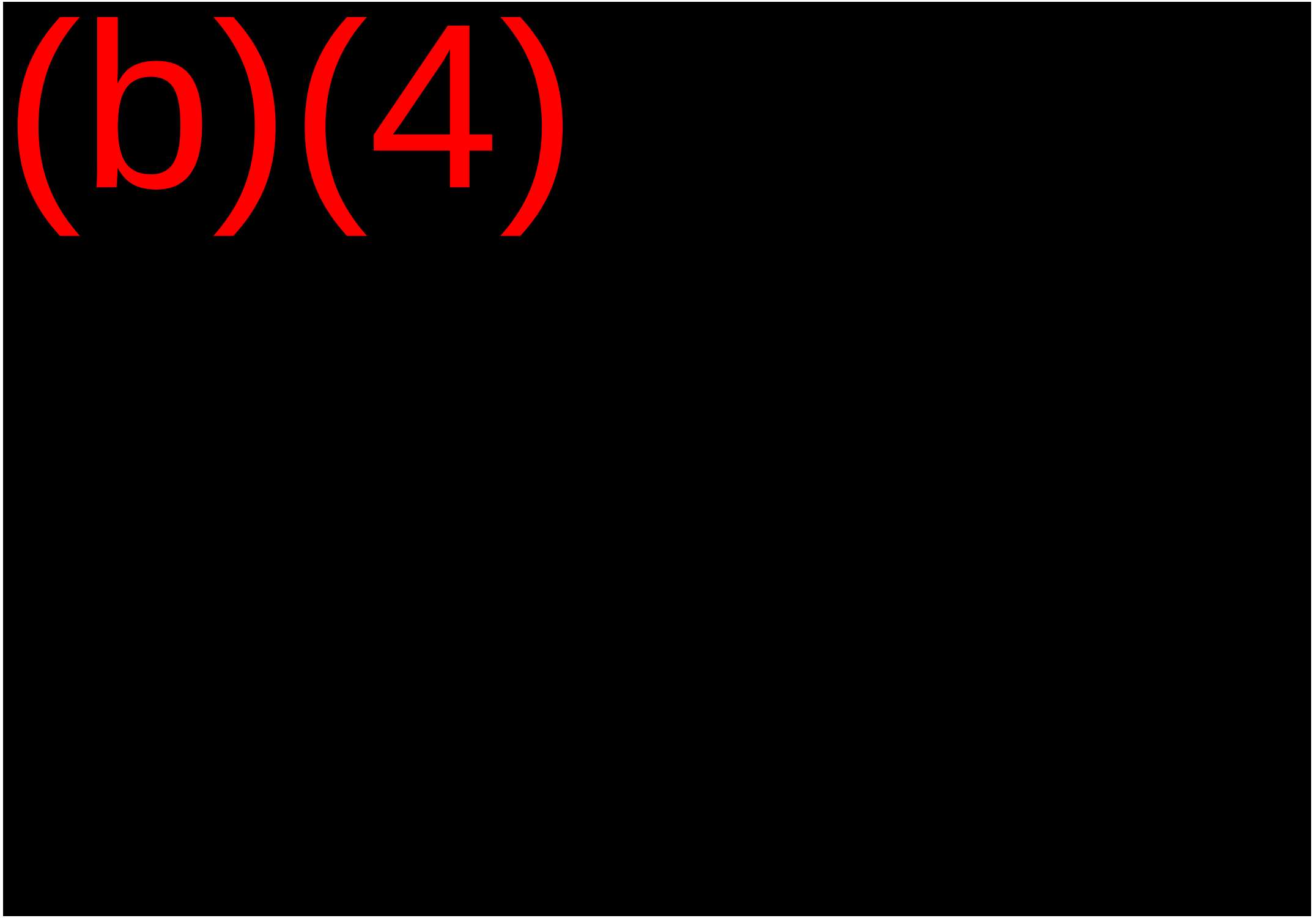
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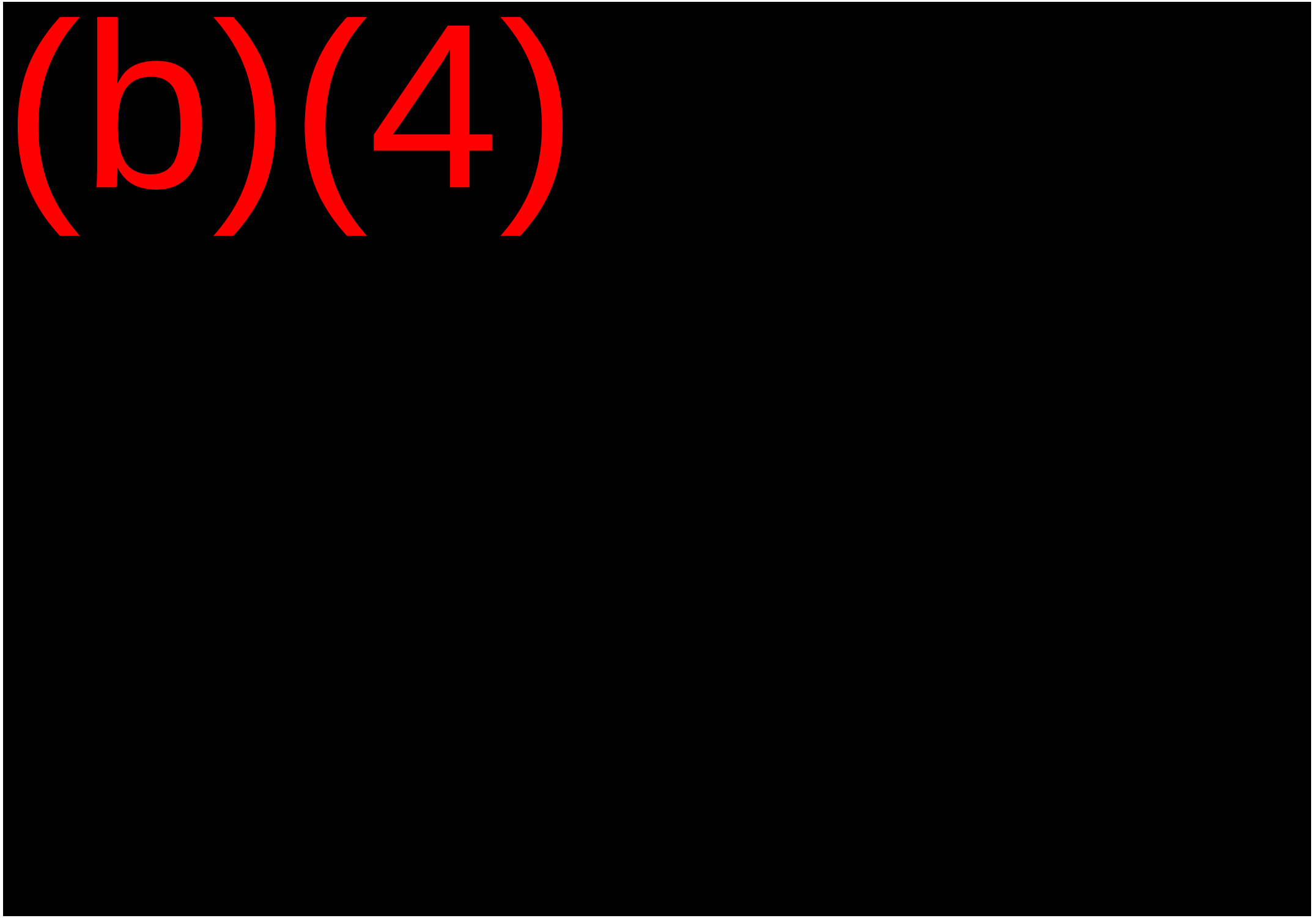
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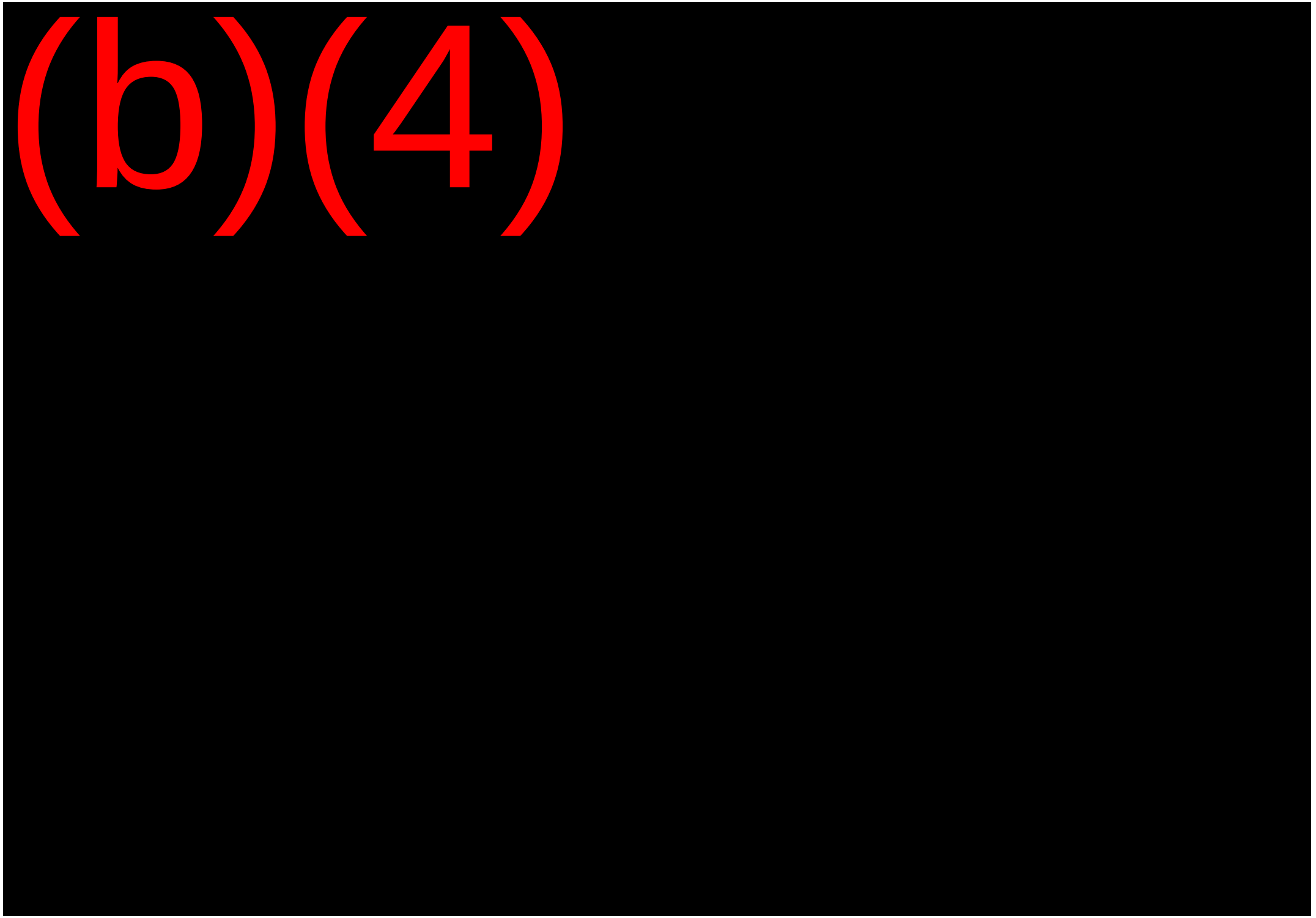
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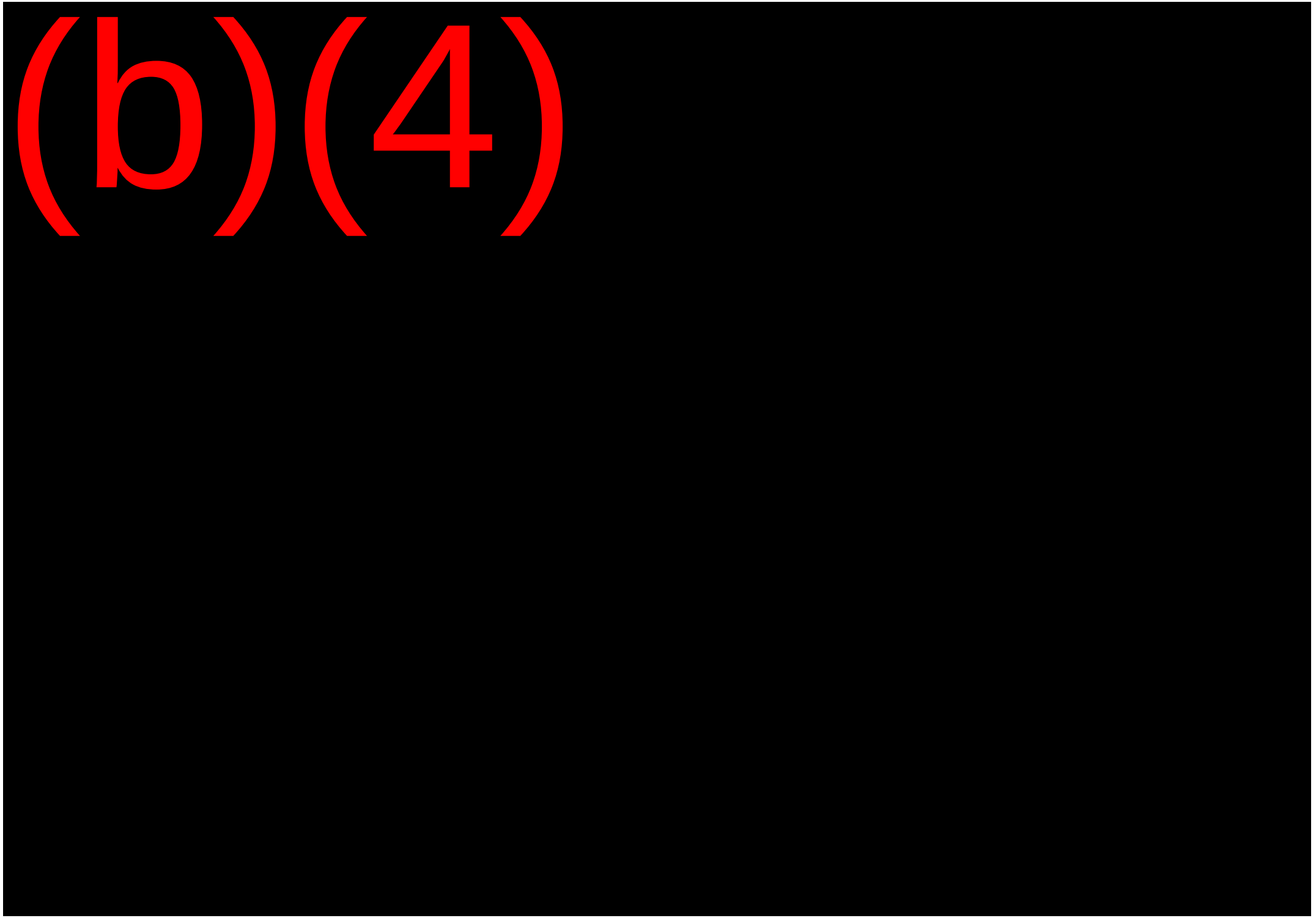
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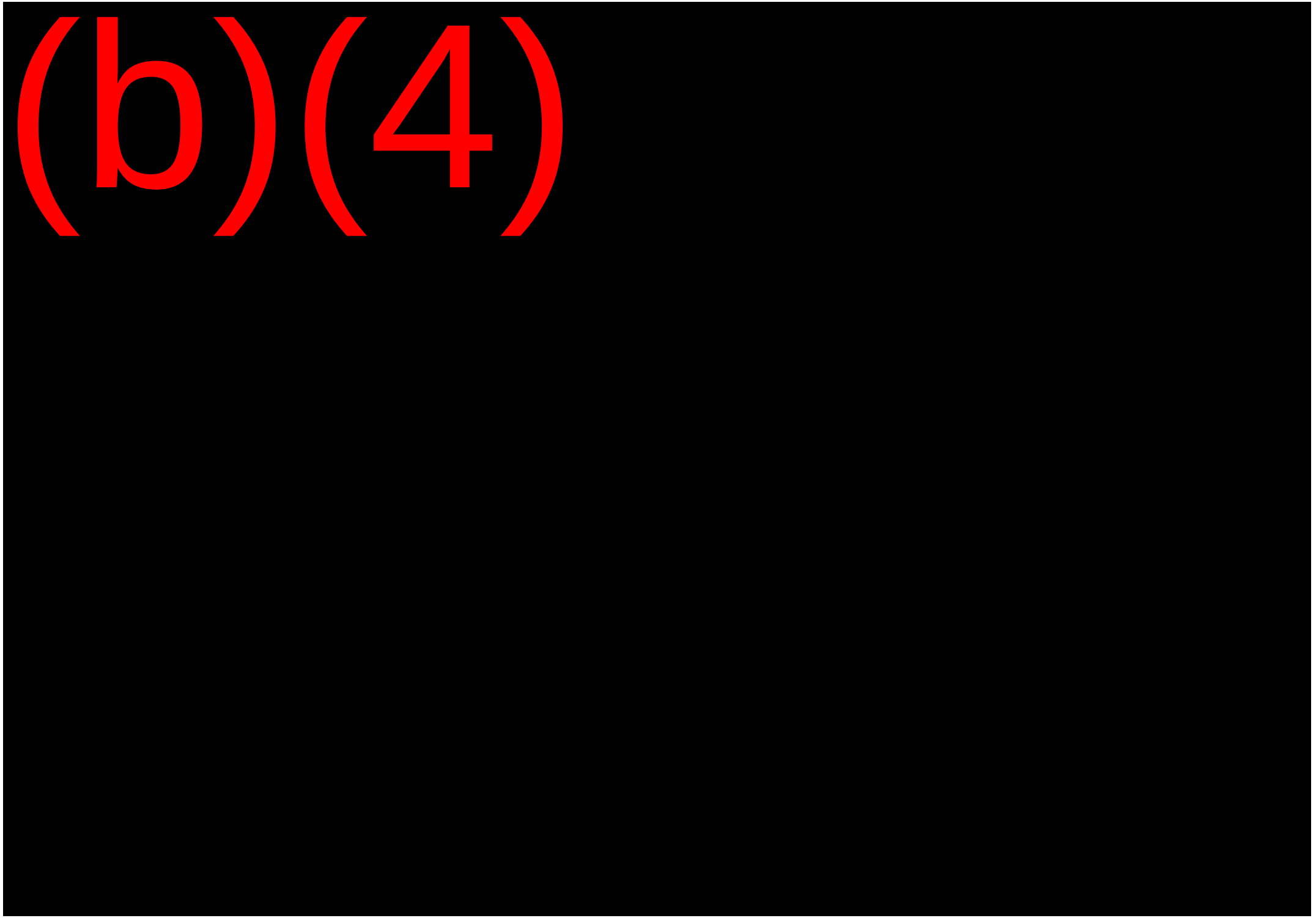
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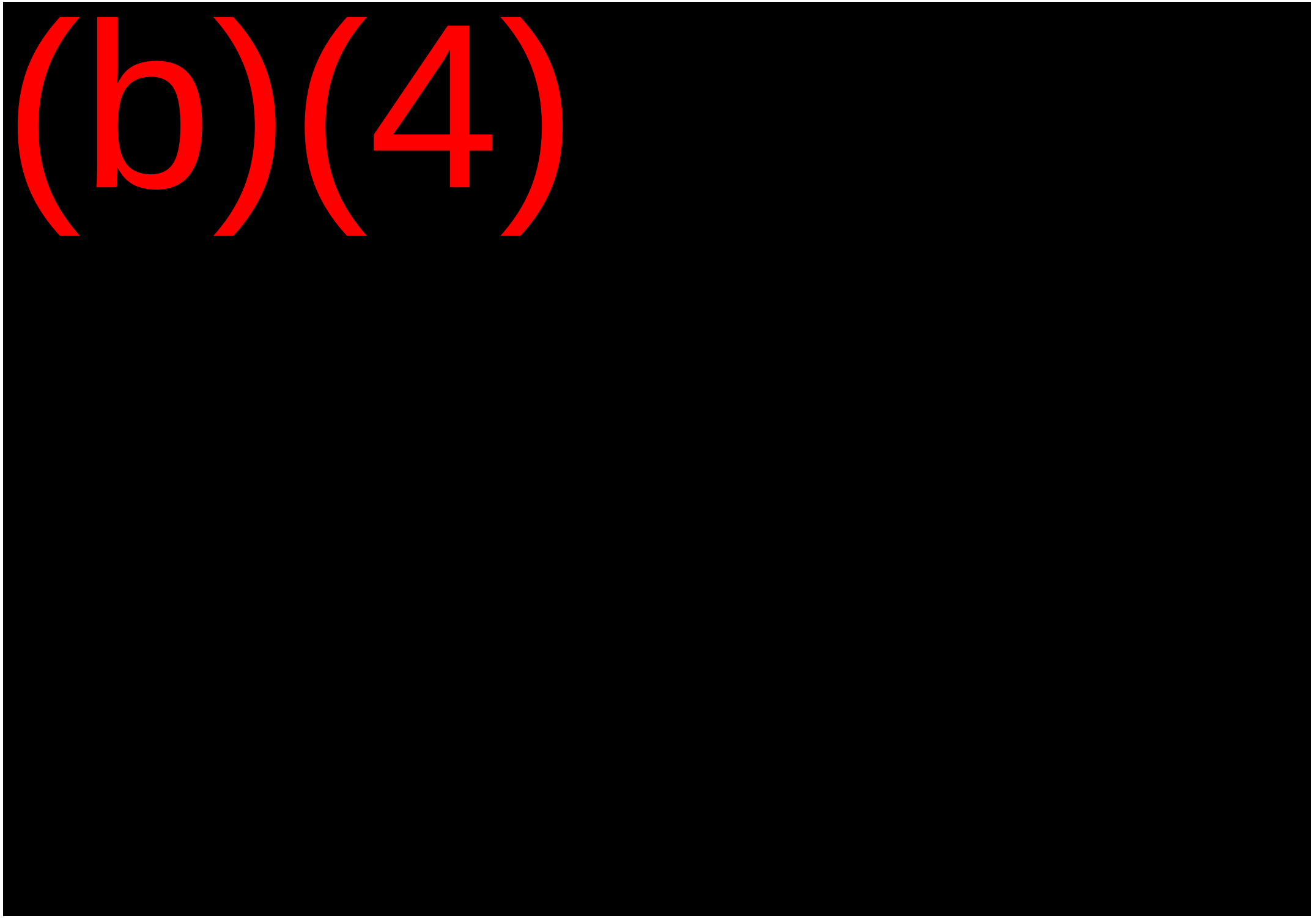
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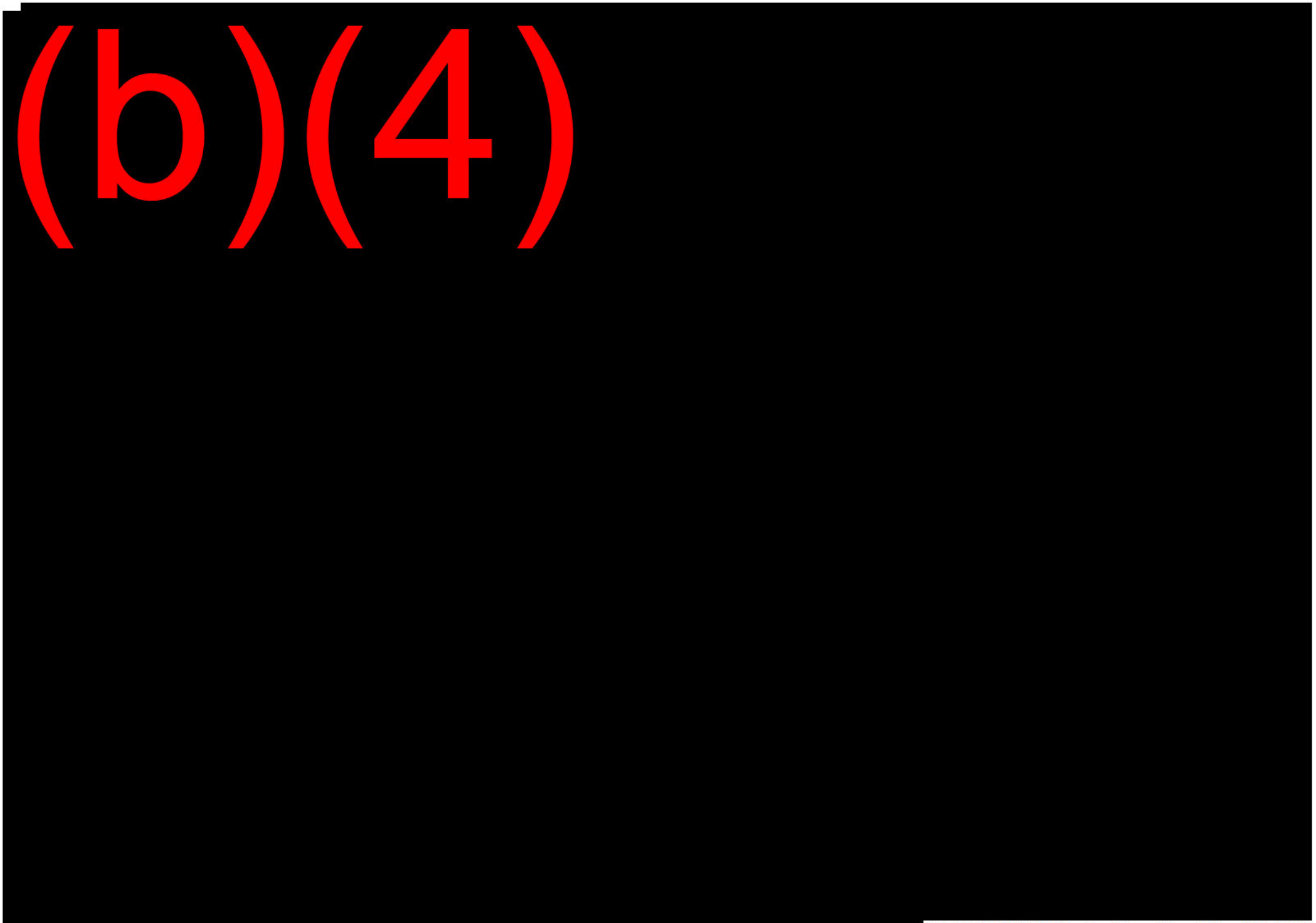
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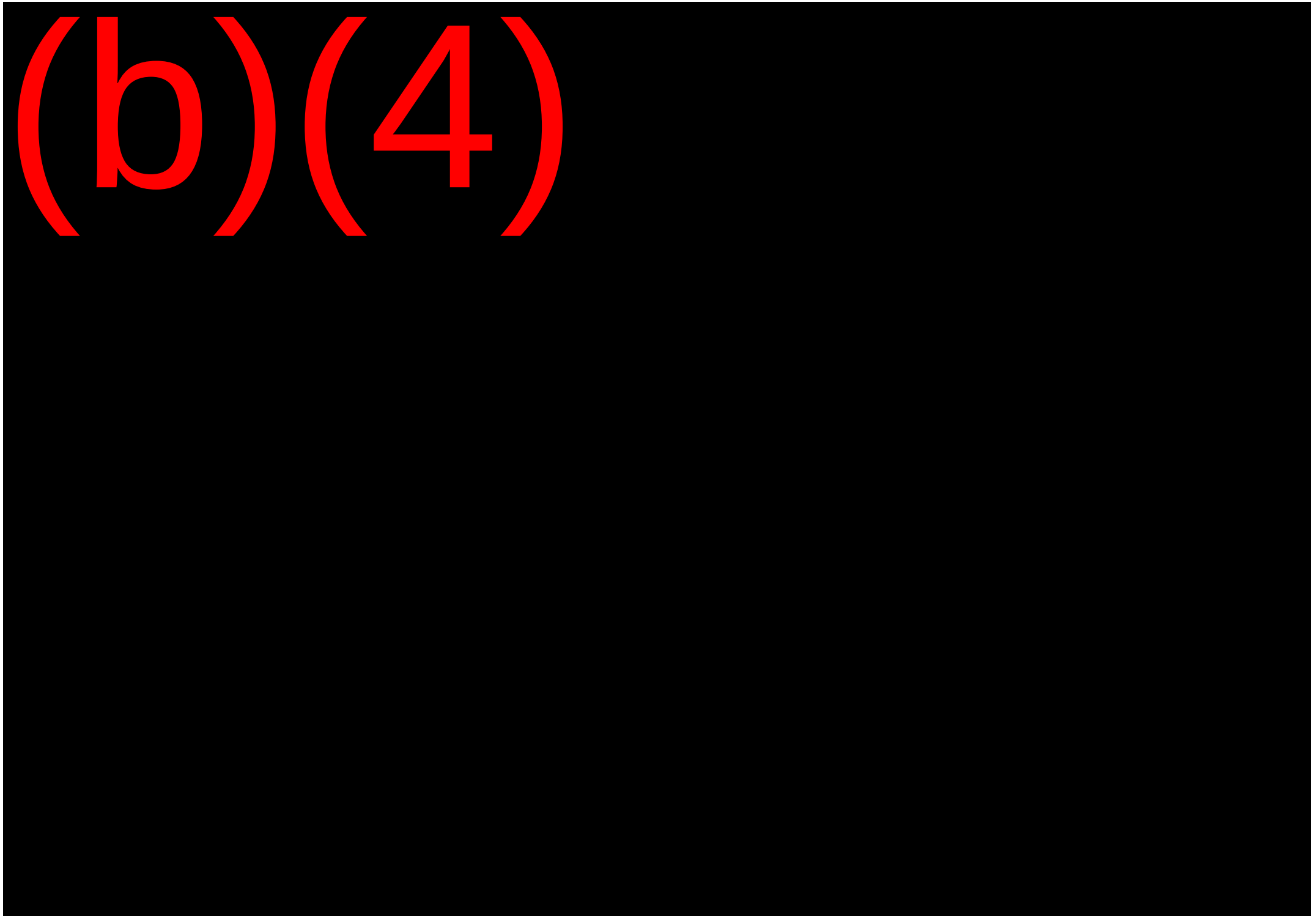
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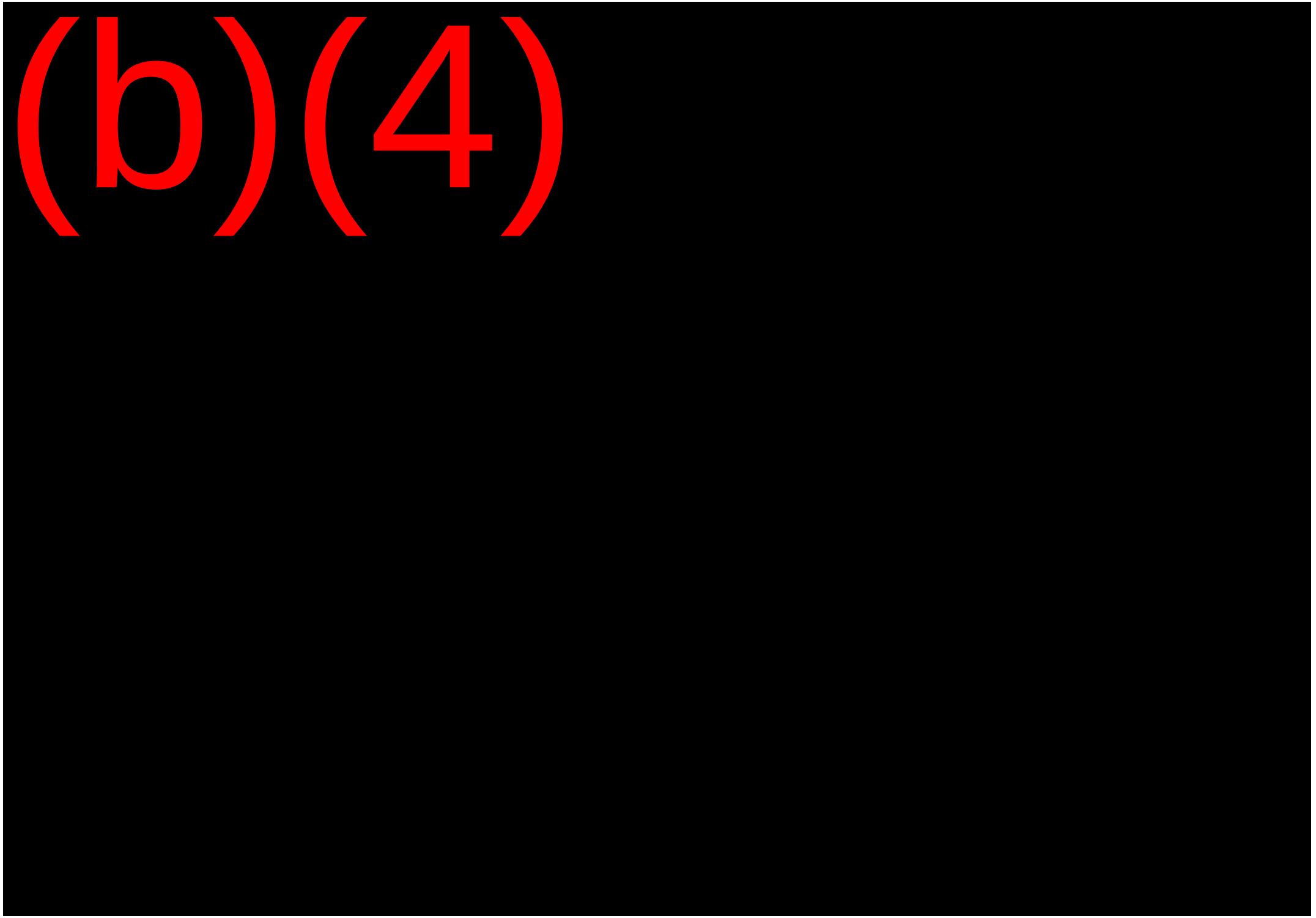
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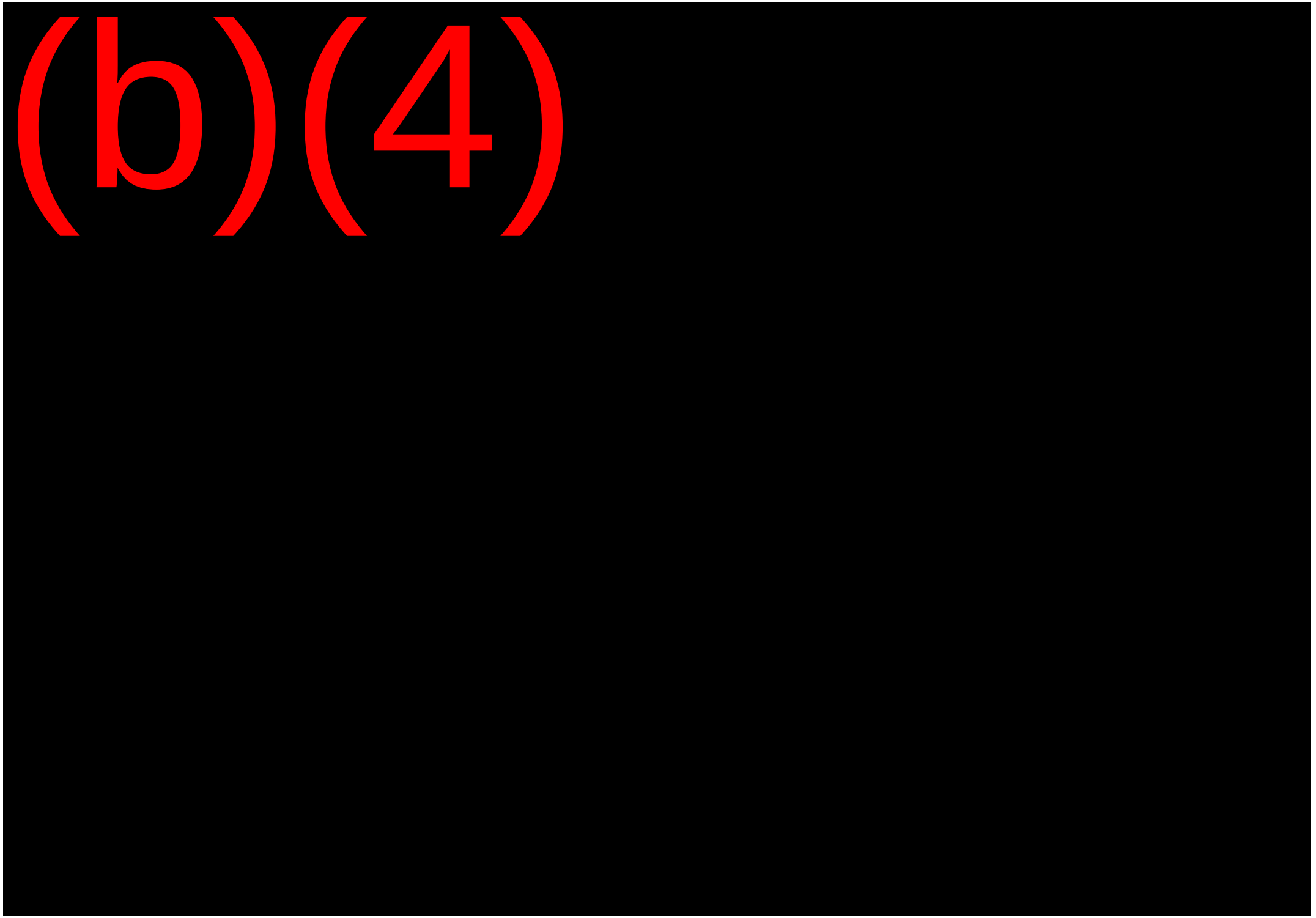
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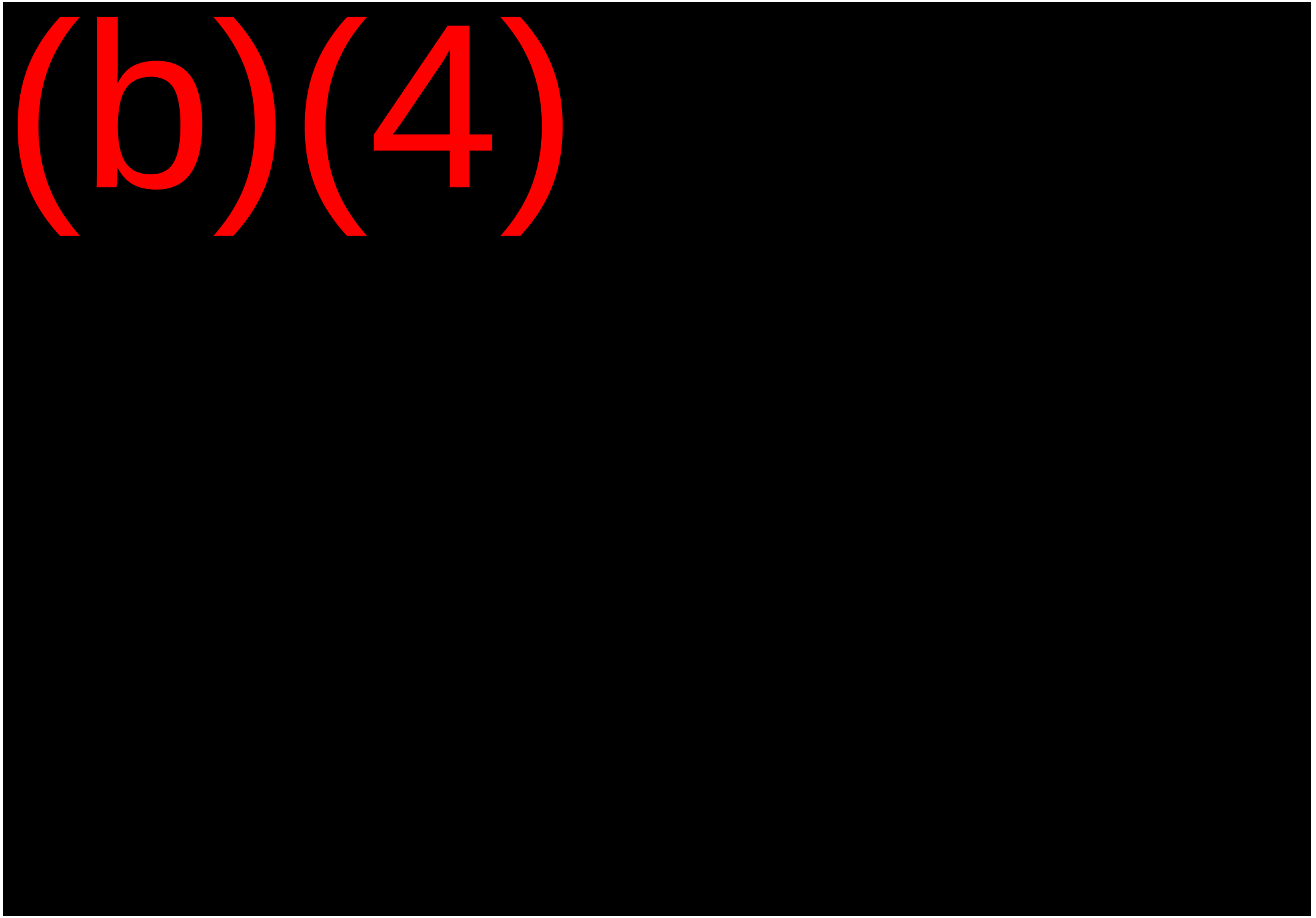
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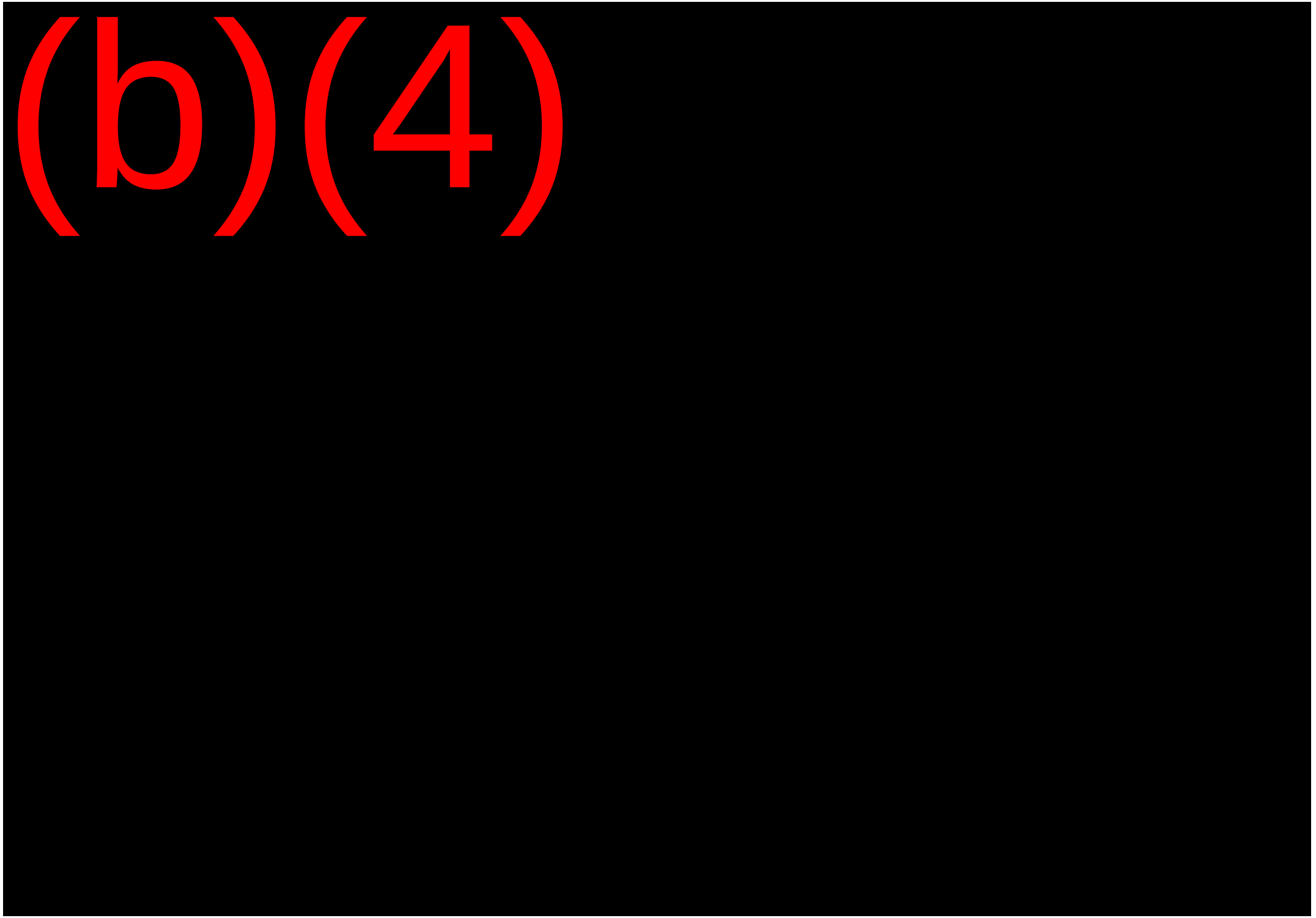
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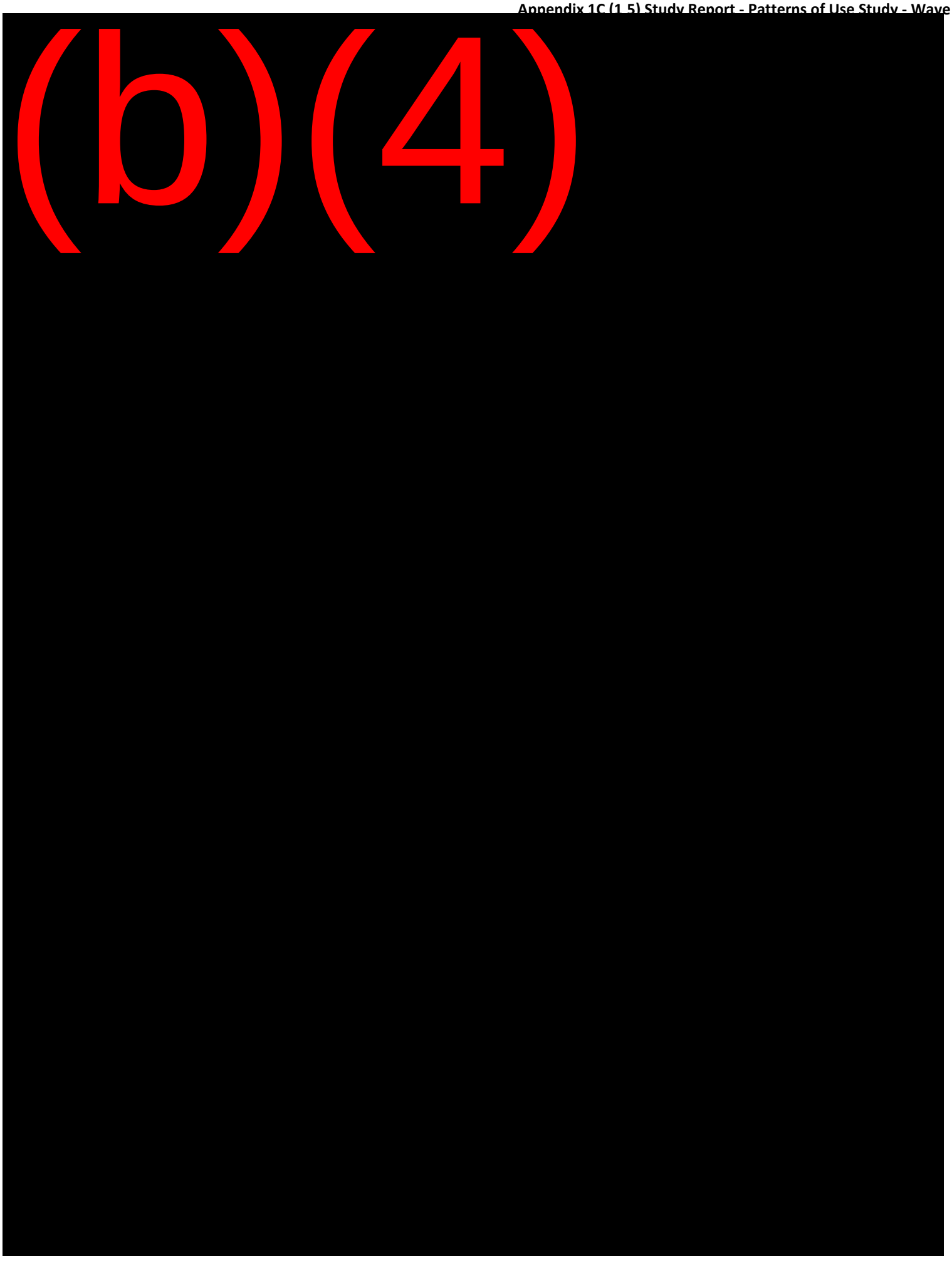
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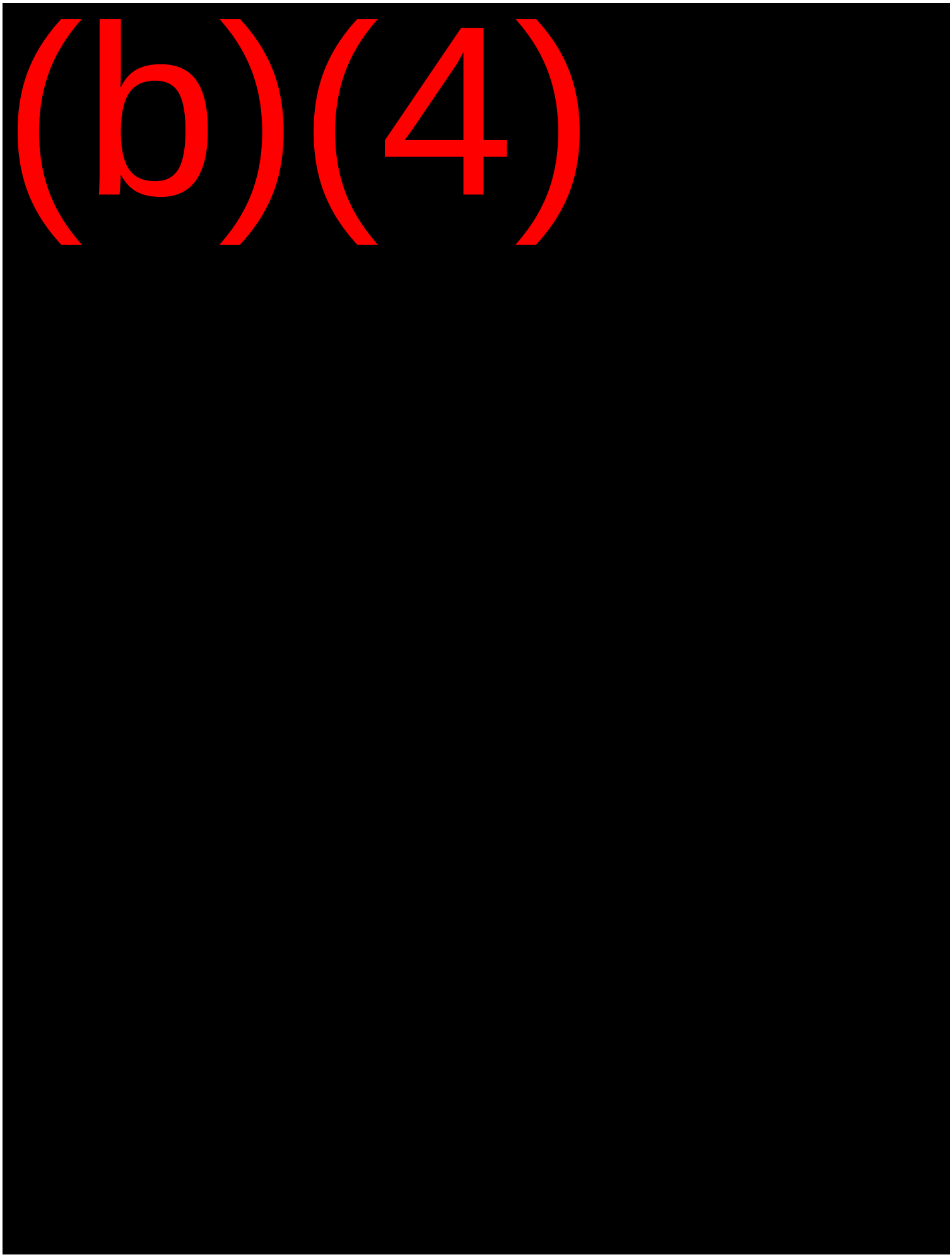
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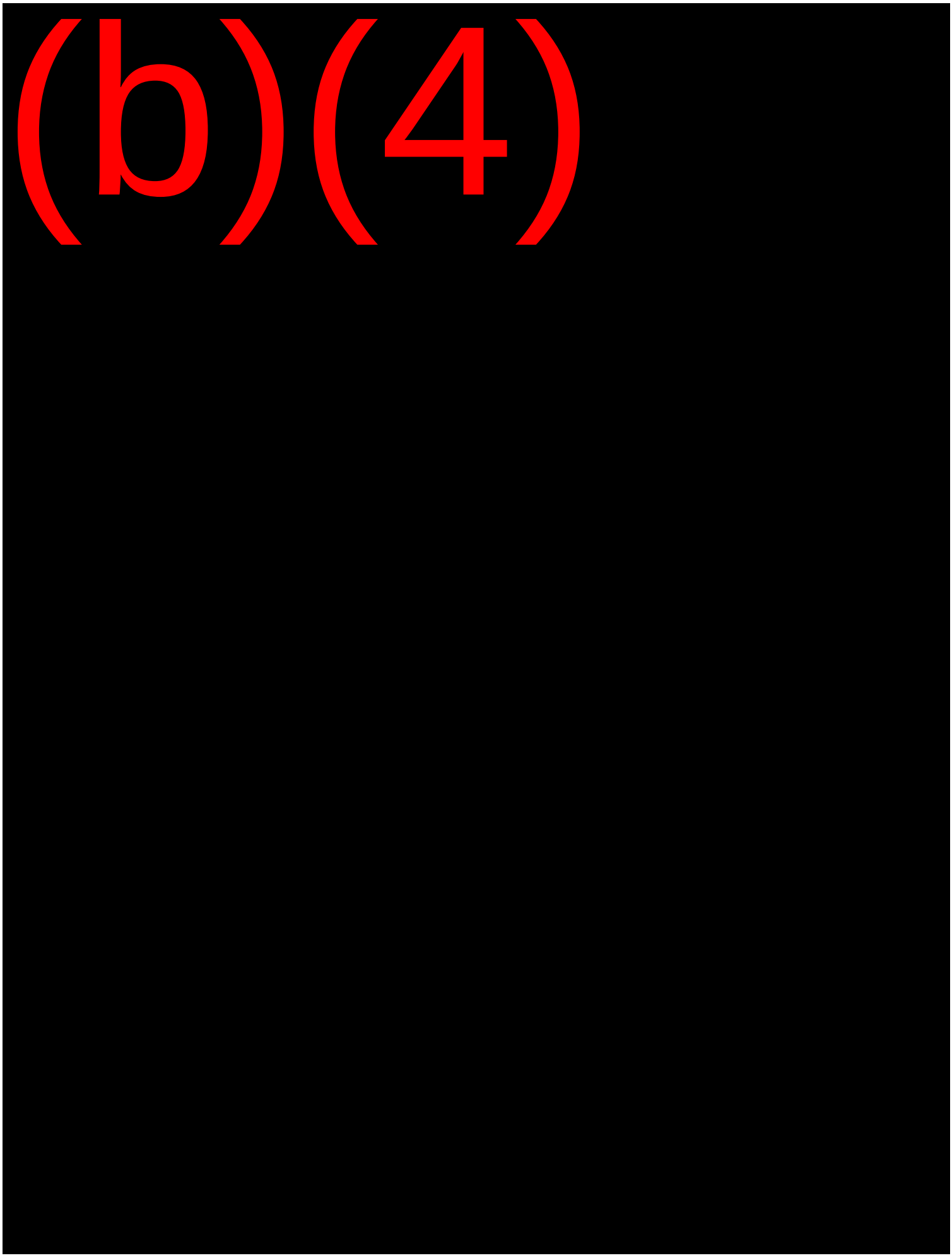
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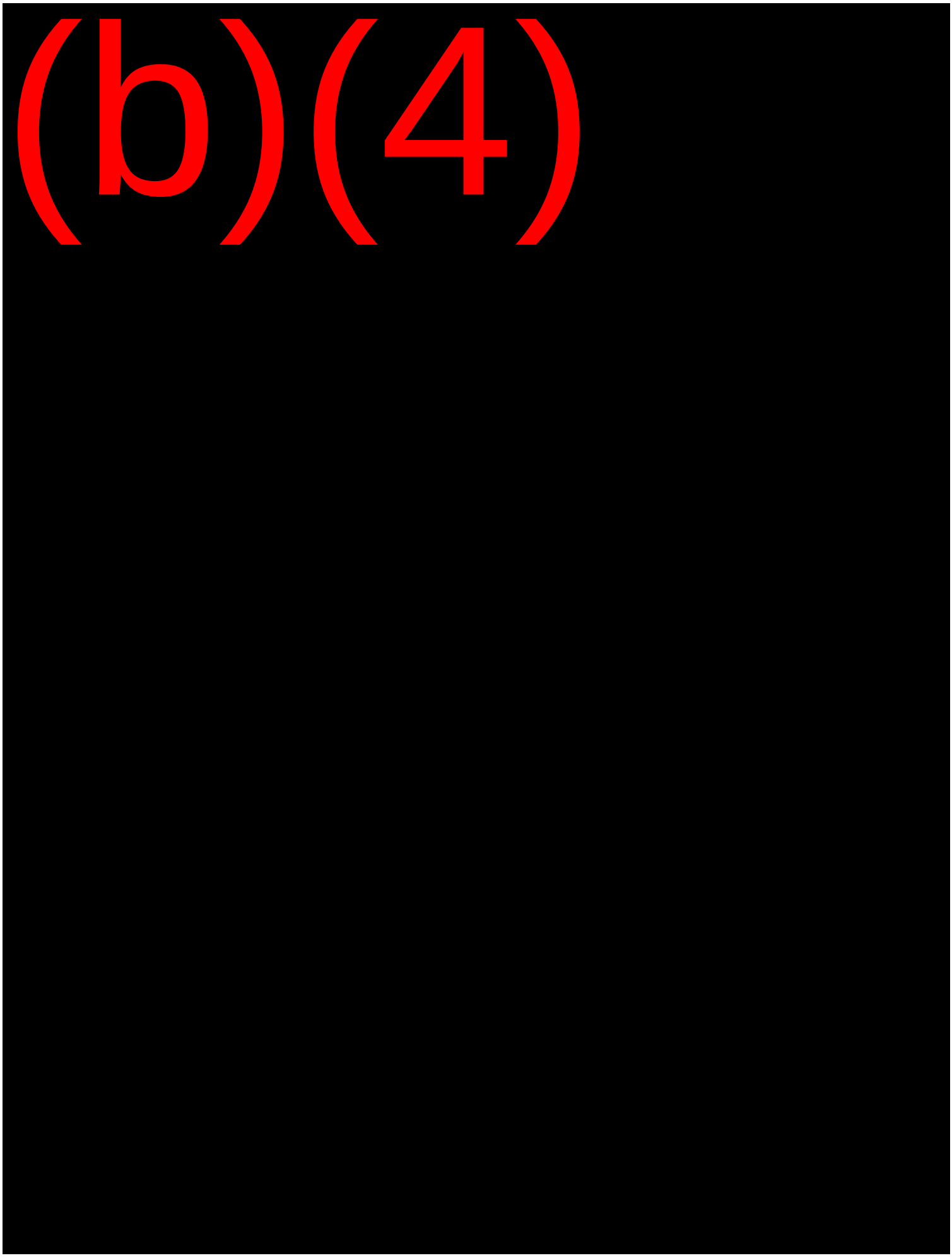
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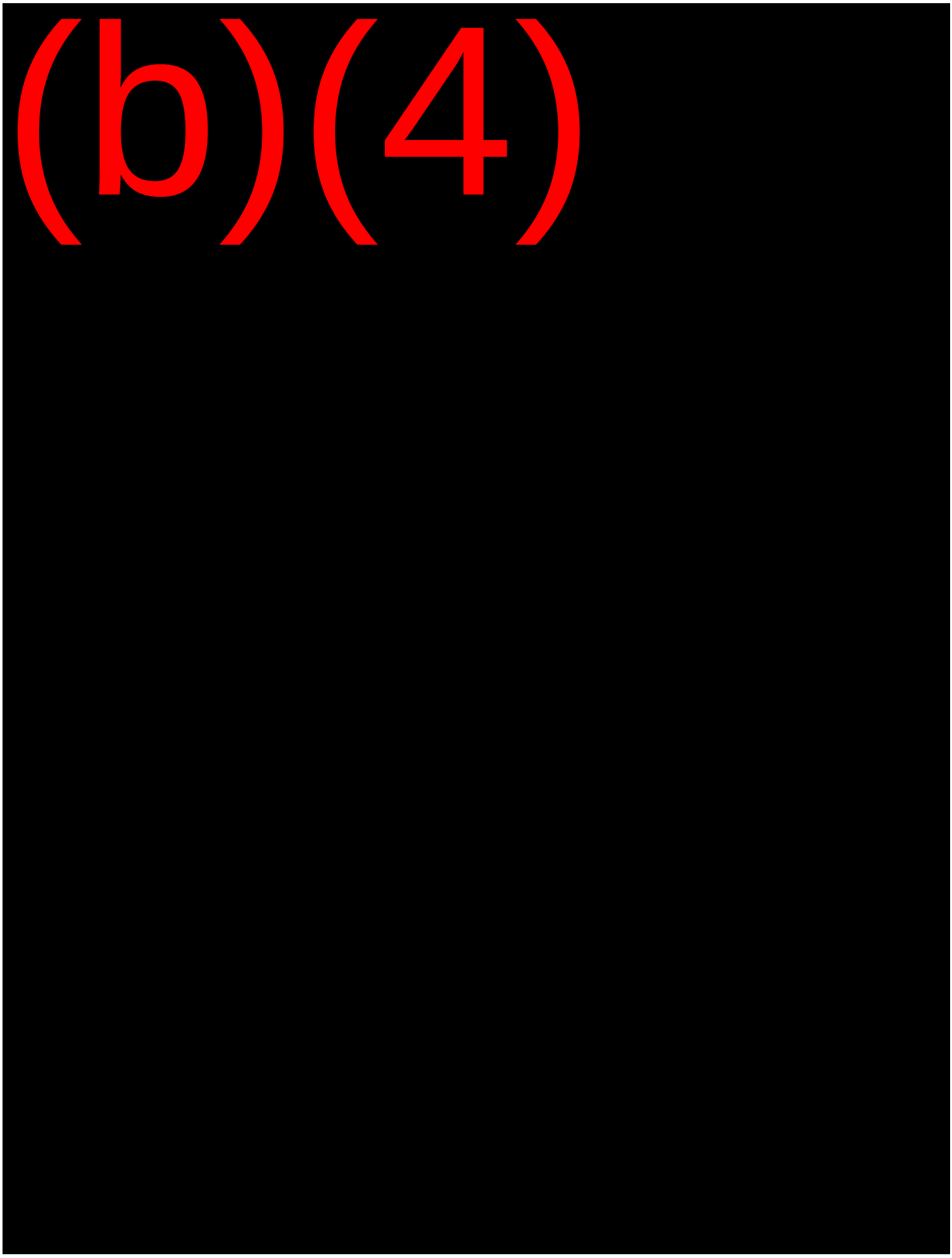
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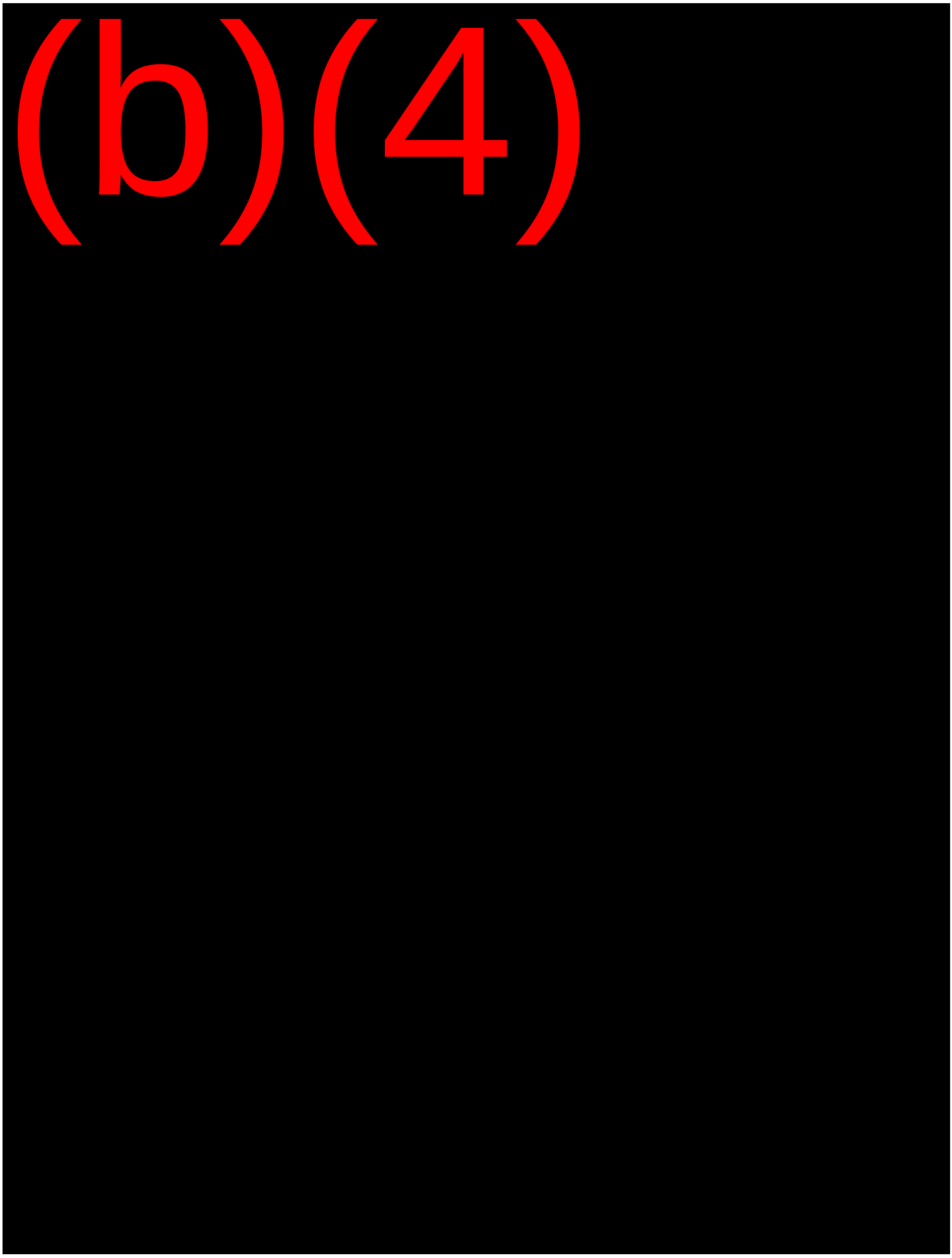
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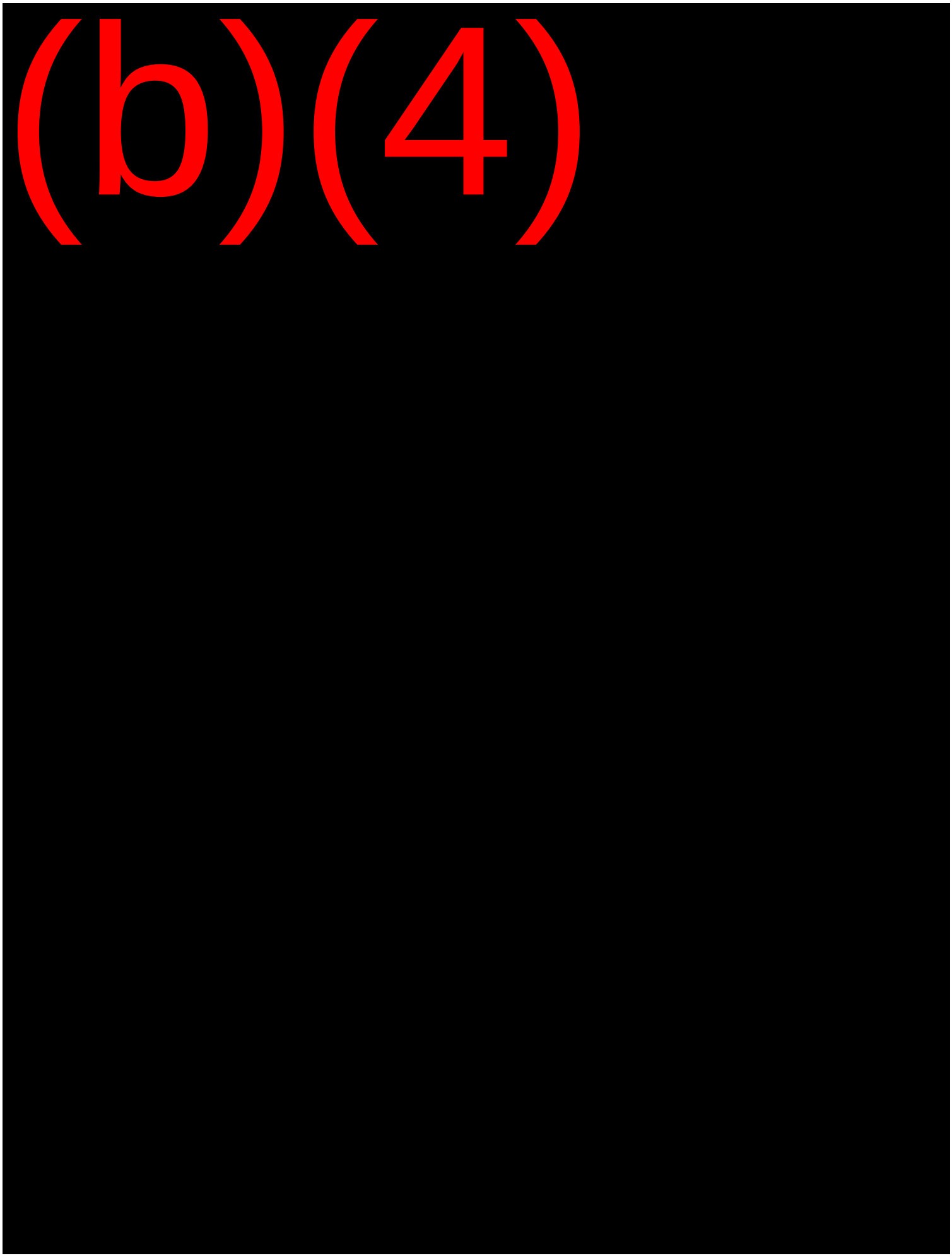
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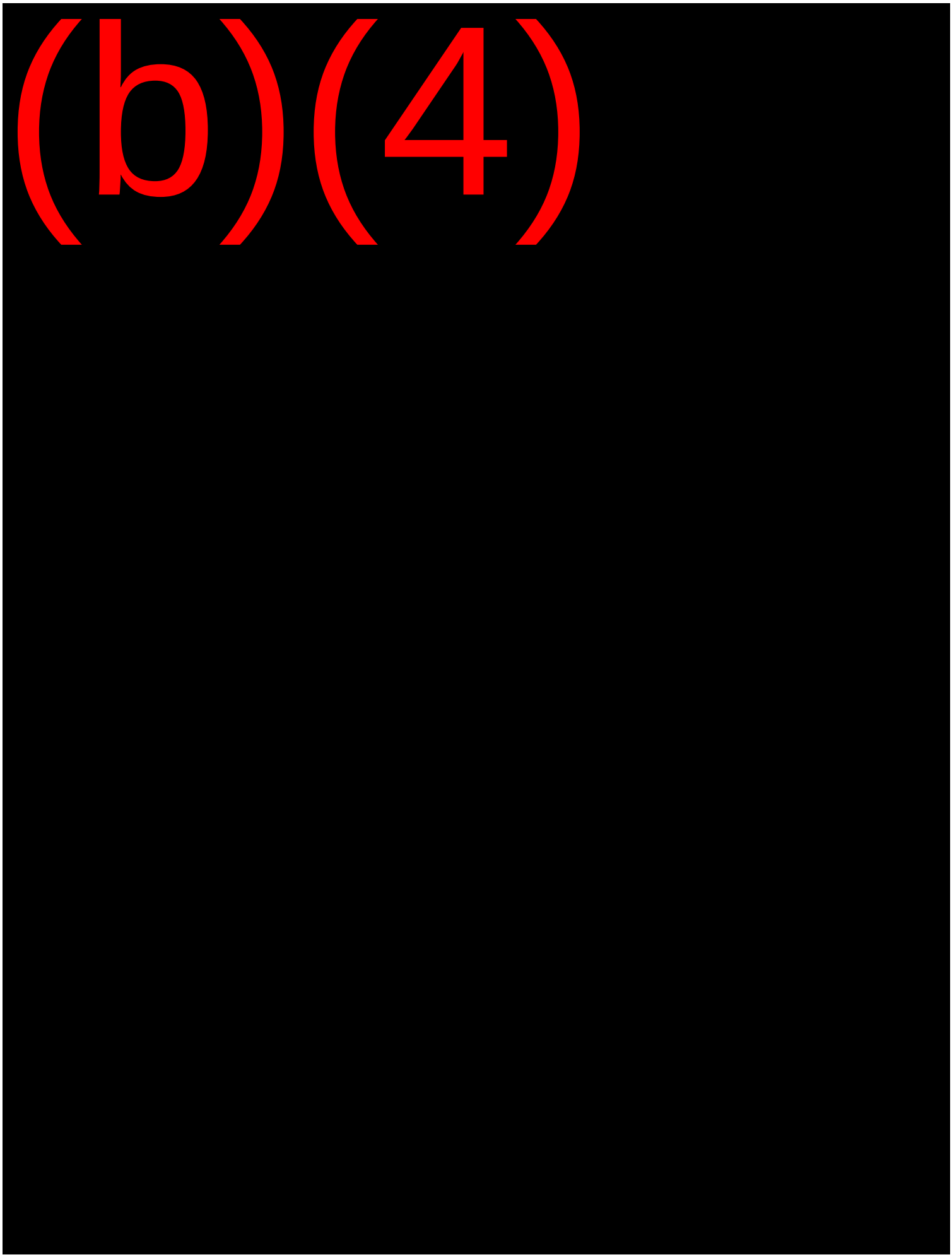
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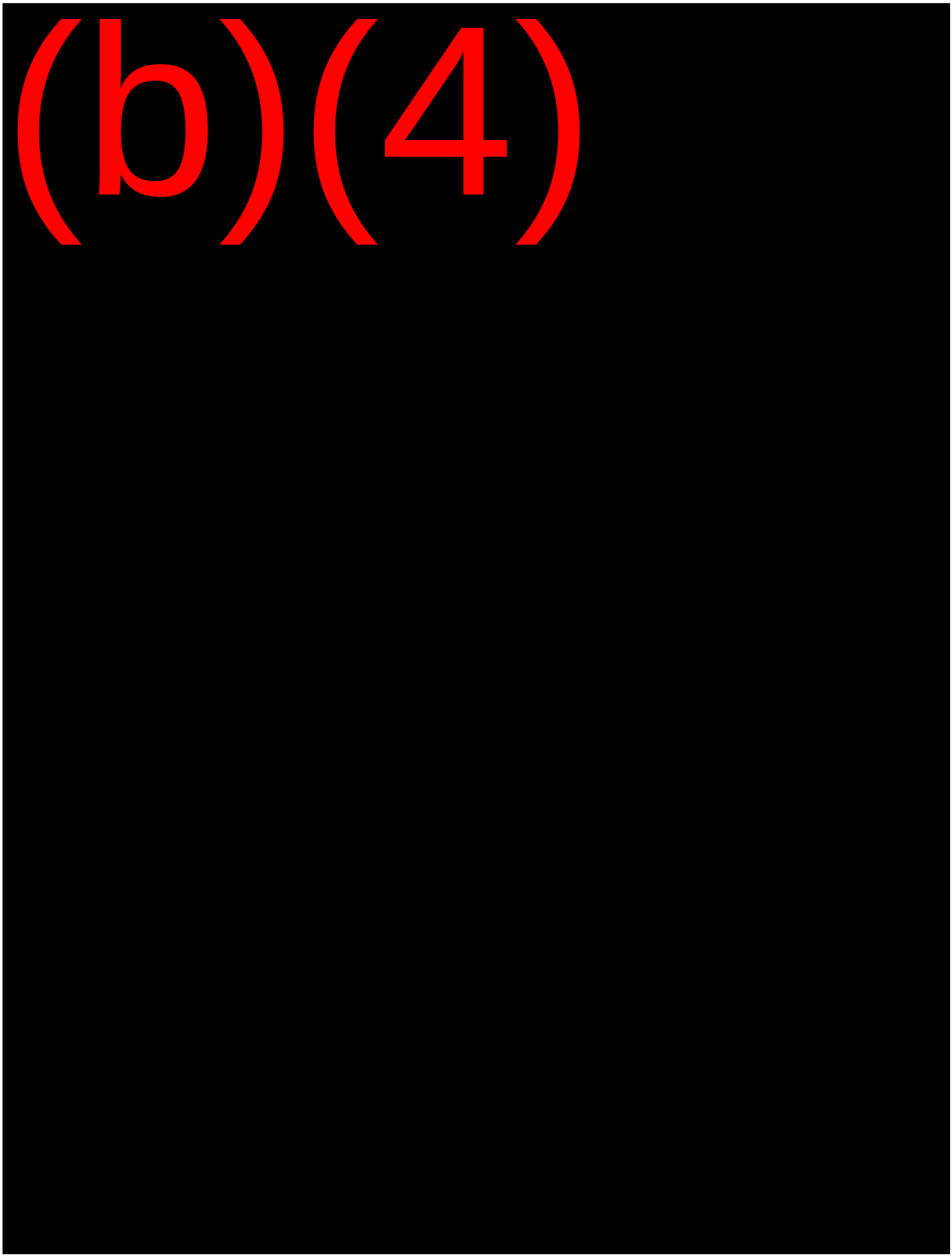
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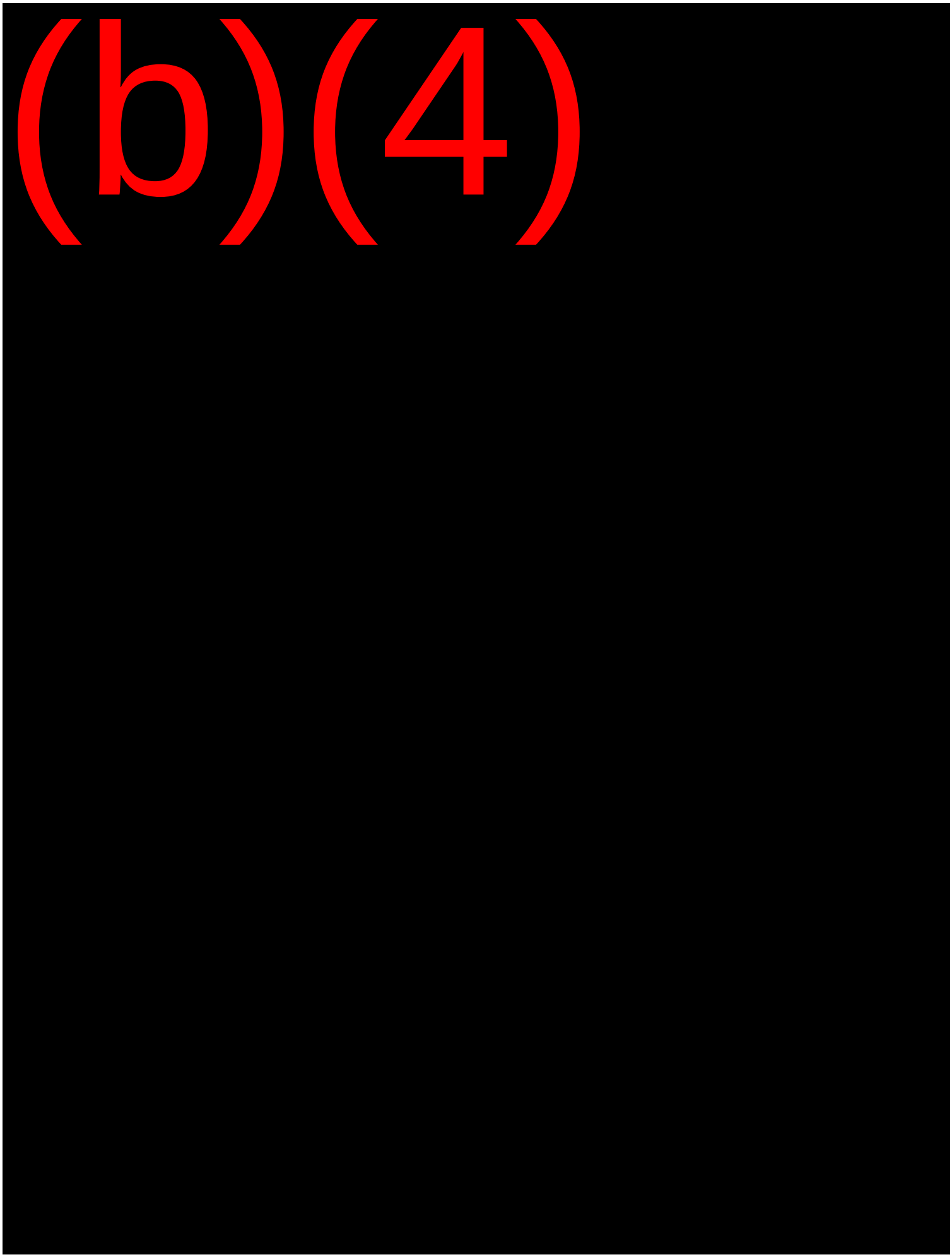
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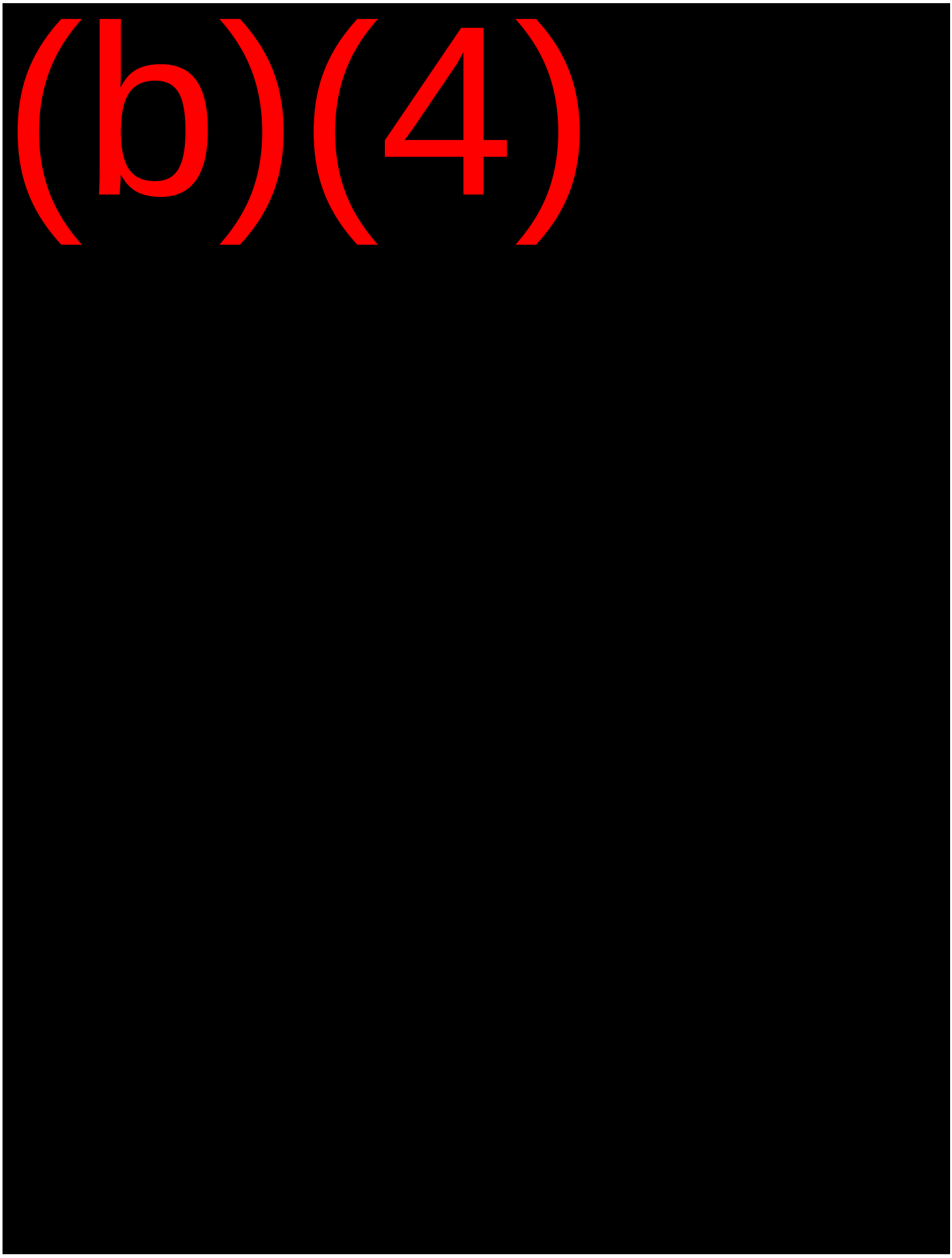
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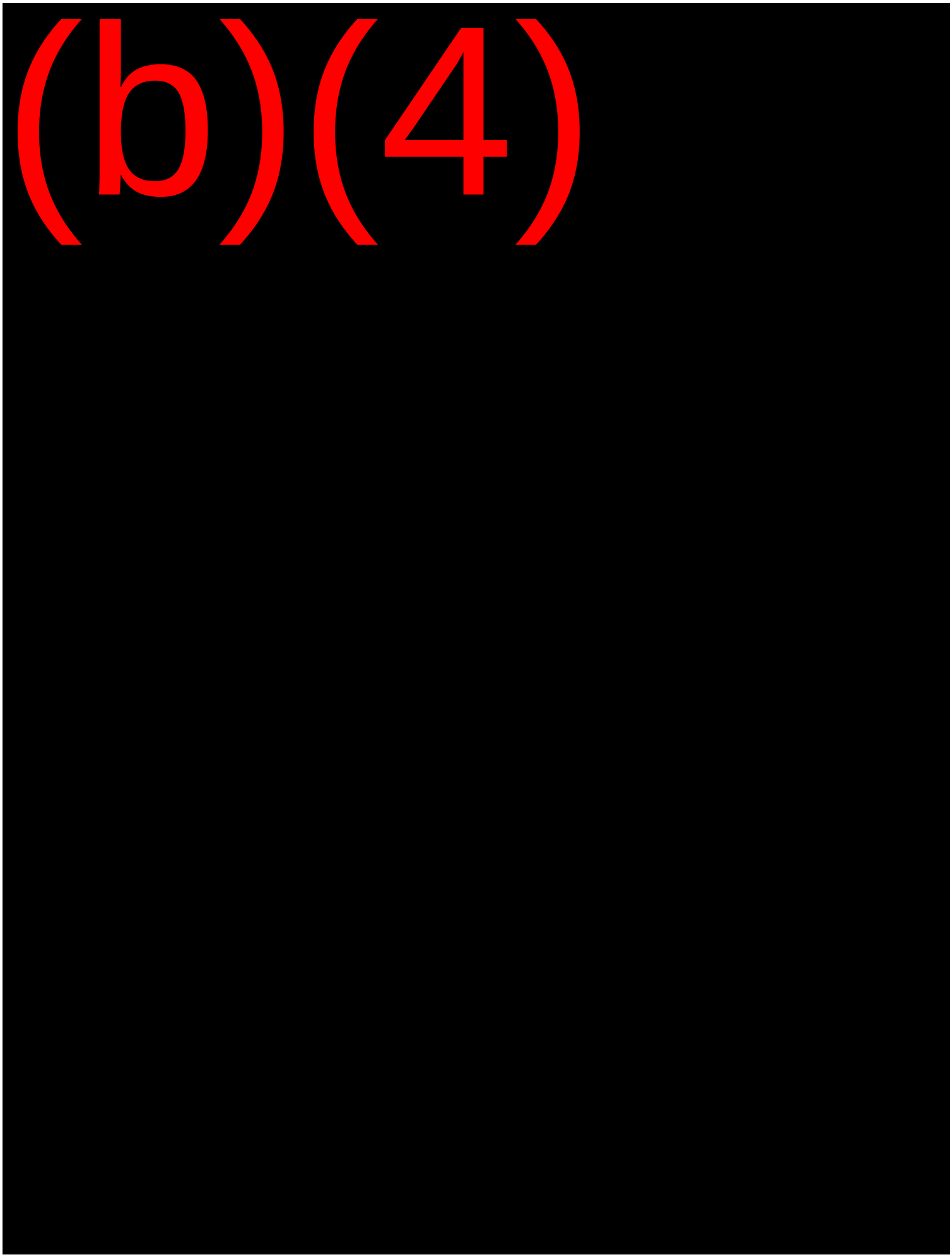
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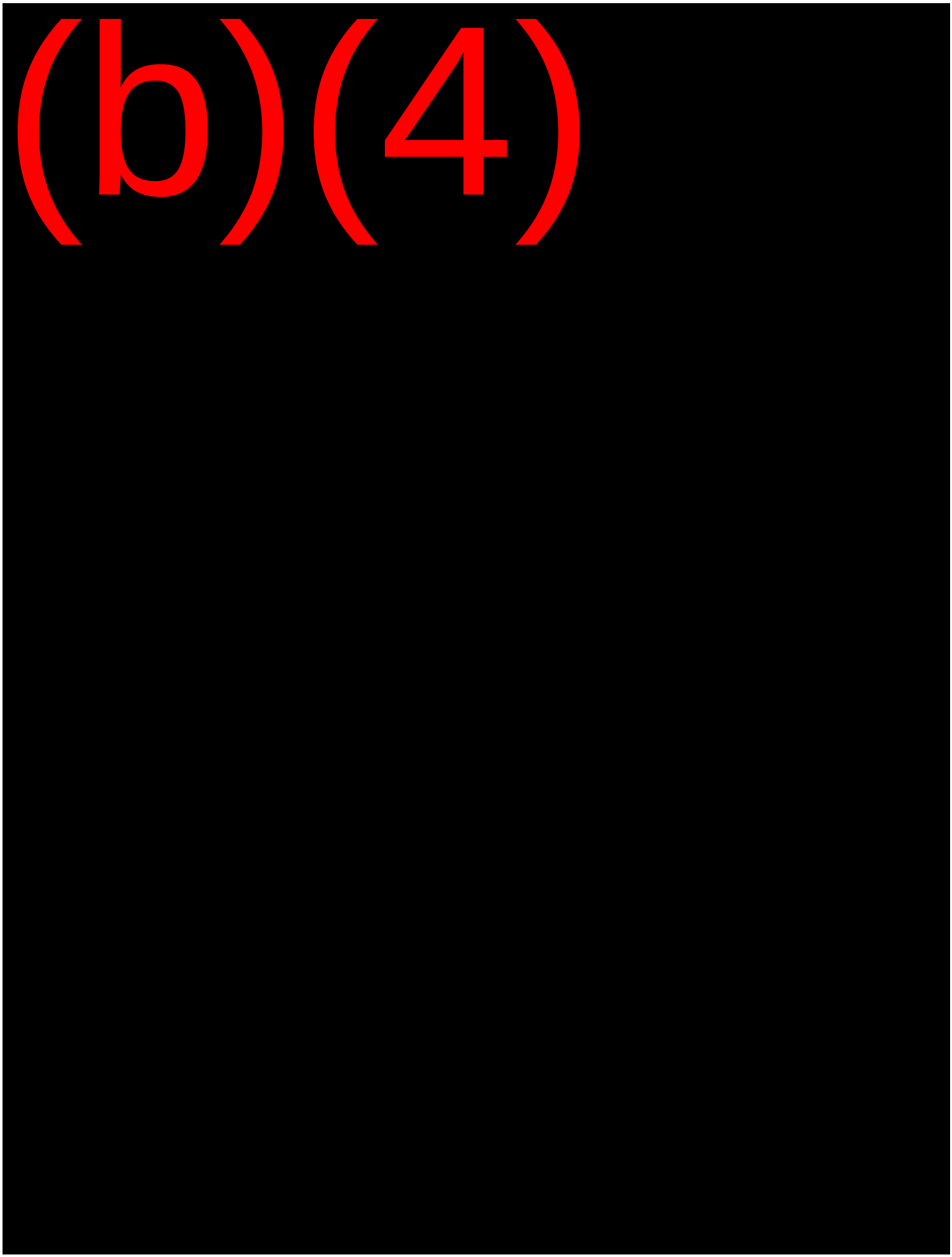
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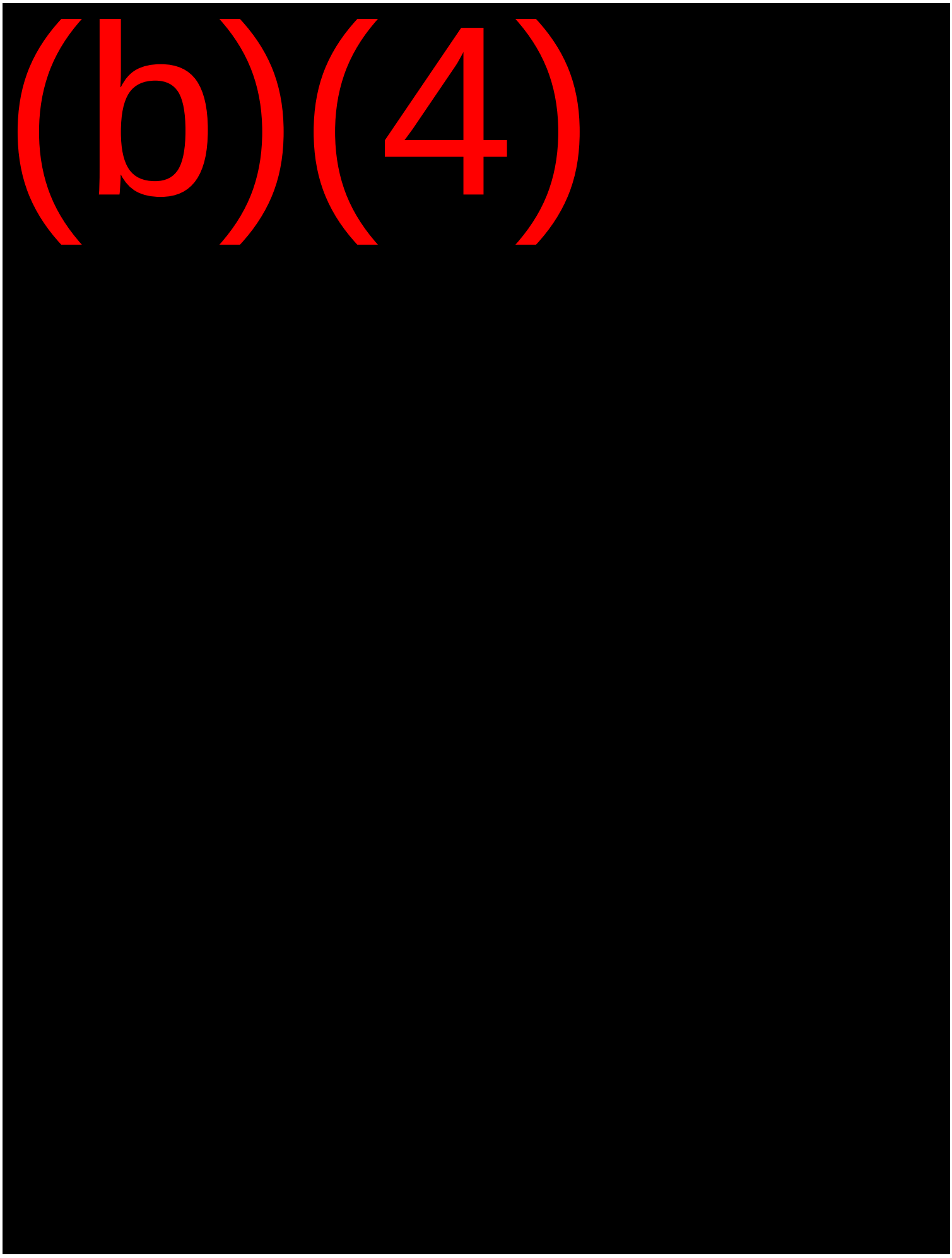
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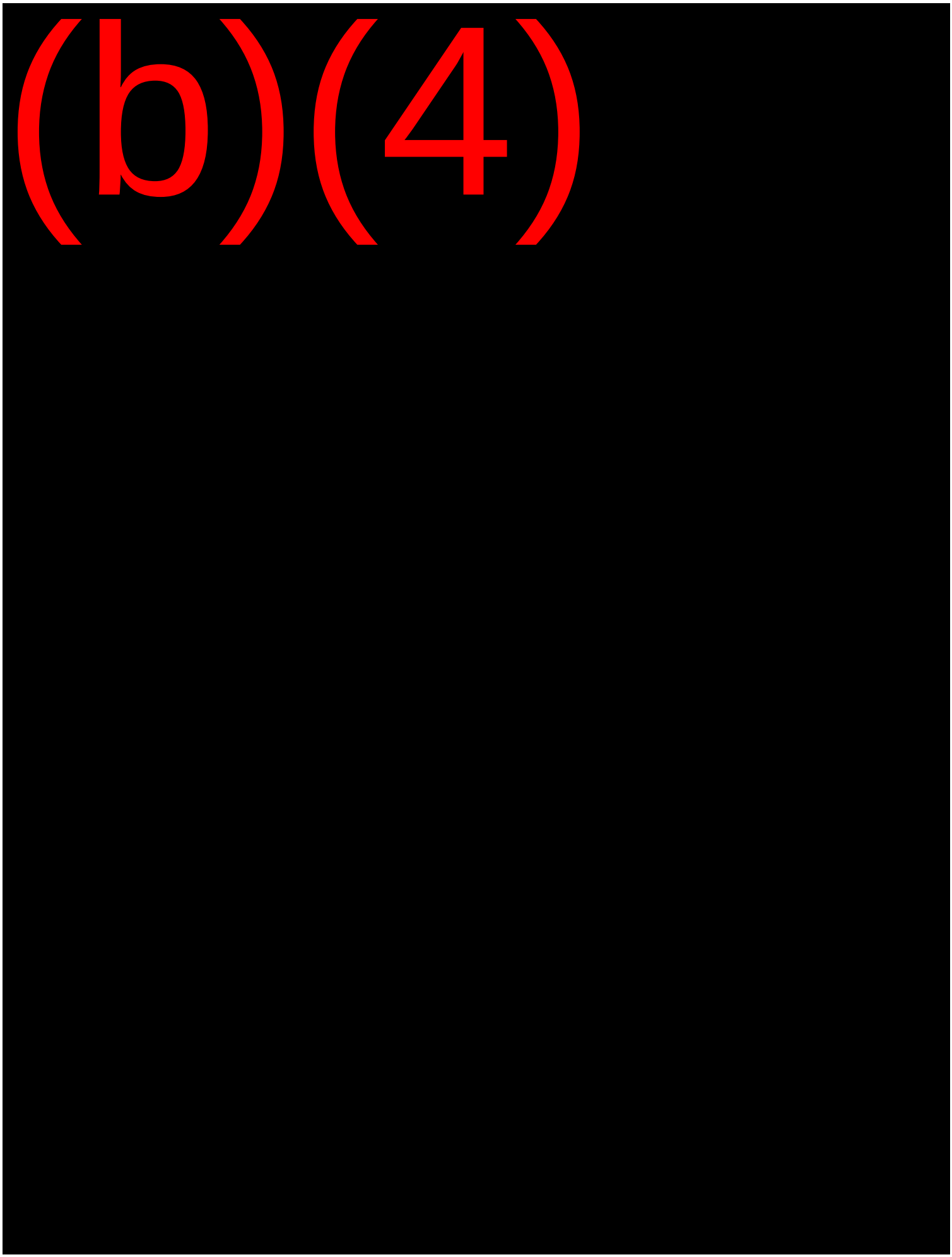
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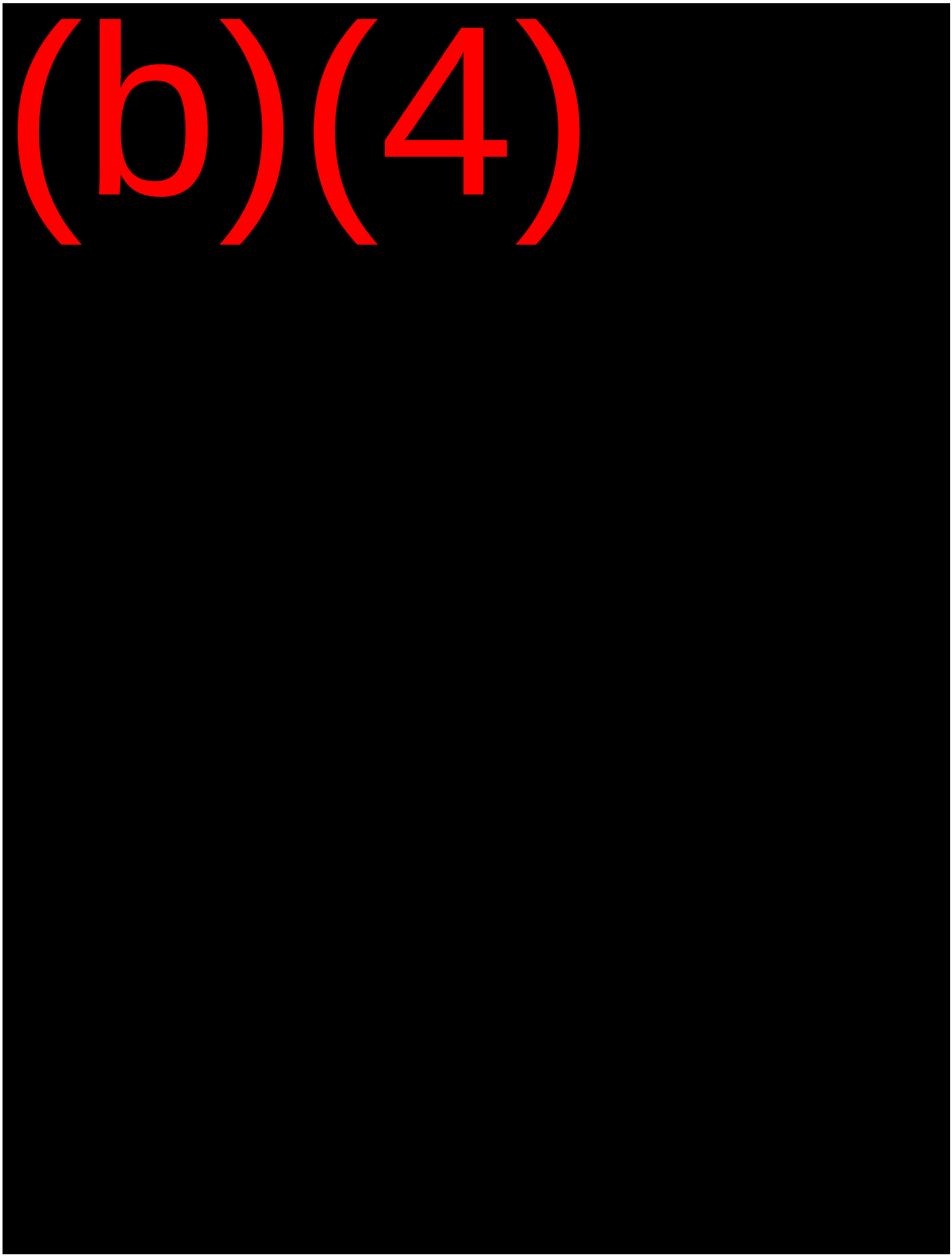
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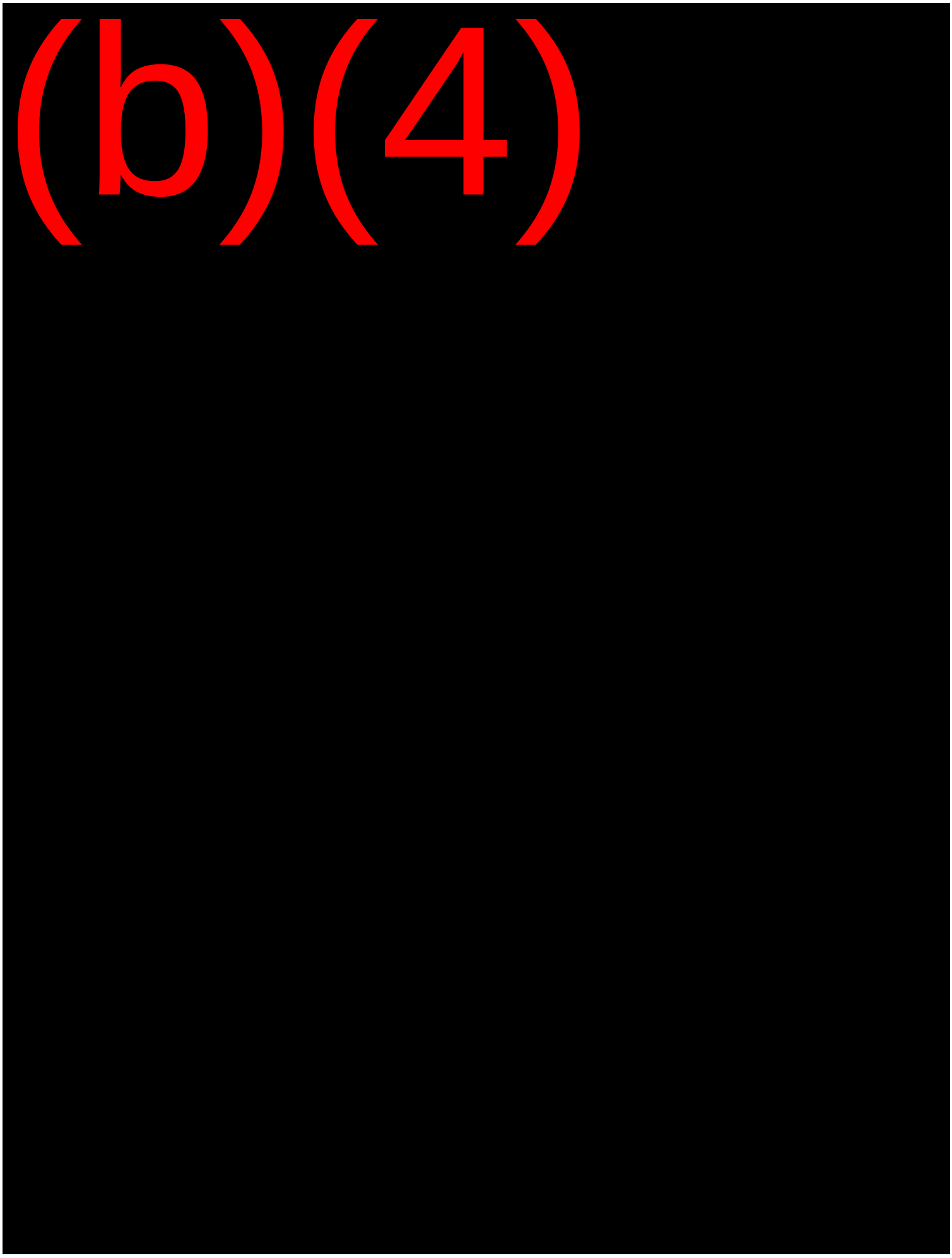
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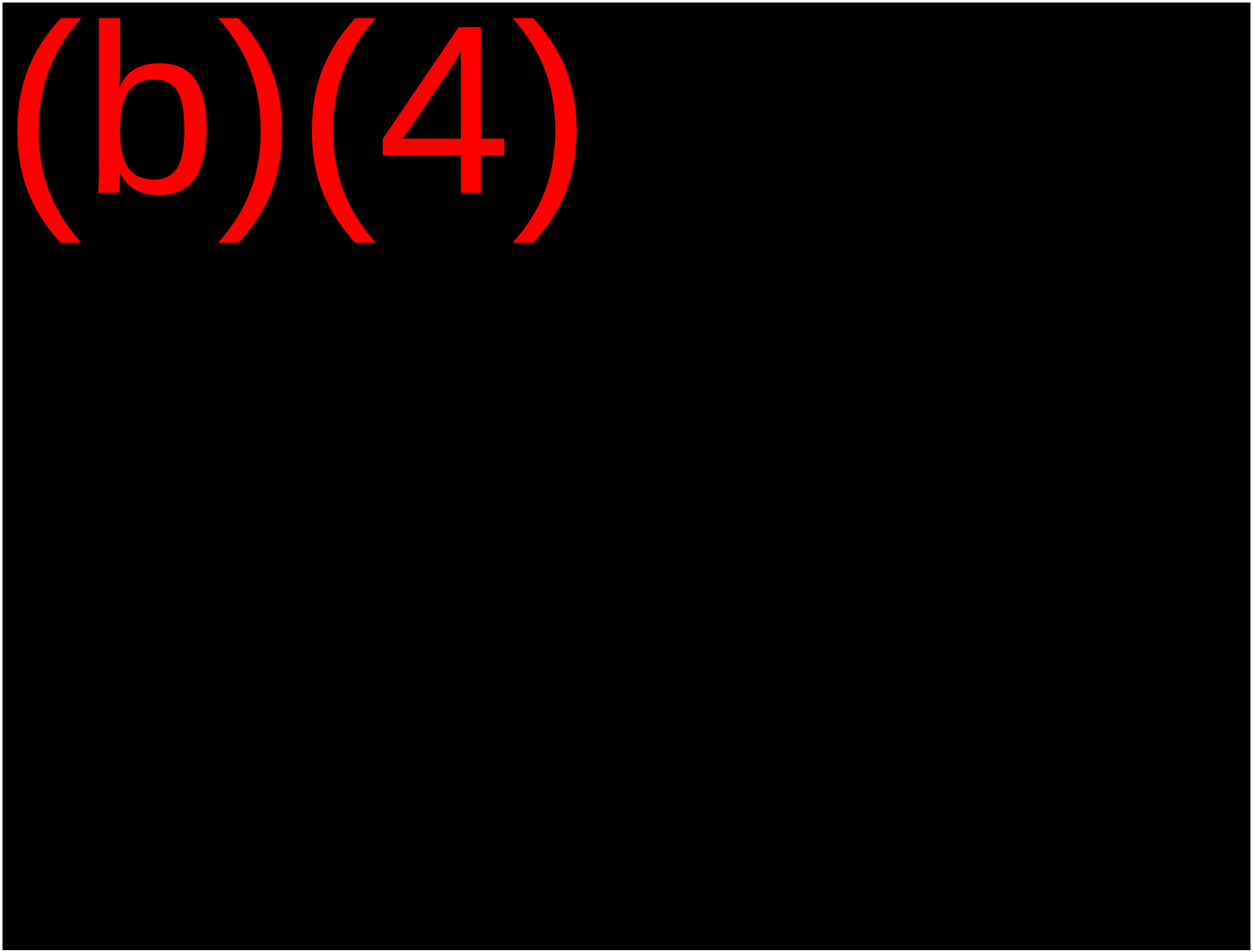
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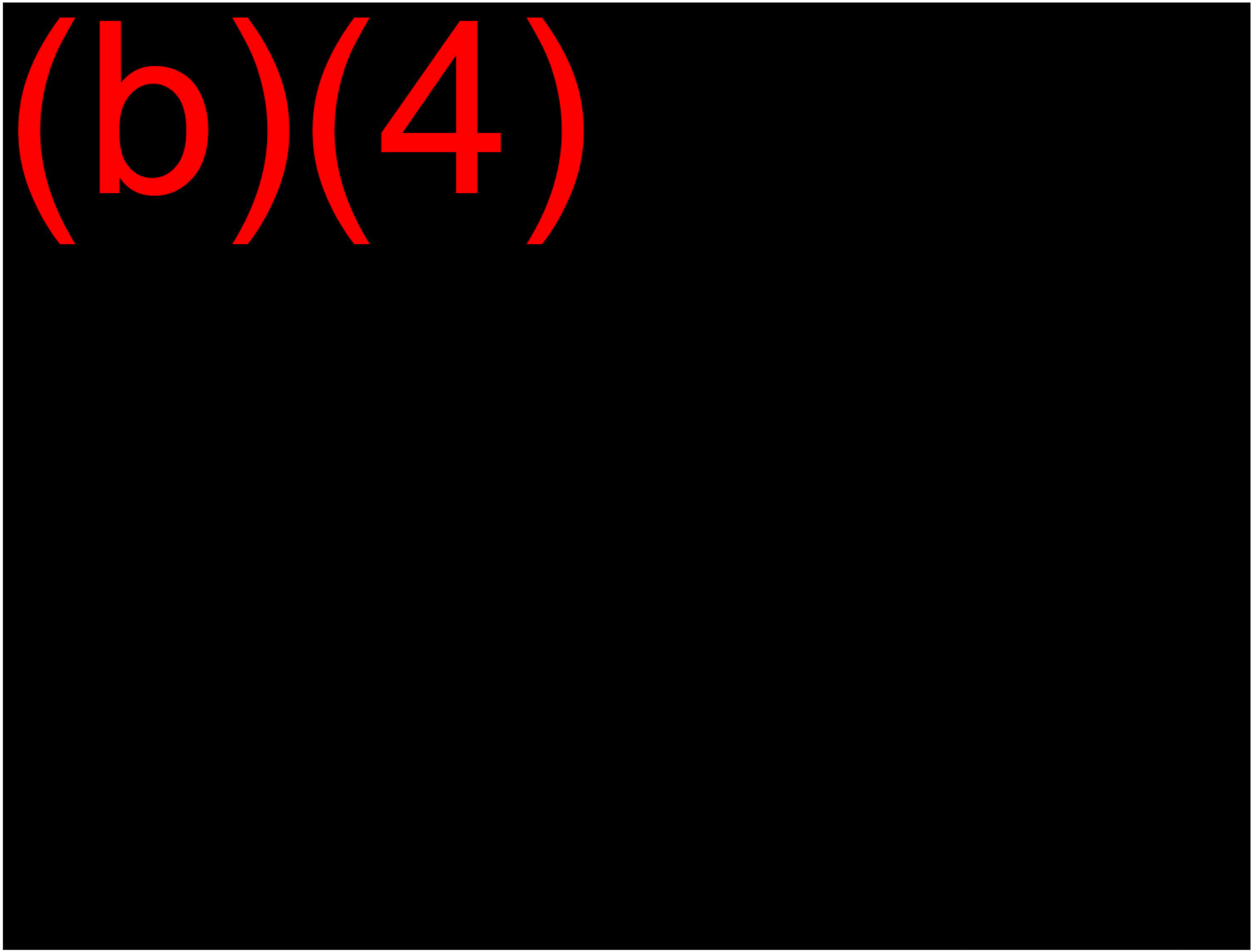
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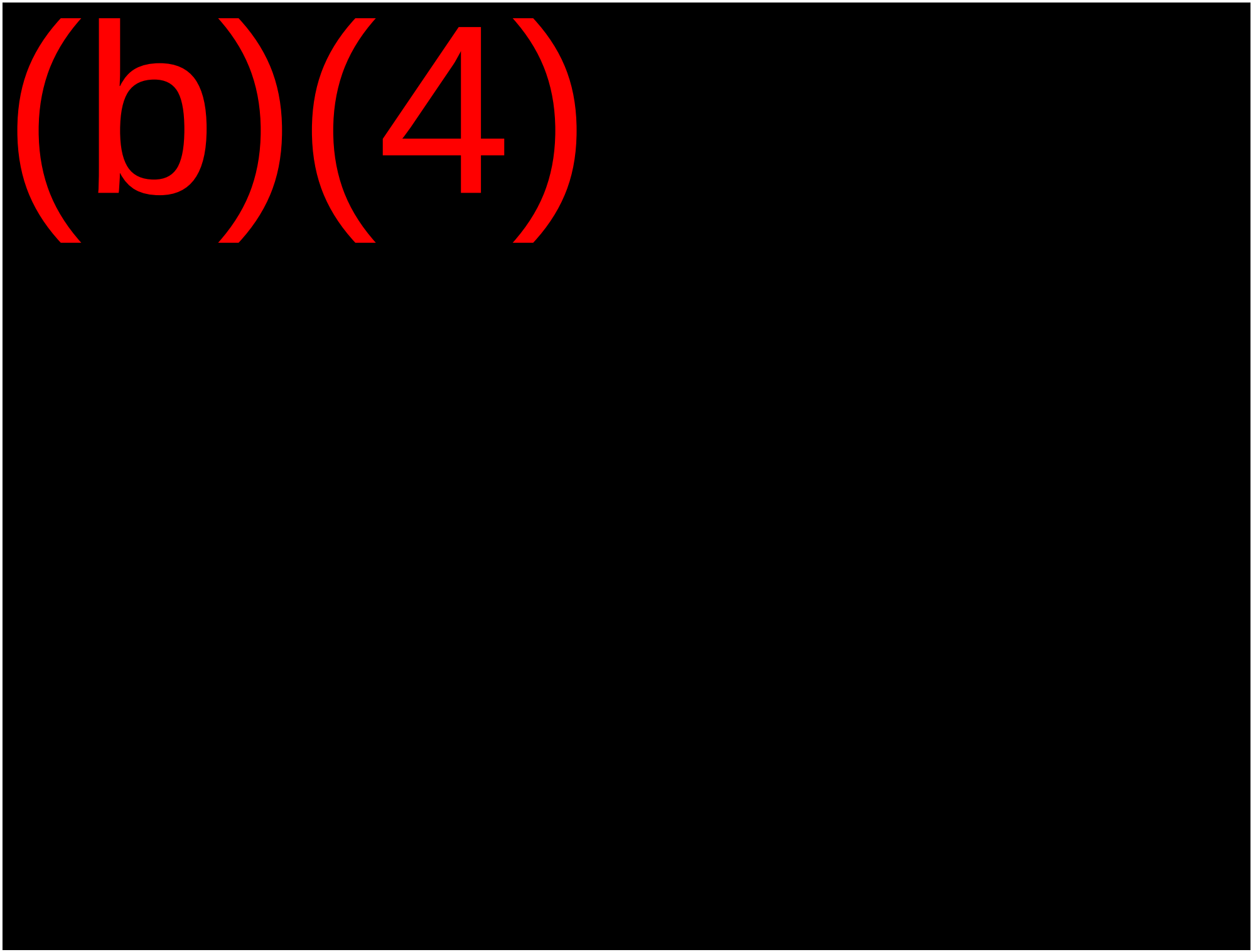
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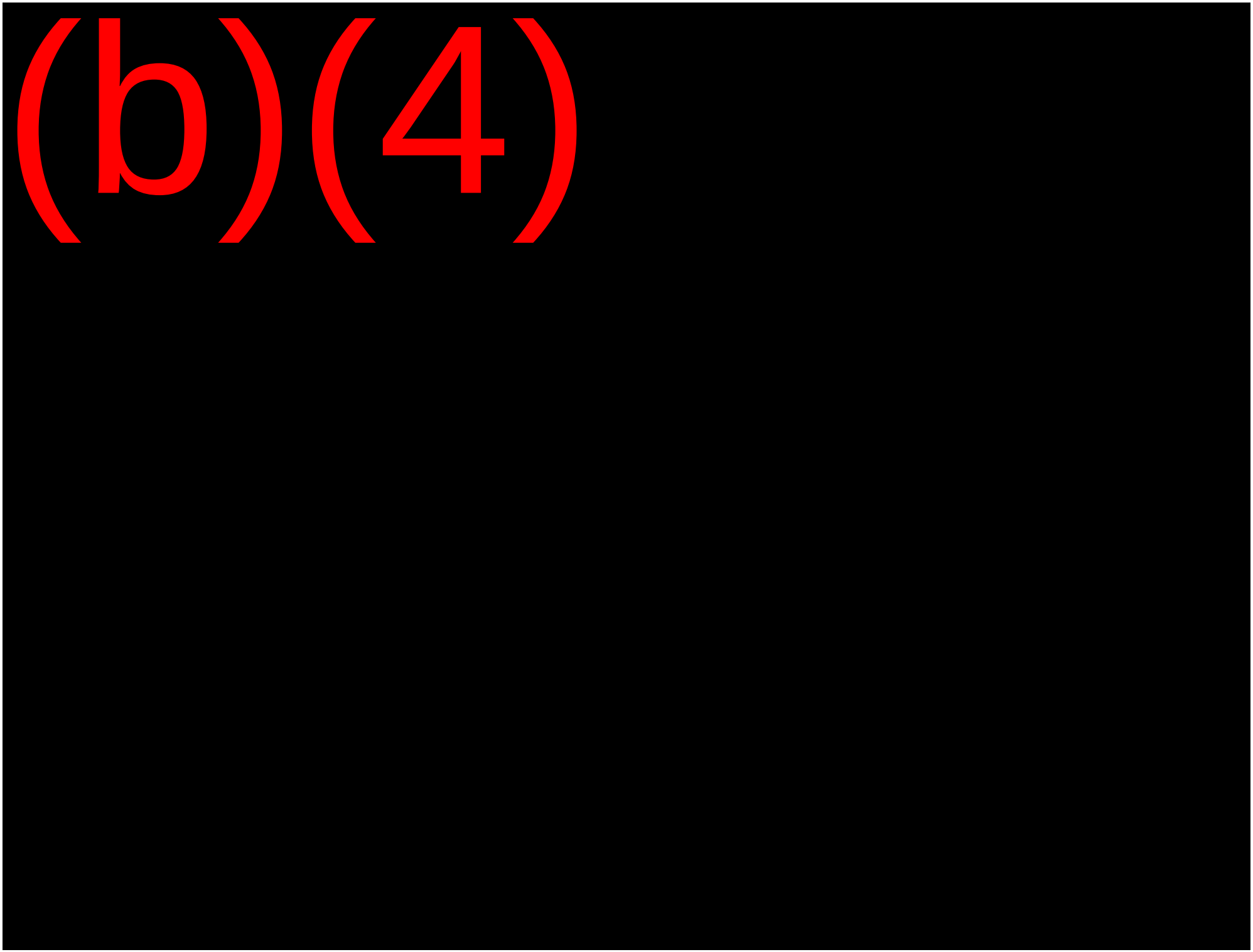
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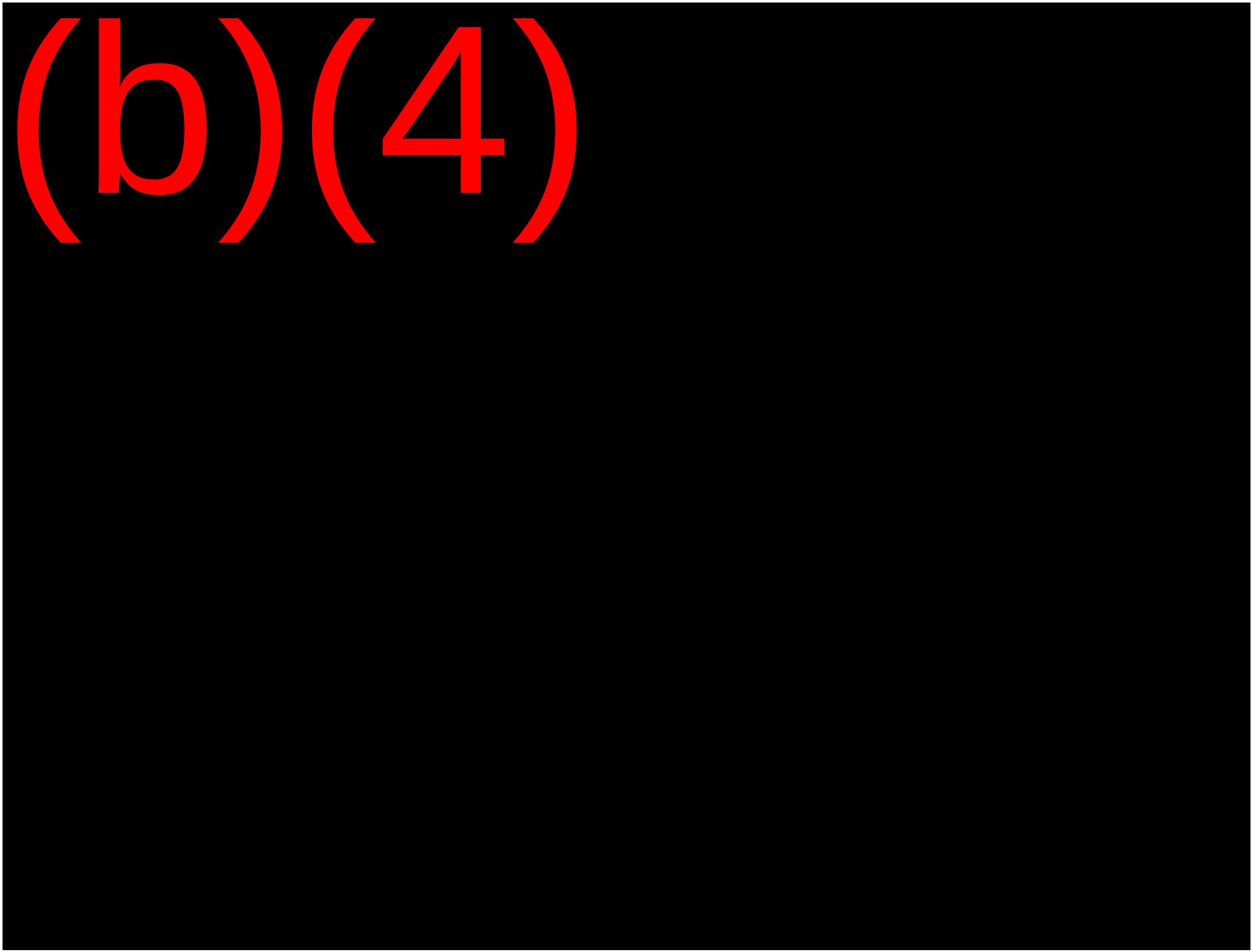
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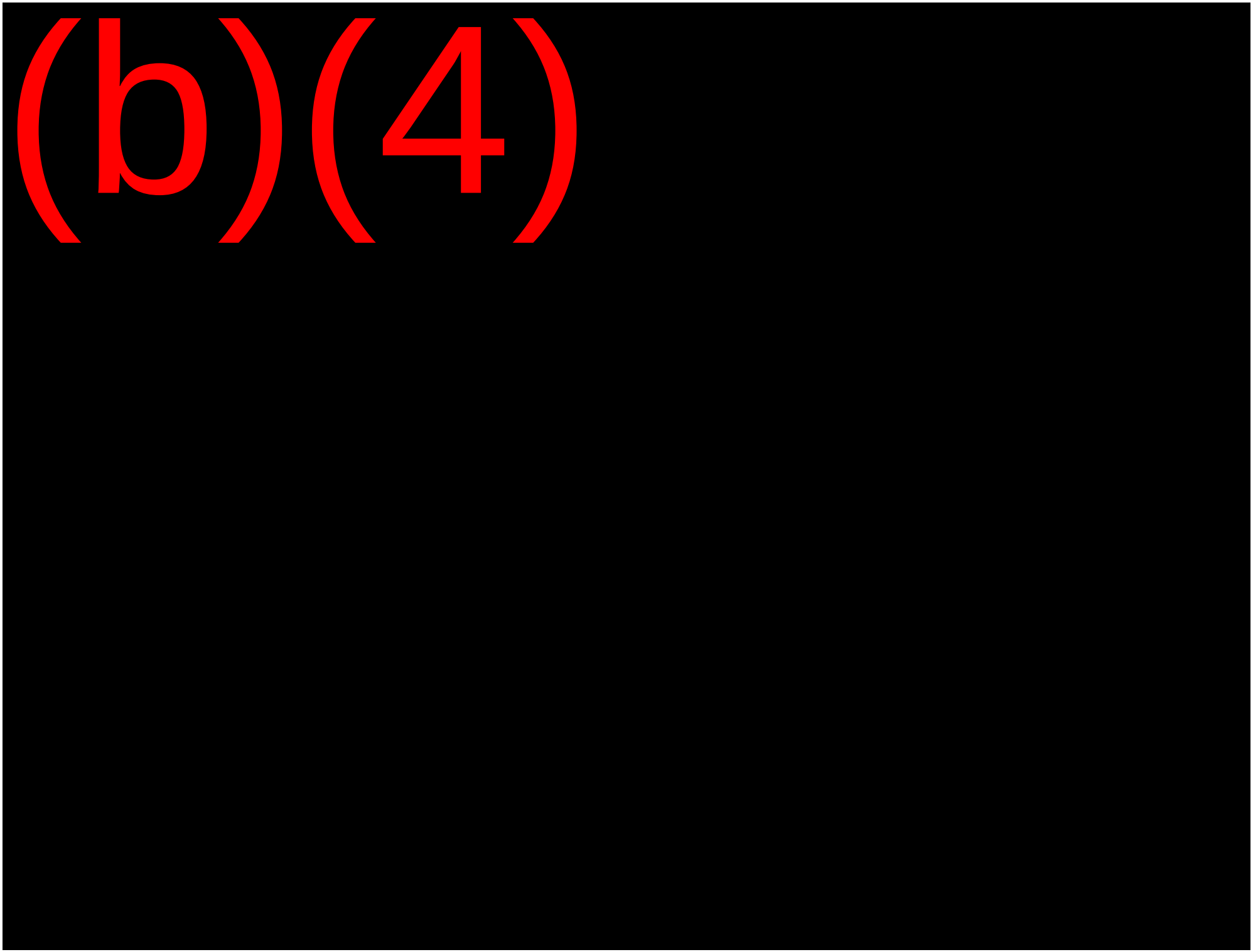
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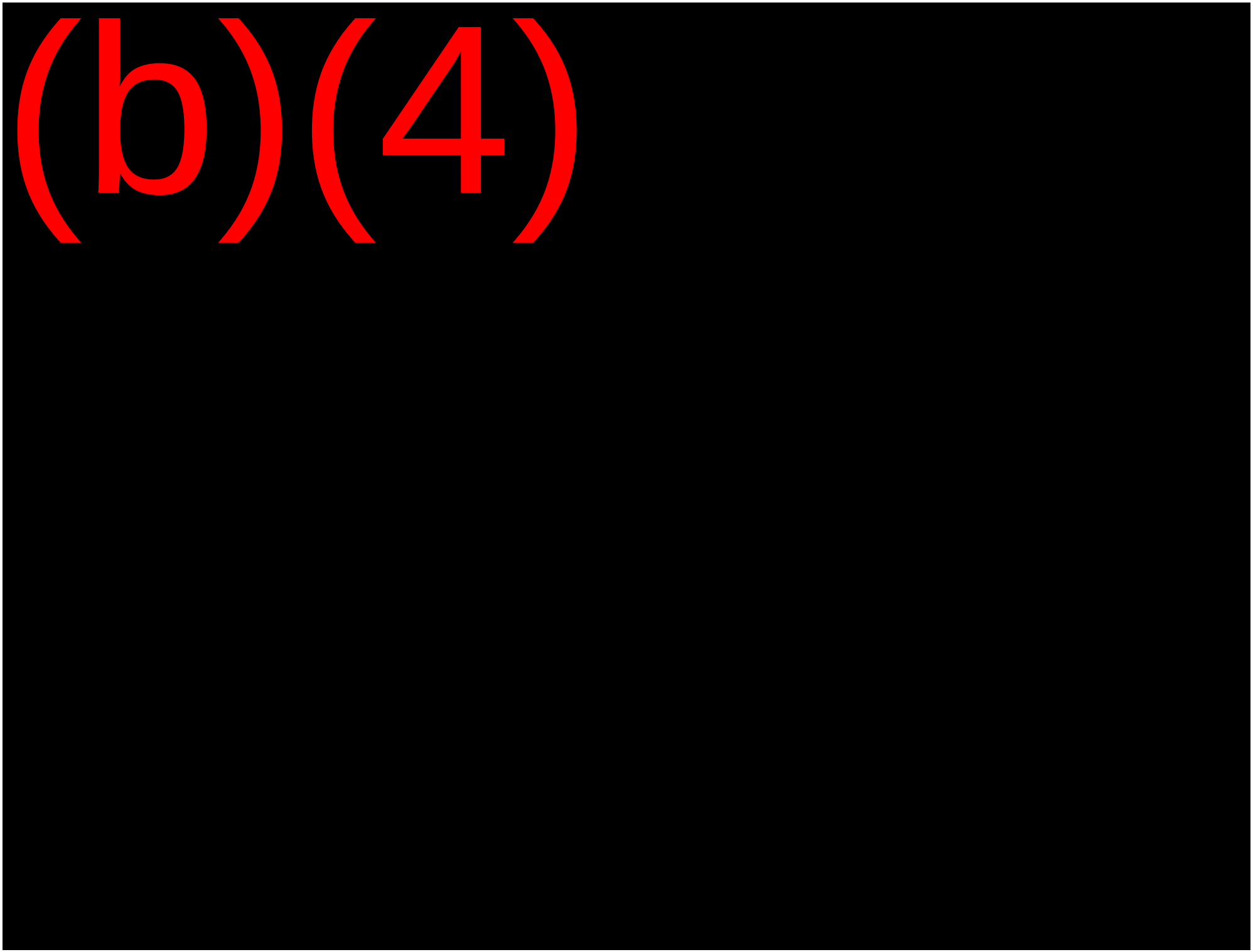
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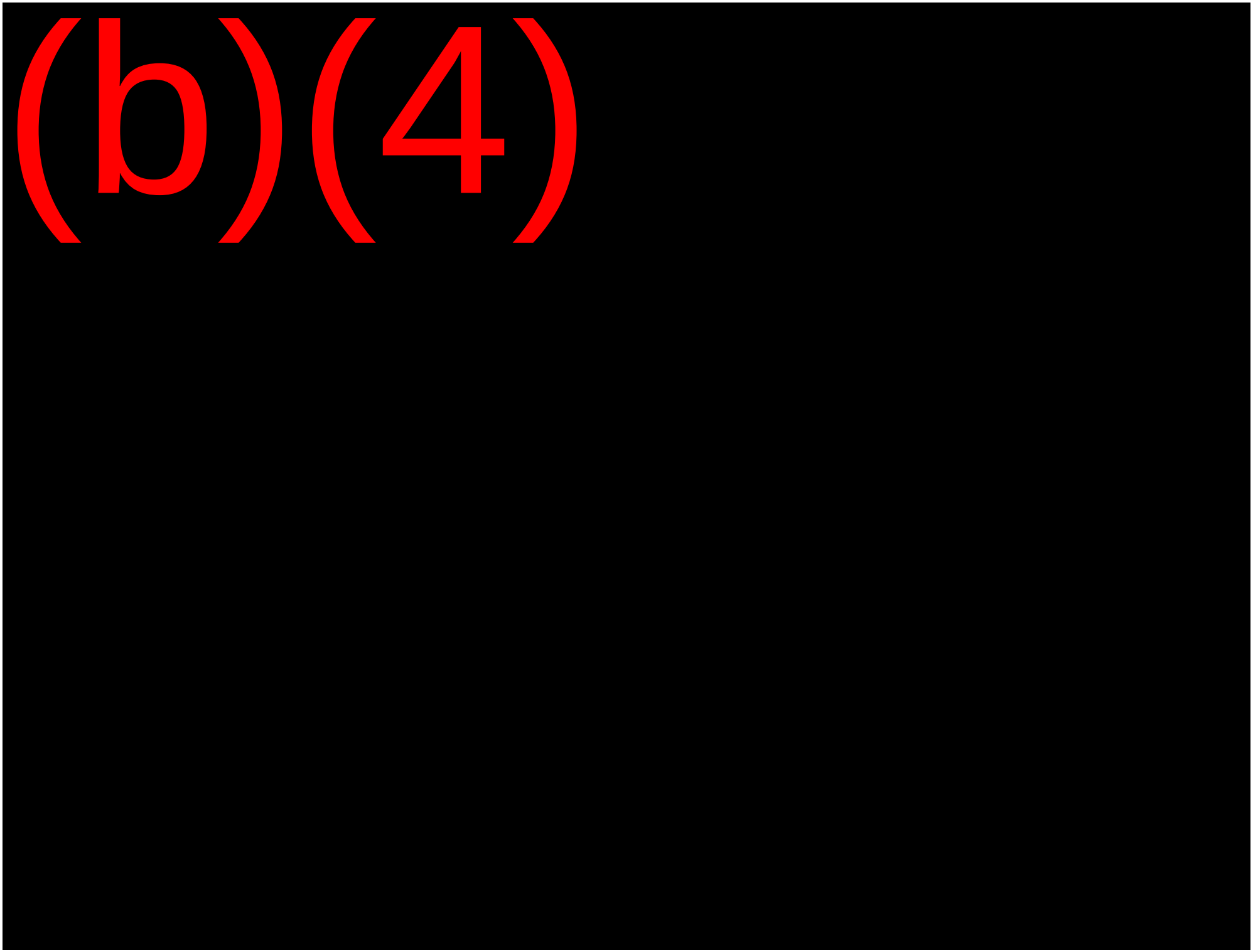
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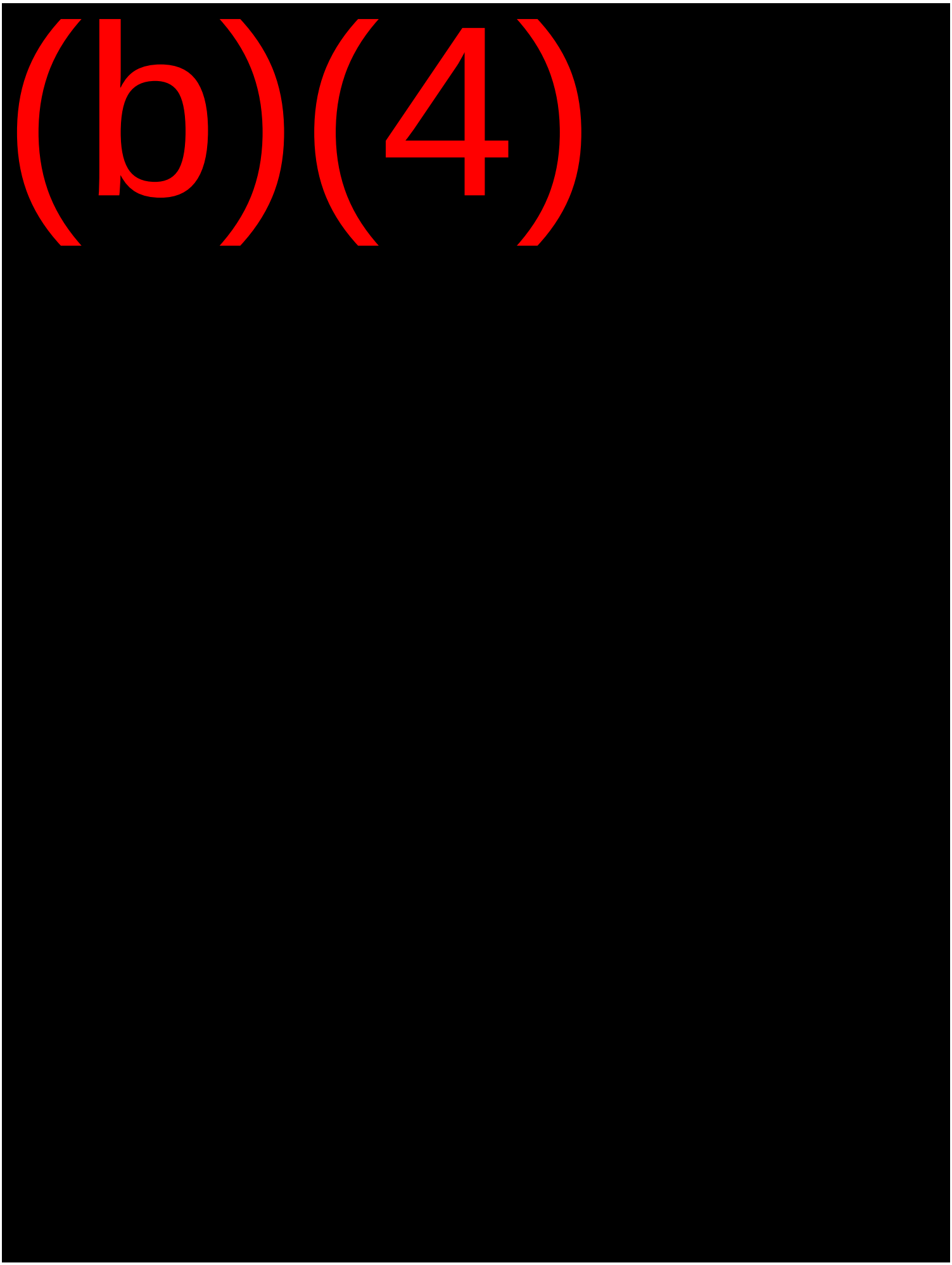
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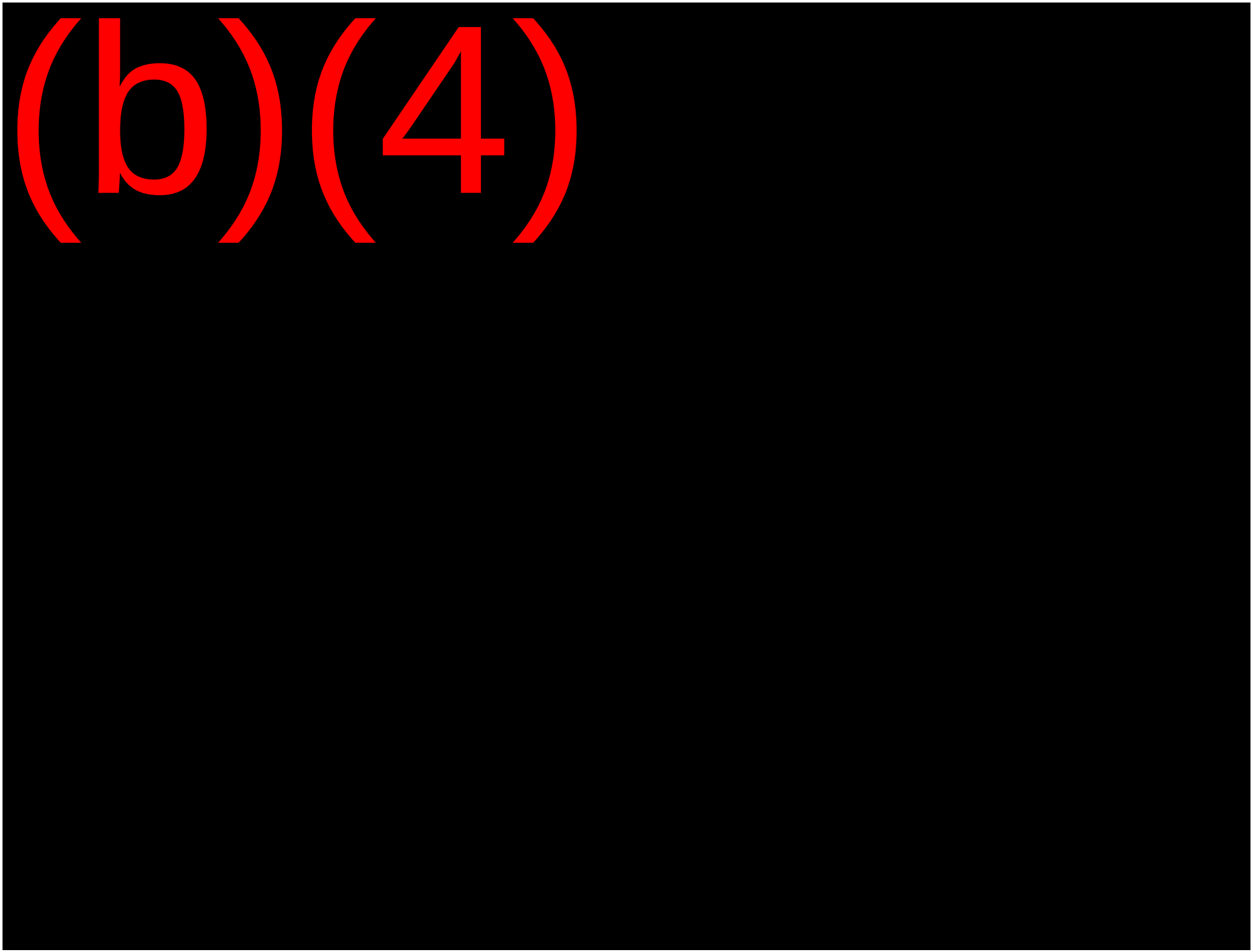
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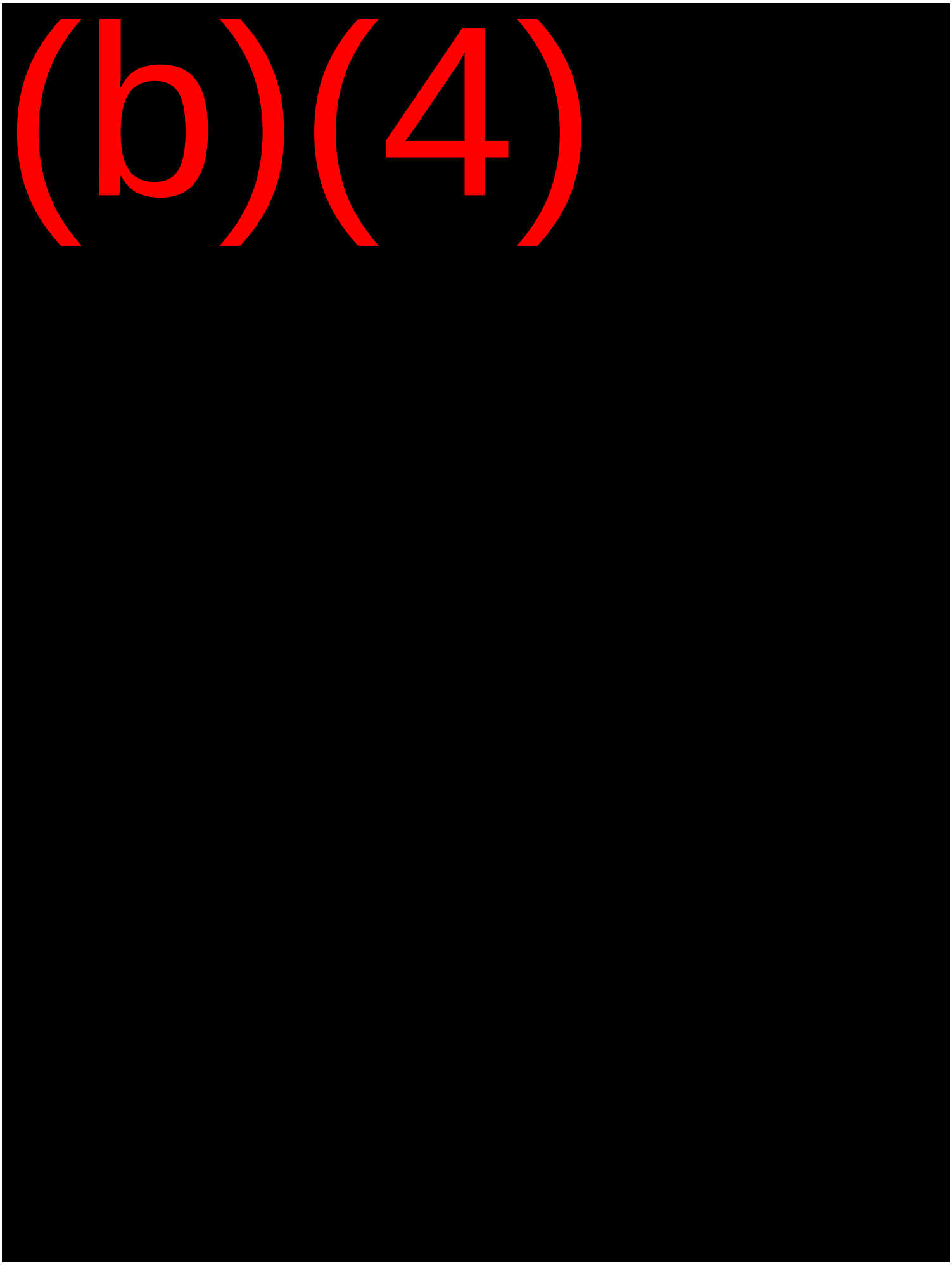
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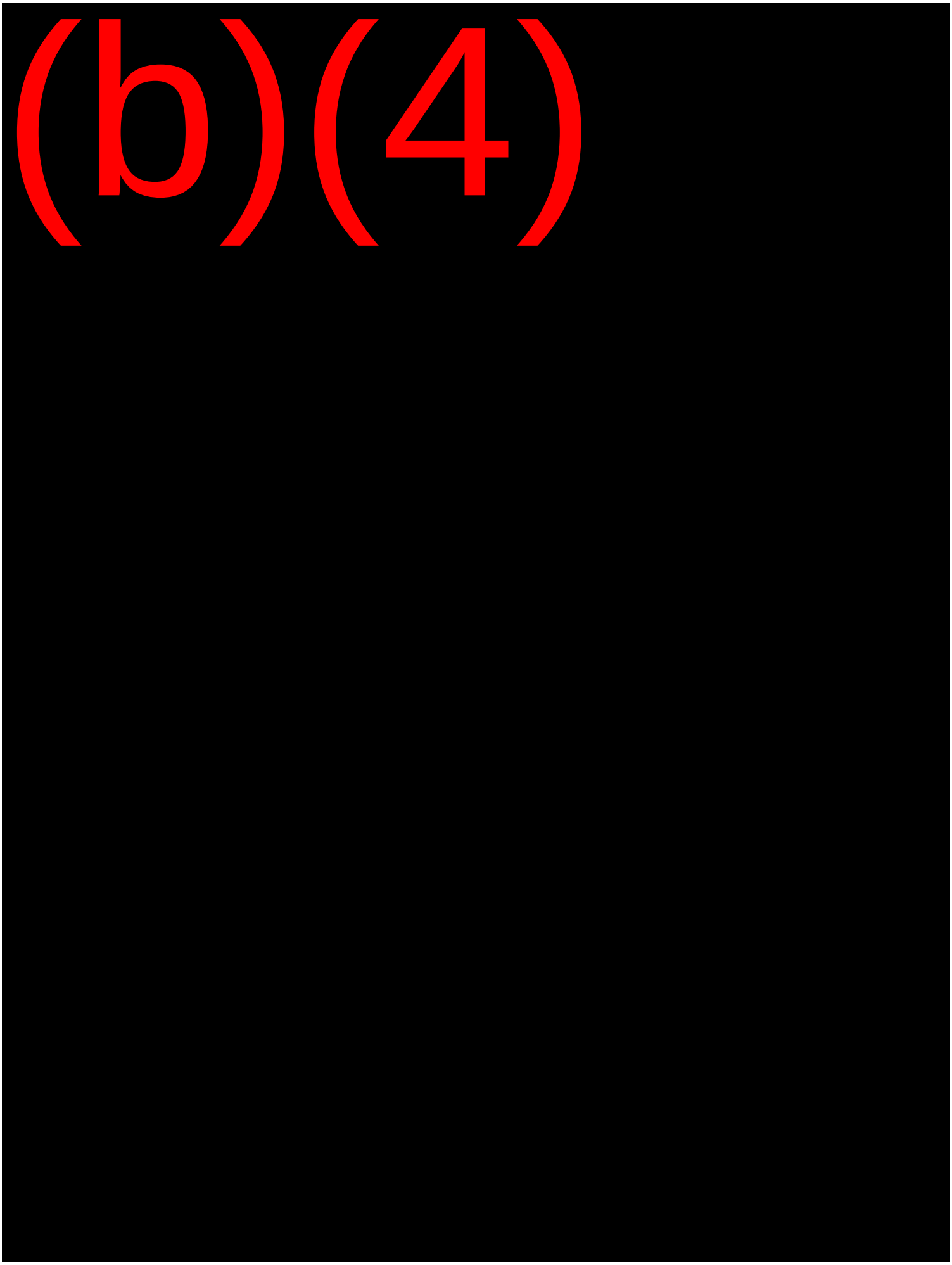
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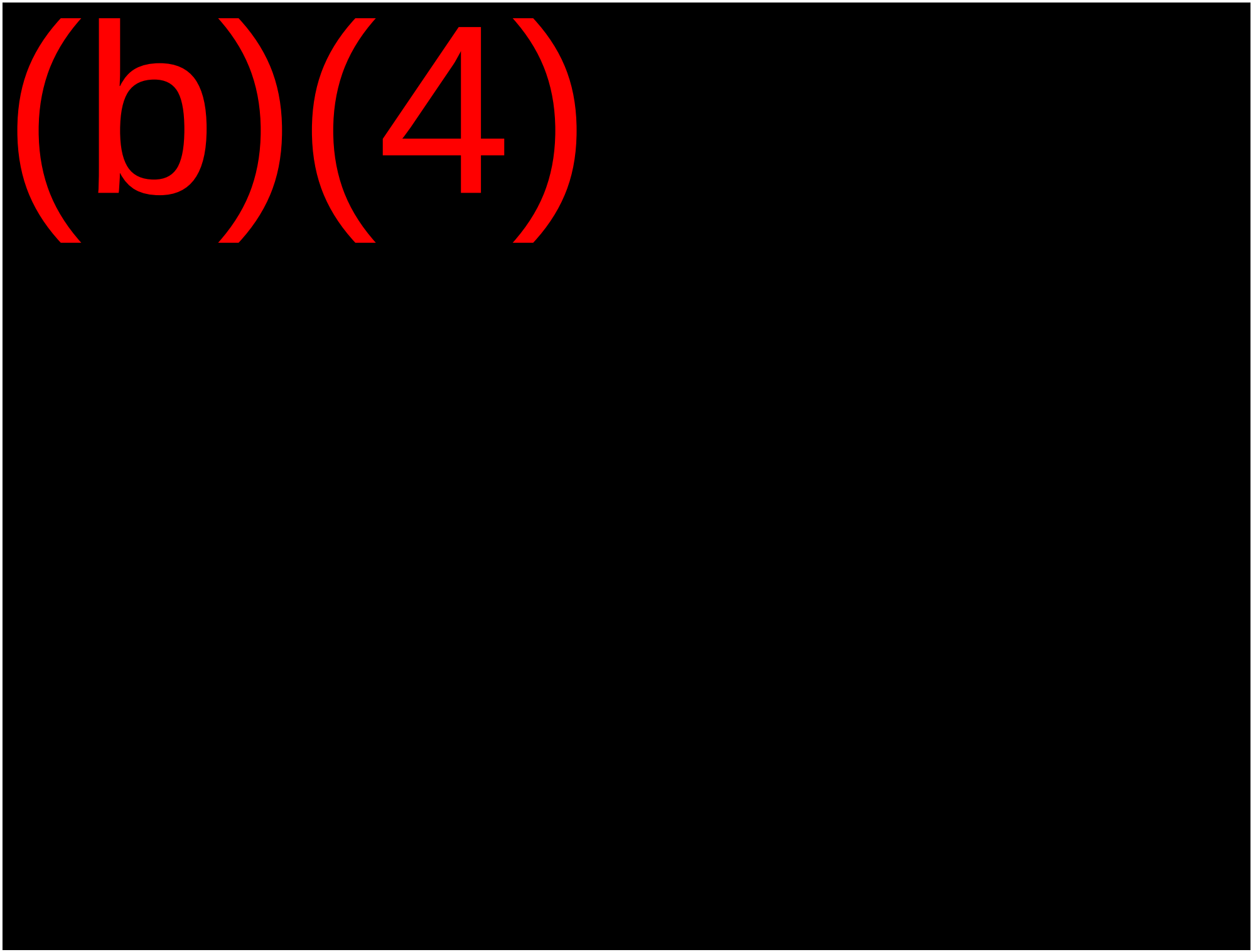
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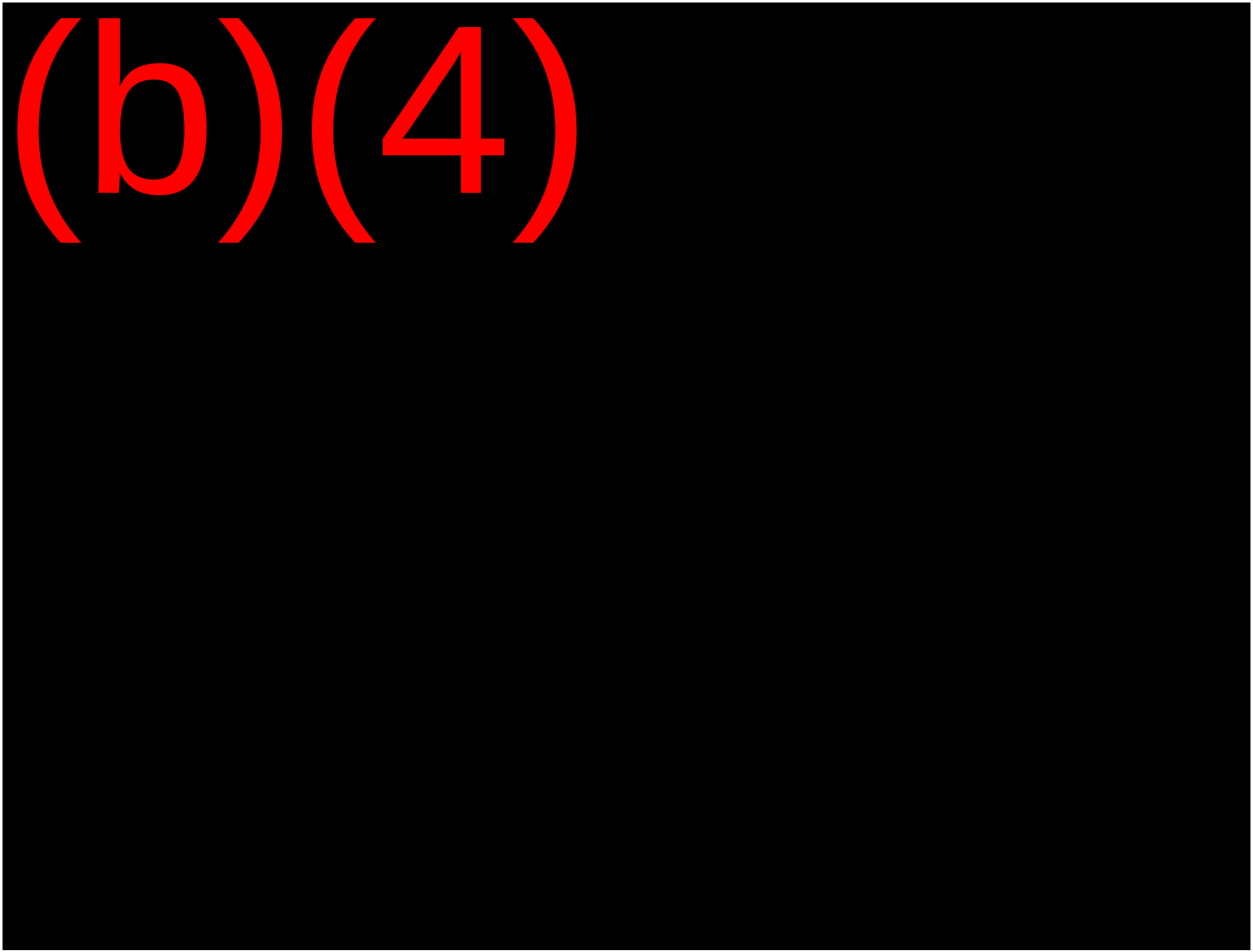
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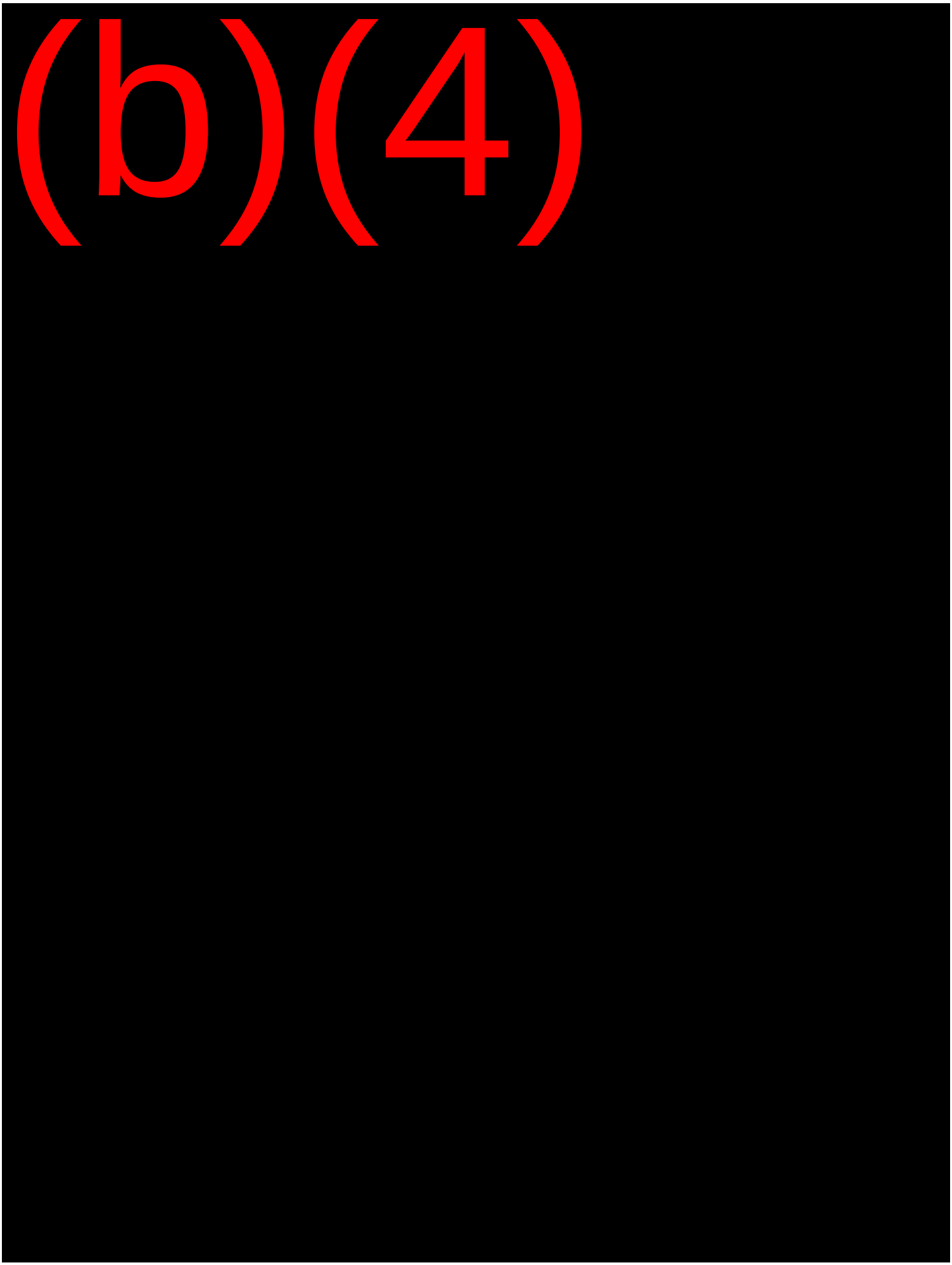
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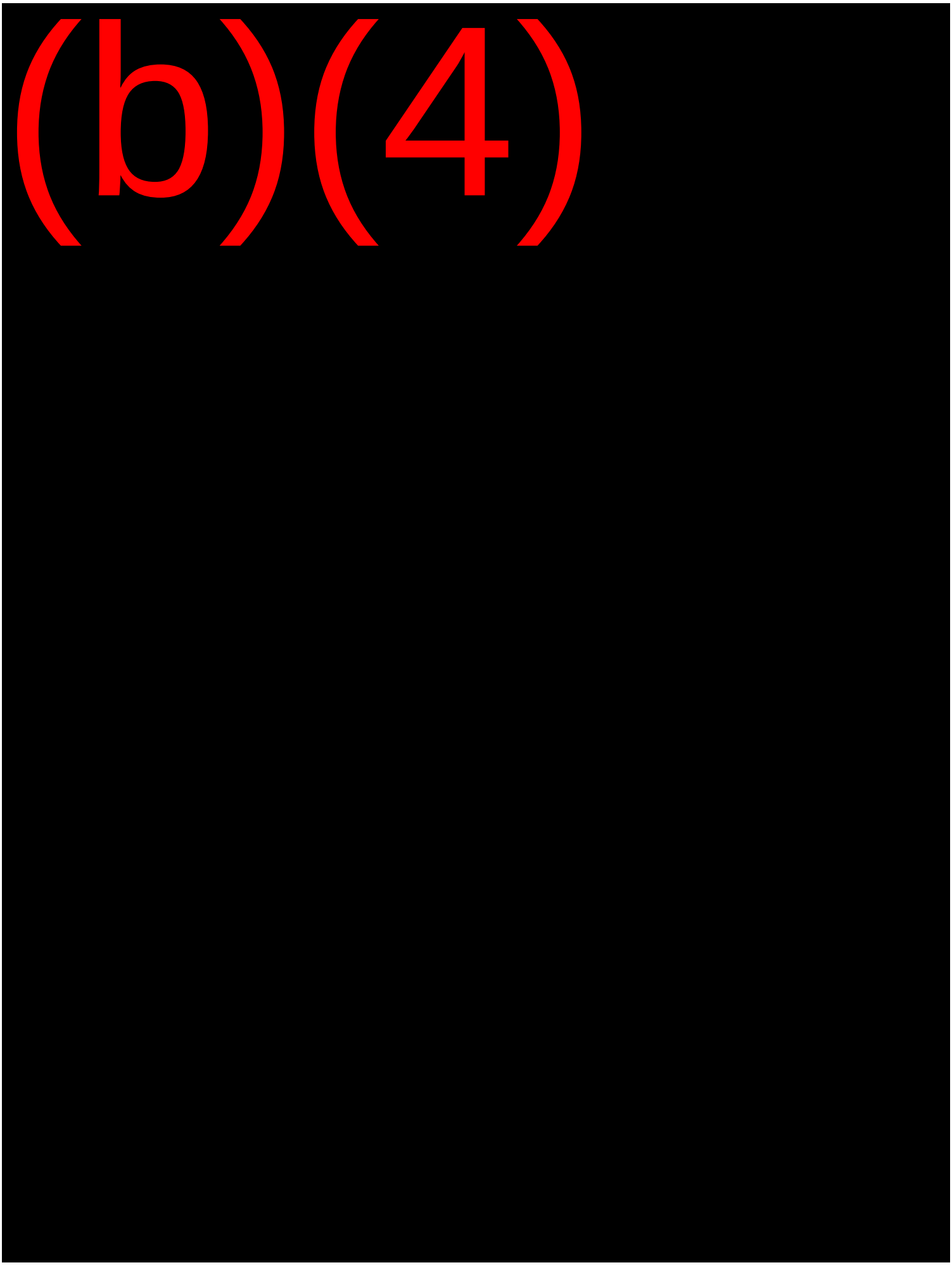
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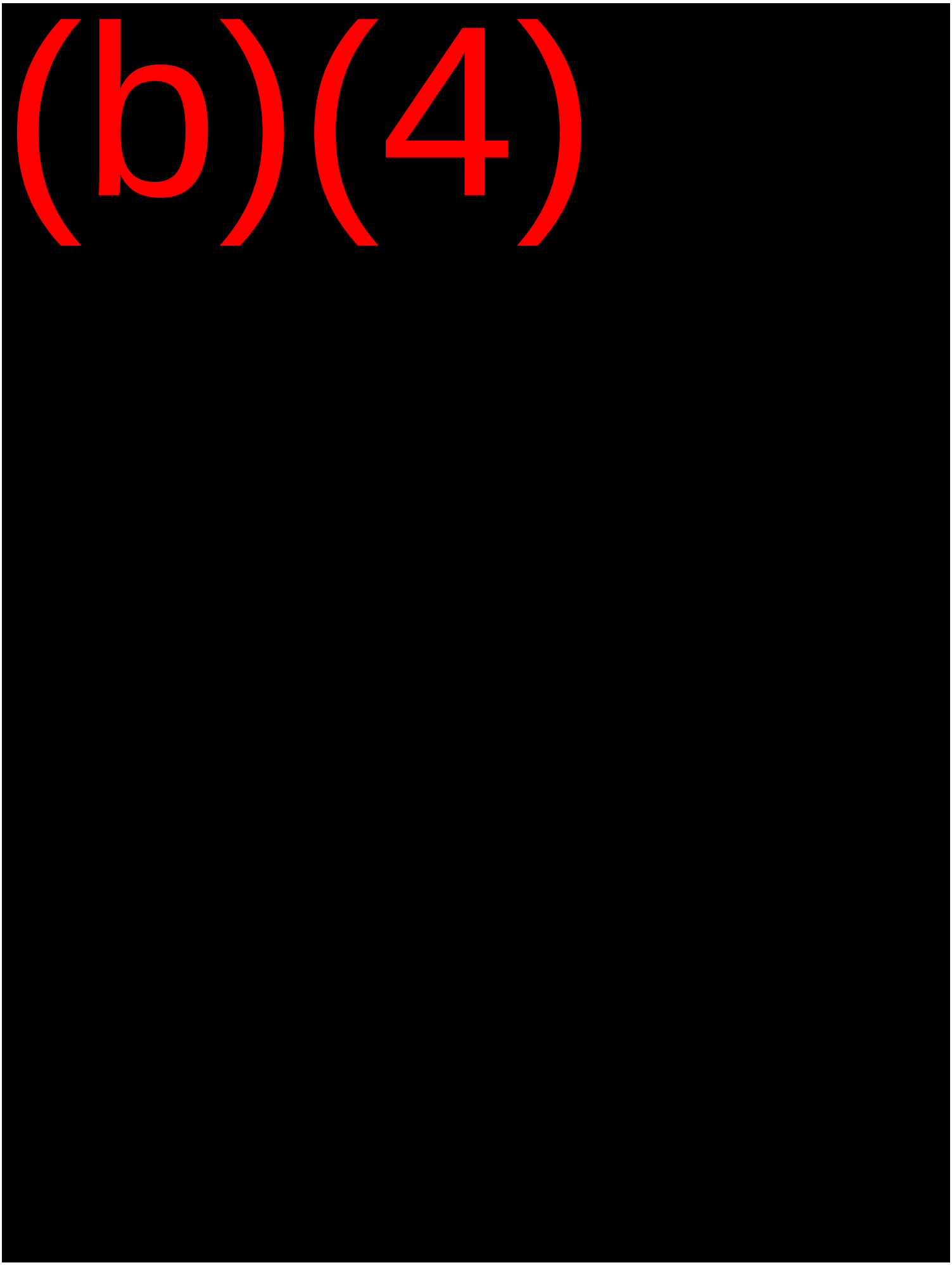
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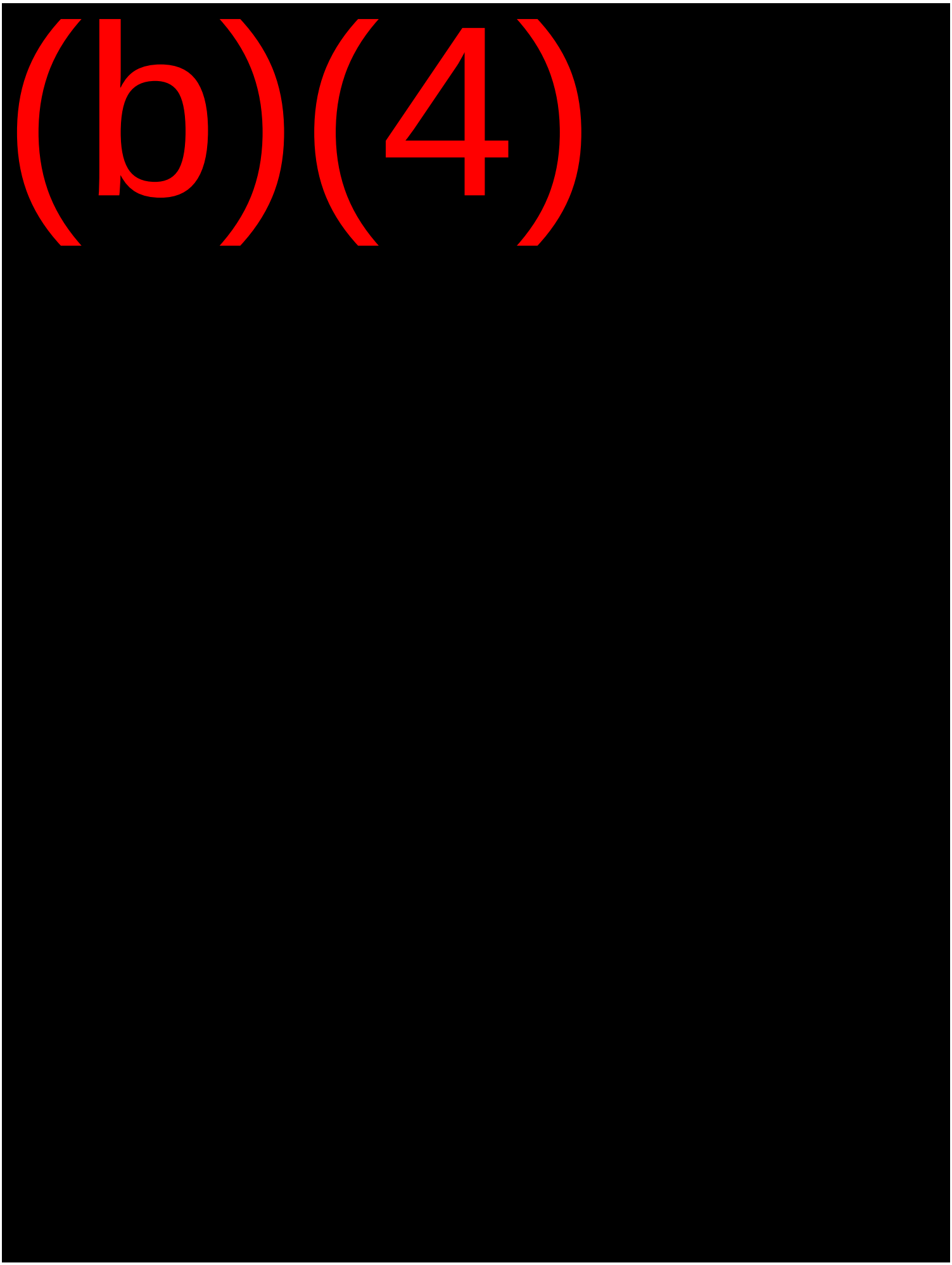
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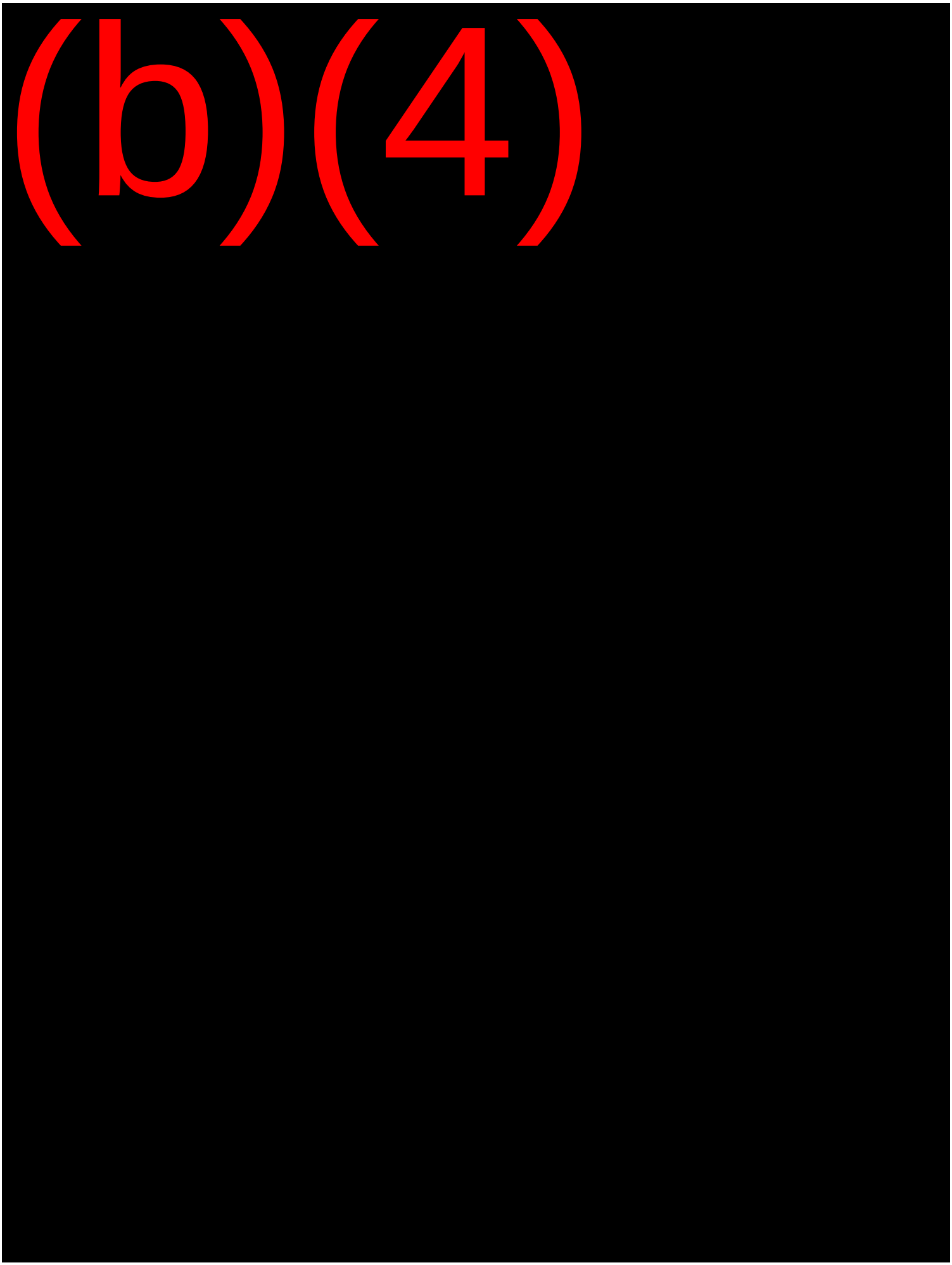
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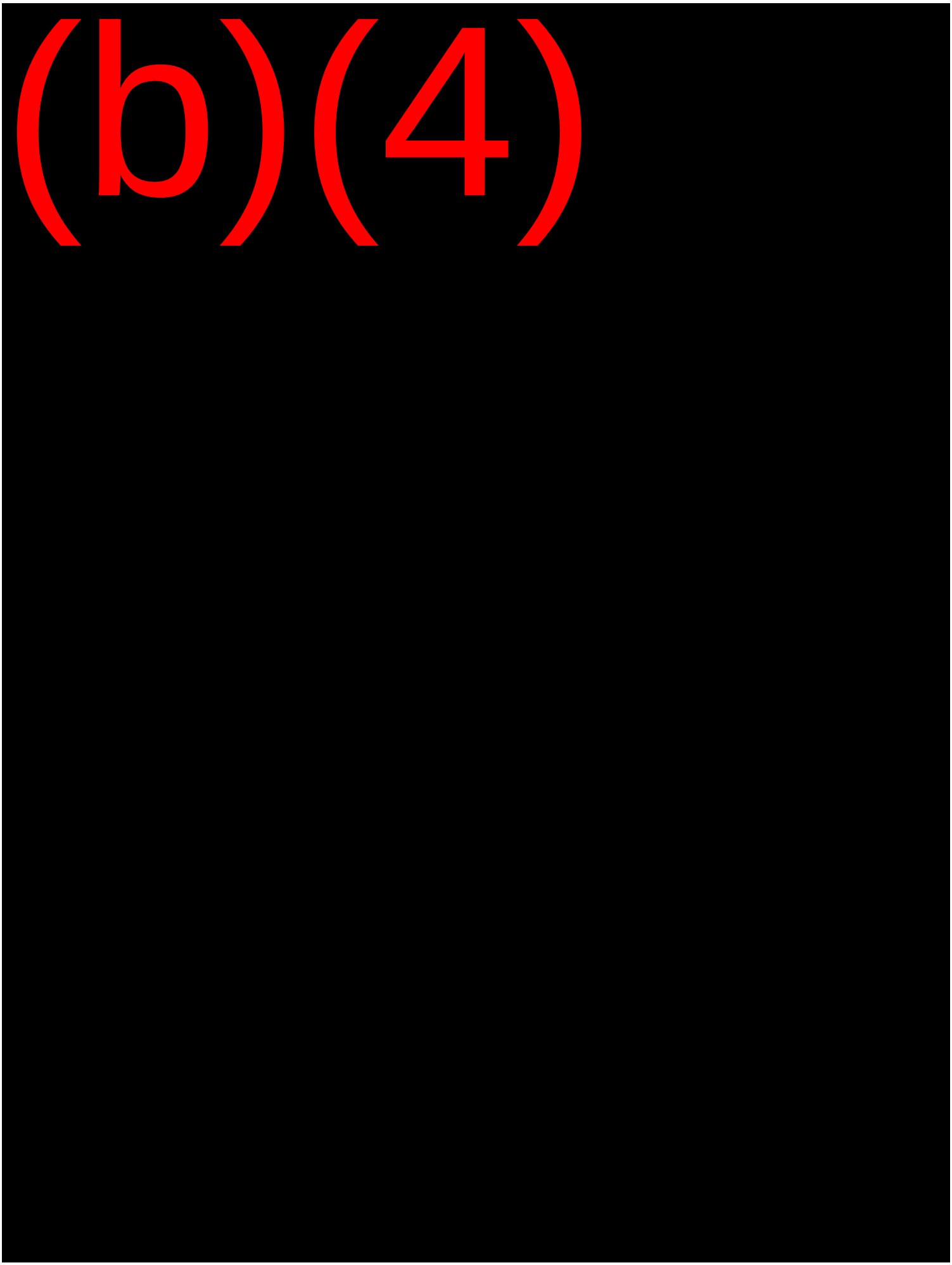
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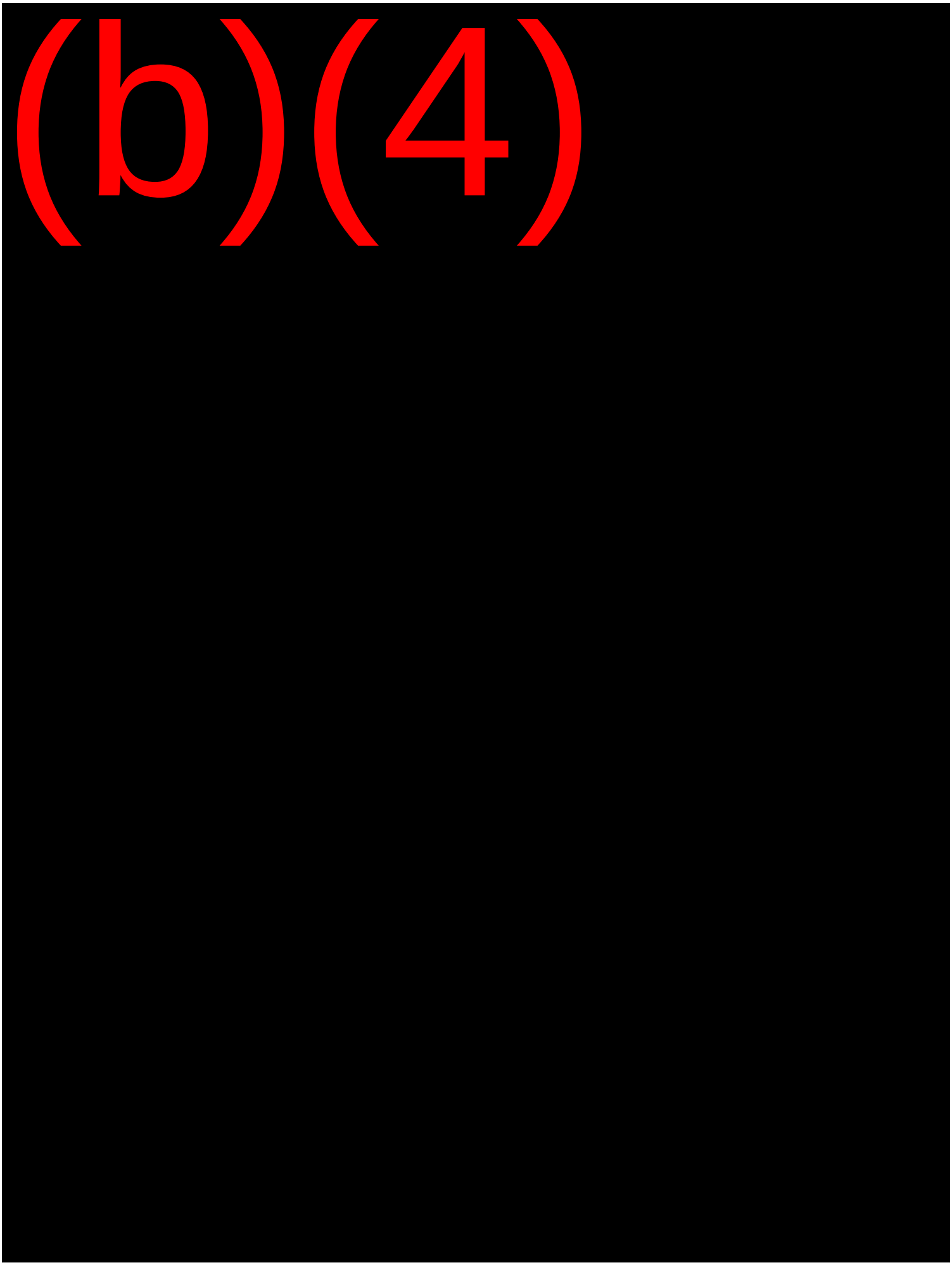
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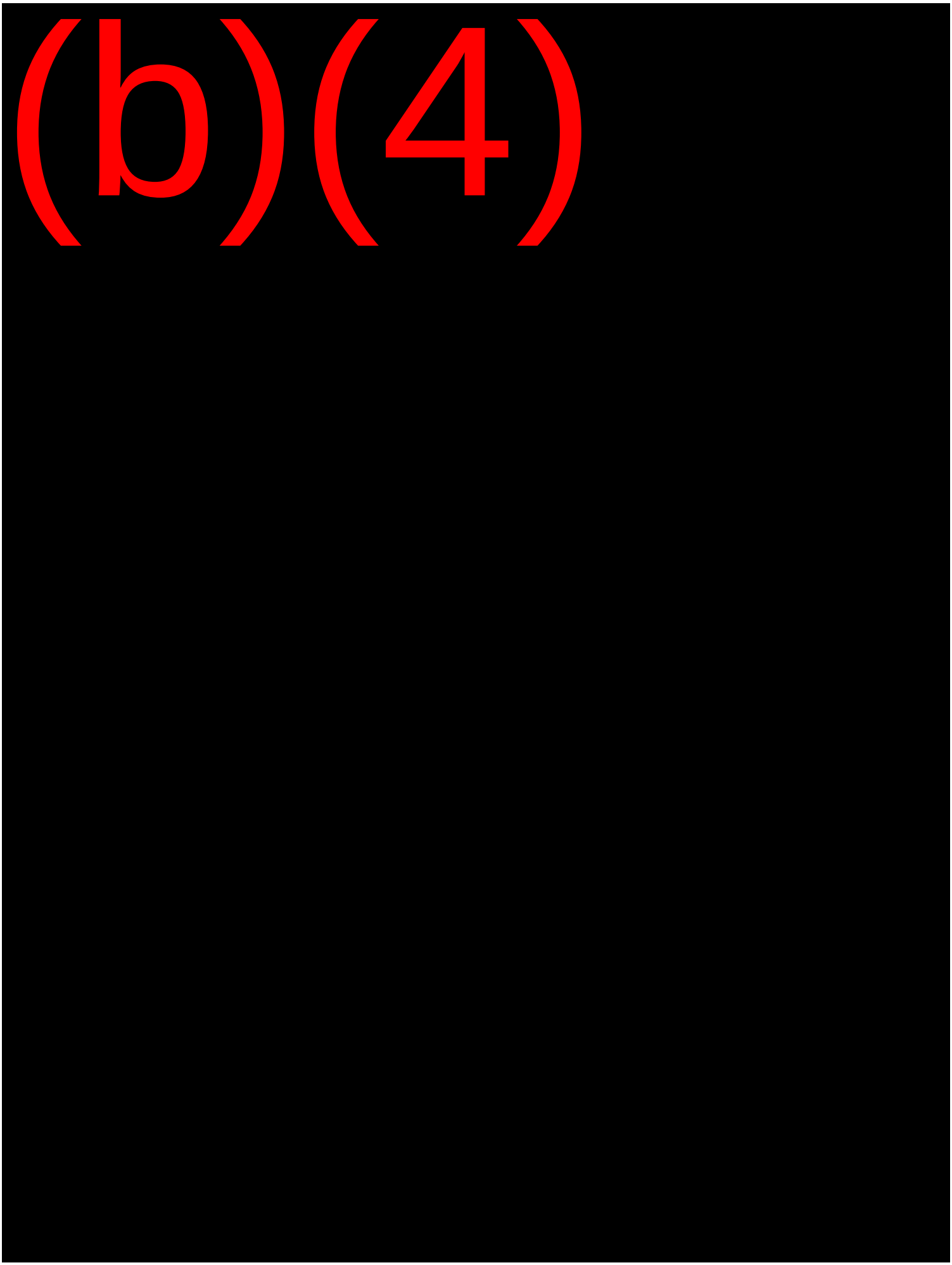
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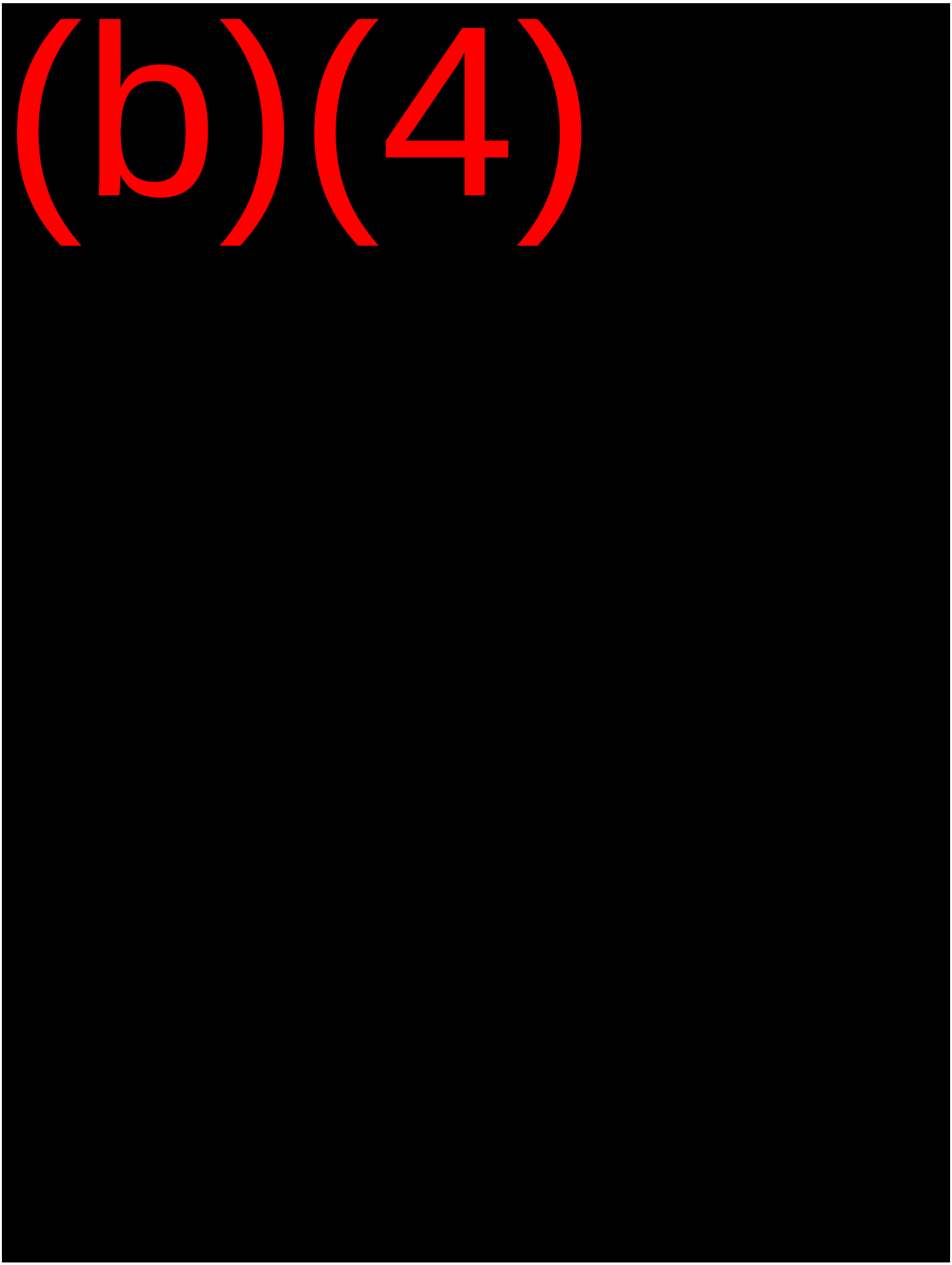
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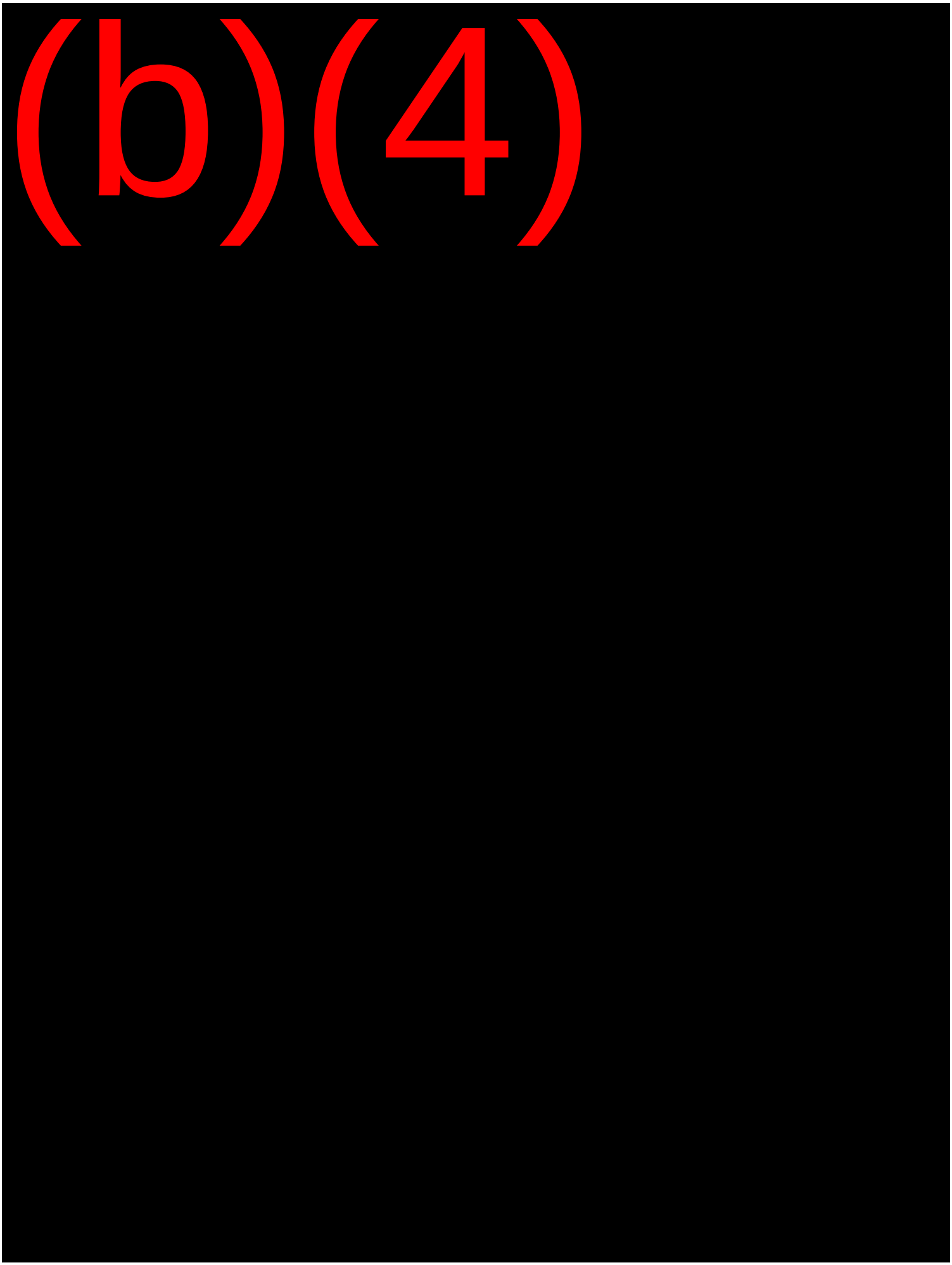
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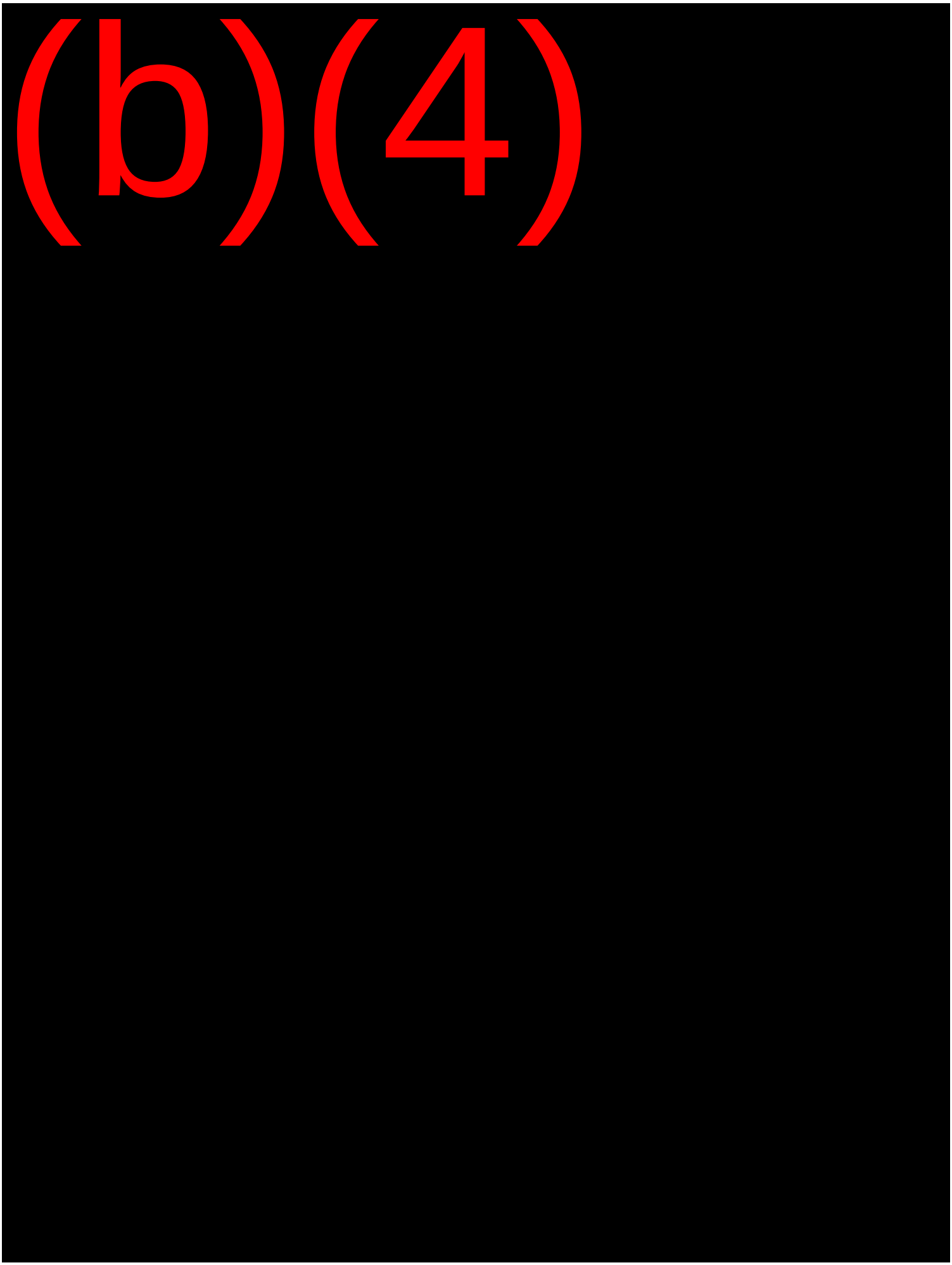
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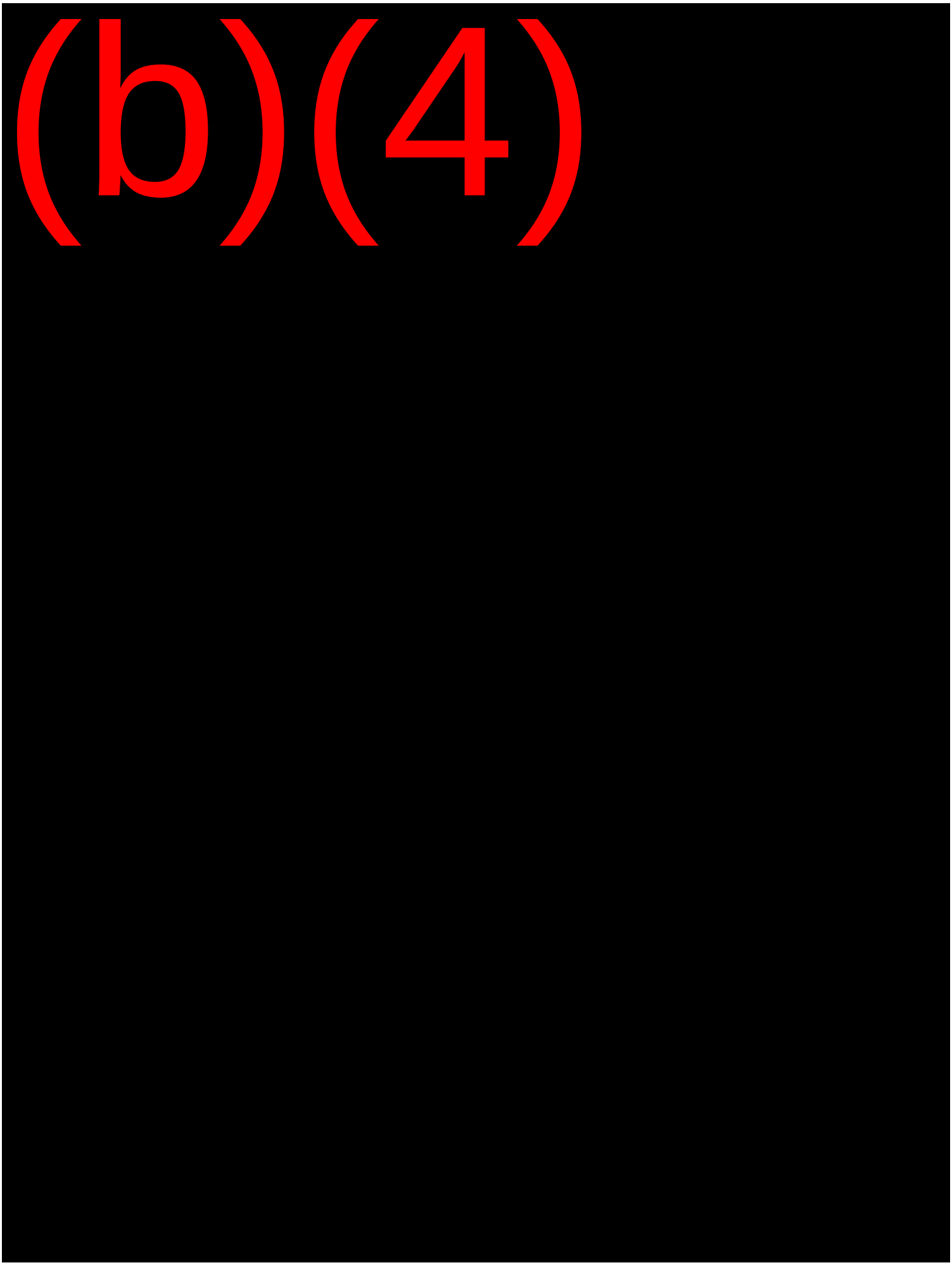
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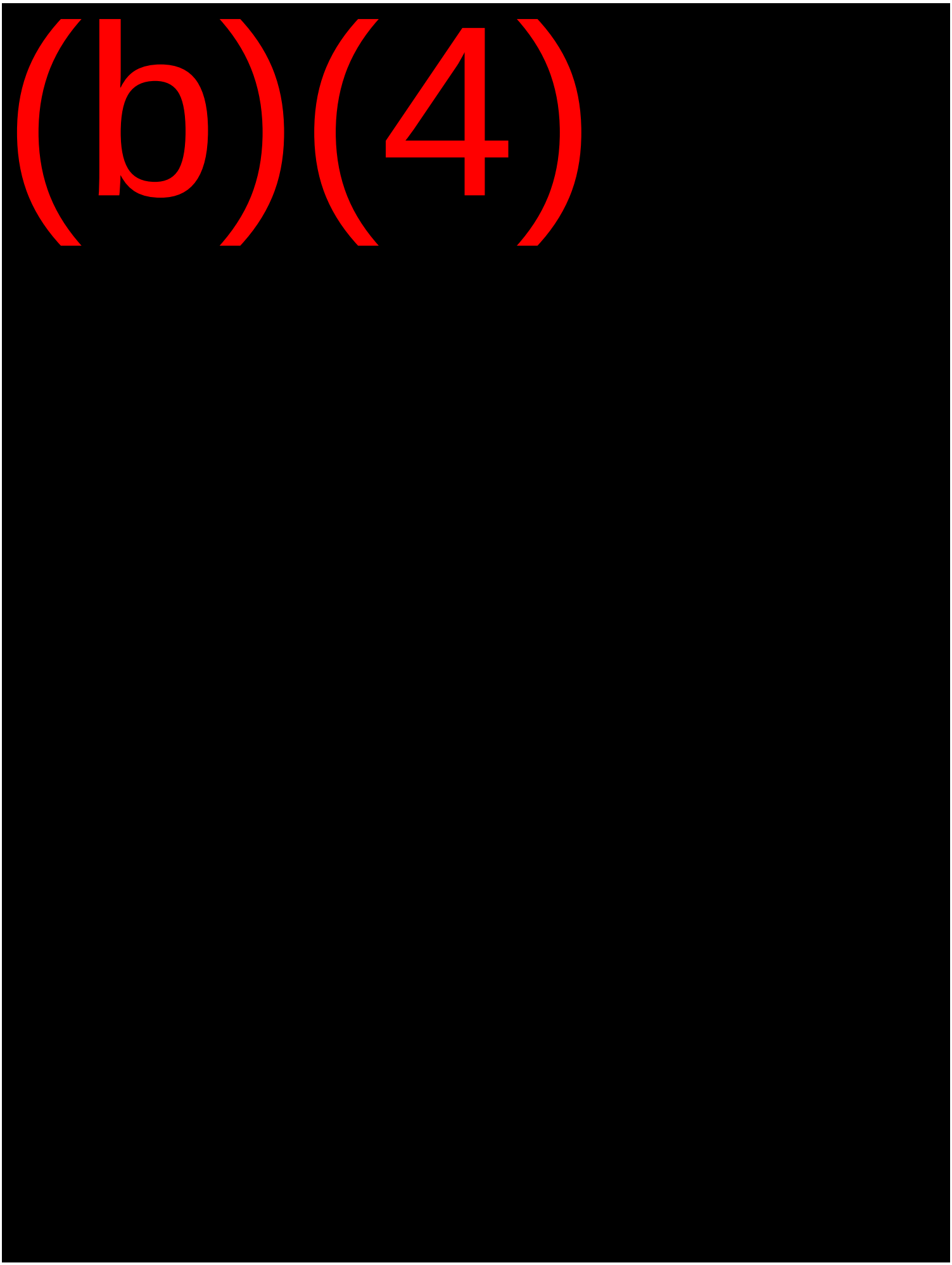
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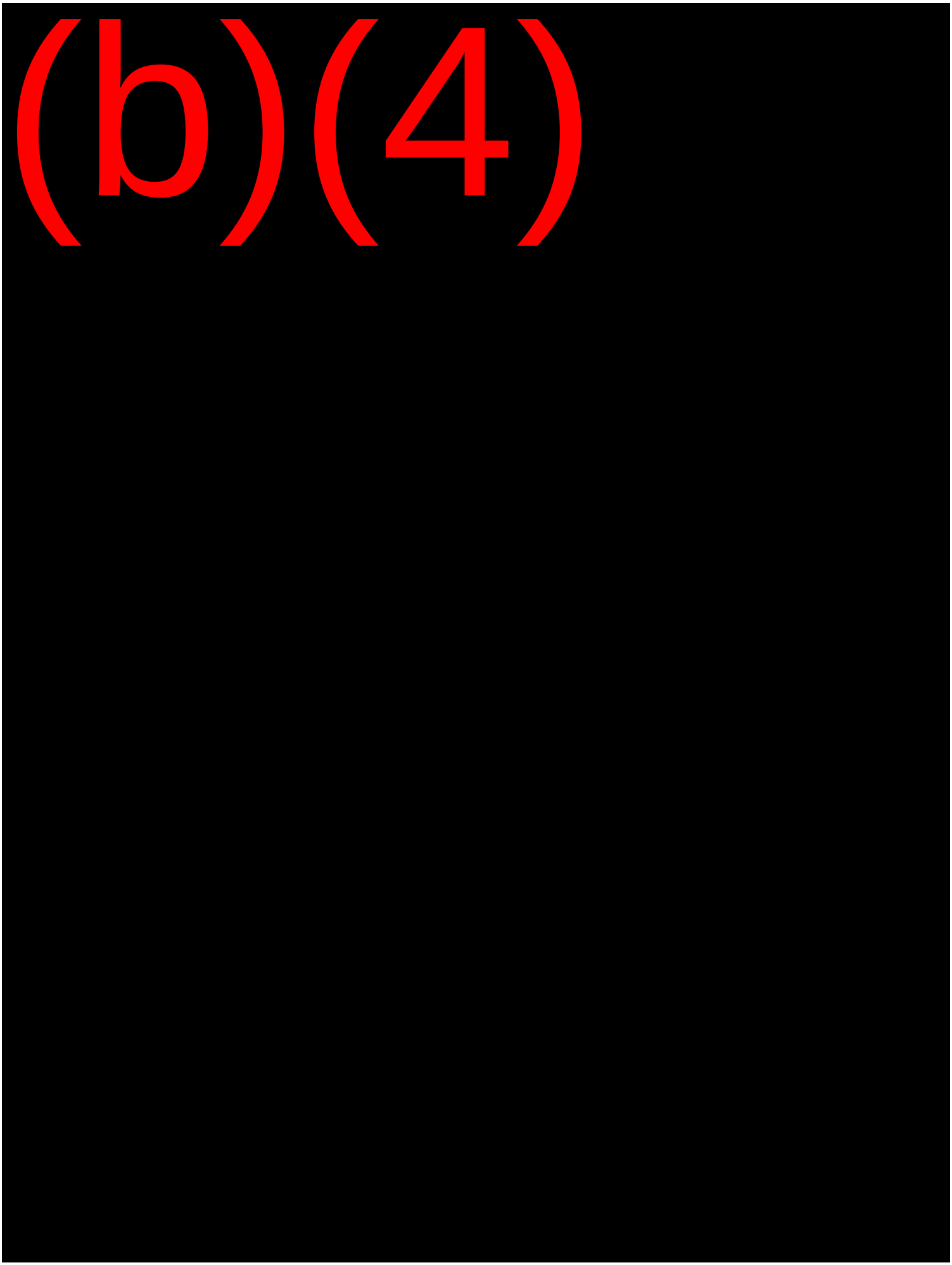
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General Snus MRTP Marketing Support Plan

Relative Size of Snus Category and General Snus Brand:

Within the United States (US), the snus category is a small portion of the smokeless tobacco segment. Swedish Match's estimate of current year snus category volume is approximately 39 million cans.[1] (b) (4) (that sell snus) in the US. For perspective, the moist snuff category is estimated at 1.1 billion cans[1]; therefore, the total snus category represents less than 4% of the moist snuff category and only 0.4% of the oral tobacco category.

General Snus' distribution is limited when compared to moist snuff. According to MSA there are 257,698 retailers that sell tobacco in the United States[1]. The convenience and smoke shop classes of trade represent 61% of tobacco sales and 59% of stores that sell tobacco in the U.S.[1] There are approximately 166,627 convenience and smoke shop retailers[1] selling tobacco products within the US[1]. (b) (4) . Further, compared to other snus brands, each competitor has a larger retail footprint[1].

(b) (4)

(b) (4)

[1] MSA Total US, Q1 – Q3 2021

Responsible Marketing Practices:

As part of our marketing and ethical code of conduct, Swedish Match takes proactive measures to ensure all marketing communication is targeted to adults aged 21+, who are current tobacco consumers. Swedish Match believes in responsibility above all to prevent youth access and youth exposure of brand communication whether it be labeling, promotions, advertising, or social media.

Our marketing efforts are tailored to prevent youth access and exposure via the following:

The website validates age of registrant ensuring 21+ through a third party, as opposed to simply asking consumers to self-report their age. (b) (4)

(b)(4)

(b)(4)

In terms of data security, the General Snus website (or any U.S. Swedish Match brand website) does not store any consumer information; (b) (4)

Social media is limited to Facebook where the feed is only visible to consumers with a verified Facebook.com account and self-identify as 21+. There is no expenditure of funds to post creative and copy nor are advertisements placed on Facebook. **See Appendix 2A (4)**, pg. 639 for Facebook metrics.

Print advertising limited to publications with a minimum of 85% of reader ages 21+.

For all MRTP-related digital marketing, Swedish Match utilized only first-party and second-party, age verified consumers for our intended audience. Registered users (first party) represented a staple of the consumers who were targeted for our remarketing efforts. This audience was then augmented with age-verified consumers from competent second-party sources where the 'tobacco purchasers' segments were intersected with 'age-group' segments in which consumers met both requirements to become a member of our intended audience. See **Appendix 2A (3)**, pgs. 623-634 for media plans, metrics and geographic profiles.

As it relates to our obligation to act responsibly, our approach was focused with an understanding of the importance of a MRTP designation.

Swedish Match used messaging to motivate interest among smokers while not appealing to non-users.

Swedish Match supported the brand and utilized the proven tactical platforms and procedures that limit exposure to youth. This included stringent age-verification to access branded content online, sending Email and direct mail communications to only those consumers who have been age-verified and opted-in to receive those communications. In addition, content is not placed on social media channels that do not utilize age-verification or self-identification.

Swedish Match did not utilize partners, influencers, bloggers and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products.

Swedish Match did not conduct consumer engagements including events at which the products were demonstrated or sold.

Swedish Match garnered some level of earned media/public relations, which is difficult to quantify.

Marketing Tactics:

Swedish Match marketed General Snus via various communication platforms to reach adult tobacco consumers 21+. All marketing tactics included prominent messaging that informed consumers how they could contact Swedish Match with any product-related concerns or questions, noted below.

MRTP Messaging Construct:

Swedish Match utilized a modified risk messaging construct that featured the authorized claim and the headline that mirrored the General Snus website MRTP video and storyboard (**see Appendix 2A, (2)**, pgs. 547-550), per the approved Marketing Plan dated December. 20, 2019. Secondary A/B test headlines (below) were used in digital advertising.

1) TEST A: FIRST EVER. The FDA granted General Snus the first-ever Modified Risk Tobacco Product (MRTP) order.

2) TEST B: THE CHOICE IS CLEAR. Claim stated. Find out why.

3) TEST C: THE CHOICE IS CLEAR. Learn more.

4) TEST D: FIRST EVER. Get the facts.

Swedish Match used this age-gated environment as the primary location for MRTP consumer educational information.

1) **Mirror of Video Stimuli - Headline:** A TOBACCO EXPERIENCE LIKE NO OTHER"

Legacy, non-MRTP related branded messaging.

Authorized Claim: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

Contraindication: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

5) **Digital Ad Testing – Headline A**: FIRST EVER. The FDA granted General Snus the first-ever Modified Risk Tobacco Product (MRTP) order. Find out why.

2) **Digital Ad Testing – Headline B**: THE CHOICE IS CLEAR. Claim stated. Find out why.

Slide 1

Slide 2

Authorized Claim: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

Tactical Platforms:

- **Branded Website** (www.GeneralSnus.com) is an age-verified (via third-party) online platform with access limited to tobacco consumers 21+.
  - (b) (4) [redacted]

  (b)(4) [redacted]
  (b)(4) [redacted]

  (b)(4) [redacted]
- **Advertising:**
  - Print Advertising in publications/websites where 85% or more of the readership is 21+.
  - Online Advertising directed at only First-Party and Second-Party age-verified consumers who met both requirements of an indication of tobacco consumption and adult age group segments included as members of our intended audience. Digital media metrics and geographic profiles are reflected in **Appendix 2A (3)**, pages 623-634.
  - Estimated impressions: (b) (4) [redacted]
    (b) (4) [redacted]

[2] Google Analytics, October 2020 – September 2021
3 Swedish Match Salesforce Database October 2020 – September 2021
4 Meltwater October 2020 – September 2021

- **Earned Media/Public Relations**[4] where representatives of Swedish Match would participate in radio, print and digital media interviews, as requested by media outlets.
  - (b) (4)

(b)(4)

(b)(4)

(b)(4)

- **Direct Mail** communication to age-verified tobacco consumers 21+ who opted-in to receive General Snus brand communications via postal mail. (b) (4)
(b)(4)

(b)(4)

- **Email** communication to age-verified tobacco consumers 21+ who opted-in to receive General Snus brand communications via Email. (b) (4)
(b)(4)
  - (b) (4)
- **Social Media** via Facebook.com/GeneralSnus, an age-restricted, social media page only visible to consumers with a verified Facebook.com account and self-identify as 21+.
  - (b) (4)

Direct Marketing Communication Safeguards:

Swedish Match's direct marketing of General Snus (via email and direct mail) was restricted to adult-tobacco consumers (21+) who opted-in to the Swedish Match consumer database. For a consumer to be added to this database, the tobacco consumer must have (1) completed third-party age-verification which confirmed that he/she was at least 21 years of age and (2) indicated that he/she wished to receive brand communications from General Snus.

Consumers were added to the database via one of two methods:

- Registration at GeneralSnus.com or any other Swedish Match website
- Through contact with the Swedish Match Consumer Call Center

5 Havas digital media plans October 2020 – September 2021

All consumers added to the Swedish Match consumer database (regardless of method of addition) were age-verified through a third-party service, which referenced public records that confirmed the information the consumer was certifying in the above steps.

These policies were designed to avoid sending direct marketing materials to youth or existing tobacco consumers who did not wish to receive brand marketing communications. Additionally, General Snus provided instructions on all communications for consumers who choose to stop receiving direct marketing communications from General Snus.

3 Swedish Match Salesforce Database October 2020 – September 2021
6 Facebook Analytics October 2020 – September 2021

Branded Website:

GeneralSnus.com, an age-gated environment was the primary consumer learning destination platform where all other marketing executions directed consumers for additional information.

The website validates age of registrant ensuring 21+ through a third party, as opposed to simply asking consumers to self-report their age. (b) (4)

(b)(4)

(b)(4)

All General Snus web pages are included on the attached MRTP Supporting Marketing Materials document (**see Appendix 2A (1)**).

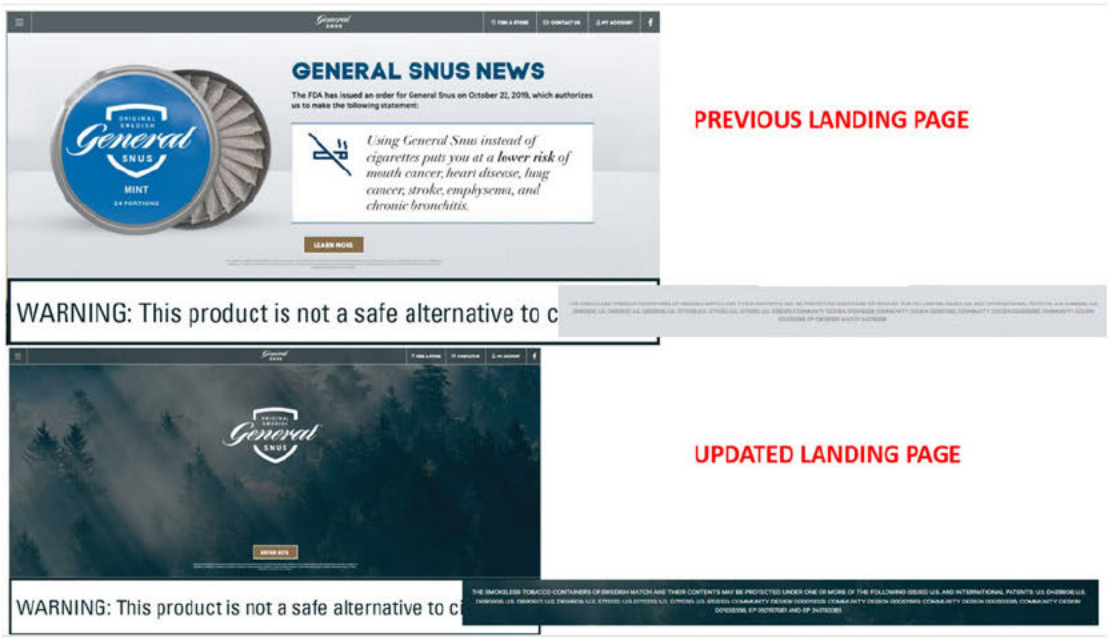
All MRTP-specific webpages which was live October 2020 that reside on GeneralSnus.com are included on the attached MRTP Supporting Marketing Materials document (**see Appendix 2A (2)**).

Upon initial visit to GeneralSnus.com, consumers were required to age-verify and register for an account. Upon successful registration/subsequent login, consumers arrived at the home page from which they could navigate to other webpages, which, among other things, contained the authorized MRTP claim.

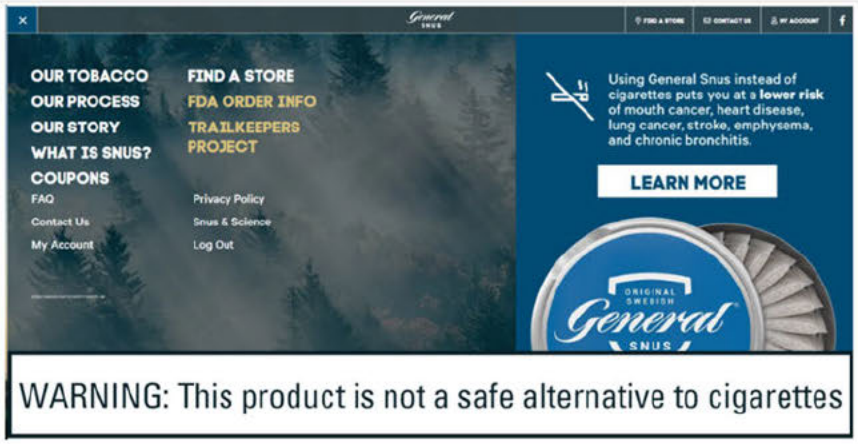
General Snus Website pre-October 2021

In December 2020 changes were made to select web pages, either those MRTP-related or ones that contained branding/brand content.

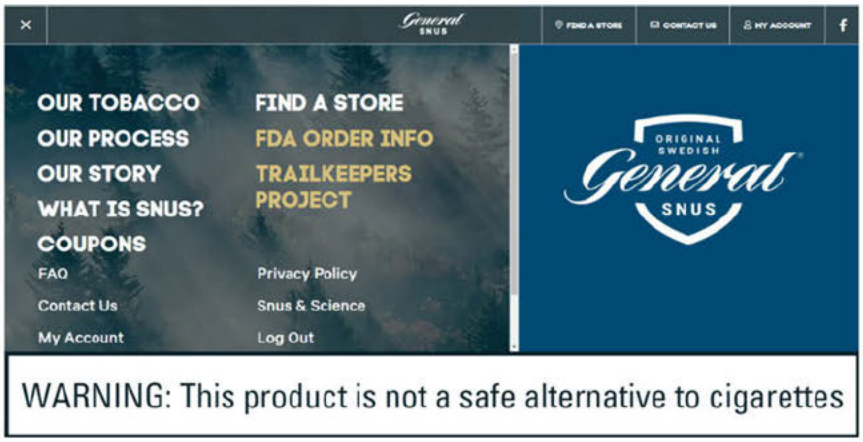
- All MRTP messaging was moved from outside age-gate to behind age-gate.
- MRTP landing page outside age gate was removed and replaced with an unbranded splash page. Below is the before and after (**see Appendix 2A (2)**, pg. 528-529).



- The General Snus can image was removed from the menu. Below is the before and after (see **Appendix 2A (2)**, pgs. 526-527).

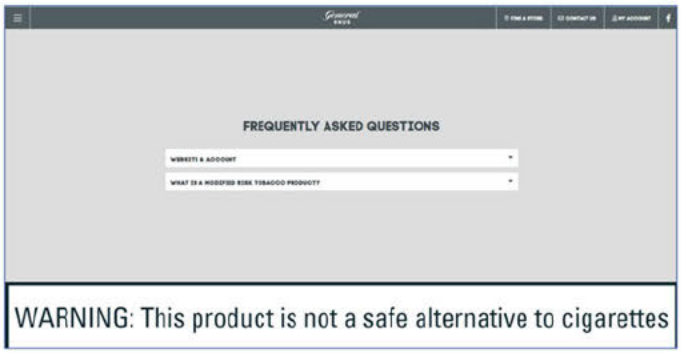


PREVIOUS MENU

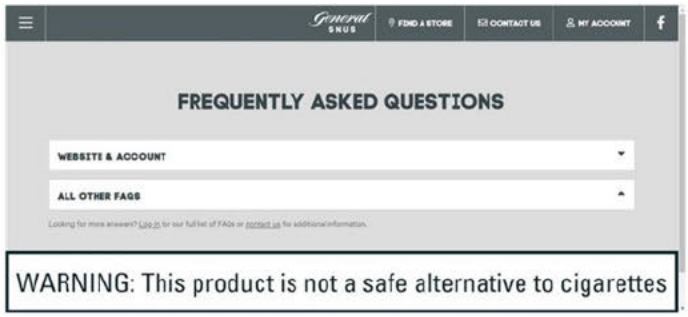


UPDATED MENU

- December 2020 all FAQs not related to the website or consumer's account were moved to behind age-gate. Below is the before and after (**see Appendix 2A (2)**, pgs. 534-538).



PREVIOUS FAQ PAGE (OUTSIDE AGE GATE)



UPDATED OUTSIDE AGE GATE FAQ PAGE

- **General Snus FDA Order Page – Extended, Behind Age Gate (see Appendix 2A (2),** pgs. 541-546): This page was displayed to any consumer after they logged-into the website or registered on the site. This page included the claim, links to both Swedish Match and the FDA's press releases, links to relevant 3rd party news articles related to the MRTP order, answers to five categories of frequently asked questions, General's core ingredients, explanation of "what is snus?" via icons, the MRTP video storyboard (**see Appendix 2A (2)**, pgs. 547-550), links to other General Snus branded website pages and the Contraindication: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician, or visit BeTobaccoFree.gov for more information.

- **Home Page – Behind Age Gate (see Appendix 2A(2)**, pg. 542): This page had a teaser for "A tobacco experience like no other" with a "Learn More" CTA. If consumers clicked the "Learn More" button, they were directed to the General Snus FDA Order Page. The Home Page could not be accessed outside age gate.

- **Navigation Menu (see Appendix 2A (2), pgs. 526-527):** Main source of website navigation that included 'FDA Order Info' page and links to other branded pages. From October 2020 – December 2020, the following menu link worked outside age gate: Abbreviated FAQs, MRTP Order, Find A Store, Contact Us, and Privacy Policy (see Appendix 2, pg. 3). From December 2020 – October 2021, the following menu links worked outside age gate: Abbreviated FAQs, Find A Store, Contact Us, and Privacy Policy (**see Appendix 2A (2)**, pg. 526). All other links in the menu required consumers to log-in or register.

- **MRTP News Page - Outside age gate (see Appendix 2A (2), pg. 528):** Was removed from the web site December 2020.

- **General Snus FDA Order Information Page - Behind age gate (see Appendix 2A (2), pgs. 541-546):** These pages were navigable from the main menu within the website after consumers were logged-in or completed the registration process. The page included the claim, links to both Swedish Match and the FDA's Press releases, linked to relevant 3rd party news articles related to the MRTP order, General's core ingredients, explanation of "what is snus?" via icons, the MRTP video (**see Appendix 2A (2)**, pgs. 547-550), 'Why General' via icons and 'How To Use' via icons and Contraindication: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician, or visit BeTobaccoFree.gov for more information.

- **Frequently Asked Questions – Outside Age Gate (see Appendix 2A (2), pgs. 533-538):**

    - **October 2020 – December 2020 (see Appendix 2A (2), pgs. 533-535) :**
      Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was not logged-in, or had not completed the registration process the registration process, was presented with two categories of FAQs: Website & Account and What is a Modified Risk Tobacco Product". This page was revised in December 2020 to omit any MTRP-related content.

    - **December 2020 – October 2021 (see Appendix 2A (2), pgs. 536-538):**
      Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was not logged-in, or had not completed the registration process the registration process, was presented with two categories of FAQs: Website & Account and All Other FAQs. The Website & Account FAQs dropdown and content could be accessed outside age gate. The "All Other FAQs" dropdown stated "Looking for more answers? Log in for our full list of FAQs or contact us for additional information." and required consumers to log-in or register before viewing content?

- **Frequently Asked Questions – Behind Age Gate (see Appendix 2A (2),** pgs. 551-554): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in or completed the registration process was presented with four categories of FAQs: General Snus Basics, Enjoying General Snus, Website & Account, and Modified Risk.

General Snus Website – October 2021 to current:

- In October 2021 the General Snus website implemented a site refresh. Changes were made to site structure and content. The only webpages that can be accessed outside age gate are the following: Find a Store, Contact Us, FAQs – Website & Account, Privacy Policy and Registration.

- All General Snus refreshed webpages which went live in October 2021 can be found in **Appendix 2A (1)**, pgs. 448-523.

- All MRTP-specific webpages which went live in October 2021 that reside on GeneralSnus.com are included on the attached MRTP Supporting Marketing Materials document (**see Appendix 2A (2)**, pgs. 555-576).

- **General Snus Modified Risk Page – Behind Age Gate (see Appendix 2A (2),** pgs. 565-569): This page was displayed to any consumer after they logged-into the website or registered on the site. This page included an announcement about General Snus' receiving a Modified Risk Tobacco Product order, the claim, the definition of a Modified Risk Tobacco Product, MRTP Order story, and links to both Swedish Match and the FDA's press releases (links to relevant 3rd party news articles related to the MRTP order).

- **General Snus Legacy, Behind Age Gate (see Appendix 2A (2)**, pgs. 562-564): This page was displayed to any consumer after they logged-into the website or registered on the website. This page displays a timeline of the General Snus brand, including a block of content for the year 2019 which contains messaging related to "Another First" and links to the Modified Risk page (**see Appendix 2A (2)**, pgs. 562,564).

- **Home Page – Behind Age Gate (see Appendix 2A (2)**, pg. 561): After-log in or registration, there are five content blocks, one related to MRTP, "The Choice Is Clear: First Ever". If consumers click the "Learn More" button, they are directed to the General Snus Modified Risk Page (**see Appendix 2A (2)**, pgs. 565-569).

- **Navigation Menu – Outside Age Gate (see Appendix 2A (2)**, pg. 557)**:** Main source of website navigation that included 'Modified Risk' page and links to other branded pages. The following menu links work outside age gate: Abbreviated FAQs, Find A Store, Contact Us, and Privacy Policy. All other links in the menu require registration or log-in.

- **Frequently Asked Questions – Truncated - Outside Age Gate (see Appendix 2A (2)**, pg. 558): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in, or had completed the registration process the registration process, was presented with one FAQ, related to Website & Account. There is no MRTP content in the FAQs outside age gate. The "Looking for more answers?" required consumers to log in or register before viewing the full list of FAQs.

- **Frequently Asked Questions – Extended- Outside Age Gate (see Appendix 2A (2),** pg. 559): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in, or had completed the registration process the registration process, was presented with one FAQ, related to Website & Account. There is no MRTP content in the FAQs outside age gate. The "Looking for more answers?" required consumers to log in or register before viewing the full list of FAQs.

- **Frequently Asked Questions – Truncated - Behind Age Gate (see Appendix 2A (2)**, pg. 569): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in, or had completed the registration process the registration process, was presented with four categories of FAQs: General Snus Basics, Enjoying General Snus, Website & Account and Modified Risk. Website & Account and All Other FAQs. The Website & Account FAQs dropdown and content could be accessed outside age gate.

- **Frequently Asked Questions – Extended - Behind Age Gate (see Appendix 2A (2),** pgs. 570-576): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in, or had completed the registration process the registration process, was presented with four categories of FAQs: General Snus Basics, Enjoying General Snus, Website & Account and Modified Risk. Website & Account and All Other FAQs. The Website & Account FAQs dropdown and content could be accessed outside age gate.
- **Modified Risk Frequently Asked Questions – Extended, Behind Age Gate (see Appendix 2A (2)**, pgs. 575-576): Any consumer who navigated (organically or via Email, digital ads or social media) to www.GeneralSnus.com/faqs via the menu, and was logged-in or completed the registration process was presented with a category of Modified Risk four FAQs.

- **Other General Snus website (Oct. 2021 – current) pages, that do not contain MRTP content, See Appendix 2A (1):**
    - Landing – see Appendix 2A (1), pg. 110
    - Forgot password – see Appendix 2A (1), pg. 111
    - Password reset on the way – see Appendix 2A (1), pg. 112
    - Registration process, outside age gate – see Appendix 2A (1), pgs. 113-117
    - Find a Store, outside age gate: - see Appendix 2A (1), pgs. 118-120
    - Contact Us, outside age gate: - see Appendix 2A (1), pg. 121
    - Privacy Policy, outside age gate: – see Appendix 2A (1), pgs. 125-139
    - Registration confirmation page: - see Appendix 2A (1), pg. 142
    - My Account, behind gate: – see Appendix 2A (1), pgs. 143-149
    - Coupons, behind age gate: – see Appendix 2A (1), pgs. 150-151
    - About General & Snus, behind age gate: – see Appendix 2A (1), pg. 153
    - What is Snus & How to Use, behind age gate: – see Appendix 2A (1), pg. 154
    - How it's Made, behind age gate: – see Appendix 2A (1), pgs. 155-157
    - Elevated Stories, behind age gate: – see Appendix 2A (1), pgs. 161-167
    - Products, behind age gate: – see Appendix 2A (1), pgs. 168-172

Trade Advertising: **See Appendix 2A (3)**, pg. 636

1. Two one-page full color print advertisements were published in the convenience store trade magazines noted below. The print advertising met the Tobacco Control Act requirements and appeared in convenience store trade publications where at least 85% or more of the readership is 21+. The print ad featured the authorized claim, "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

The schedule for all Convenience Store Trade advertisements was as follows (**see Appendix 2A (7)**):

1) (b) (4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)
(b)(4)

Consumer-Facing Print Advertising: (**See Appendix 2A (3)**, pgs. 579-580)

(b) (4)
(b)(4)
(b)(4)

Consumer-Facing Online Advertising: (**See Appendix 2A (3)** pgs. 581-622)

In addition to print advertising, various sizes of digital ads were placed that contained the authorized MRTP claim. Online advertising met Tobacco Control Act requirements and was only displayed to age-verified consumers who met the first party and/or second-party criteria. See **Appendix 2A (3),** pgs. 623-634 for digital media plans and metrics.

There were three primary objective of the digital ads was to drive consumers directly to GeneralSnus.com:

1) Pre-October 2021, Consumers were required to log-in/register and were then automatically directed to the 'General Snus FDA Order' page where they could view MRTP-related content behind the age gate (**see Appendix 2A (2)**, pg. 541). October 2021-current, consumers were required to log-in/register and are automatically directed to the 'Modified Risk' page (**see Appendix 2A (2)**, pg. 565).

2) Pre-October 2021, Consumers were directed to the 'Store Locator' page, to interact with the Store Locator, to aid consumers in finding General Snus in a store near a location of the consumer's interest. Consumers were not required to log-in/register. (**see Appendix 2A (1),** pg. 350). October 2021 – current, consumers are directed to the 'Find a Store' page. Consumers are not required to log-in/register. (**see Appendix 2A (1)**, pgs. 457-459). Any subsequent links, except for Website & My Account FAQs, Contact Us and Privacy Policy required consumers to log-in/register to view.

3) Pre-October 2021, consumers were required to log-in/register and were then automatically directed to the 'Our Tobacco' page, which provided product information. (**see Appendix 2A (1)**, pgs. 399-403). October 2021 – current, consumers are required to log-in/register and are then automatically direct to the "Products" page (**see Appendix 2A (1)**, pgs. 507-511).

The schedule for consumer-facing online digital advertisements was as follows:

1) Programmatic display and native January 2021 – September 2021: Smokers, Tobacco Consumers 21+ and retargeting visitors to GeneralSnus.com. Total of 111M impressions (**see Appendix 2A (3)**, pgs. 623-634 for media plans and results).

Online Advertising Audience & Placement Reach Overview*:*

General Snus executed a digital campaign in 2021 that targeted both 21+ tobacco users and current users of General Snus that utilized the MRTP messaging construct. This digital campaign distributed ads across the internet to only age verified consumers using the most advanced reach technology available today. See the following appendices for digital media data.

Digital Campaign Reach Technology

While older methods of digital marketing would focus ads on websites and webpages directly related to tobacco usage and smoking, newer methods are far more effective at reaching tobacco users by displaying ads on device IDs that are identified as tobacco purchasers or consumers.

Tobacco Consumer Audiences Device IDs (Desktop & Mobile)

(b) (4)
(b)(4)
(b)(4)

Audiences Incorporated in General Snus MRTP 2021 Campaigns:

- (b) (4)
- (b)(4)
- (b)(4)
- (b)(4)
- (b)(4)
- (b)(4)

Users must also belong to an age-verification audience below:

- (b) (4)
- (b)(4)
- (b)(4)
- (b)(4)

Ad Exchange Inventory

Once an audience of identified tobacco user device IDs was aggregated, they were reached through the different 'inventory exchanges' that were available. Each exchange could be described as a

network of websites and publishers that have conformed to required guidelines and were 'ad supported' by the exchange.

In short, online ad exchanges enabled Swedish Match to place ads on websites by bidding on the open market in real-time without establishing individual media buys on each website and domain.

(b) (4)
(b)(4)

Layering Intended Audiences into Ad Exchanges

"Audience activation" was utilized, the process that layered the known tobacco user audiences with the exchanges in real-time so that the intended device IDs were reached at any time, that they are seen across different websites and mobile apps. This was more efficient than placement-based digital campaigns.

Swedish Match took this reach a step further and blocked ads to known tobacco users if they were on sites within categories that were not well aligned with our communication safeguards and did not fit the criteria such as site within certain categories that were not well aligned with the General Snus brand images; sites that are otherwise deemed unsafe and not in alignment with the General Snus brand image. Blacklisted website categories included: Adult content, Youth Content, Kids Content, Gaming, Education, Family & Parenting, Pets & Animals, Social & Networking.

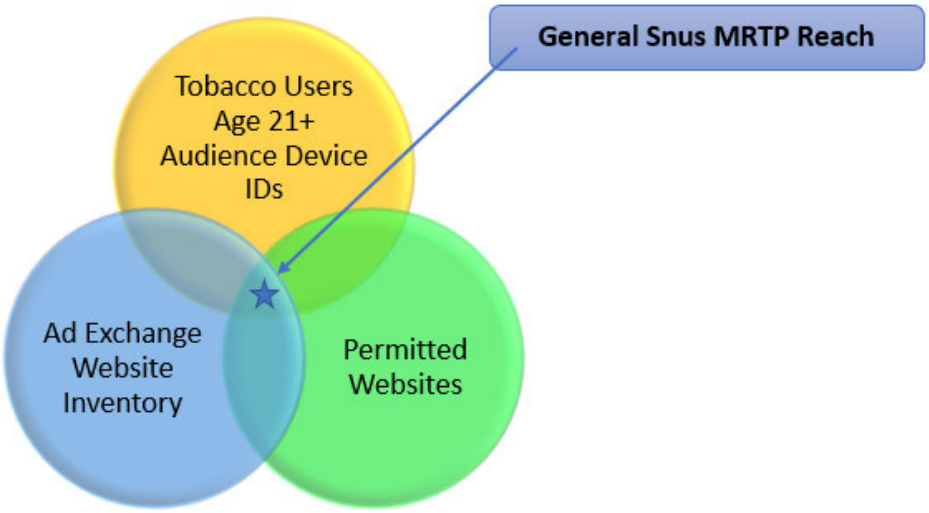
FDA Requested Site Lists

The existing tobacco user audience reach strategy that was deployed for the General Snus MRTP online advertising campaign focused on the specific first-party and second-party age verified consumers and their corresponding user & device ID placing ads on thousands of eligible websites and domains during the Oct. 2020 – Oct. 2021 campaign.

A list of all possible domains has been included, (see Appendix 6). This list indicates that which domains General Snus' MRTP digital media appeared. (b) (4) , the technology that monitors General's ad delivery.

Reach Method Outcome

First-party and second-party age verified tobacco consumers that were over the age of 21+ were eligible to receive ads on websites within (b) (4) exchanges listed above, except on placements within 'blacklisted categories.'



Earned Media/Public Relations:

Swedish Match participated in radio, digital and print media interviews when asked to provide comments about its products and would expect that a MRTP designation would generate media interest. Representatives of Swedish Match participated in such interviews and provided content consistent with any such MRTP designation and the Tobacco Control Act generally. It is not possible to provide an estimate of how many media impressions may occur as reach is dependent upon media interest in Swedish Match receiving a MRTP designation.

Direct Mail:

A specialty direct mail that included MRTP content was distributed in January 2021 to communicate educational information (**see Appendix 2A (4),** pgs. 752-754). To supplement this mailer, the bi-weekly (b) (4) mailer creative reflected MRTP messaging and began being distributed in early May 2021 (**see Appendix 2A (4)**, pg. 755). The direct mail creative was a postcard type, printed in color and directed consumers to GeneralSnus.com where they could access the previously mentioned primary location of MRTP educational information.

A monthly mailer was distributed to registered consumers who opted-in to receive direct mail during their birthday month (birthday self-reported via website registration), **see Appendix 2A (4)**, pg. 756.

Beginning May 2021, a welcome mailer was sent to new website registrants who opted-in for direct mail, but was subsequently halted and revised in September 2021 to omit The Continuum of Risk, **see Appendix 2A (4)**, pgs. 757-758).

Direct Mail metrics are included on **Appendix 2A (4)**, pg. 751. All MRTP-related Direct Mail communications are included on **Appendix 2A (4)**, 752-753, 757-758.

Email:

The MRTP-related email communications are included on **Appendix 2A (4)** pgs. 714-715, 717-725,727-728,731,734,736,739-740,742-749.

Its intent was to provide education and awareness and motivate the reader to click the "Learn More' call-to-action button, which directed consumers to Generalsnus.com to log-in/register, then automatically directed to: Pre-Oct. 2021 'FDA Order Info' page (**see Appendix 2A (2)**, pg. 541) and from Oct. 2021-current 'Modified Risk' page (**see Appendix 2A (2)**, pg. 565-569), which included full array of MRTP content. This content could be accessed only after they logged-in or successfully passed the age-verification process and registered. Subsequent emails that included MRTP messaging were deployed, sent to the same consumer group noted above. Note any reference and creative related to "Continuum of Risk" were not used after this Email and will not be used in future marketing communications.

Swedish Match implemented the procedures in place that ensured emails complied with applicable restrictions, regulations, and laws including compliance with the CAN SPAM ACT (Controlling the Assault of Non-Solicited Pornography and Marketing Act) which included unsubscribe copy on each email. Email metrics can be referenced on **Appendix 2A (4)**, pg. 713.

Social Media:

Social media metrics can be found on **Appendix 2A (4),** pg. 639. Four MRTP social media posts were designed that appeared on Facebook.com/GeneralSnus (**see Appendix 2A (4),** pgs. 642,645,650,655,692). The posts were based on an abbreviated version of the MRTP message construct and were only displayed in the social media feed of consumers who (1) conformed with the platform-specific age-restriction controls and (2) chose to follow the General Snus Facebook page. The posts were intended to drive awareness and understanding of General Snus' MRTP designation among loyalist consumers and directed consumers to log-in/register then automatically directed to: Pre-Oct. 2021, the 'General Snus News-Truncated' page (**see Appendix 2A (2)**, pg.541) and Oct. 2020-current, the "Modified Risk" page (**see Appendix 2A (2)**, pgs. 565-568)

The MRTP-related social media communications are included on **Appendix 2A (4)** pgs. 642, 645, 650, 655, 692.

***Point of Sale Materials (see Appendix 2A (4)**, pgs. 765-767):*

Point of sale material was the primary method of communicating marketing messaging in the retail environment. Original point of sale that communicated MRTP messaging construct began being placed in retail locations on January 20, 2020 was refreshed in September 2021. These materials were placed by the Swedish Match sales force as they completed retail visits as part of their regular routing. The POS materials included:

- **Poster** designed to be displayed on the inside of a store.
- **Vertical Door Spanner** designed to be placed on the interior windows/doors of retail locations.
- **Chiller Header** designed to be placed within the primary branding area on the inside of the most common chiller utilized at retail locations.
- **Shelf Talker** designed to be placed on or near all other chiller displays at retail.
- **Yard Sign** designed to be used either outside the store entrance or hung inside the store.

Images of MRTP-related Point-of-Sale communications are included on the attached MRTP Supporting Marketing Materials document (**see Appendix 2A (4)** pgs. 765-767).

Additionally, a list of the (b) (4) retail locations that received shipments of General Snus as reported by our sales force through September '21 has been provided (**see Appendix 2A (6)**). On any given

day, several of these stores may have chosen to delist General Snus while simultaneously, our sales force added additional stores.

Appendix 1: Full Website

CATEGORY: SNUS

BRAND: GENERAL SNUS

Annual Report

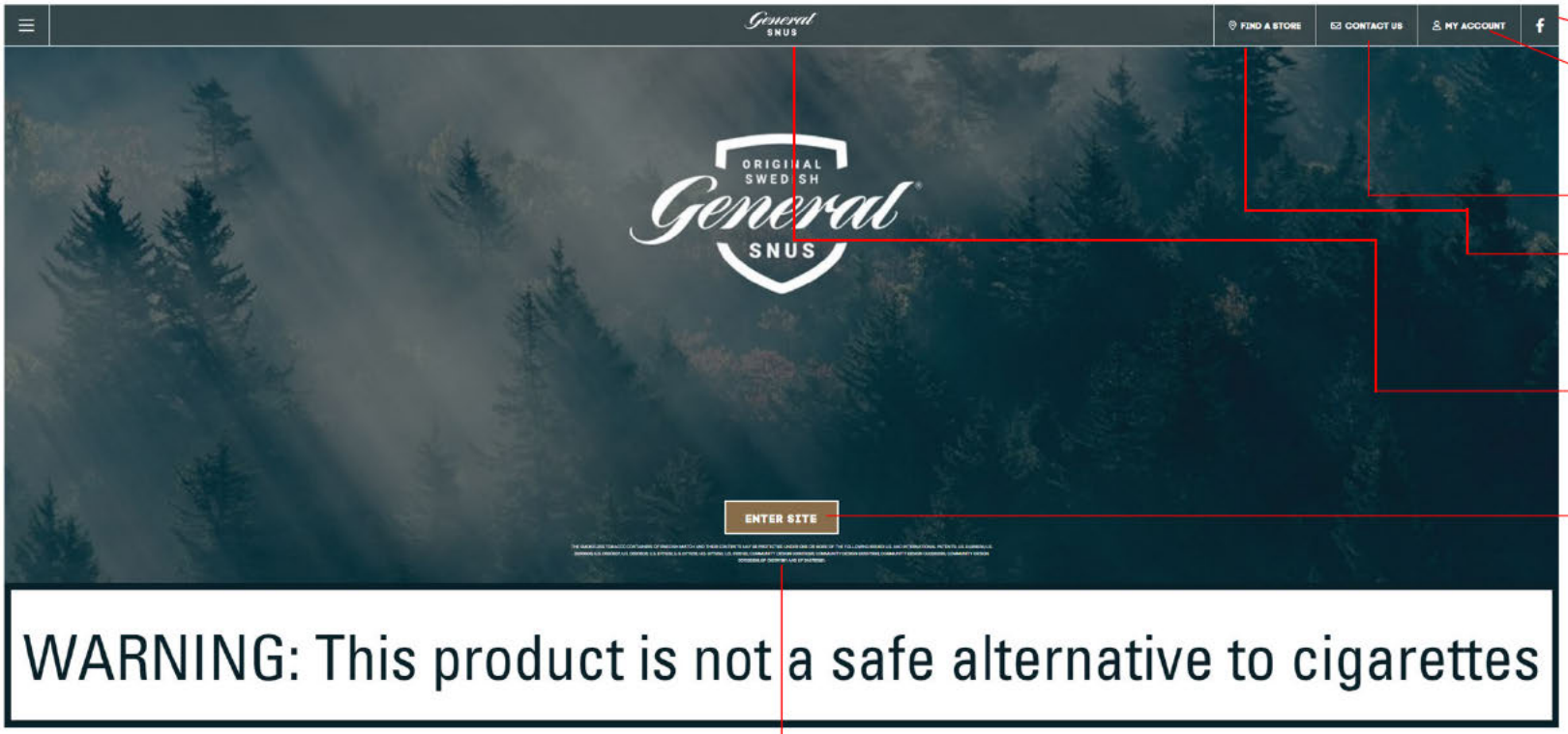
October 2020 – October 2021

Swedish Match

General Snus Website
Outside Age Gate
Oct. 2020 – Oct. 2021

Swedish Match

PRE-LOGIN/REGISTRATION SPLASH PAGE (outside age gate)
Oct. 2020 – Oct. 2021



Links to facebook.com/GeneralSnus

Links to 'My Account' page

Links to 'Contact Us' page (outside age gate)

Links to 'Store Locator' page (outside age gate)

No link

Links to 'Sign-in/Registration' page (outside age gate)

THE SMOKELESS TOBACCO CONTAINERS OF SWEDISH MATCH AND THEIR CONTENTS MAY BE PROTECTED UNDER ONE OR MORE OF THE FOLLOWING ISSUED U.S. AND INTERNATIONAL PATENTS: U.S. D489606; U.S. D690606; U.S. D690607; U.S. D690608; U.S. D711232; U.S. D711233; U.S. D711250; U.S. 6135120; COMMUNITY DESIGN 000019328; COMMUNITY DESIGN 000511993; COMMUNITY DESIGN 000933395; COMMUNITY DESIGN 001035398; EP 0921978B1 AND EP 2457833B1.

SIGN IN/REGISTRATION PAGE (outside age gate) Oct. 2020 – Oct. 2021

Links to facebook.com/GeneralSnus

Links to 'My Account' page

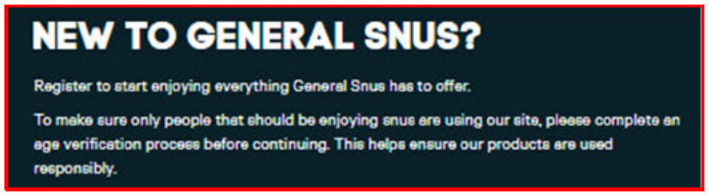
Links to 'Contact Us' page (outside age gate)

Links to 'Store Locator' page (outside age gate)

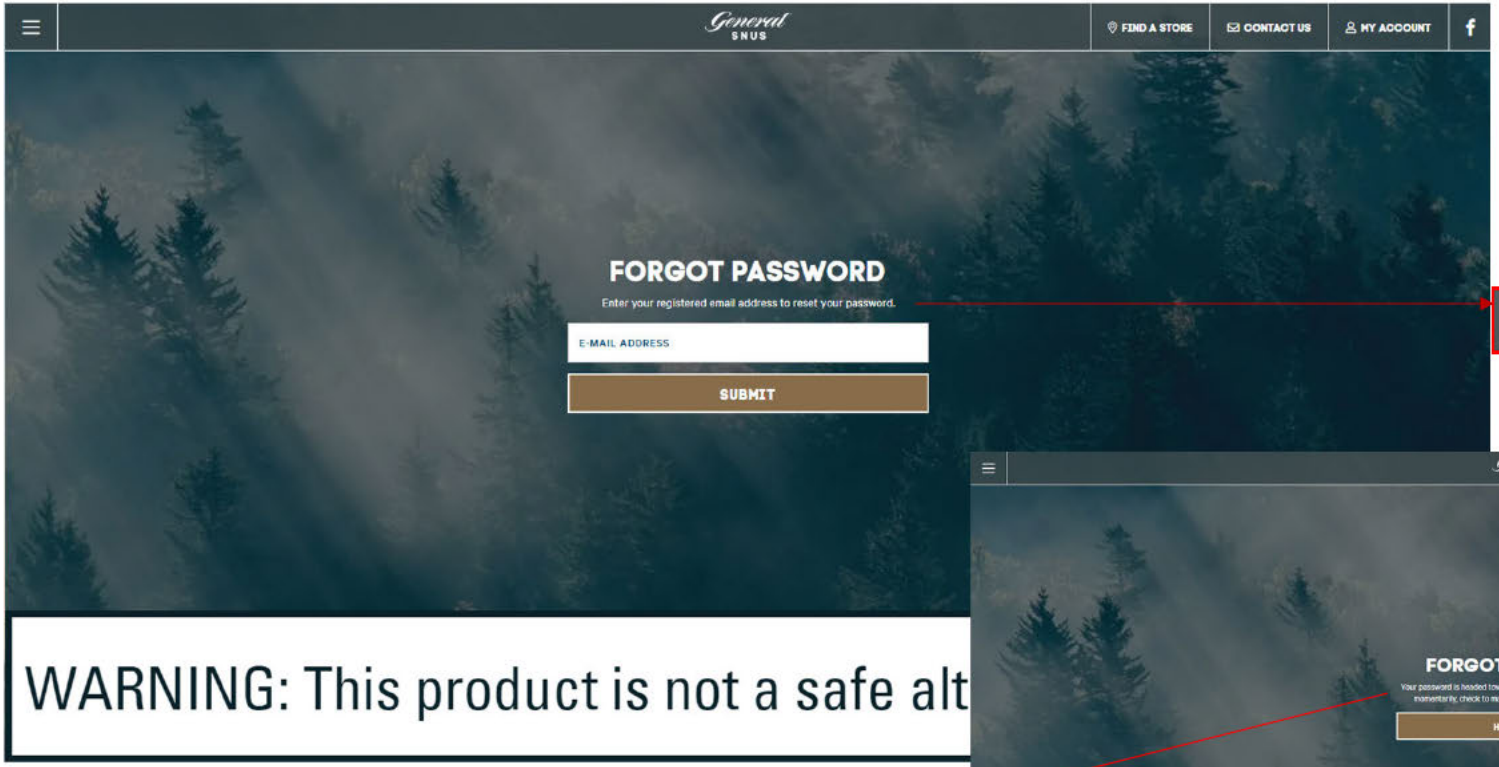
Links to 'Pre log-in Splash' page (outside age gate)

Links to 'Registration' page (outside age gate)

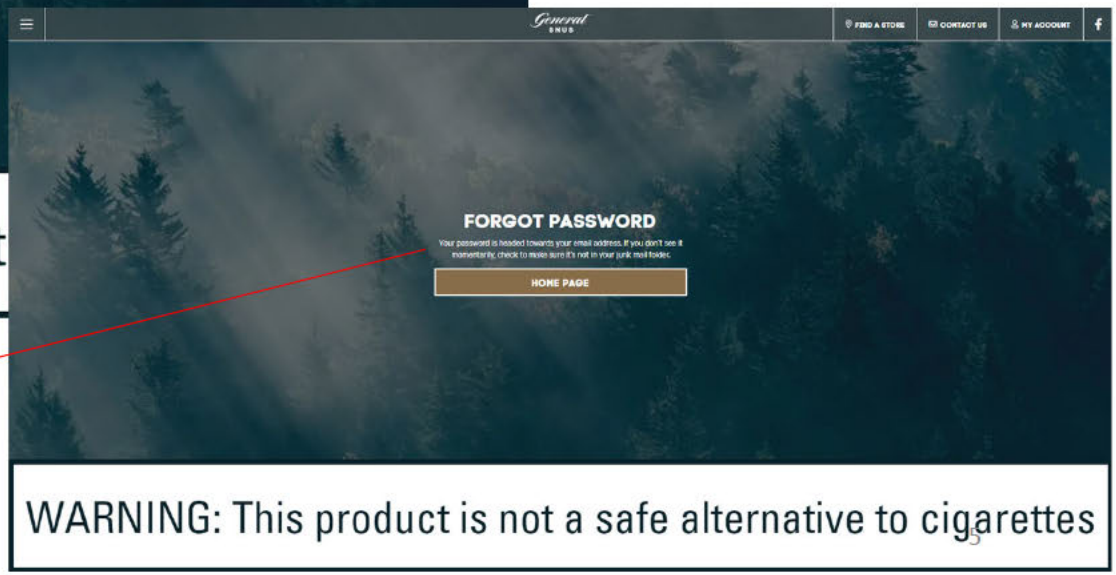
See Forgot Password page



FORGOT PASSWORD PAGE (outside age gate) – Oct. 2020 – Oct. 2021



Enter your registered email address to reset your password.



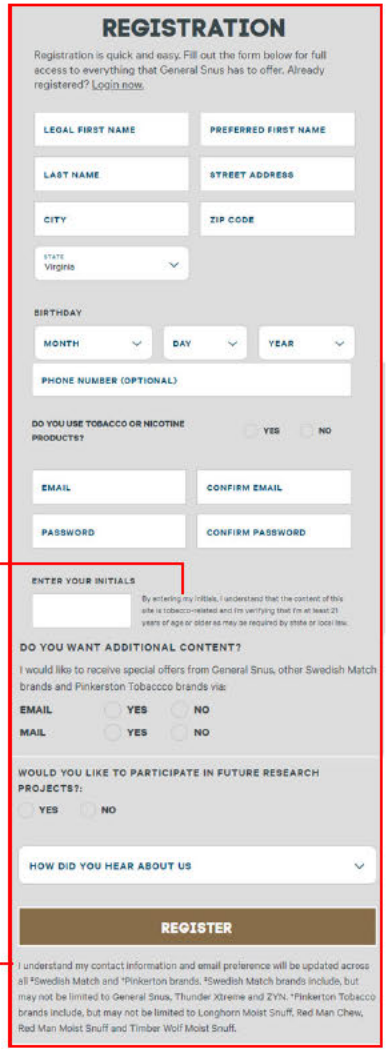
Your password is headed towards your email address. If you don't see it momentarily, check to make sure it's not in your junk mail folder.

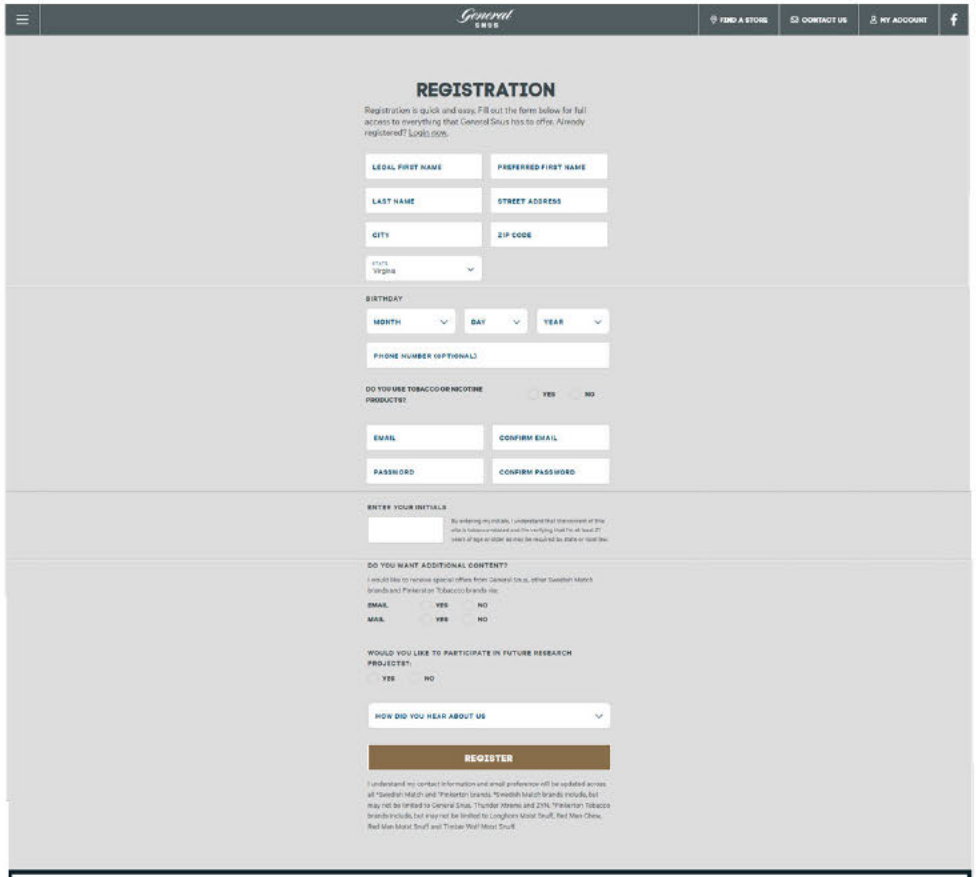
Swedish Match

REGISTRATION PAGE (outside age gate)
Oct. 2020 – Oct. 2021

By entering my initials, I understand that the content of this site is tobacco-related and I'm verifying that I'm at least 21 years of age or older as may be required by state or local law.

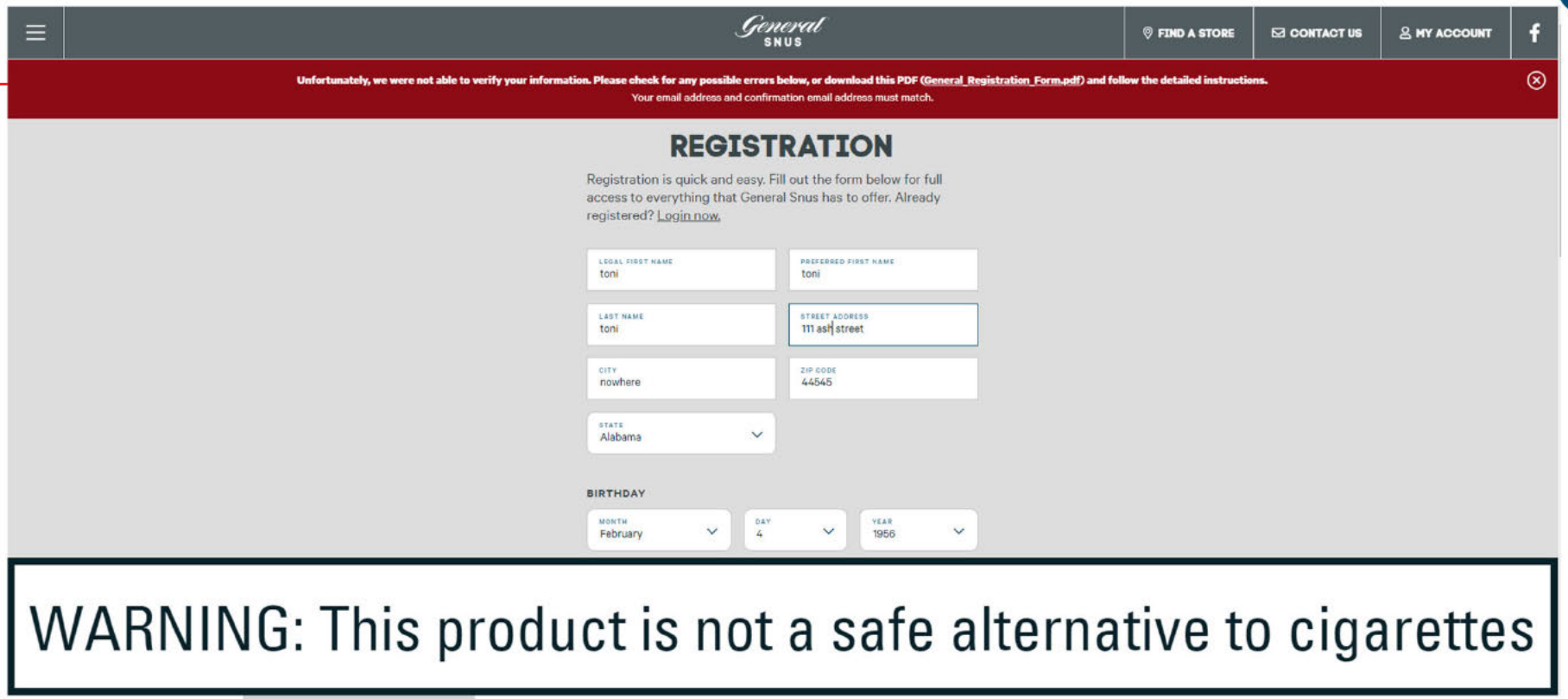
I understand my contact information and email preference will be updated across all ‡Swedish Match and *Pinkerton brands. ‡Swedish Match brands include, but may not be limited to General Snus, Thunder Xtreme and ZYN. *Pinkerton Tobacco brands include, but may not be limited to Longhorn Moist Snuff, Red Man Chew, Red Man Moist Snuff and Timber Wolf Moist Snuff.





WARNING: This product is not a safe alternative to cigarettes

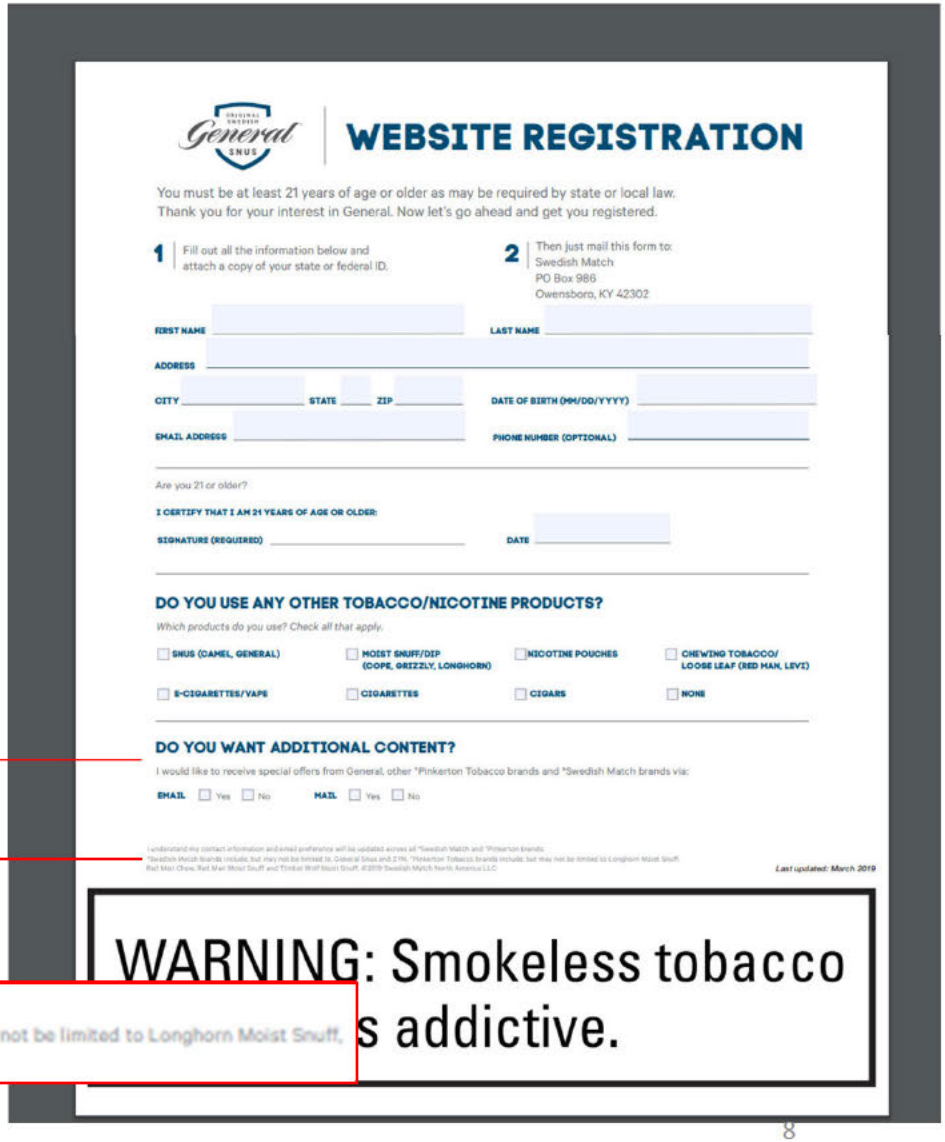
REGISTRATION ERROR PAGE (outside age gate)
Oct. 2020 – Oct. 2021



Unfortunately, we were not able to verify your information. Please check for any possible errors below, or download this PDF (General_Registration_Form.pdf) and follow the detailed instructions.
Your email address and confirmation email address must match.

See Registration PDF Page

REGISTRATION PDF PAGE (outside age gate)
Oct. 2020 – Oct. 2021



General SNUS

WEBSITE REGISTRATION

You must be at least 21 years of age or older as may be required by state or local law.
Thank you for your interest in General. Now let's go ahead and get you registered.

1 Fill out all the information below and attach a copy of your state or federal ID.

2 Then just mail this form to:
Swedish Match
PO Box 986
Owensboro, KY 42302

FIRST NAME _____ LAST NAME _____

ADDRESS _____

CITY _____ STATE ____ ZIP _____ DATE OF BIRTH (MM/DD/YYYY) _____

EMAIL ADDRESS _____ PHONE NUMBER (OPTIONAL) _____

Are you 21 or older?

I CERTIFY THAT I AM 21 YEARS OF AGE OR OLDER:

SIGNATURE (REQUIRED) _____ DATE _____

DO YOU USE ANY OTHER TOBACCO/NICOTINE PRODUCTS?

Which products do you use? Check all that apply.

☐ SNUS (CAMEL, GENERAL) ☐ MOIST SNUFF/DIP (COPE, GRIZZLY, LONGHORN) ☐ NICOTINE POUCHES ☐ CHEWING TOBACCO/ LOOSE LEAF (RED MAN, LEVI)

☐ E-CIGARETTES/VAPE ☐ CIGARETTES ☐ CIGARS ☐ NONE

DO YOU WANT ADDITIONAL CONTENT?

I would like to receive special offers from General, other *Pinkerton Tobacco brands and *Swedish Match brands via:

EMAIL ☐ Yes ☐ No MAIL ☐ Yes ☐ No

I understand my contact information and email preference will be updated across all *Swedish Match and *Pinkerton brands.
*Swedish Match brands include, but may not be limited to, General Snus and ZYN. *Pinkerton Tobacco brands include, but may not be limited to Longhorn Moist Snuff, Red Man Chew, Red Man Moist Snuff and Timber Wolf Moist Snuff. ©2019 Swedish Match North America LLC

Last updated: March 2019

WARNING: Smokeless tobacco
s addictive.

DO YOU WANT ADDITIONAL CONTENT?

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EMAIL ☐ Yes ☐ No MAIL ☐ Yes ☐ No

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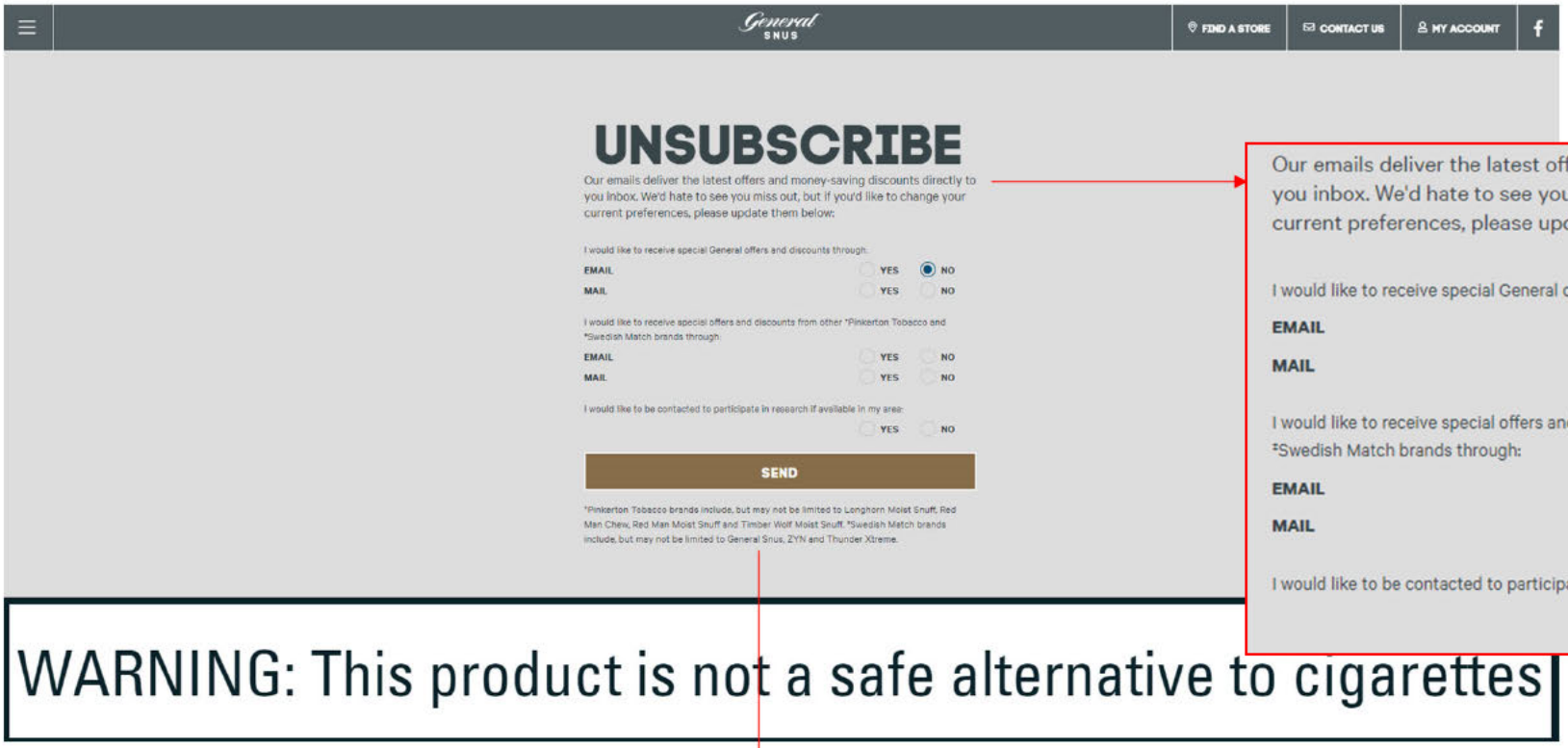
*Swedish Match brands include, but may not be limited to, General Snus and ZYN. *Pinkerton Tobacco brands include, but may not be limited to Longhorn Moist Snuff, Red Man Chew, Red Man Moist Snuff and Timber Wolf Moist Snuff. ©2019 Swedish Match North America LLC

Swedish Match

Unsubscribe Page (outside age gate)
Oct. 2020 – Oct. 2021



Our emails deliver the latest offers and money-saving discounts directly to you inbox. We'd hate to see you miss out, but if you'd like to change your current preferences, please update them below:

I would like to receive special General offers and discounts through:

EMAIL YES **NO**

MAIL YES NO

I would like to receive special offers and discounts from other †Pinkerton Tobacco and ‡Swedish Match brands through:

EMAIL YES NO

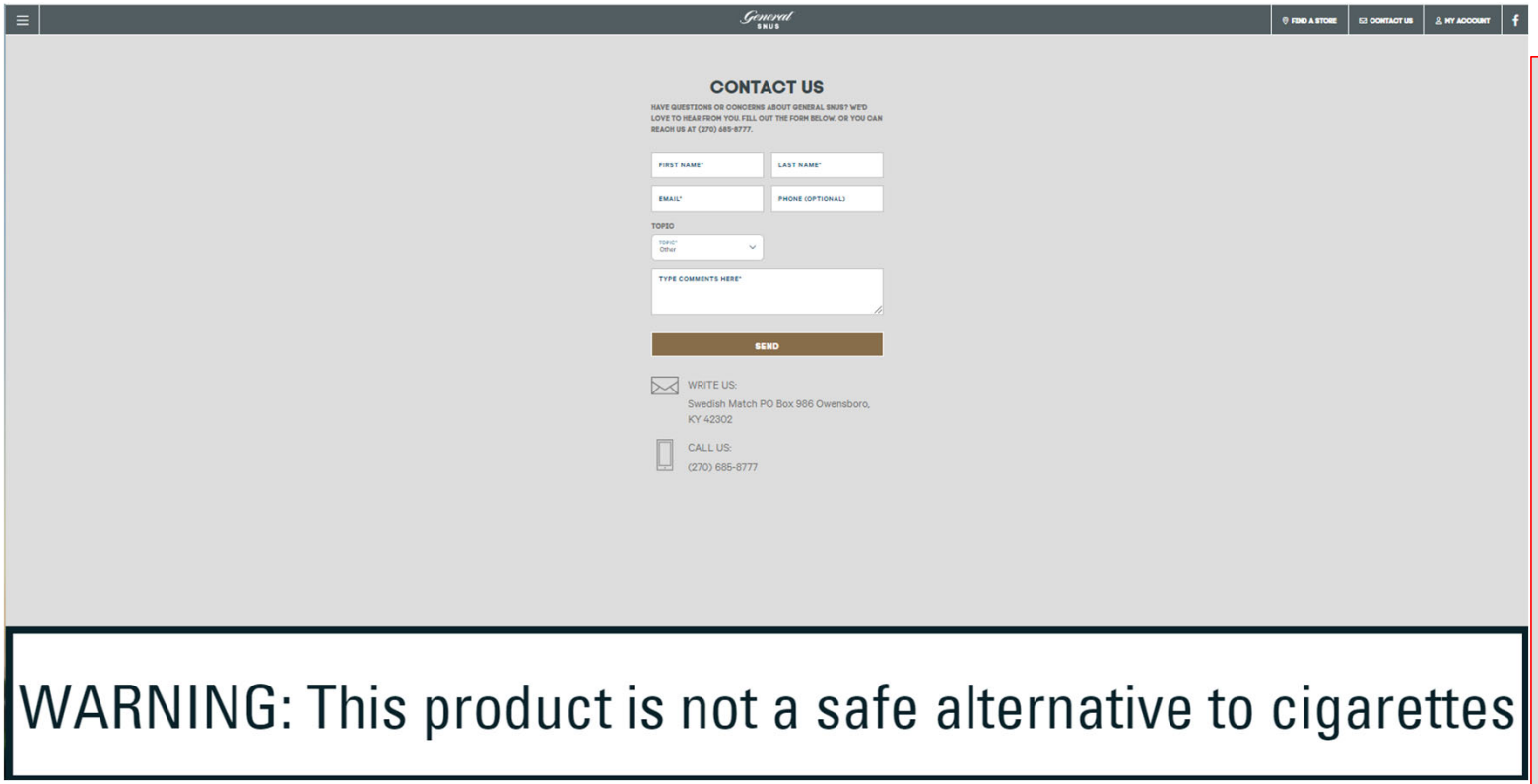
MAIL YES NO

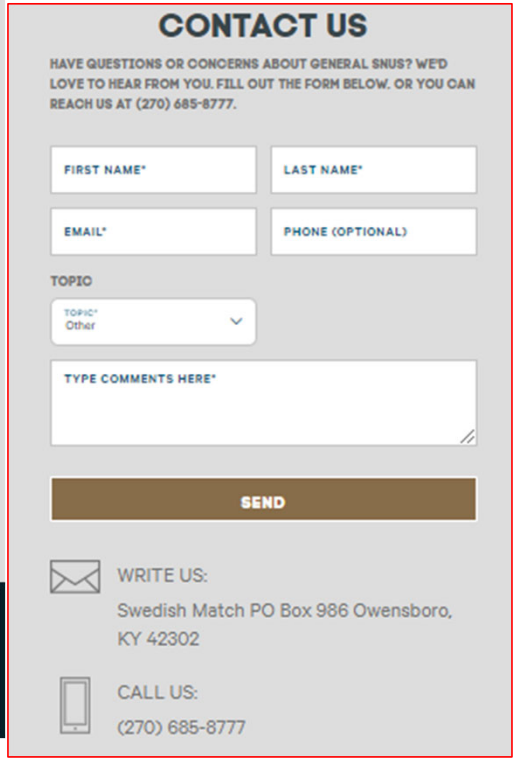
I would like to be contacted to participate in research if available in my area:

YES NO

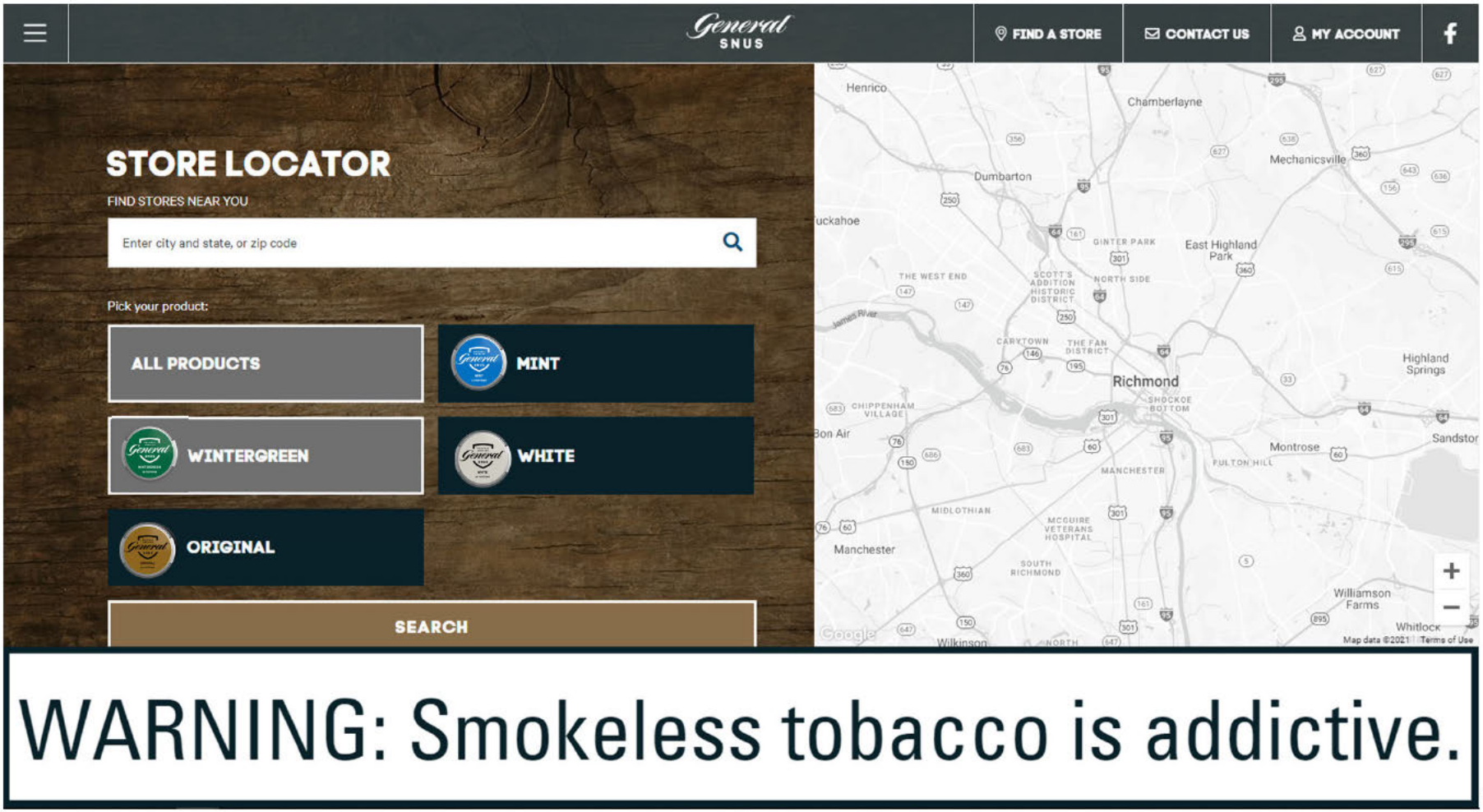
*Pinkerton Tobacco brands include, but may not be limited to Longhorn Moist Snuff, Red Man Chew, Red Man Moist Snuff and Timber Wolf Moist Snuff. *Swedish Match brands include, but may not be limited to General Snus, ZYN and Thunder Xtreme.

MASTHEAD CONTACT US PAGE (outside age gate)
Oct. 2020 – Oct. 2021

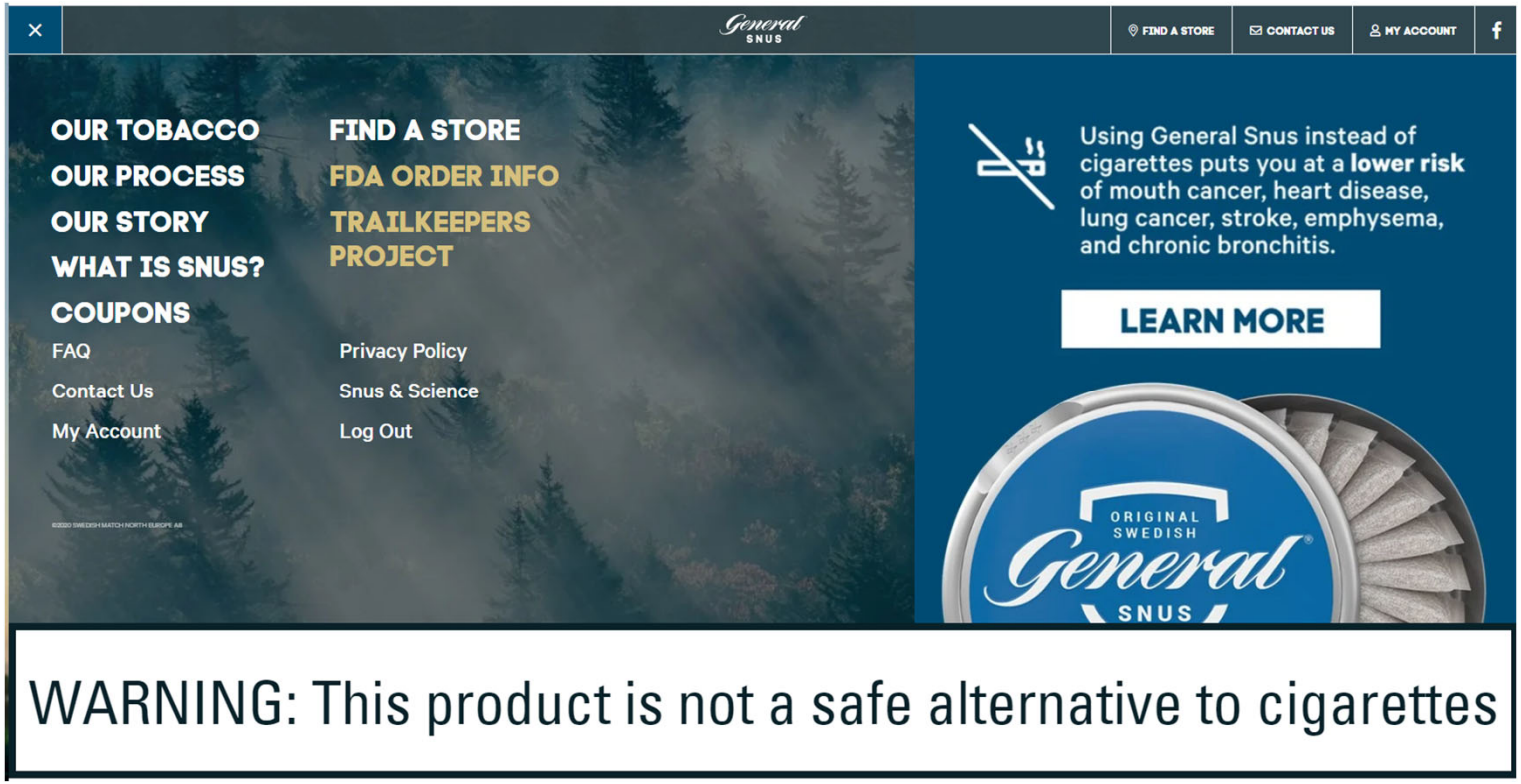


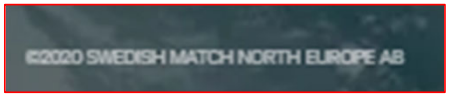


GENERAL SNUS Store Locator (Outside AGE GATE) Jan. 2021 – Oct. 2021



MENU (outside age gate)
Oct. 2020 – Dec. 2020

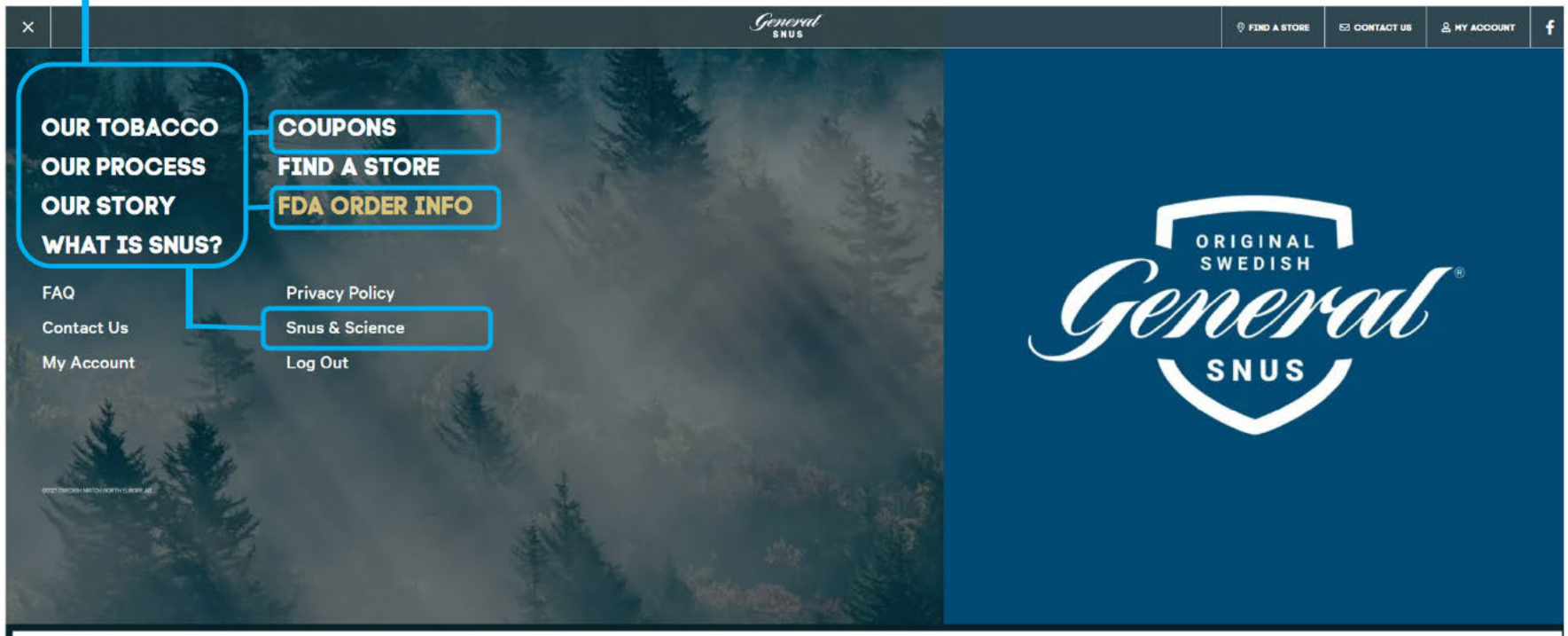




MENU (outside age gate) Dec. 2020 – Oct. 2021

Removed can image, revised menu copy

Behind Age-Gate



WARNING: This product is not a safe alternative to cigarettes

LANDING PAGE (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020

generalsnus.com/StoreLocator/

generalsnus.com/Contact/

LINKS TO LOG-IN/REGISTRATION PAGE
(my account is behind age gate)

facebook.com/GeneralSnus

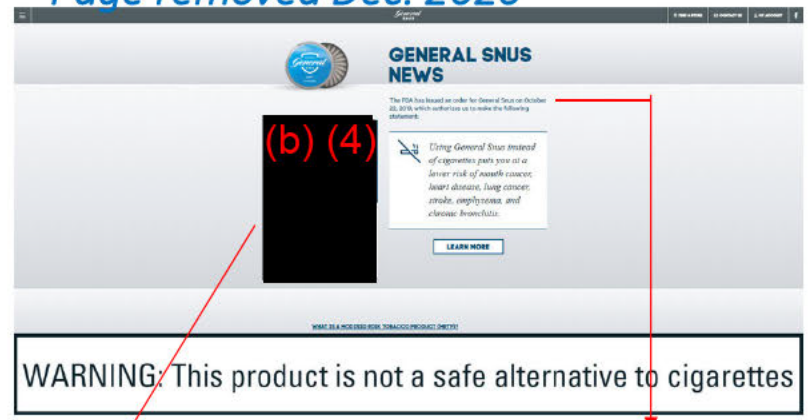
LINKS TO MRTP NEWS (outside age gate)

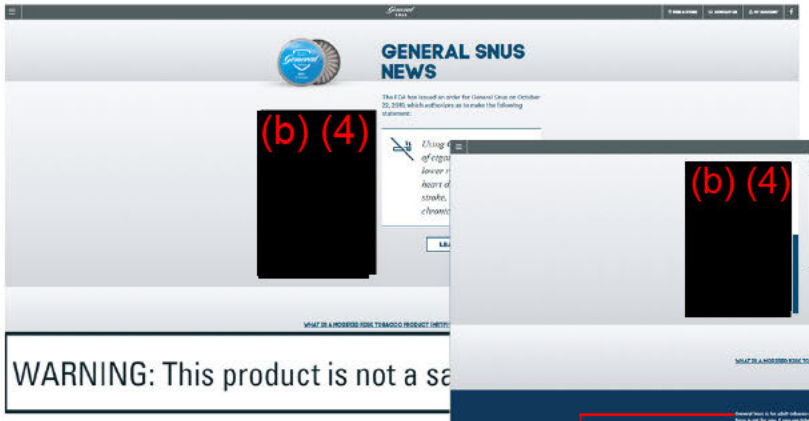
Swedish Match

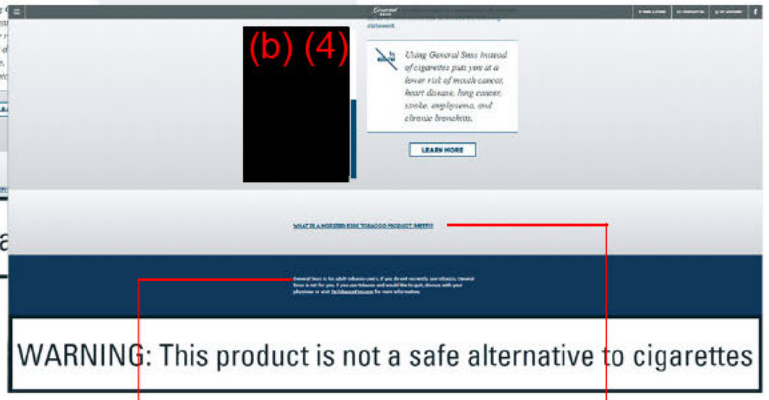
THE SMOKELESS TOBACCO CONTAINERS OF SWEDISH MATCH AND THEIR CONTENTS MAY BE PROTECTED UNDER ONE OR MORE OF THE FOLLOWING ISSUED U.S. AND INTERNATIONAL PATENTS: U.S. D489606; U.S. D690606; U.S. D690607; U.S. D690608; U.S. D711232; U.S. D711233; U.S. D711250; U.S. 6135120; COMMUNITY DESIGN 000019328; COMMUNITY DESIGN 000511993; COMMUNITY DESIGN 000933395; COMMUNITY DESIGN 001035398; EP 092197881 AND EP 245783381.

MRTP NEWS PAGE (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020







The FDA has issued an order for General Snus on October 22, 2019, which authorizes us to make the following statement:

(b) (4)

(b) (4)

fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

(b) (4)

(b) (4)

fda.gov/tobacco-products/market-and-distribute-tobacco-product/qa-modified-risk-tobacco-products

(b) (4)

WHAT IS A MODIFIED RISK TOBACCO PRODUCT (MRTP)?

A Modified Risk Tobacco Product (MRTP) is defined as a product that (b) (4) (b) (4) On October 22, 2019 the FDA issued an order for General Snus which authorizes us to make the following statement:

Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Learn more:

FDA grants first-ever modified risk orders to eight smokeless tobacco products

Q&A: Modified Risk Tobacco Products

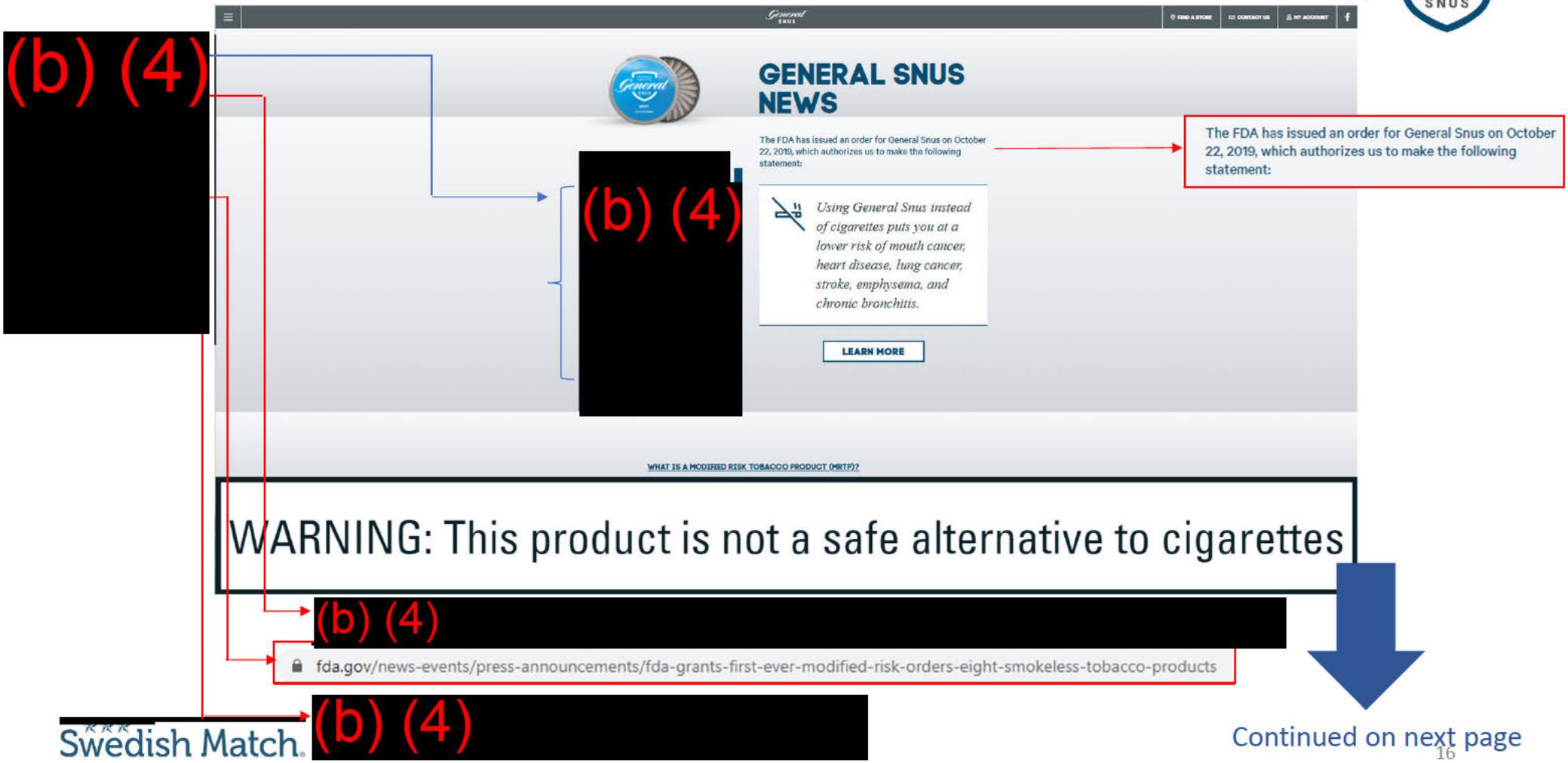
General Snus is for adult-tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit (b)(4)

(b)(4)

Swedish Match

MRTP NEWS PAGE CON'T (outside age gate) Oct. 2020 – Dec. 2020

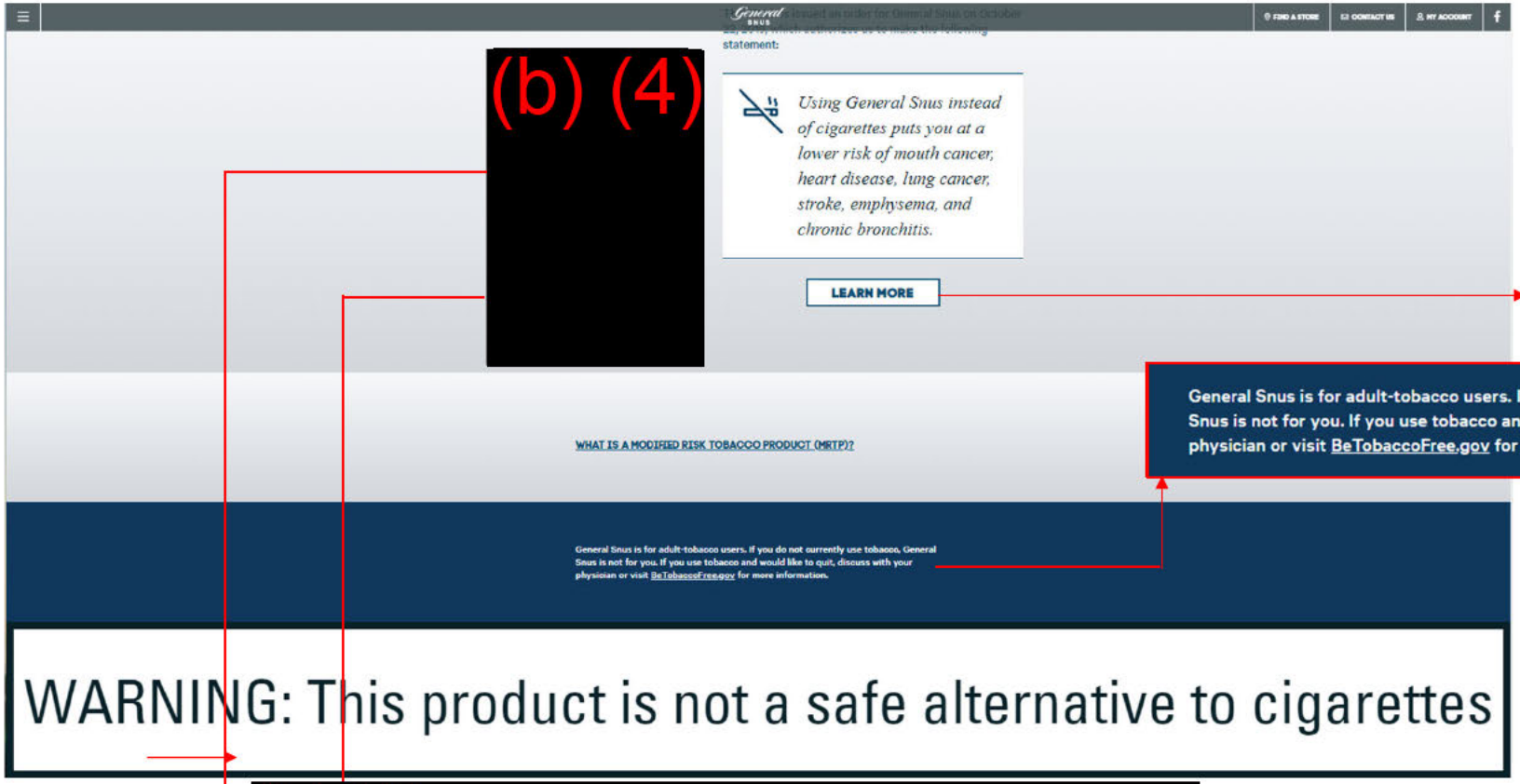
Page removed Dec. 2020



Continued on next page

MRTP NEWS PAGE CON'T (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020



Links to MRTP Experience Like No Other Page (behind age gate)

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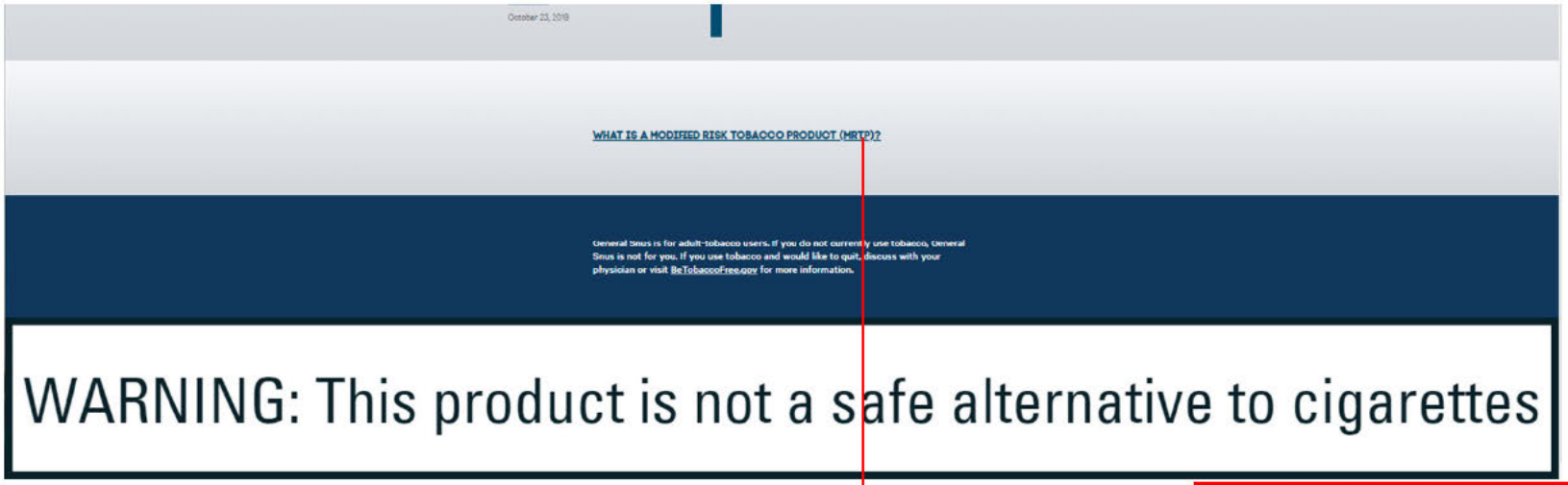
Swedish Match

Continued on next page

MRTP NEWS PAGE CON'T (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020



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fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

fda.gov/tobacco-products/market-and-distribute-tobacco-product/qa-modified-risk-tobacco-products

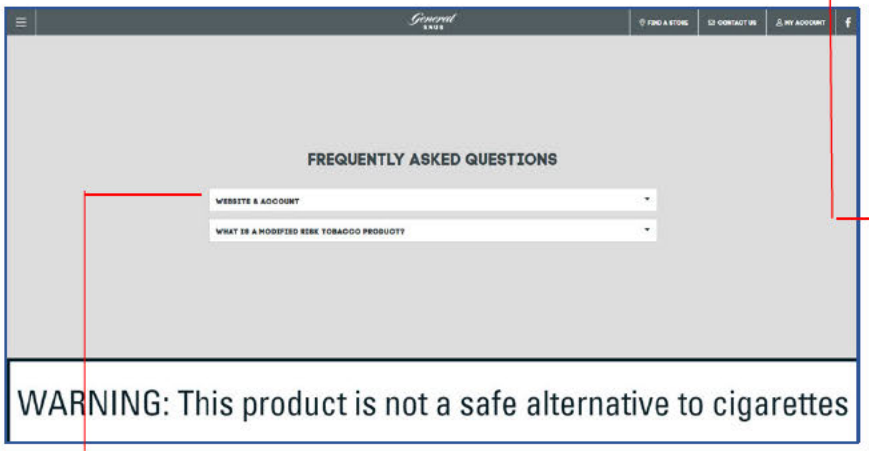
Swedish Match

Continued on next page

FAQ PAGE: WEBSITE & ACCOUNT (outside age gate)
Oct. 2020 – Dec. 2020

MRTP content removed from outside age gate Dec. 2020

See My Account Page [behind age-gate]



I forgot my password. What can I do?

Follow these steps and your password will be emailed to you.

1. Go to Forgot Password page → See Forgot Password Page
2. Enter your email address and hit submit
3. Check your inbox. A secure link will be sent for you to reset your password.

I've entered my login info but can't get into the site. What should I do?

If you receive a message saying that your email address/password has been entered incorrectly, try again.

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My age can't be verified. What can I do?

To register, you must be 21 years of age or meet the legal age requirements dictated by state or local law. Ensure the information you entered during registration is correct. If you're still having issues, follow the instructions on this PDF. → See PDF Page

What if I don't own a computer?

Our site is accessible through public computers with internet access.

Can I opt out of receiving emails in the future?

Yes. There are three ways to opt out:

1. Go to My Account, then update your communication preferences by selecting "No" under the email section.
2. Send an email to info@smna.com. It may take 10 business days to process your request.
3. Send a written request to:

Swedish Match North Europe AB

PO Box 986

Owensboro, KY 42302

Provide your name and the email address to be removed from the mailing list in the request.

How is my privacy protected?

Visit our Privacy Policy for more information. → See Privacy Policy Page

I'm having issues viewing images and messages on the site. What causes these issues?

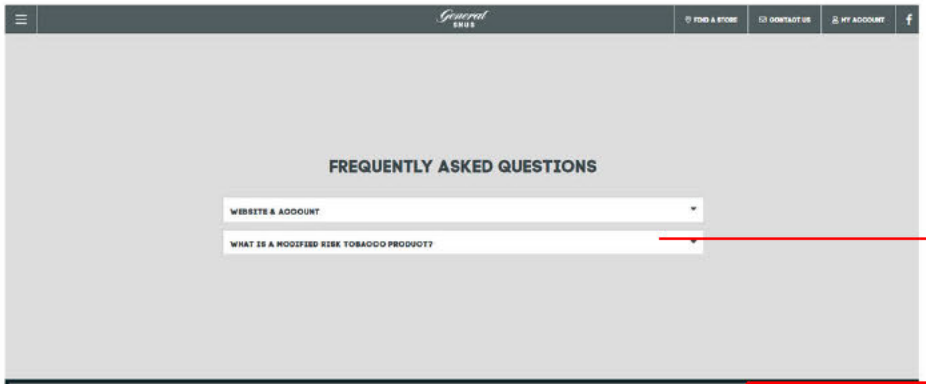
If images are not appearing on the site, make sure you are viewing the site in one of the supported browsers:

- Internet Explorer 11+ or Edge 12+ (WIN)
- Firefox 40+ (WIN/MAC)
- Safari 9+ (MAC)
- Google Chrome 50+ (WIN/MAC)

Swedish Match

FAQ PAGE: WHAT IS A MODIFIED RISK TOBACCO PRODUCT? (outside age gate)
Oct. 2020 – Dec. 2020

MRTP content removed from outside age gate Dec. 2020



WARNING: This product is not a safe alternative to

WHAT IS A MODIFIED RISK TOBACCO PRODUCT?

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October 22, 2019m the FDA issues an order for

(b)(4)

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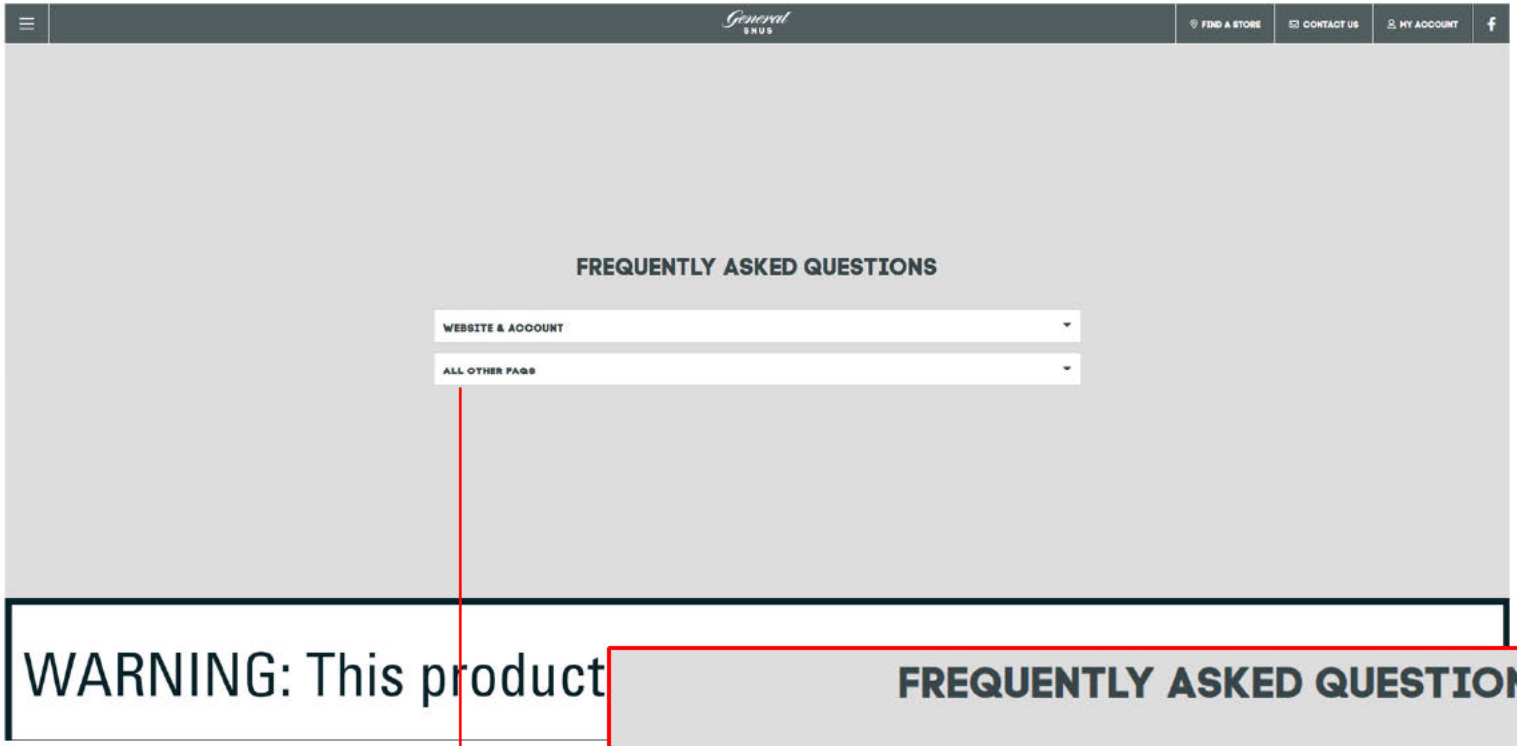
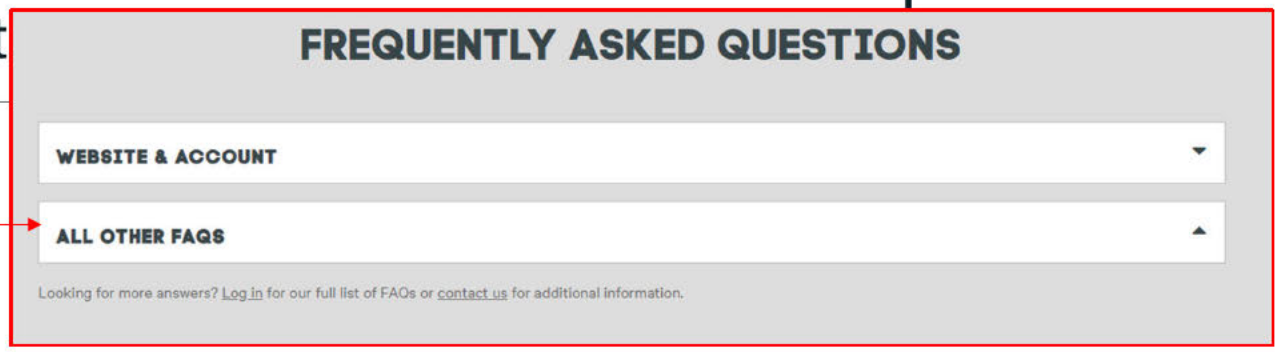
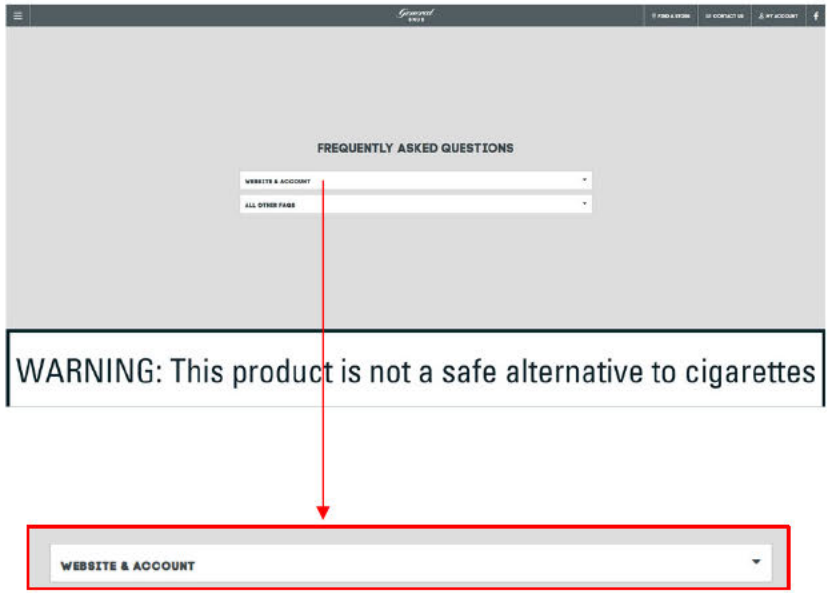
FAQ PAGE: WHAT IS A MODIFIED RISK TOBACCO PRODUCT? (outside age gate)
Dec. 2020 – Oct. 2021





FAQ PAGE: WEBSITE & ACCOUNT (outside age gate) Dec. 2020 – Oct. 2021



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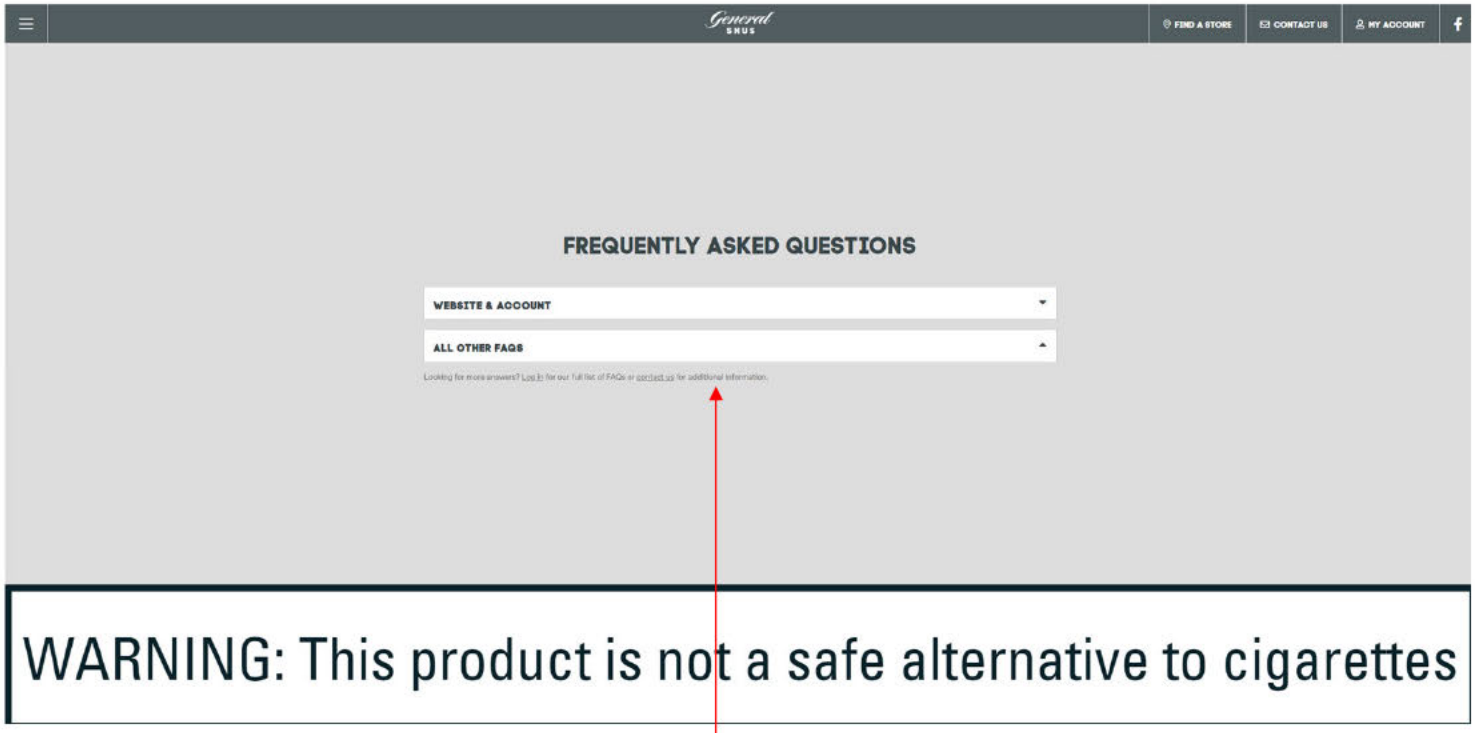
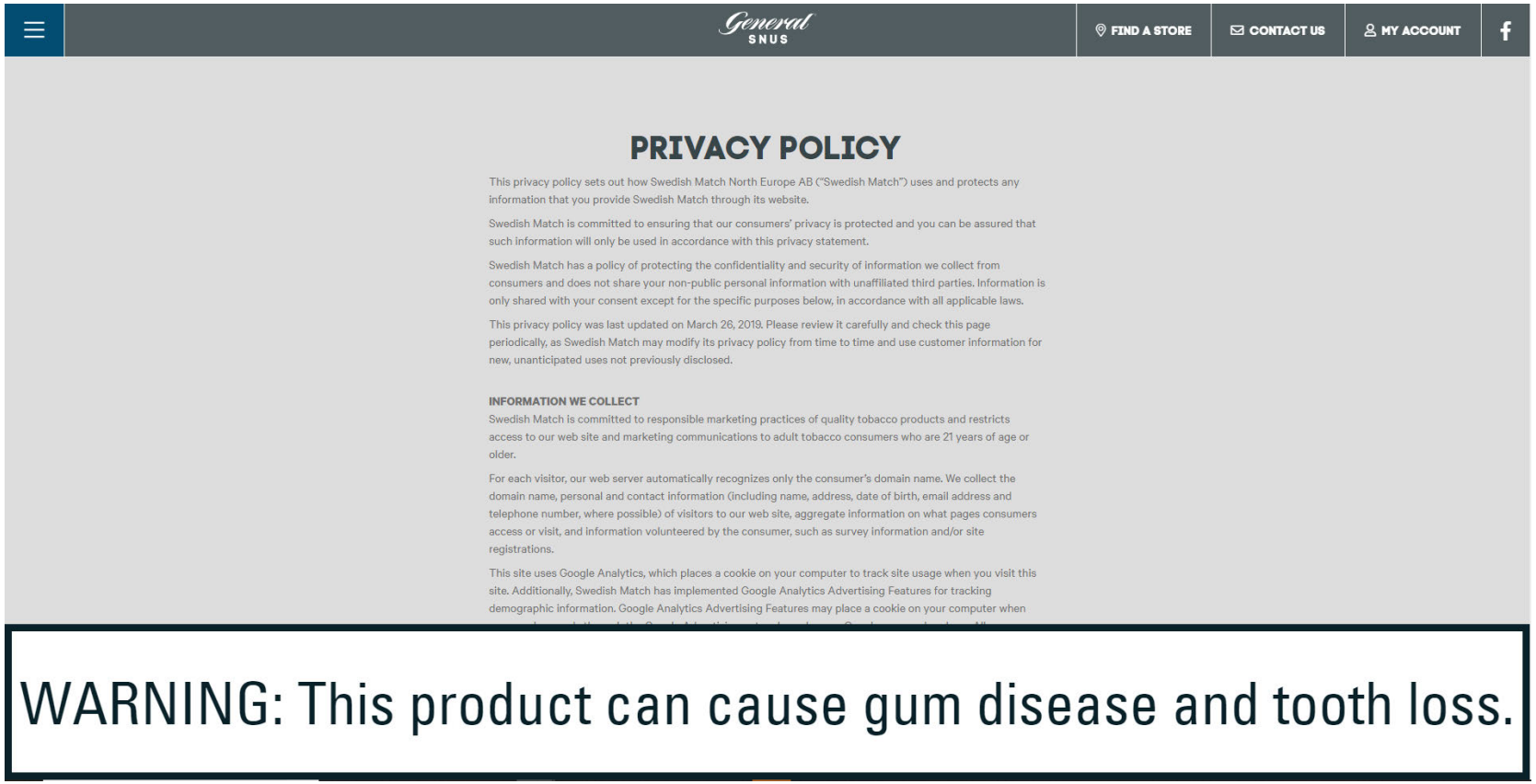
Swedish Match

FAQ PAGE: WEBSITE & ACCOUNT (outside age gate) Dec. 2020 – Oct. 2021

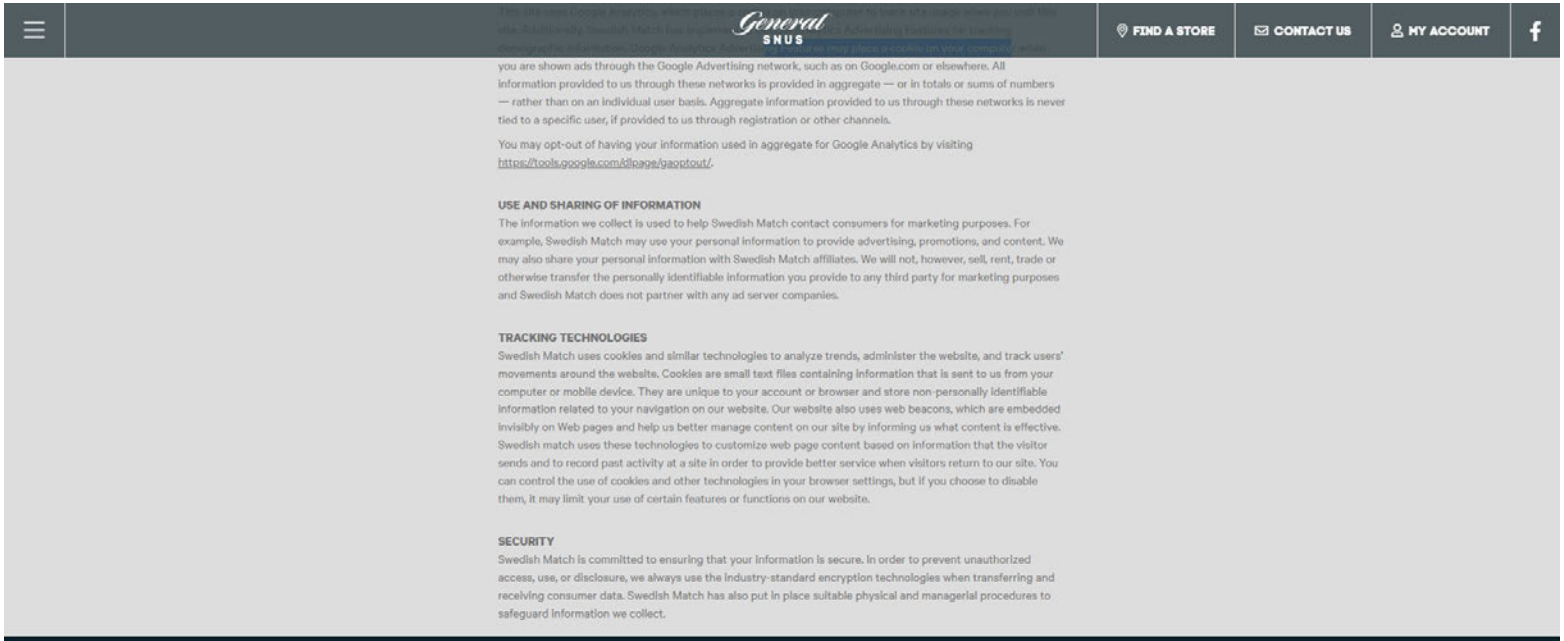


Privacy Policy

Outside Age Gate
Oct. 2020 – Oct. 2021



Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate



Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate

FIND A STORE | CONTACT US | MY ACCOUNT

OPTING OUT

If you no longer wish to receive e-mail from Swedish Match, you may opt out by letting us know using any of the following options: visiting the My Account section of this website, via email to info@smna.com; calling us at (270) 685-8777; or, writing us at Swedish Match North Europe AB, PO Box 986, Owensboro, KY 42302.
If you supplied us with your postal address, you may receive periodic mailings from us with information on new products and services or upcoming events. You can request to have your name removed from our mailing list by any of the methods above. Please make sure to provide us with your proper name and address when doing so.

YOUR CALIFORNIA PRIVACY RIGHTS

If you reside in California, you have the right to ask us one time each year if we have shared personal information with third parties for their direct marketing purposes. To make a request, please email or write to us at Swedish Match North Europe AB, PO Box 986 Owensboro, KY 42302. Indicate in your letter that you are a California resident making a "Shine the Light" inquiry.

PRIVACY POLICY FOR CALIFORNIA RESIDENTS

Effective Date: 1/1/2020
Last Reviewed on: 12/05/2019

This **Privacy Notice for California Residents** supplements the information contained in the Generalsnus.com Privacy Policy and applies solely to all visitors, users, and others who reside in the State of California ("consumers" or "you"). We adopt this notice to comply with the California Consumer Privacy Act of 2018 (**CCPA**) and terms defined in the **CCPA** have the same meaning when used in this notice.

INFORMATION WE COLLECT

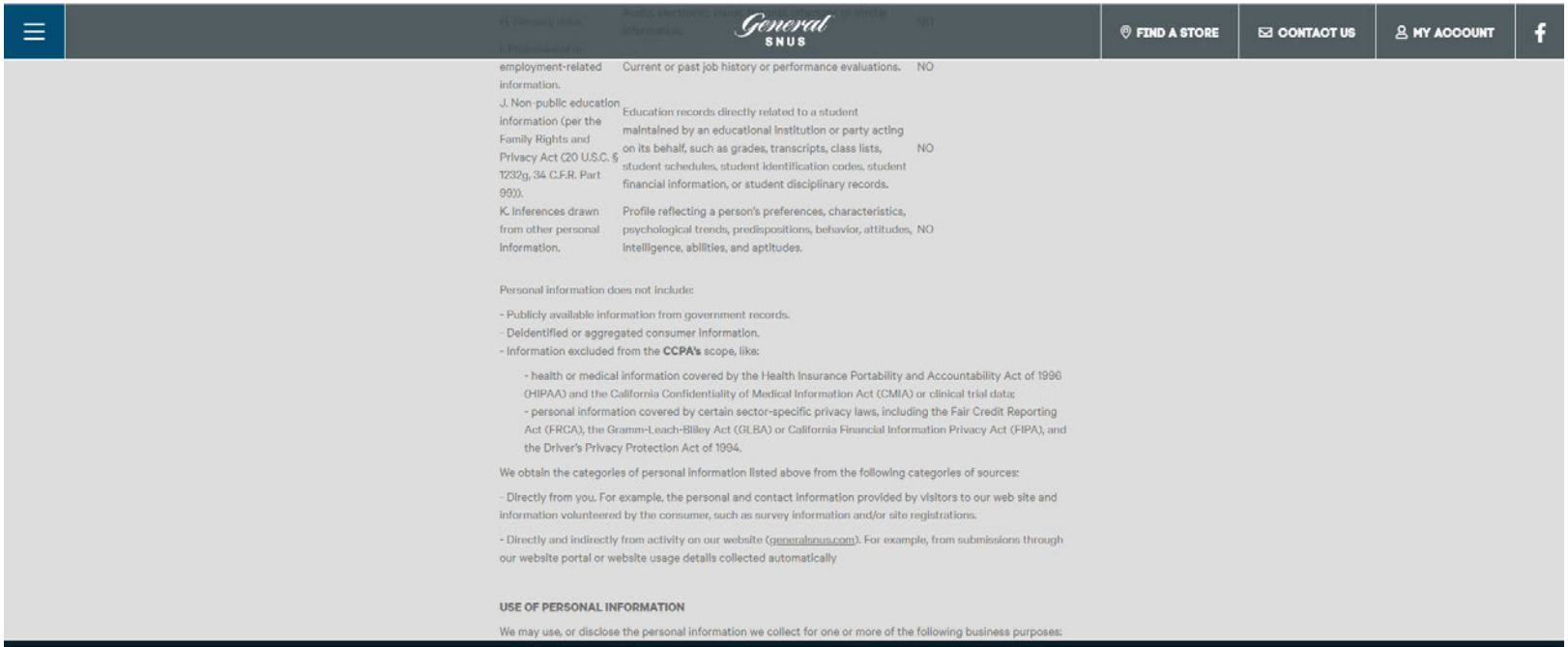
Our website collects information that identifies, relates to, describes, references, is capable of being associated with, or could reasonably by linked, directly or indirectly, with a particular consumer or device (**"personal information"**). In particular, GENERALSNUS.COM has collected the following categories of personal information from its consumers within the last twelve (12) months:

CATEGORY	EXAMPLES	COLLECTED
A. Identifiers.	A real name, alias, postal address, unique personal identifier, online identifier, Internet Protocol address, email address, account name, driver's license number, passport	YES

WARNING: This product can cause gum disease and tooth loss.

Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate

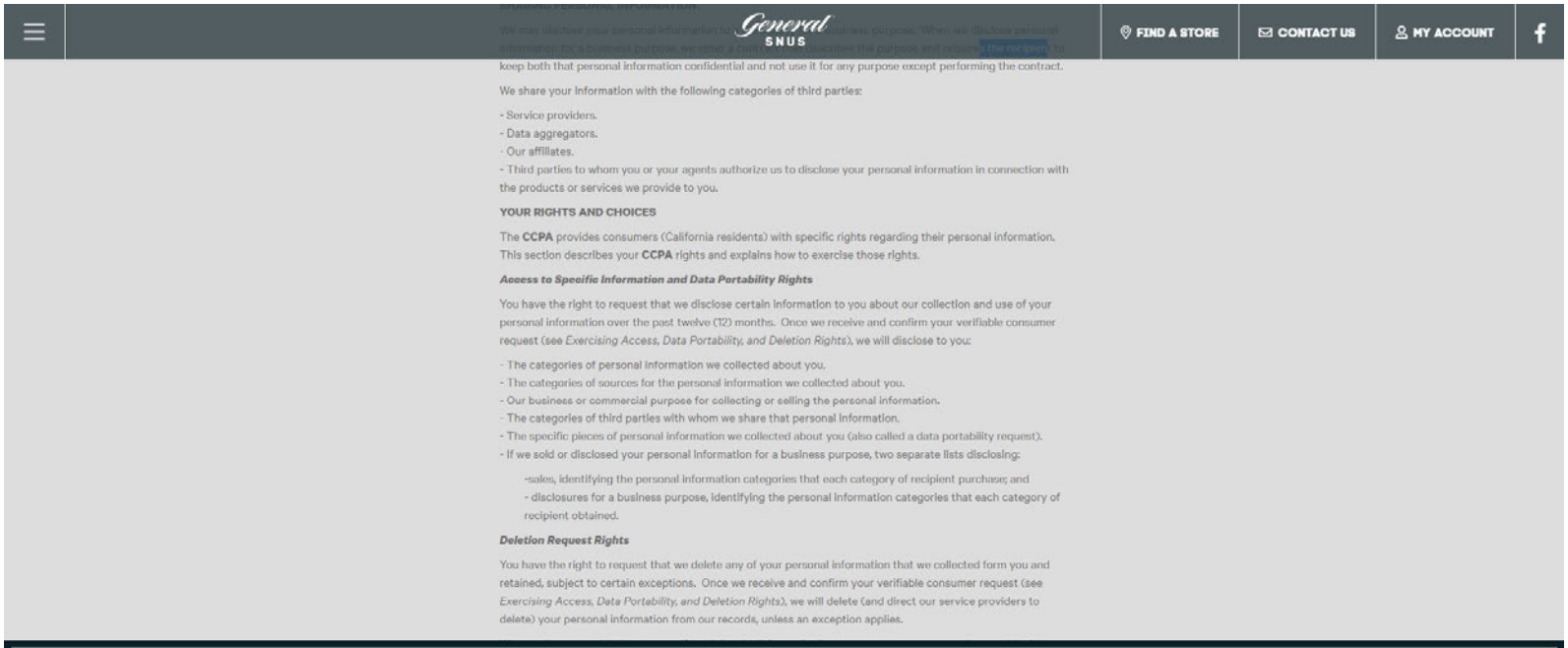
Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate



Swedish Match

Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate

Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate



Privacy Policy Cont. – Oct. 2020 – Oct. 2021

Outside Age Gate

Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate

Swedish Match

Privacy Policy Cont. – Oct. 2020 – Oct. 2021
Outside Age Gate

WARNING: This product can cause gum disease and tooth loss.

Swedish Match

Privacy Policy (outside & behind age gate) Oct. 2020 – Oct. 2021

This privacy policy sets out how Swedish Match North Europe AB ("Swedish Match") uses and protects any information that you provide Swedish Match through its website.

Swedish Match is committed to ensuring that our consumers' privacy is protected, and you can be assured that such information will only be used in accordance with this privacy statement.

Swedish Match has a policy of protecting the confidentiality and security of information we collect from consumers and does not share your non-public personal information with unaffiliated third parties. Information is only shared with your consent except for the specific purposes below, in accordance with all applicable laws.

This privacy policy was last updated on March 26, 2019. Please review it carefully and check this page periodically, as Swedish Match may modify its privacy policy from time to time and use customer information for new, unanticipated uses not previously disclosed.

INFORMATION WE COLLECT
Swedish Match is committed to responsible marketing practices of quality tobacco products and restricts access to our web site and marketing communications to adult tobacco consumers who are 21 years of age or older.

For each visitor, our web server automatically recognizes only the consumer's domain name. We collect the domain name, personal and contact information (including name, address, date of birth, email address and telephone number, where possible) of visitors to our web site, aggregate information on what pages consumers access or visit, and information volunteered by the consumer, such as survey information and/or site registrations.

This site uses Google Analytics, which places a cookie on your computer to track site usage when you visit this site. Additionally, Swedish Match has implemented Google Analytics Advertising Features for tracking demographic information. Google Analytics Advertising Features may place a cookie on your computer when you are shown ads through the Google Advertising network, such as on Google.com or elsewhere. All information provided to us through these networks is provided in aggregate — or in totals or sums of numbers — rather than on an individual user basis. Aggregate information provided to us through these networks is never tied to a specific user, if provided to us through registration or other channels.

You may opt-out of having your information used in aggregate for Google Analytics by visiting https://tools.google.com/dlpage/gaoptout/.

USE AND SHARING OF INFORMATION
The information we collect is used to help Swedish Match contact consumers for marketing purposes. For example, Swedish Match may use your personal information to provide advertising, promotions, and content. We may also share your personal information with Swedish Match affiliates. We will not, however, sell, rent, trade or otherwise transfer the personally identifiable information you provide to any third party for marketing purposes and Swedish Match does not partner with any ad server companies.

TRACKING TECHNOLOGIES
Swedish Match uses cookies and similar technologies to analyze trends, administer the website, and track users' movements around the website. Cookies are small text files containing information that is sent to us from your computer or mobile device. They are unique to your account or browser and store non-personally identifiable information related to your navigation on our website. Our website also uses web beacons, which are embedded invisibly on Web pages and help us better manage content on our site by informing us what content is effective. Swedish match uses these technologies to customize web page content based on information that the visitor sends and to record past activity at a site in order to provide better service when visitors return to our site. You can control the use of cookies and other technologies in your browser settings, but if you choose to disable them, it may limit your use of certain features or functions on our website.

Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

SECURITY
Swedish Match is committed to ensuring that your information is secure. In order to prevent unauthorized access, use, or disclosure, we always use the industry-standard encryption technologies when transferring and receiving consumer data. Swedish Match has also put in place suitable physical and managerial procedures to safeguard information we collect.

OPTING OUT
If you no longer wish to receive e-mail from Swedish Match, you may opt out by letting us know using any of the following options: visiting the My Account section of this website, via email to info@smna.com; calling us at (270) 685-8777; or, writing us at Swedish Match North Europe AB, PO Box 986, Owensboro, KY 42302.
If you supplied us with your postal address, you may receive periodic mailings from us with information on new products and services or upcoming events. You can request to have your name removed from our mailing list by any of the methods above. Please make sure to provide us with your proper name and address when doing so.

YOUR CALIFORNIA PRIVACY RIGHTS
If you reside in California, you have the right to ask us one time each year if we have shared personal information with third parties for their direct marketing purposes. To make a request, please email or write to us at Swedish Match North Europe AB, PO Box 986 Owensboro, KY 42302. Indicate in your letter that you are a California resident making a “Shine the Light” inquiry.

PRIVACY POLICY FOR CALIFORNIA RESIDENTS
Effective Date: 1/1/2020
Last Reviewed on: 12/05/2019

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INFORMATION WE COLLECT

Our website collects information that identifies, relates to, describes, references, is capable of being associated with, or could reasonably by linked, directly or indirectly, with a particular consumer or device (“personal information”). In particular, GENERALSNUS.COM has collected the following categories of personal information from its consumers within the last twelve (12) months:

CATEGORY EXAMPLES COLLECTED
A. Identifiers.
A real name, alias, postal address, unique personal identifier, online identifier, Internet Protocol address, email address, account name, driver’s license number, passport number, or other similar identifiers.
YES

B. Personal information listed in the California Customer Records statute (Cal. Civ. Code § 1798.80(e)).
A name, signature, physical characteristics or description, address, telephone number, passport number, driver’s license or state identification card number, education, employment or employment history.
Some personal information in this category may overlap with other categories.
YES

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Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

C. Protected classification characteristics under California or federal law.
Age (40 years or older), race, color, ancestry, national origin, citizenship, religion or creed, marital status, medical condition, physical or mental disability, sex (including gender, gender identity, gender expression, pregnancy or childbirth and related medical conditions), sexual orientation, veteran or military status, genetic information (including familiar genetic information).
NO

D. Commercial information.
Records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.
YES

E. Biometric information.
Genetic, physiological, behavioral, and biological characteristics, or activity patterns used to extract a template or other identifier or identifying information, such as, fingerprints, faceprints, and voiceprints, iris or retina scans, keystroke, gait, or other physical patterns, and sleep, health, or exercise data.
NO

F. Internet or other similar network activity.
Browsing history, search history, information on a consumer's interaction with a website, application, or advertisement.
YES

G. Geolocation data.
Physical location or movements.
YES

H. Sensory data.
Audio, electronic, visual, thermal, olfactory, or similar information.
NO

I. Professional or employment-related information.
Current or past job history or performance evaluations.
NO

J. Non-public education information (per the Family Rights and Privacy Act (20 U.S.C. § 1232g, 34 C.F.R. Part 99)).
Education records directly related to a student maintained by an educational institution or party acting on its behalf, such as grades, transcripts, class lists, student schedules, student identification codes, student financial information, or student disciplinary records.
NO

Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

K. Inferences drawn from other personal information.
Profile reflecting a person's preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.
NO

Personal information does not include:
- Publicly available information from government records.
- Deidentified or aggregated consumer information.
- Information excluded from the CCPA's scope, like:
- health or medical information covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the California Confidentiality of Medical Information Act (CMIA) or clinical trial data;
- personal information covered by certain sector-specific privacy laws, including the Fair Credit Reporting Act (FRCA), the Gramm-Leach-Bliley Act (GLBA) or California Financial Information Privacy Act (FIPA), and the Driver's

Privacy Protection Act of 1994.
We obtain the categories of personal information listed above from the following categories of sources:
- Directly from you. For example, the personal and contact information provided by visitors to our web site and information volunteered by the consumer, such as survey information and/or site registrations.
- Directly and indirectly from activity on our website (generalsnus.com). For example, from submissions through our website portal or website usage details collected automatically

USE OF PERSONAL INFORMATION

We may use, or disclose the personal information we collect for one or more of the following business purposes:

- To fulfill or meet the reason you provided the information. For example, if you share your name and contact information to request a price quote or ask a question about our products or services, we will use that personal information to respond to your inquiry. If you provide your personal information to purchase a product or service, we will use that information to process your payment and facilitate delivery. We may also save your information to facilitate new product orders or process returns.
- To provide, support, personalize, and develop our Website, products, and services.
- To create, maintain, customize, and secure your account with us.
- To process your requests, purchases, transactions, and payments and prevent transactional fraud.
- To provide you with support and to respond to your inquiries, including to investigate and address your concerns and monitor and improve our responses.
- To personalize your Website experience and to deliver the content and product and service offerings relevant to your interests, including targeted offers and ads through our Website, third-party sites, and via email or text message (with your consent, where required by law).
- To help maintain the safety, security, and integrity of our Website, products and services, databases and other technology assets, and business.
- For testing, research, analysis, and product development, including to develop and improve our Website, products, and services.
- To respond to law enforcement requests and as required by applicable law, court order, or governmental regulations.
- As described to you when collecting your personal information or as otherwise set forth in the CCPA.
- To evaluate or conduct a merger, divestiture, restructuring, reorganization, dissolution, or other sale or transfer of some or all of our assets, whether as a going concern or as part of bankruptcy, liquidation, or similar proceeding, in which personal information held by us about our Website users is among the assets transferred.

Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

We will not collect additional categories of personal information or use the personal information we collect for materially different, unrelated, or incompatible purposes without providing you notice.

SHARING PERSONAL INFORMATION

We may disclose your personal information to a third party for a business purpose. When we disclose personal information for a business purpose, we enter a contract that describes the purpose and requires the recipient to keep both that personal information confidential and not use it for any purpose except performing the contract.

We share your information with the following categories of third parties:

- Service providers.
- Data aggregators.
- Our affiliates.
- Third parties to whom you or your agents authorize us to disclose your personal information in connection with the products or services we provide to you.

YOUR RIGHTS AND CHOICES

The CCPA provides consumers (California residents) with specific rights regarding their personal information. This section describes your CCPA rights and explains how to exercise those rights.

Access to Specific Information and Data Portability Rights

You have the right to request that we disclose certain information to you about our collection and use of your personal information over the past twelve (12) months. Once we receive and confirm your verifiable consumer request (see Exercising Access, Data Portability, and Deletion Rights), we will disclose to you:

- The categories of personal information we collected about you.
- The categories of sources for the personal information we collected about you.
- Our business or commercial purpose for collecting or selling the personal information.
- The categories of third parties with whom we share that personal information.
- The specific pieces of personal information we collected about you (also called a data portability request).
- If we sold or disclosed your personal information for a business purpose, two separate lists disclosing:

-sales, identifying the personal information categories that each category of recipient purchase; and
- disclosures for a business purpose, identifying the personal information categories that each category of recipient obtained.

Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

Deletion Request Rights

You have the right to request that we delete any of your personal information that we collected form you and retained, subject to certain exceptions. Once we receive and confirm your verifiable consumer request (see Exercising Access, Data Portability, and Deletion Rights), we will delete (and direct our service providers to delete) your personal information from our records, unless an exception applies.

We may deny your deletion request if retaining the information is necessary to us or our service provider(s) to:

Complete the transaction for which we collected the personal information, provide a good or service that you requested, take actions reasonably anticipated within the context of our ongoing business relationship with you, or otherwise perform our contract with you.
Detect security incidents, protect against malicious, deceptive, fraudulent, or illegal activity, or prosecute those responsible for such activities.
Debug product to identify and repair errors that impair existing intended functionality.
Exercise free speech, ensure the right of another consumer to exercise their free speech rights, or exercise another right provided for by law.
Comply with the California Electronic Communications Privacy Act (Cal. Penal Code § 1546 et seq.).
Engage in public or peer-reviewed scientific, historical, or statistical research in the public interest that adheres to all other applicable ethics and privacy laws, when the information's deletion may likely render impossible or seriously impair the research's achievement, if you previously provided informed consent.
Enable solely internal uses that are reasonably aligned with consumer expectations based on your relationship with us.
Comply with a legal obligation.
Make other internal and lawful uses of that information that are compatible with the context in which you provided it.
Exercising Access, Data Portability, and Deletion Rights

To exercise the access, data portability, and deletion rights described above, please submit a verifiable consumer request to us by either:

- Calling us at (270) 685-8777

- Emailing us at info@smna.com

Only you, or a person registered with the California Secretary of State that you authorize to act on your behalf, may make a verifiable consumer request related to your personal information. You may also make a verifiable request on behalf of your minor child.

You may only make a verifiable consumer request for access or data portability twice within a twelve (12) month period. The verifiable consumer request must:

- Provide sufficient information that allows us to reasonably verify you are the person about whom we collected personal information or an authorized representative.

- Describe your request with sufficient detail that allows us to properly understand, evaluate, and respond to it.

Continued on next page

Privacy Policy Cont. (outside & behind age gate) Oct. 2020 – Oct. 2021

We cannot respond to your request or provide you with personal information if we cannot verify your identity or authority to make the request and confirm the personal information relates to you.

Making a verifiable consumer request does not require you to create an account with us. However, we do consider requests made through your password protected account sufficiently verified when the request relates to personal information associated with that specific account.

We will only use personal information provided in a verifiable consumer request to verify the requestor's identity or authority to make the request.

Response Timing and Format

We endeavor to respond to a verifiable consumer request within forty-five (45) days of its receipt. If we require more time (up to 90 days), we will inform you of the reason and extension period in writing.

If you have an account with us, we will deliver our written response to that account. If you do not have an account with us, we will deliver our written response by mail or electronically, at your option.

Any disclosures we provide will only cover the twelve (12) month period preceding the verifiable consumer request's receipt. The response we provide will also explain the reasons we cannot comply with a request, if applicable. For data portability requests, we will select a format to provide your personal information that is readily useable and should allow you to transmit the information from one entity without hindrance.

We do not charge a fee to process or respond to your verifiable consumer request unless its excessive, repetitive, or manifestly unfounded. If we determine that the request warrants a fee, we will tell you why we made that decision and provide you with a cost estimate before completing your request.

NON-DISCRIMINATION

We will not discriminate against you for exercising any of your CCPA rights. Unless permitted by the CCPA, we will not:

- Deny you goods or services.
- Charge you different prices or rates for goods or services, including granting discounts or other benefits, or imposing penalties.
- Provide you a different level of quality of goods or services.
- Suggest that you may receive a different price or rate for goods or service or a different level or quality of goods or services.

OTHER CALIFORNIA PRIVACY RIGHTS

California's "Shine the Light" law (Civil Code § 1798.83) permits users of our Website that are California residents to request certain information regarding our disclosure of personal information to third parties for their direct marketing purposes. To make such a request, please send an email to info@smna.com or write us at Swedish Match, P.O. Box 986, Owensboro, KY 42302.

CHANGES TO OUR PRIVACY NOTICE

We reserve the right to amend this privacy notice at our discretion at any time. When we make changes to this privacy notice, we will notify you by email or through a notice on our website homepage.

Continued on next page

Privacy Policy Cont. (outside & behind age gate)
Oct. 2020 – Oct. 2021

CONTACT INFORMATION

If you have any questions or comments about this privacy policy for California residents, the ways in which we collect and use your personal information, your choices and rights regarding such use, or with to exercise your rights under California law, please do not hesitate to contact us at:

Phone: (270) 685-8777

Website: http://www.generalsnus.com

Email: info@smna.com

Postal Address:

Swedish Match
P.O. Box 986
Owensboro, KY 42302

CONTACTING US
If you have any questions or concerns about Swedish Match's Privacy Policy, please contact us at info@smna.com or call us at (270) 685-8777.

General Snus Website
Dec. 2020 changes

- All MRTP content moved behind age gate
- General Snus Mint Can image removed from menu
- MRTP FAQ removed from FAQs outside age gate
- A/O FAQs answers (aside from Website & Account) moved behind age gate

Swedish Match

General Snus Website
Behind Age Gate
Oct. 2020 – Oct. 2021

Swedish Match

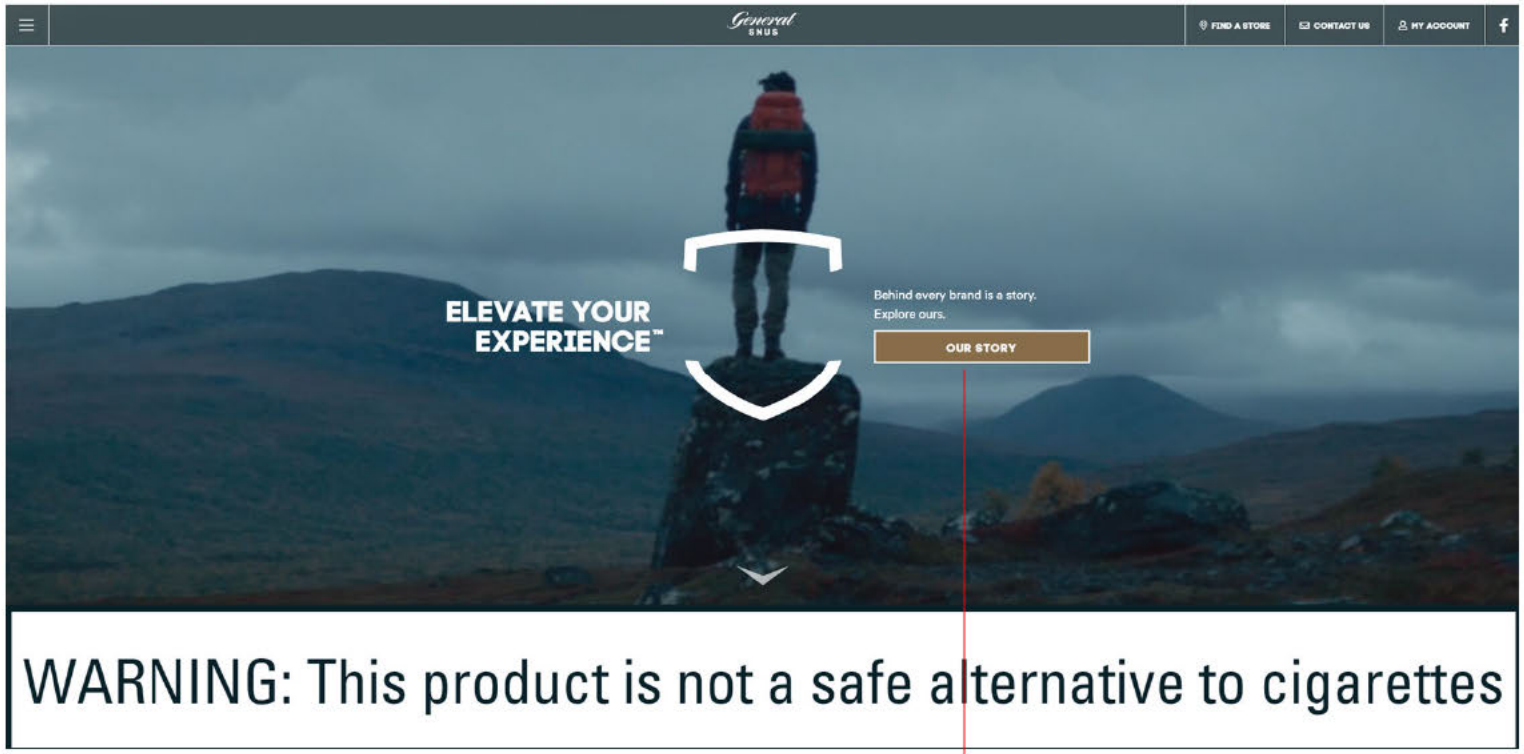
Home Page (behind age gate): Oct. 2020 – Oct. 2021

See file (behind age gate):

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

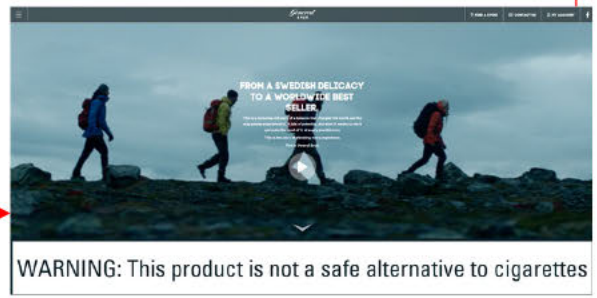
Links to 'FDA Order Info' (behind age gate)

Home Page (behind age gate): Oct. 2020 – Oct. 2021

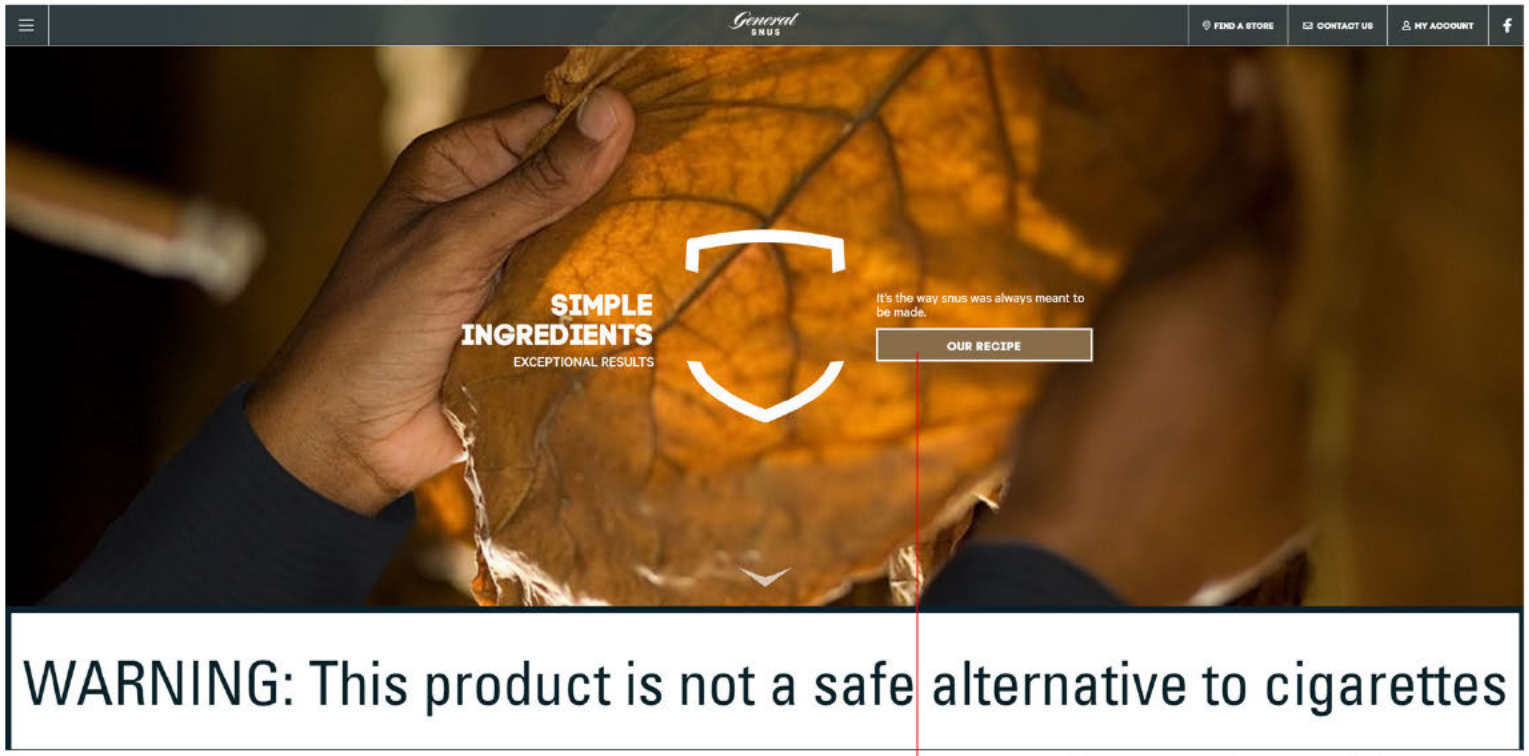


See file (behind age gate):
gen_website_2019_desktop_homepage-video.mp4

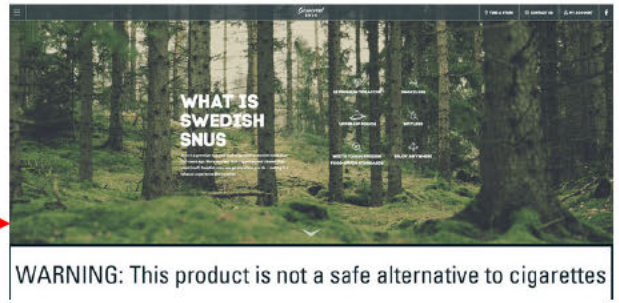
Links to 'Our Story' (behind age gate)



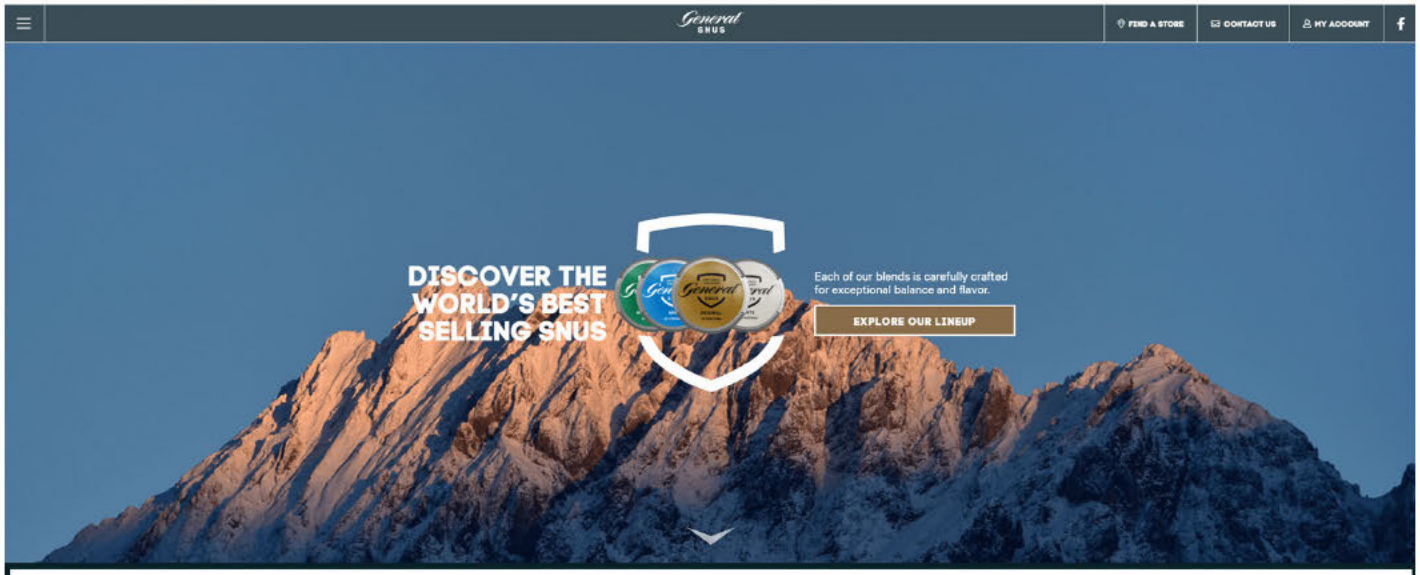
Home Page (behind age gate): Oct. 2020 – Oct. 2021



Links to 'What is Snus?' (behind age gate)



Home Page (behind age gate): Oct. 2020 – Oct. 2021



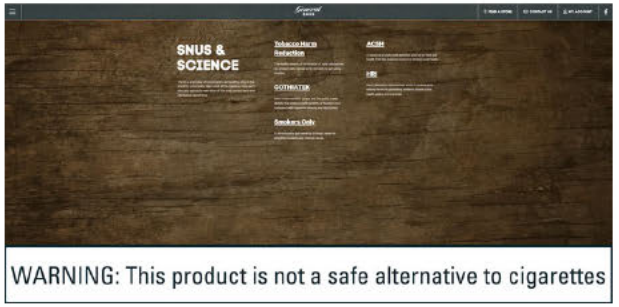
WARNING: This product is not a safe alternative to cigarettes

Links to 'Our Products' (behind age gate)

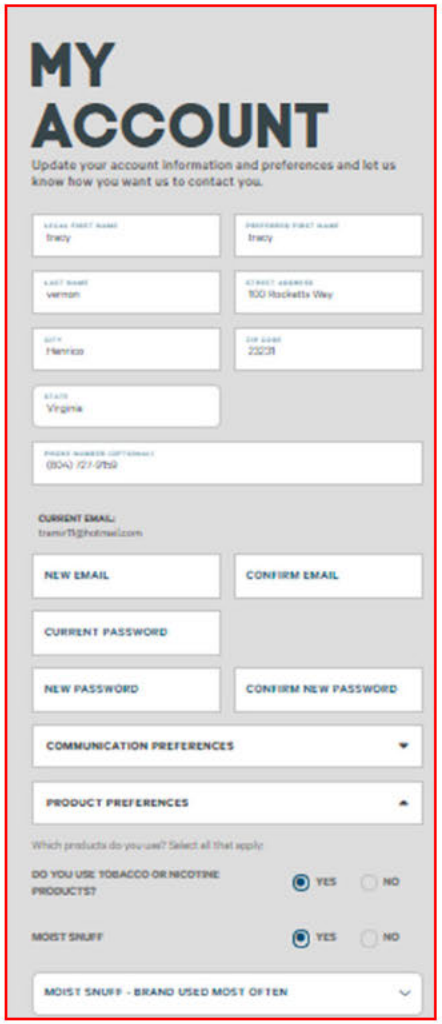
WARNING: This product is not a safe alternative to cigarettes

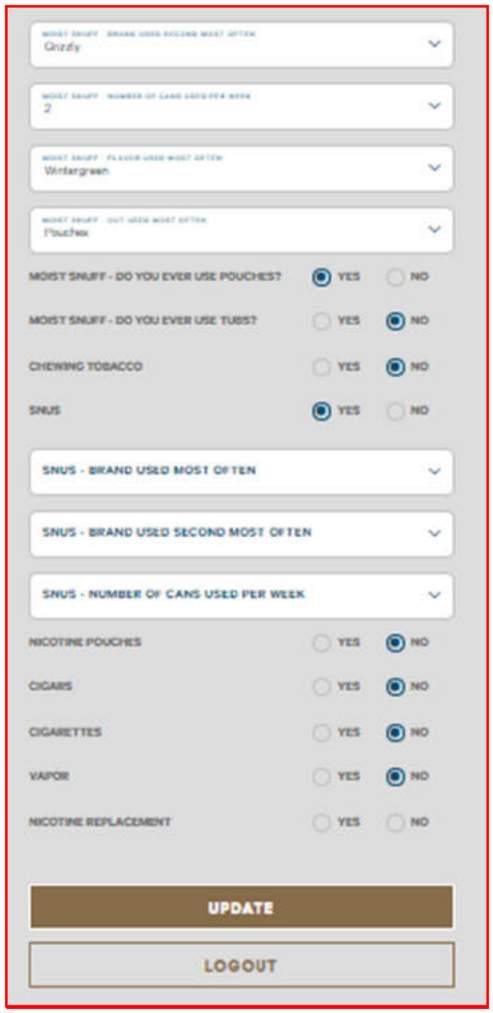
Home Page (behind age gate): Oct. 2020 – Oct. 2021

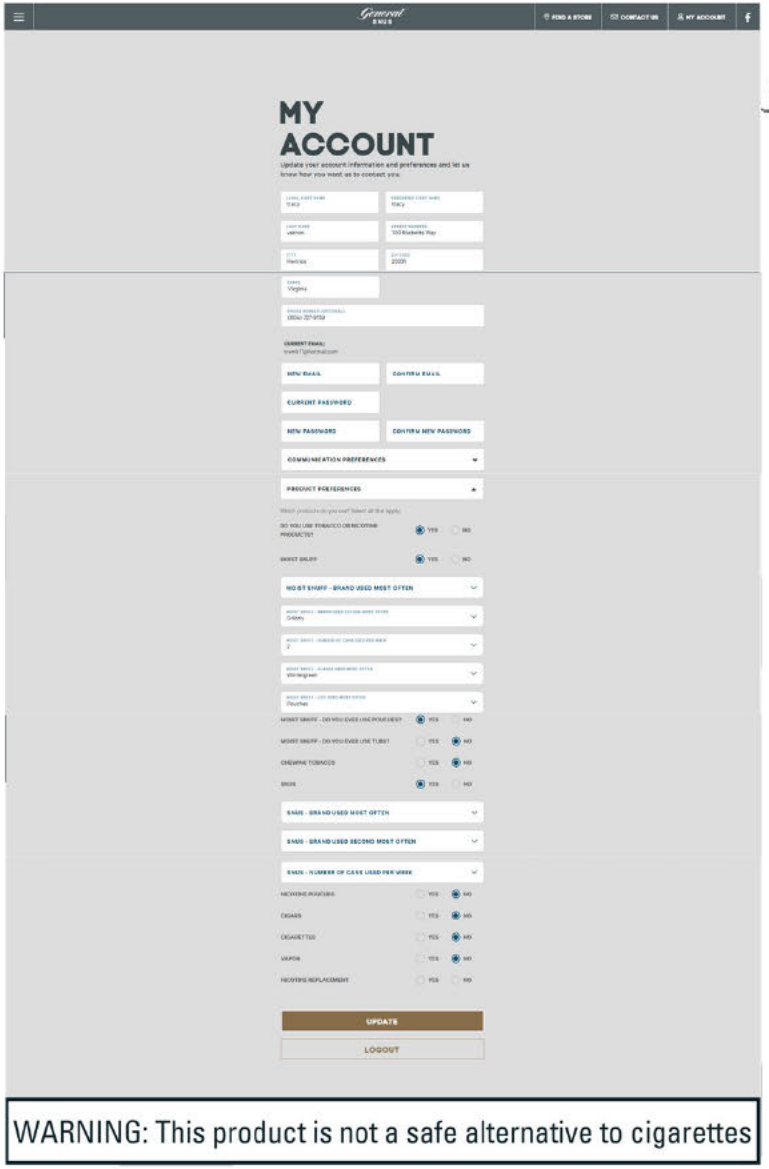
Links to 'Snus & Science' (behind age gate)



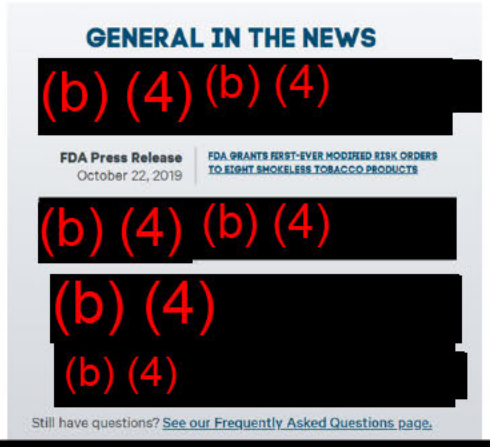
MY ACCOUNT PAGE (behind age gate) via Menu Oct. 2020 – Oct. 2021







MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021



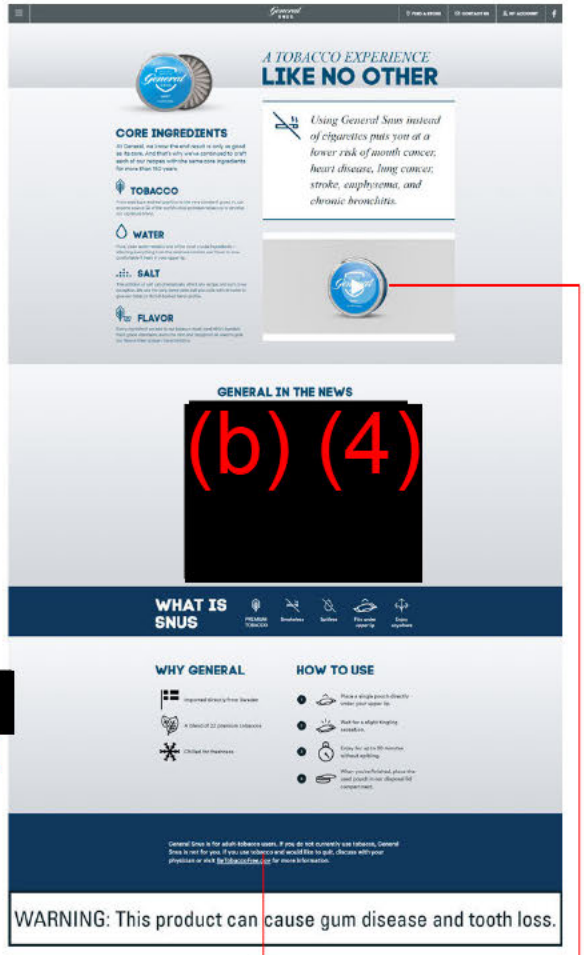
Links:

(b) (4)

fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

(b) (4)

See FAQ Page



General Snus is for adult-tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

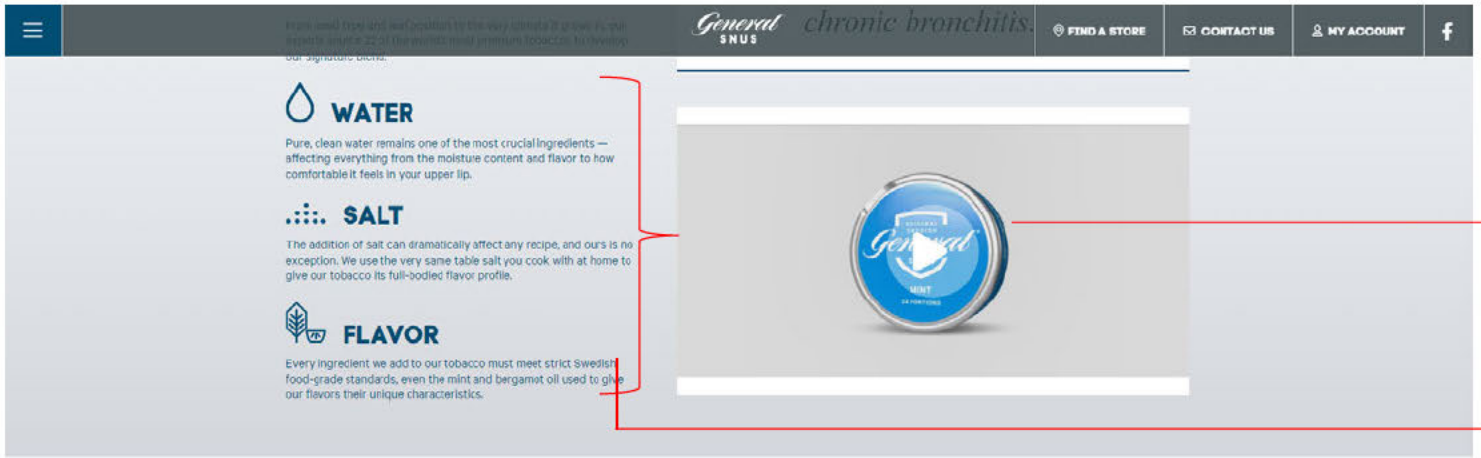
MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021

TOBACCO

From seed type and leaf position to the very climate it grows in, our experts source 22 of the world's most premium tobaccos to develop our signature blend.

Continued on next page

MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021



See file:

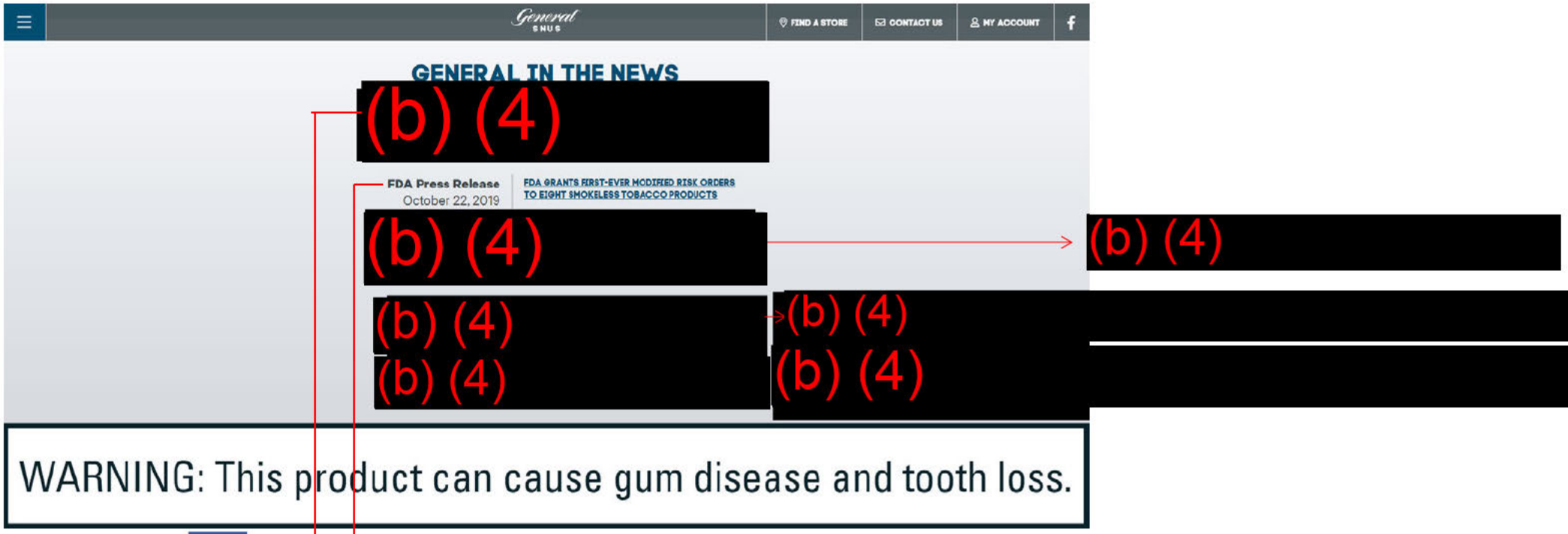
GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

GENERAL IN THE NEWS

WARNING: This product can cause gum disease and tooth loss.

Continued on next page

MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021



fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

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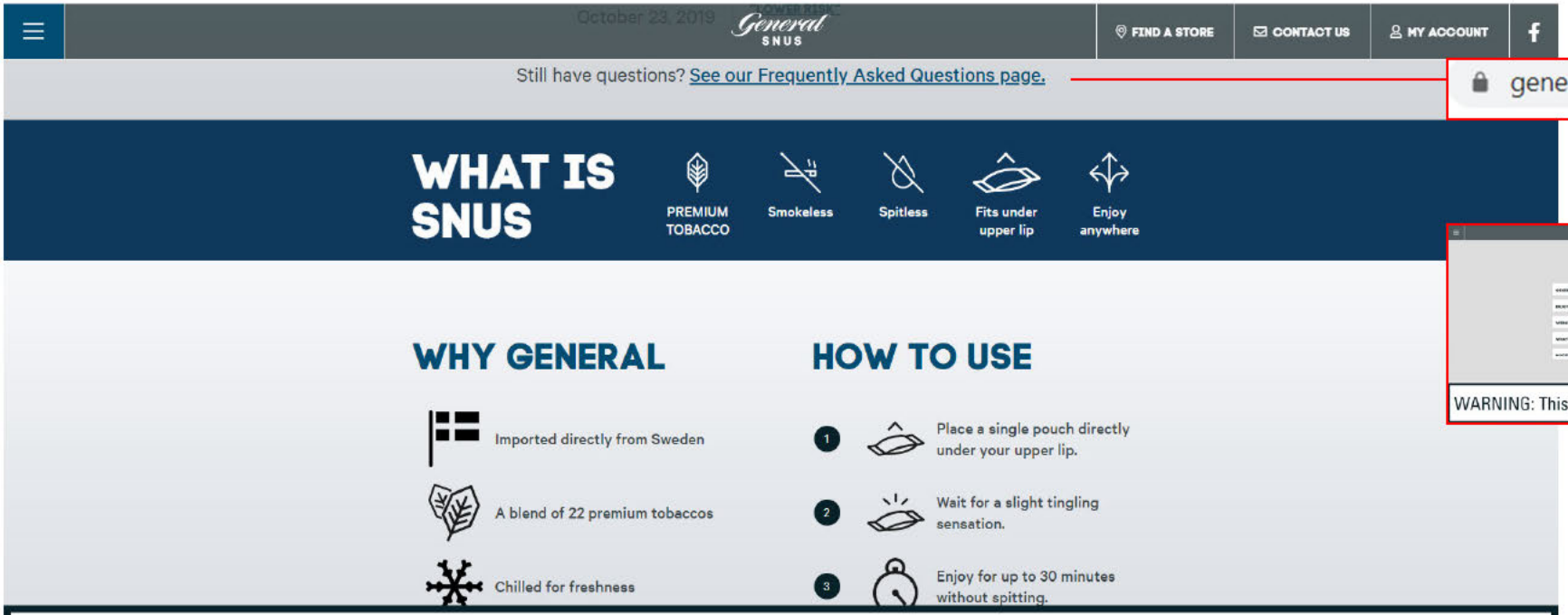
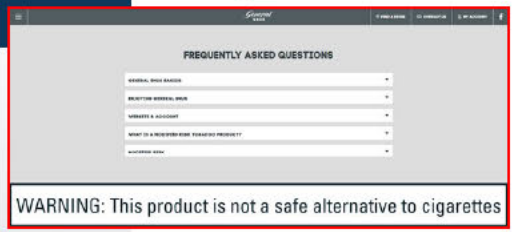
MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021



generalsnus.com/Questions/



See FAQ Page (behind age gate, page)

WARNING: This product can cause gum disease and tooth loss.

Continued on next page

MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021

betobaccofree.hhs.gov

Video Storyboards for MRTP Video – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

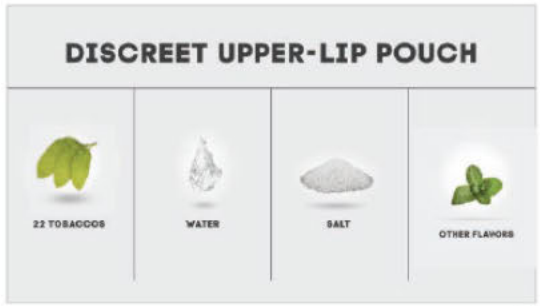
Audio Voice Over	
"Since 1866, General Snus, the Original Swedish Snus, has continued to create a tobacco experience like no other.	 01
Smokeless, spitless, and chilled for freshness,	 02
General's discreet upper-lip pouch is made with only the best:	 03

Continued on next page

Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

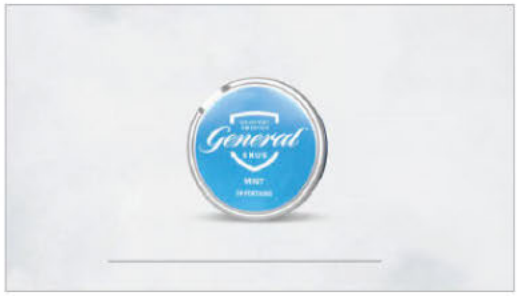
Audio Voice Over	
	 04
A blend of 22 air-dried tobaccos, pure, clean water, a hint of salt, and other natural and artificial flavors found in everyday food items.	 05
	 06

Continued on next page

Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

Audio Voice Over	
But the true difference is in our process.	07
General's blend is steam-heated and cooled,	 08
making a product that meets tough Swedish food-grade standards.	09

Continued on next page

Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

Audio Voice Over	
Learn more at GeneralSnus.com.	13
WARNING: Smokeless tobacco is addictive.	14

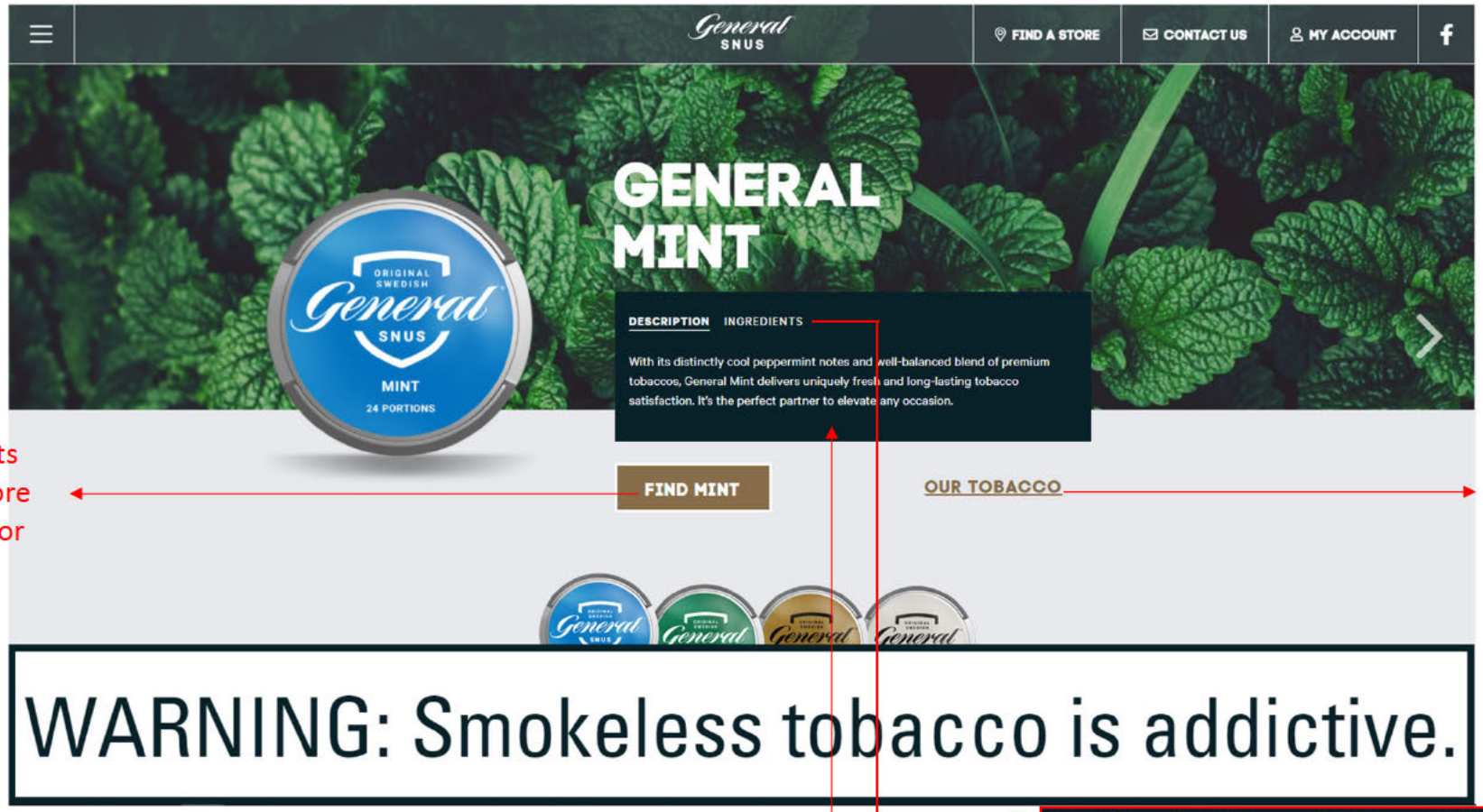
GENERAL SNUS all tobacco page CHANGES – BEHIND AGE GATE:
Jan. 2021 – Oct. 2021

Links to each respective flavor page

See Our Process page

Swedish Match

GENERAL SNUS mint product page CHANGES – BEHIND AGE GATE: Jan. 2021 – Oct. 2021



Directs to Store Locator page

Directs back to main Our Tobacco Page

[redacted]

With its distinctly cool peppermint notes and well-balanced blend of premium tobaccos, General Mint delivers uniquely fresh and long-lasting tobacco satisfaction. It's the perfect partner to elevate any occasion.

Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate and Magnesium Carbonate), Natural and Artificial Flavors, Artificial Sweetener (Acesulfame K)

GENERAL SNUS wintergreen flavor page CHANGES – BEHIND AGE GATE: Jan. 2021 – Oct. 2021

Directs to Store Locator page

Directs back to main Our Tobacco Page

[redacted]

Our most invigorating blend starts with an earthy tobacco flavor and ends with a subtly satisfying wintergreen finish. General Wintergreen also features traces of rich leather and wood smoke to give you an unforgettable tobacco experience in every portion.

Water, Tobacco, Taste Enhancer (Salt), Natural and Artificial Flavors including Artificial Smoke Flavor, Humectant (Propylene Glycol), pH Adjuster (Sodium Carbonate) Artificial Sweetener (Acesulfame K)

GENERAL SNUS original flavor page CHANGES – BEHIND AGE GATE: Jan. 2021 – Oct. 2021

Directs to Store Locator page

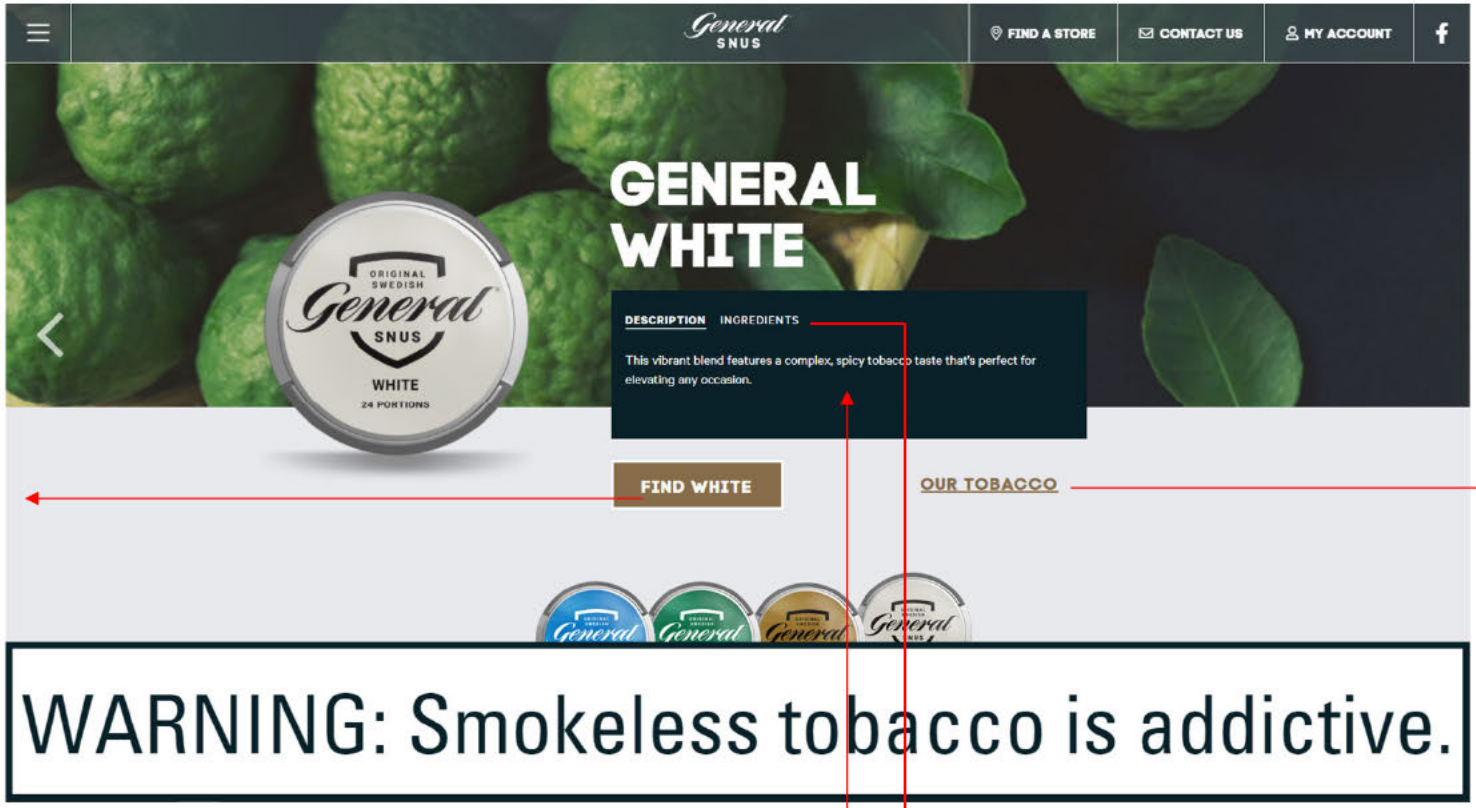
Directs back to main Our Tobacco Page

[redacted]

The snus that started it all. General Original's unique blend of 22 tobaccos offers you a rich natural experience. And with its fast-release pouches, it's ready when you are.

Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate and Magnesium Carbonate), Natural and Artificial Flavors, Artificial Smoke Flavor

GENERAL SNUS white flavor page CHANGES – BEHIND AGE GATE: Jan. 2021 – Oct. 2021



Directs to Store Locator page

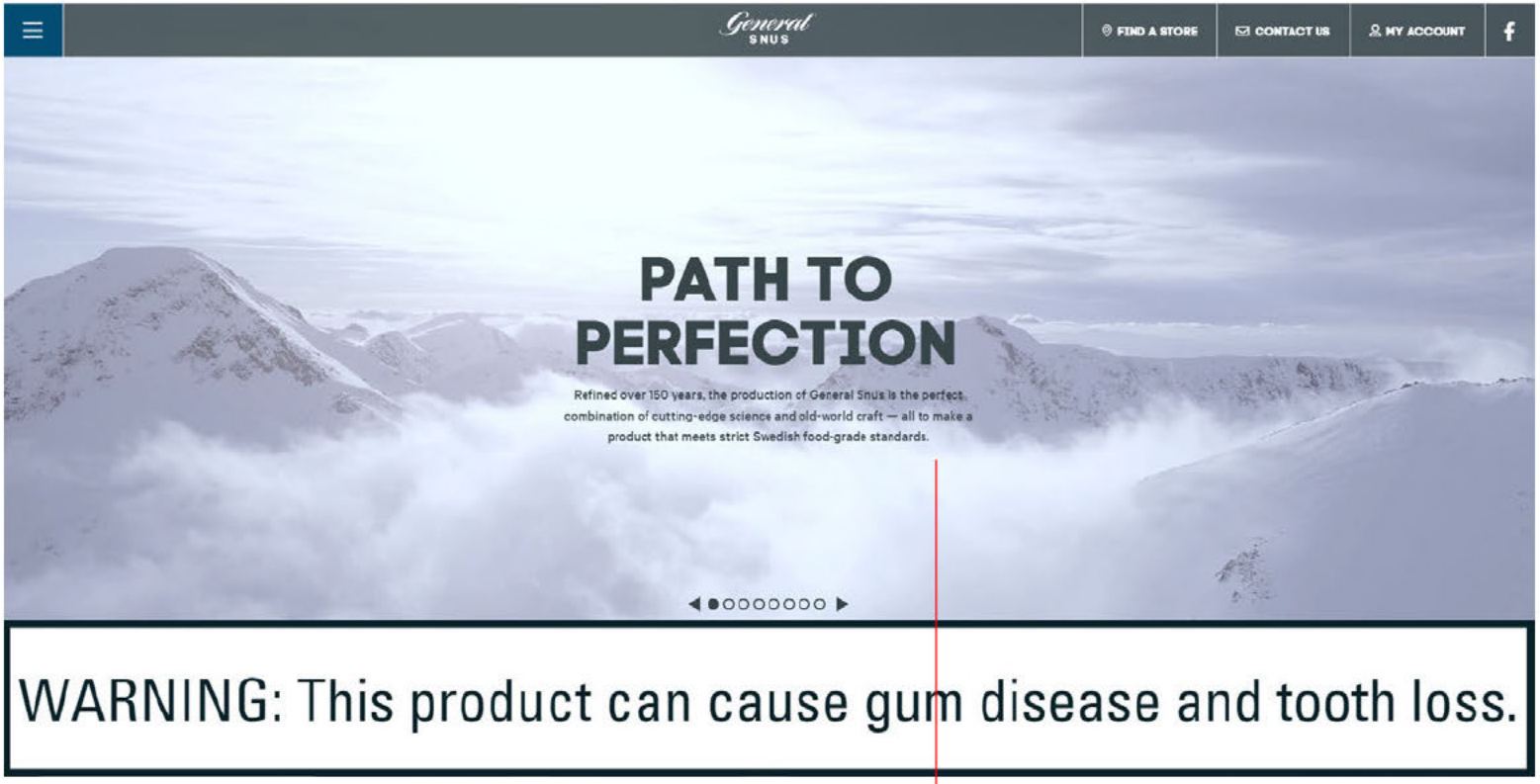
Directs back to main Our Tobacco Page

This vibrant blend features a complex, spicy tobacco taste that's perfect for elevating any occasion.

Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate), Natural and Artificial Flavors, Artificial Smoke Flavor

[redacted]

Menu: Our Process (behind age gate) Oct. 2020 – Oct. 2021



See file:

OurProcess_Path_to_Perfection.mp4

Refined over 150 years, the production of General Snus is the perfect combination of cutting-edge science and old-world craft — all to make a product that meets strict Swedish food-grade standards.

Menu: Our Process Harvest (behind age gate) Oct. 2020 – Oct. 2021

Tobacco seeds carefully sourced from around the world are grown under strict supervision for two full months.

See file:

OurProcess_Harvest.mp4

Menu: Our Process Curing & Grinding (behind age gate) Oct. 2020 – Oct. 2021

See file:

OurProcess_CuringGrinding.mp4

The harvested tobacco is air cured for up to eight weeks and then fed into a mill to be ground into fine grains.

Menu: Our Process Salt & Water (behind age gate) Oct. 2020 – Oct. 2021

See file:

OurProcess_SaltWater.mp4

Salt and water are added to the fine tobacco powder for moisture, flavor and to preserve freshness.

Menu: Our Process Heating & Cooling (behind age gate) Oct. 2020 – Oct. 2021

See file:

OurProcess_HeatingCooling.mp4

The tobacco blend is then steam-heated and immediately cooled to help ensure consistent quality.

Menu: Our Process Other Flavors (behind age gate) Oct. 2020 – Oct. 2021

See file:

OurProcess_OtherFlavors.mp4

Natural and artificial flavors found in everyday food products are added to enhance the flavor and aroma.

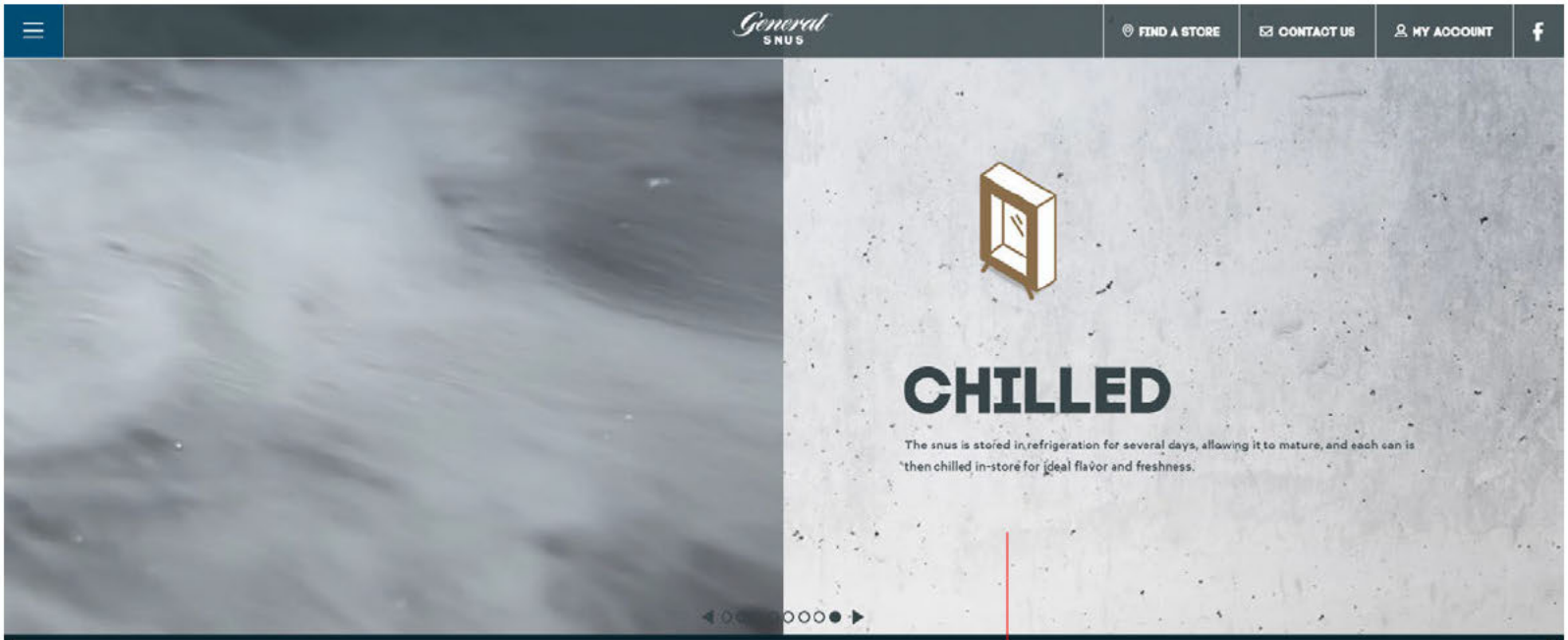
Our Process Packaging (behind age gate) Oct. 2020 – Oct. 2021

See file:

OurProcess_Packaging.mp4

Samples of the blend undergo a strict quality check before pouches are filled, sealed, cut and arranged into our signature star formation.

Our Process Chilled (behind age gate) Oct. 2020 – Oct. 2021



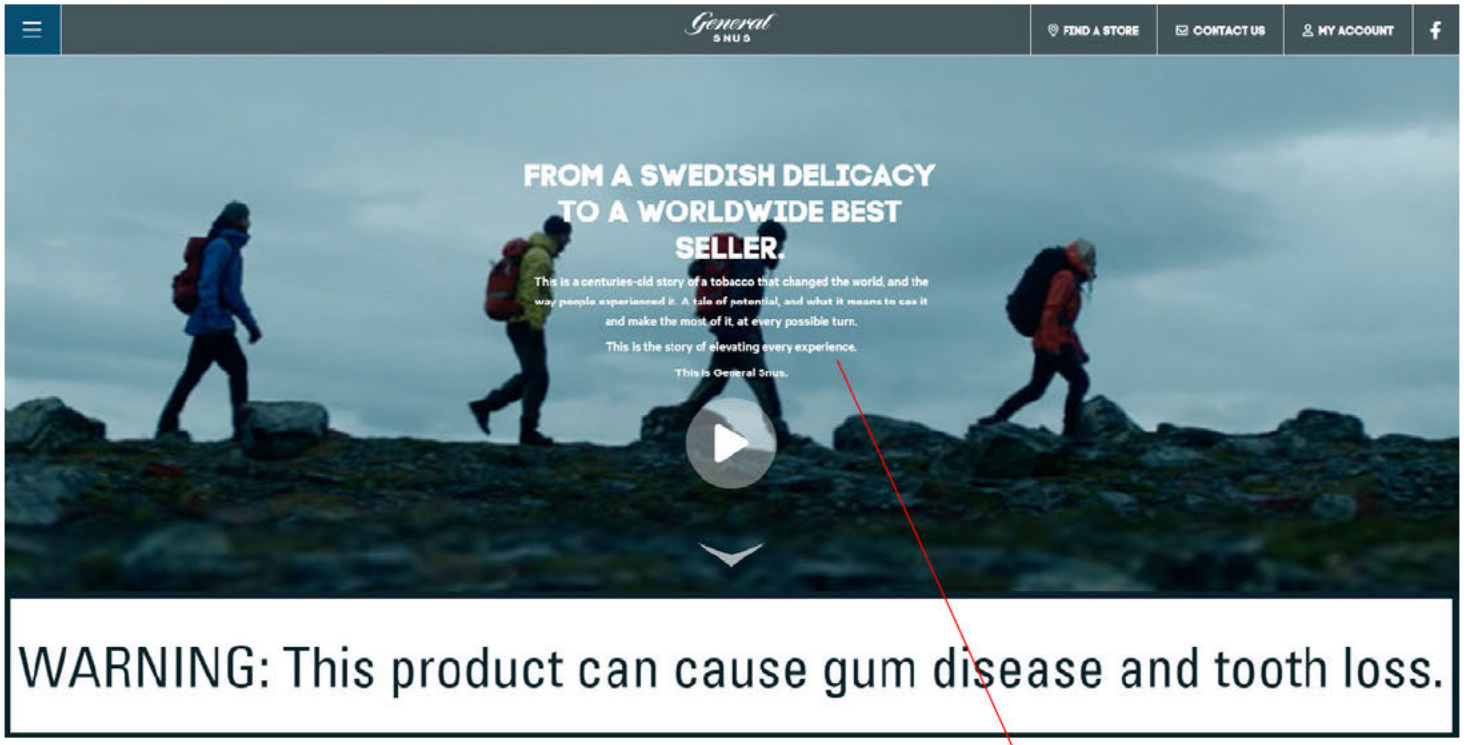
WARNING: This product can cause gum disease and tooth loss.

See file:

OurProcess_Chilled.mp4

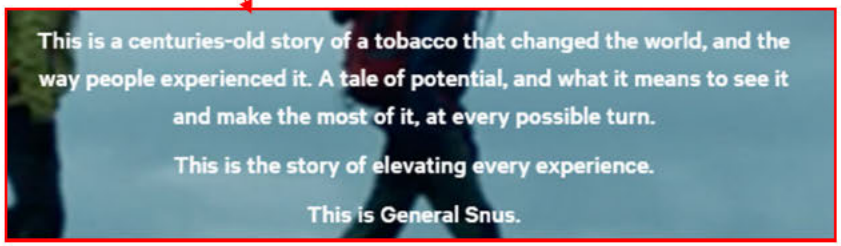
The snus is stored in refrigeration for several days, allowing it to mature, and each can is then chilled in-store for ideal flavor and freshness.

Our Story: Into (behind age gate) Oct. 2020 – Oct. 2021



See file:

OurStory_This_is_Sweden_NOPRODUCT_1.mp4



Our Story: Timeline 1862 (behind age gate) Oct. 2020 – Oct. 2021

Unsatisfied with the tobacco of his time, revered Swedish craftsman Johan A. Boman sets out to craft a higher quality product.

Our Story: Timeline 1866 (behind age gate) Oct. 2020 – Oct. 2021

1862 – THE JOURNEY BEGINS

1866 – GENERAL DEBUTS

LATE 1800S – COMING TO AMERICA

1970 – THE PERFECT PORTION

1982 – CHILLED TO PERFECTION

LATE 1990S– A HIGHER STANDARD

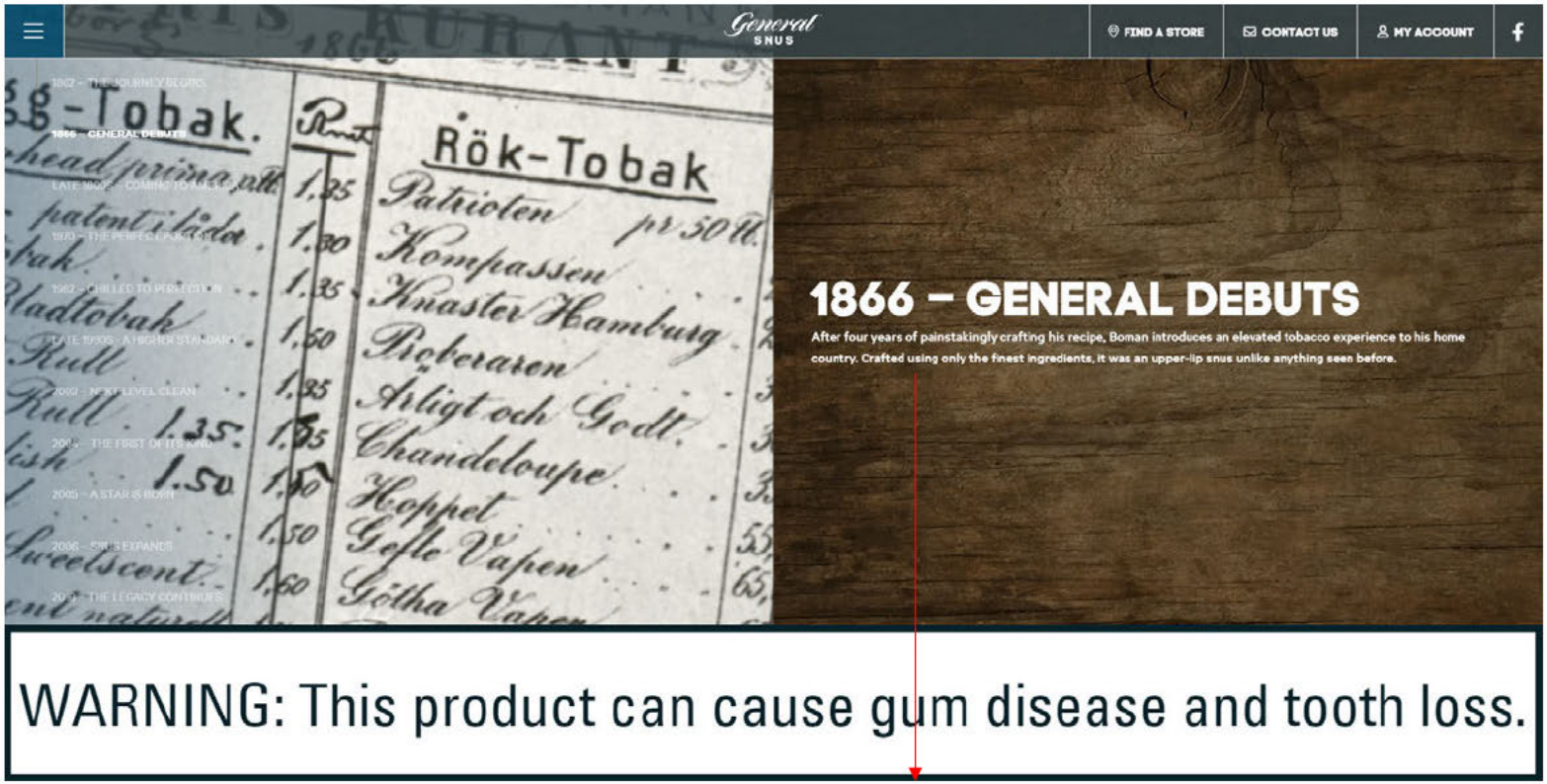
2003 – NEXT LEVEL CLEAN

2004 – THE FIRST OF ITS KIND

2005 – A STAR IS BORN

2006 – SNUS EXPANDS

2016 – THE LEGACY CONTINUES

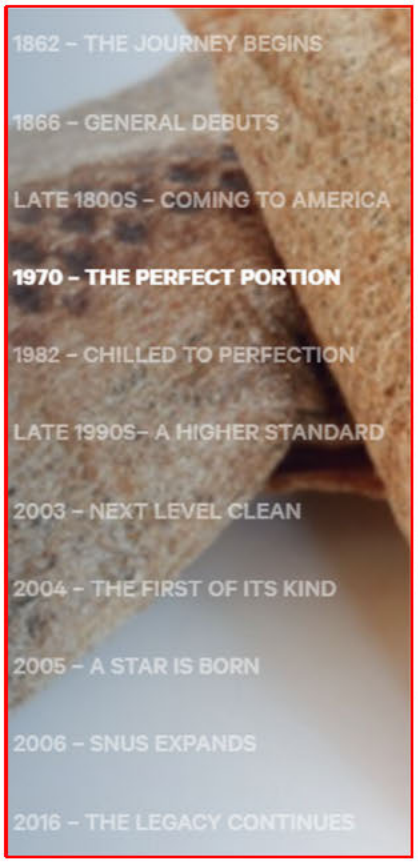


After four years of painstakingly crafting his recipe, Boman introduces an elevated tobacco experience to his home country. Crafted using only the finest ingredients, it was an upper-lip snus unlike anything seen before.

Our Story: Timeline Late 1800s (behind age gate) Oct. 2020 – Oct. 2021

Snus becomes an identifying mark for the millions of Swedes immigrating to America. Main streets in Swedish neighborhoods even earn the name "Snus Boulevard."

Our Story: Timeline 1970 (behind age gate) Oct. 2020 – Oct. 2021



The first portion-packed pouch is developed in Sweden, making snus convenient and more appealing to the broader public.

Our Story: Timeline Linee 1982 (behind age gate) Oct. 2020 – Oct. 2021

1862 – THE JOURNEY BEGINS

1866 – GENERAL DEBUTS

LATE 1800S – COMING TO AMERICA

1970 – THE PERFECT PORTION

1982 – CHILLED TO PERFECTION

LATE 1990S– A HIGHER STANDARD

2003 – NEXT LEVEL CLEAN

2004 – THE FIRST OF ITS KIND

2005 – A STAR IS BORN

2006 – SNUS EXPANDS

2016 – THE LEGACY CONTINUES

General Snus begins selling its snus in temperature-controlled chillers, ensuring the product is at its freshest, the very moment it's purchased. Once opened, it will stay fresh for up to a week without refrigeration.

Our Story: Timeline Late 1990s (behind age gate) Oct. 2020 – Oct. 2021

Swedish Match introduces the Gothiatek Standard, which guarantees that every can of General Snus exceeds even the toughest Swedish food-grade requirements. It also promises to ensure every can meets our standards through a quality-controlled process, starting with the very soil where the tobacco seed is planted.

Our Story: Timeline 2003 (behind age gate) Oct. 2020 – Oct. 2021

1862 – THE JOURNEY BEGINS

1866 – GENERAL DEBUTS

LATE 1800S – COMING TO AMERICA

1970 – THE PERFECT PORTION

1982 – CHILLED TO PERFECTION

LATE 1990S– A HIGHER STANDARD

2003 – NEXT LEVEL CLEAN

2004 – THE FIRST OF ITS KIND

2005 – A STAR IS BORN

2006 – SNUS EXPANDS

2016 – THE LEGACY CONTINUES

General Snus is the first to take cleanliness to the next level by introducing "white portions" – a new process that delivers cleaner, white pouches that are still sold today in wintergreen, white and mint.

Our Story: Timeline 2004 (behind age gate) Oct. 2020 – Oct. 2021

1862 – THE JOURNEY BEGINS

1866 – GENERAL DEBUTS

LATE 1800S – COMING TO AMERICA

1970 – THE PERFECT PORTION

1982 – CHILLED TO PERFECTION

LATE 1990S– A HIGHER STANDARD

2003 – NEXT LEVEL CLEAN

2004 – THE FIRST OF ITS KIND

2005 – A STAR IS BORN

2006 – SNUS EXPANDS

2016 – THE LEGACY CONTINUES

General develops a new type of can with a unique disposal compartment that holds used portions of snus.

Our Story: Timeline 2005 (behind age gate) Oct. 2020 – Oct. 2021

WARNING: This product can cause gum disease and tooth loss.

General's signature Star Formation makes its first appearance in select cans. Not only does it maximize the number of portions per can, but each pouch is shaped to fit more comfortably under the upper lip.

Our Story: Timeline 2006 (behind age gate) Oct. 2020 – Oct. 2021

1862 – THE JOURNEY BEGINS

1866 – GENERAL DEBUTS

LATE 1800S – COMING TO AMERICA

1970 – THE PERFECT PORTION

1982 – CHILLED TO PERFECTION

LATE 1990S– A HIGHER STANDARD

2003 – NEXT LEVEL CLEAN

2004 – THE FIRST OF ITS KIND

2005 – A STAR IS BORN

2006 – SNUS EXPANDS

2016 – THE LEGACY CONTINUES

General Snus is first introduced to retailers in the United States. Today, it can be found in more than 20,000 stores nationwide and has earned the title of best-selling snus in the world.

Swedish Match

Our Story: Timeline 2016 (behind age gate) Oct. 2020 – Oct. 2021

General Snus celebrates 150 years of elevating the tobacco experience, and pledges to continue its pursuit for years to come.

What is Snus? (behind age gate) Oct. 2020 – Oct. 2021

Delivers tobacco satisfaction like a cigarette, without the smoke.

A unique blend sourced from around the world.

Upper-lip placement means less saliva, and no need to spit.

Placed in the upper lip for maximum discretion.

Clean, discreet pouches that can go anywhere you do.

Snus is a premium tobacco that originated in Sweden more than 200 years ago. More discreet than cigarettes and cleaner than moist snuff, Swedish snus can go anywhere you do – making it a tobacco experience like no other.

Crafted in Sweden using a process similar to pasteurization to ensure consistent quality.

Swedish Match

What is Snus?: Ingredients(behind age gate) Oct. 2020 – Oct. 2021

Directs to Ingredients Tobacco Page

Directs to Ingredients Water Page

Directs to Ingredients Flavor Page

Directs to Ingredients Salt Page

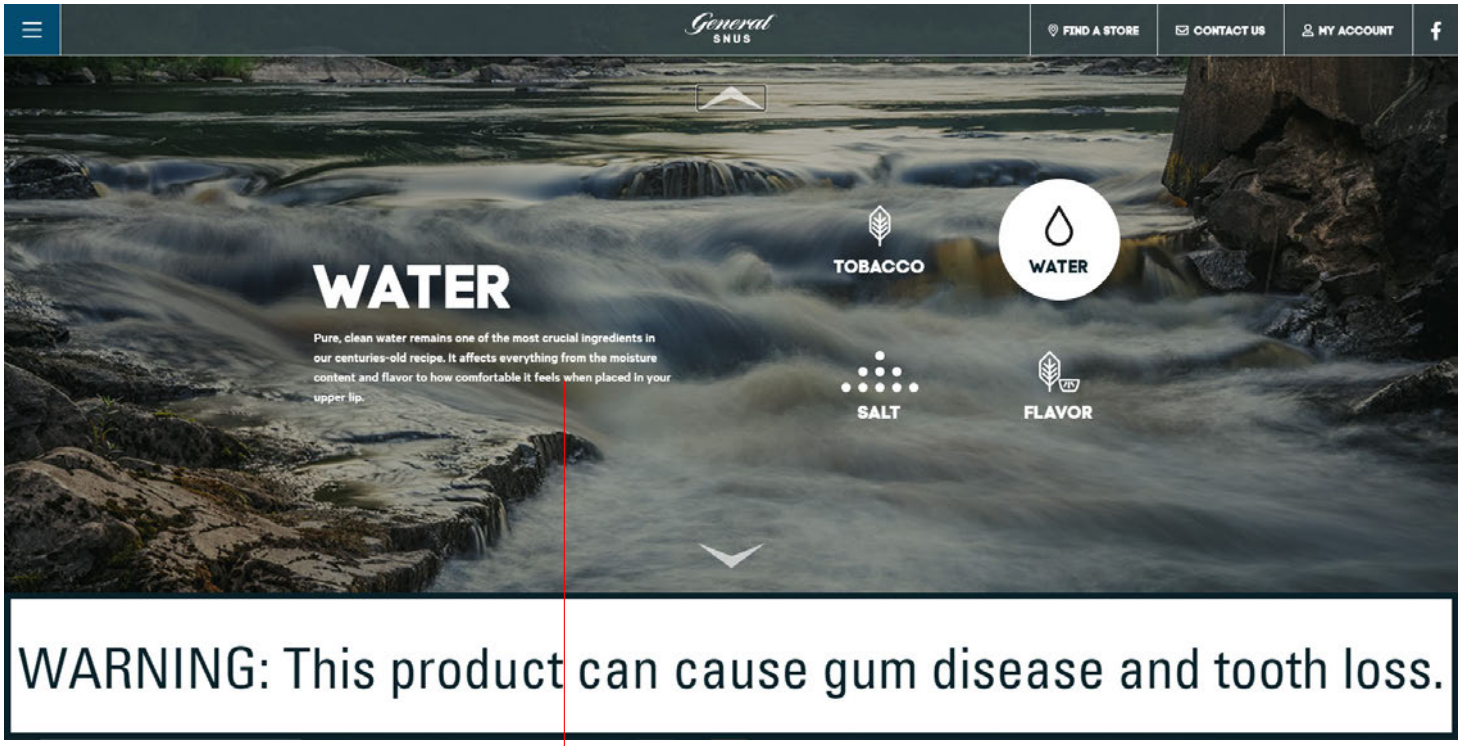
Today, it's a recipe that's earned us the title of best-selling snus in the world. But the true secret isn't in the carefully sourced, hand-selected ingredients. It's the ability to recognize when someone gets it right the first time.

[redacted]

What is Snus?: Ingredients Tobacco (behind age gate) Oct. 2020 – Oct. 2021

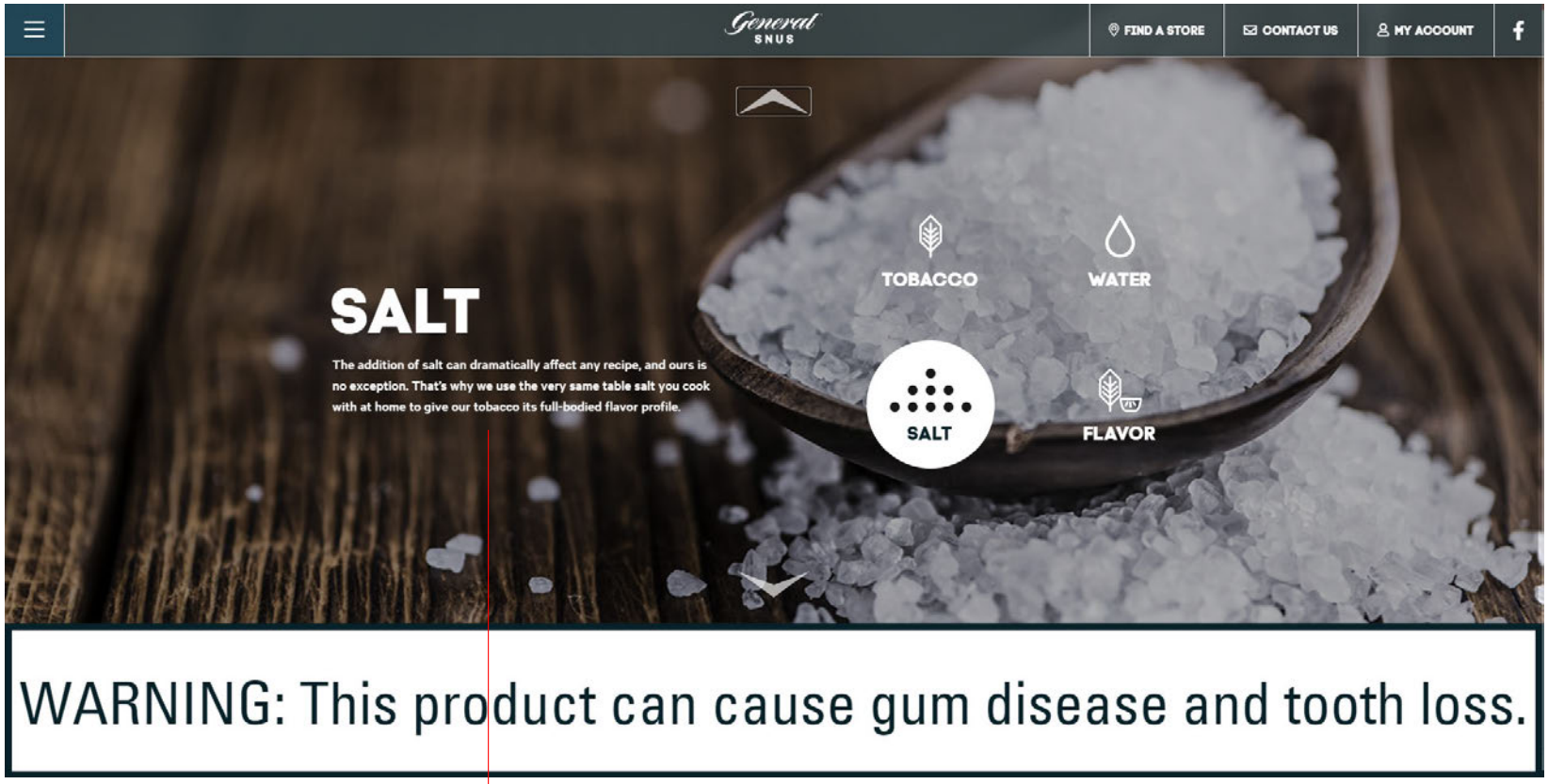
Our experts source 22 of the world's most premium tobaccos to develop our signature blend. Every plant is carefully selected from seed type to leaf position to the very climate it's grown in, which results in a consistent tobacco experience no matter the season.

What is Snus?: Ingredients Water (behind age gate) Oct. 2020 – Oct. 2021



Pure, clean water remains one of the most crucial ingredients in our centuries-old recipe. It affects everything from the moisture content and flavor to how comfortable it feels when placed in your upper lip.

What is Snus?: Ingredients Salt (behind age gate) Oct. 2020 – Oct. 2021



The addition of salt can dramatically affect any recipe, and ours is no exception. That's why we use the very same table salt you cook with at home to give our tobacco its full-bodied flavor profile.

Swedish Match

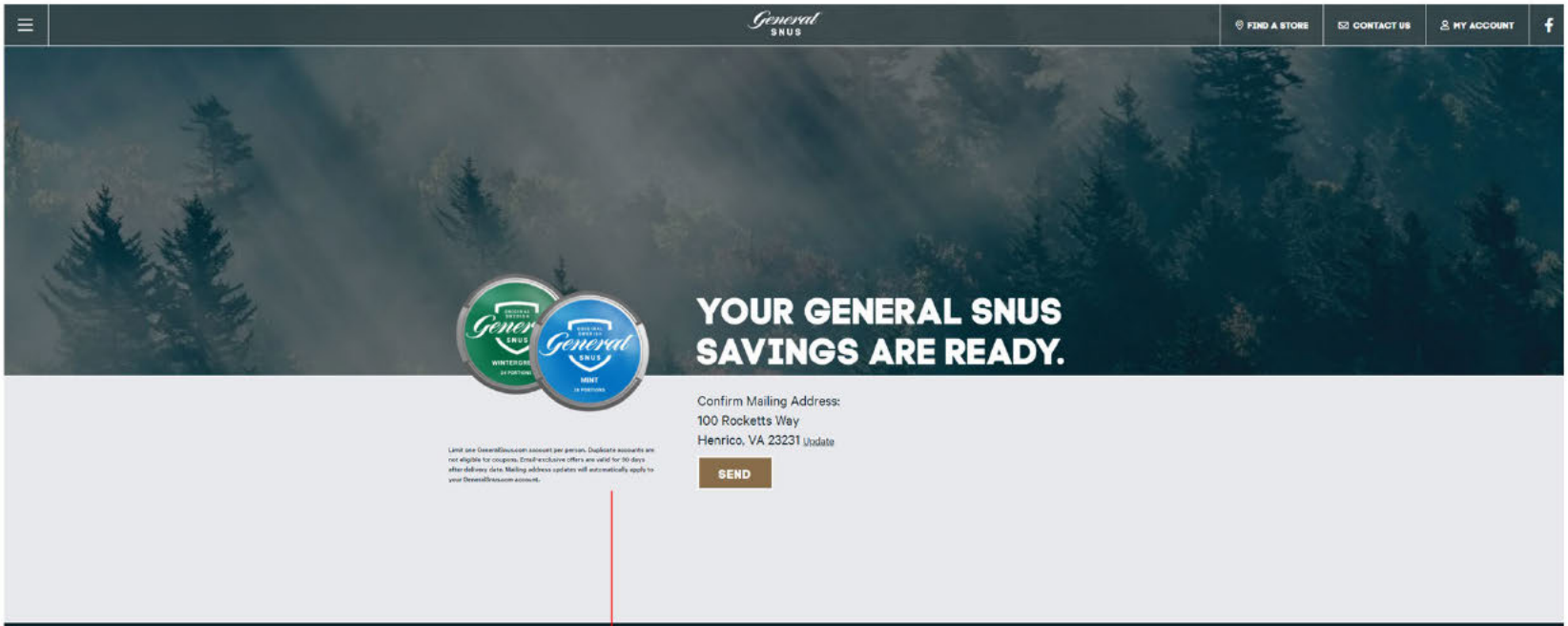
What is Snus?: Ingredients Flavor (behind age gate) Oct. 2020 – Oct. 2021

Tobacco leaves provide the most important flavor. But ingredients like mint and bergamot oil help complement our authentic Swedish snus in a truly unique and flavorful way.

What is Snus? How to Use – Oct. 2020 – Oct. 2021

Swedish Match

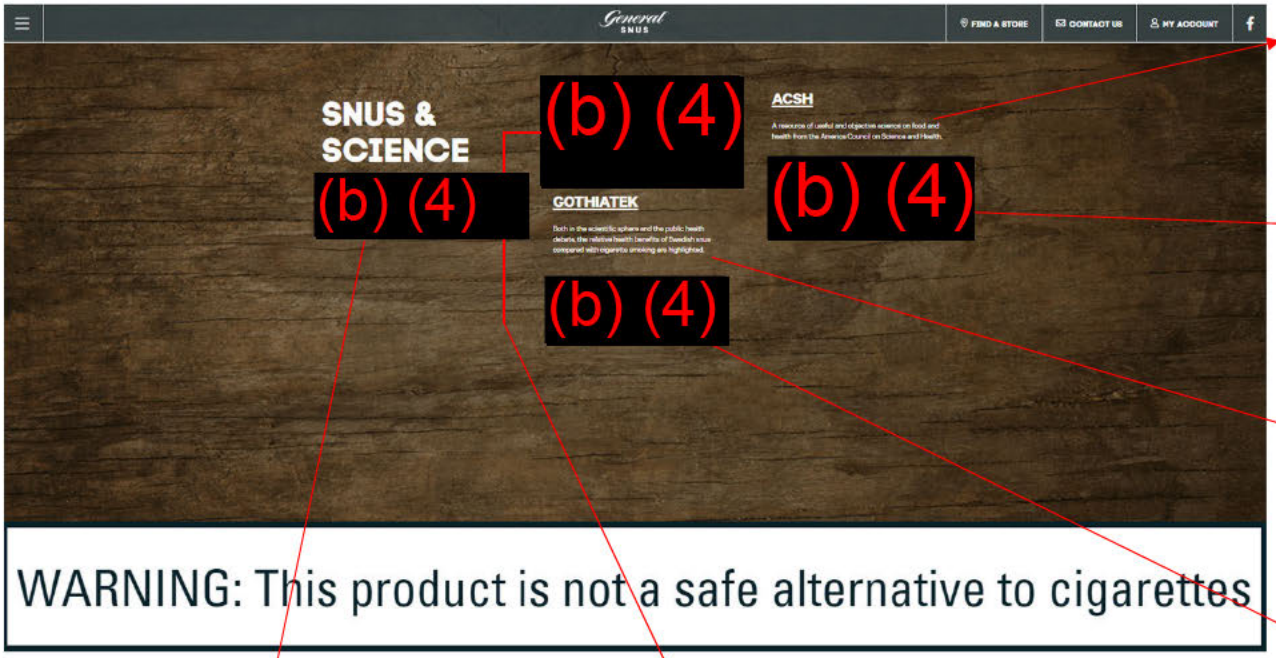
Coupon – Success – Oct. 2020 – Oct. 2021



WARNING: This product is not a safe alternative to cigarettes

Limit one GeneralSnus.com account per person. Duplicate accounts are not eligible for coupons. Email-exclusive offers are valid for 90 days after delivery date. Mailing address updates will automatically apply to your GeneralSnus.com account.

Snus & Science (behind age gate) via Menu
Oct. 2020 – Oct. 2021



A resource of useful and objective science on food and health from the America Council on Science and Health.

Hyperlink to: acsh.org

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A revolutionary quit-smoking strategy based on scientific research and common sense.

yperlink to: e | smokersonly.org

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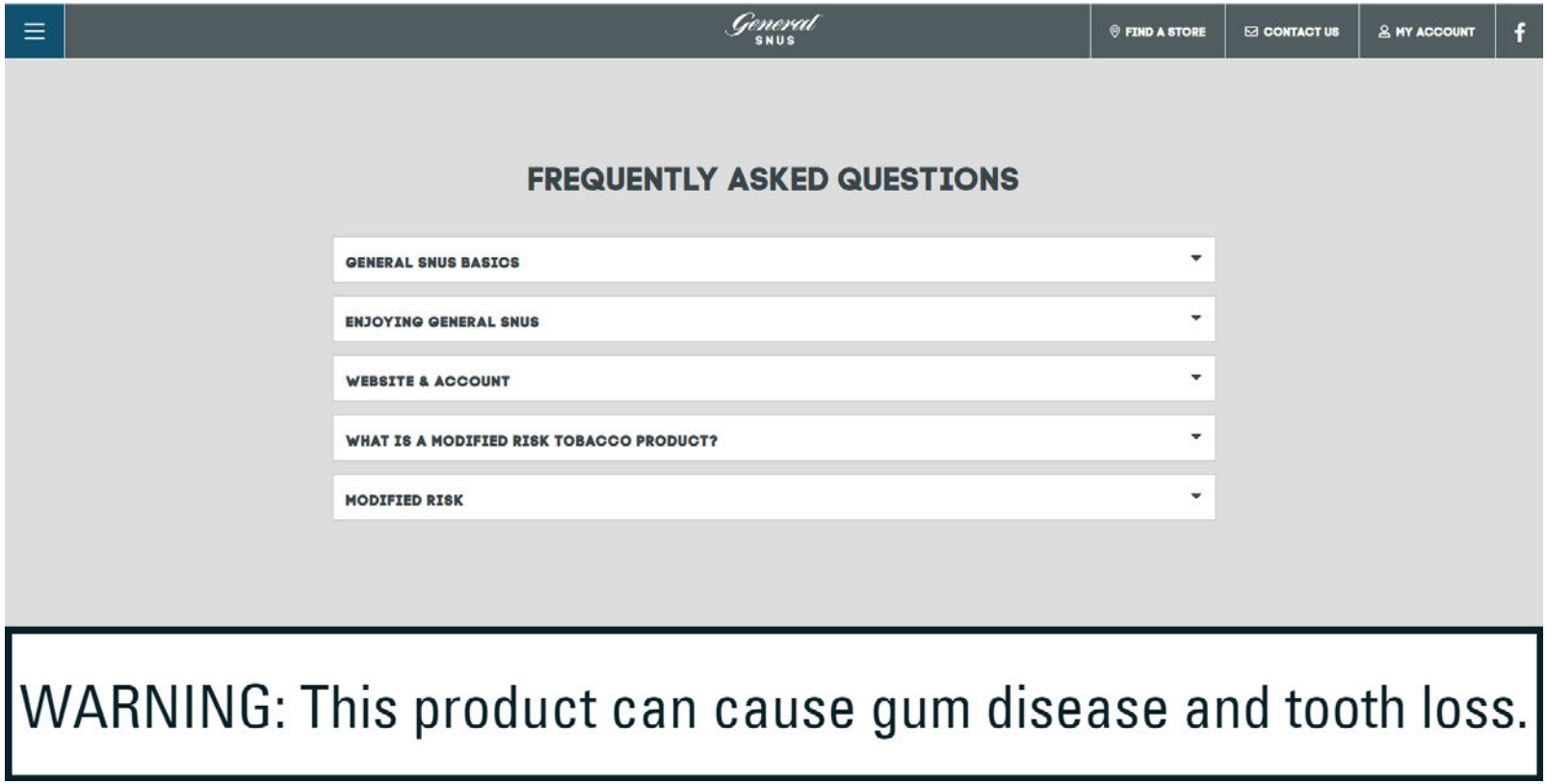
Swedish Match

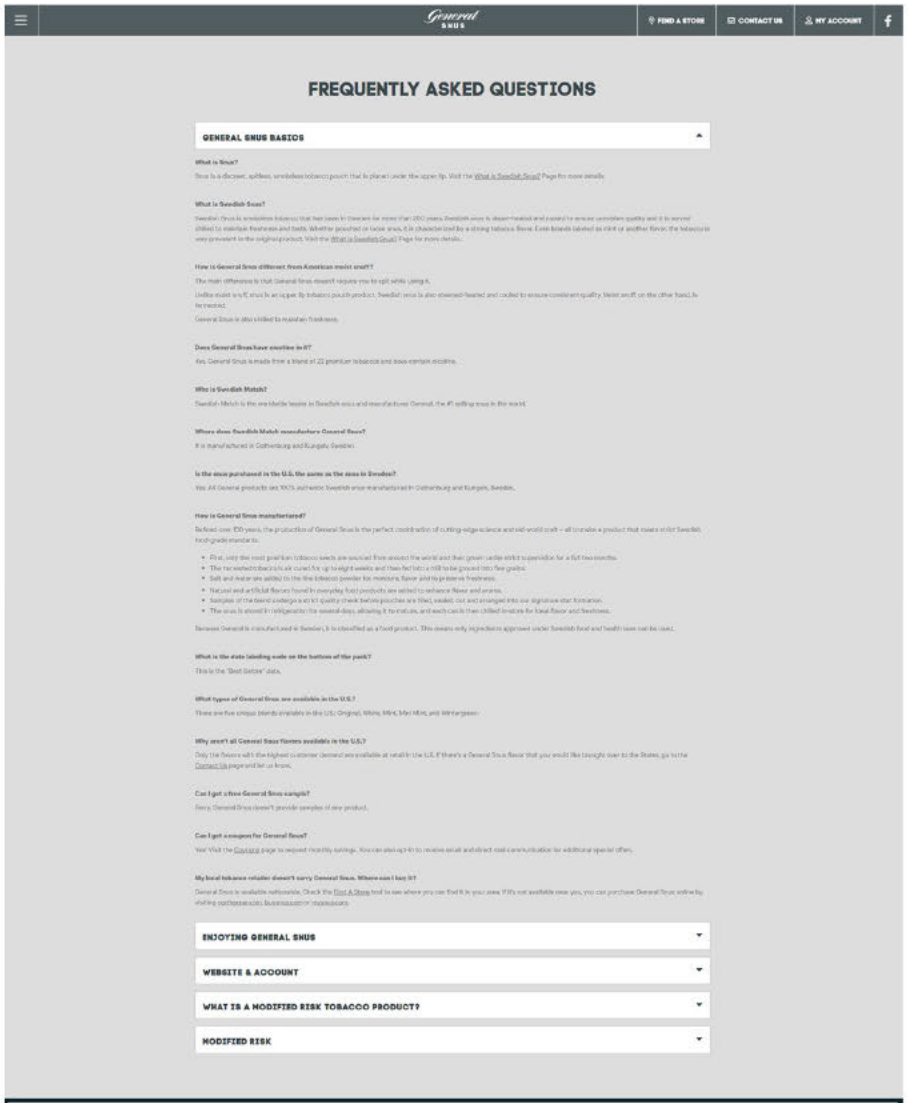
Snus & Science (behind age gate)
Oct. 2020 – Oct. 2021

FAQ PAGE (behind age gate) – Oct. 2020 – Oct. 2021



FAQs (behind age gate) General Snus Basics Oct. 2020 – Oct. 2021

See FAQs on following 3 pages



WARNING: This product can cause gum disease and tooth loss.

Swedish Match

FAQs (behind age gate) – General Snus Basics Copy – Oct. 2020 – Oct. 2021

What is Snus?

Snus is a discreet, spitless, smokeless tobacco pouch that is placed under the upper lip. Visit the What is Swedish Snus? Page for more details.

What is Swedish Snus?

Swedish Snus is smokeless tobacco that has been in Sweden for more than 200 years. Swedish snus is steam-heated and cooled to ensure consistent quality and it is served chilled to maintain freshness and taste. Whether pouched or loose snus, it is characterized by a strong tobacco flavor. Even brands labeled as mint or another flavor, the tobacco is very prevalent in the original product. Visit the What is Swedish Snus? Page for more details.

How is General Snus different from American moist snuff?

The main difference is that General Snus doesn't require you to spit while using it.

Unlike moist snuff, snus is an upper lip tobacco pouch product. Swedish snus is also steamed-heated and cooled to ensure consistent quality. Moist snuff, on the other hand, is fermented.

General Snus is also chilled to maintain freshness.

Does General Snus have nicotine in it?

Yes. General Snus is made from a blend of 22 premium tobaccos and does contain nicotine.

Who is Swedish Match?

Swedish Match is the worldwide leader in Swedish snus and manufactures General, the #1 selling snus in the world.

Where does Swedish Match manufacture General Snus?

It is manufactured in Gothenburg and Kungalv, Sweden.

Is the snus purchased in the U.S. the same as the snus in Sweden?

Yes. All General products are 100% authentic Swedish snus manufactured in Gothenburg and Kungalv, Sweden.

Swedish Match

FAQs (behind age gate) General Snus Basics Copy Cont. Oct. 2020 – Oct. 2021

How is General Snus manufactured?

Refined over 150 years, the production of General Snus is the perfect combination of cutting-edge science and old-world craft – all to make a product that meets strict Swedish food-grade standards.

First, only the most premium tobacco seeds are sourced from around the world and then grown under strict supervision for a full two months.

The harvested tobacco is air cured for up to eight weeks and then fed into a mill to be ground into fine grains.

Salt and water are added to the fine tobacco powder for moisture, flavor and to preserve freshness.

Natural and artificial flavors found in everyday food products are added to enhance flavor and aroma.

Samples of the blend undergo a strict quality check before pouches are filled, sealed, cut and arranged into our signature star formation.

The snus is stored in refrigeration for several days, allowing it to mature, and each can is then chilled in-store for ideal flavor and freshness.

Because General is manufactured in Sweden, it is classified as a food product. This means only ingredients approved under Swedish food and health laws can be used.

What is the date labeling code on the bottom of the pack?

This is the “Best Before” date.

What types of General Snus are available in the U.S.?

There are five unique blends available in the U.S.: Original, White, Mint, Mini Mint, and Wintergreen.

Why aren't all General Snus flavors available in the U.S.?

Only the flavors with the highest customer demand are available at retail in the U.S. If there's a General Snus flavor that you would like brought over to the States, go to the Contact Us page and let us know.

Can I get a free General Snus sample?

Sorry, General Snus doesn't provide samples of any product.

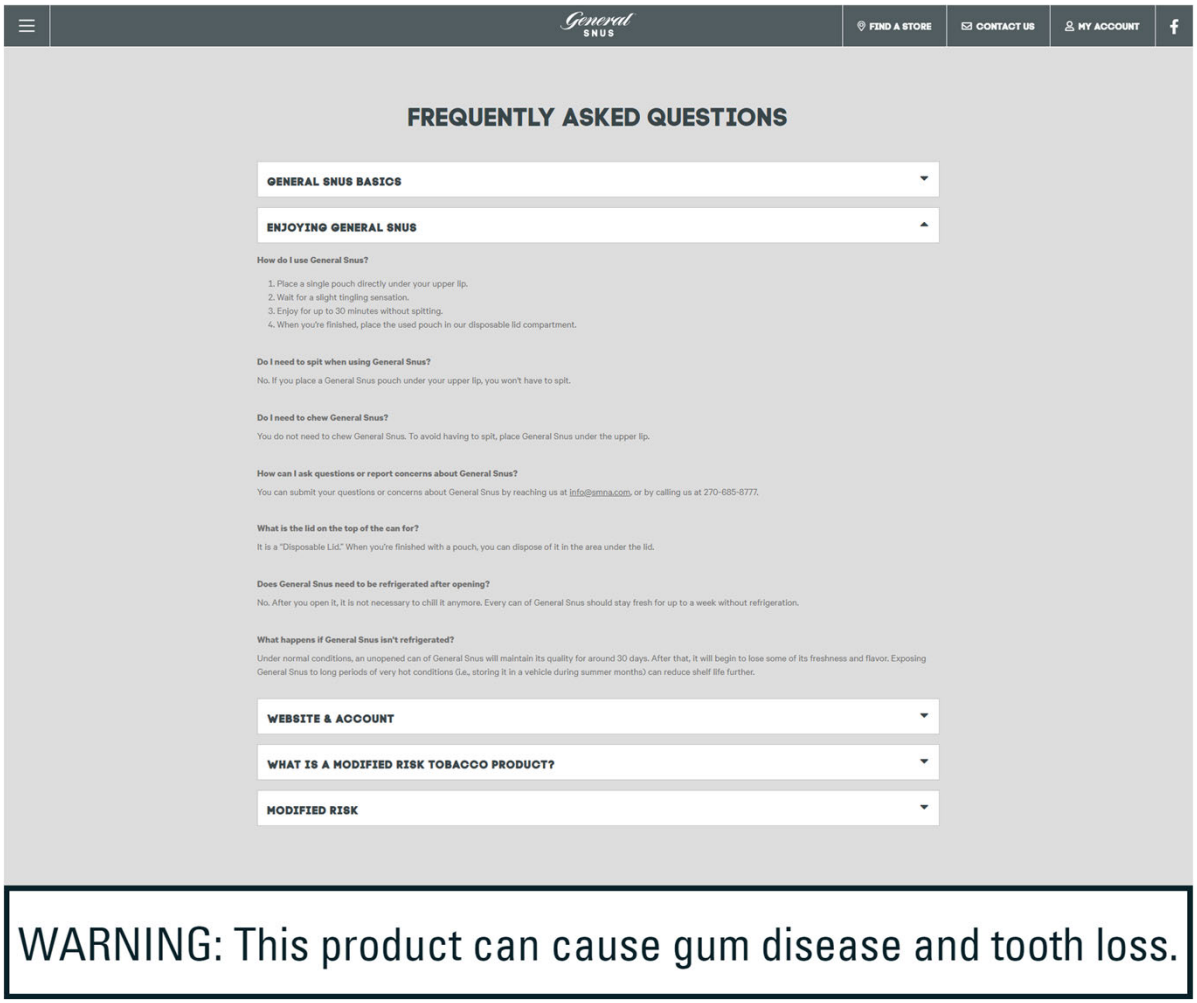
Can I get a coupon for General Snus?

Yes! Visit the Coupons page to request monthly savings. You can also opt-in to receive email and direct mail communication for additional special offers.

My local tobacco retailer doesn’t carry General Snus. Where can I buy it?

General Snus is available nationwide. Check the Find A Store tool to see where you can find it in your area. If it’s not available near you, you can purchase General Snus online by visiting northerner.com, buysnus.com or mysnus.com.

FAQs (behind age gate) Enjoying General Snus – Oct. 2020 – Oct. 2021



See FAQs on following 3 pages

FAQs – Enjoying General Snus Copy – Oct. 2020 – Oct. 2021

How do I use General Snus?
Place a single pouch directly under your upper lip.
Wait for a slight tingling sensation.
Enjoy for up to 30 minutes without spitting.
When you're finished, place the used pouch in our disposable lid compartment.

Do I need to spit when using General Snus?
No. If you place a General Snus pouch under your upper lip, you won't have to spit.

Do I need to chew General Snus?
You do not need to chew General Snus. To avoid having to spit, place General Snus under the upper lip.

How can I ask questions or report concerns about General Snus?
You can submit your questions or concerns about General Snus by reaching us at info@smna.com, or by calling us at 270-685-8777.

What is the lid on the top of the can for?
It is a "Disposable Lid." When you're finished with a pouch, you can dispose of it in the area under the lid.

Does General Snus need to be refrigerated after opening?
No. After you open it, it is not necessary to chill it anymore. Every can of General Snus should stay fresh for up to a week without refrigeration.

What happens if General Snus isn't refrigerated?
Under normal conditions, an unopened can of General Snus will maintain its quality for around 30 days. After that, it will begin to lose some of its freshness and flavor. Exposing General Snus to long periods of very hot conditions (i.e., storing it in a vehicle during summer months) can reduce shelf life further.

FAQs (behind age gate) Website & Account Oct. 2020 – Oct. 2021

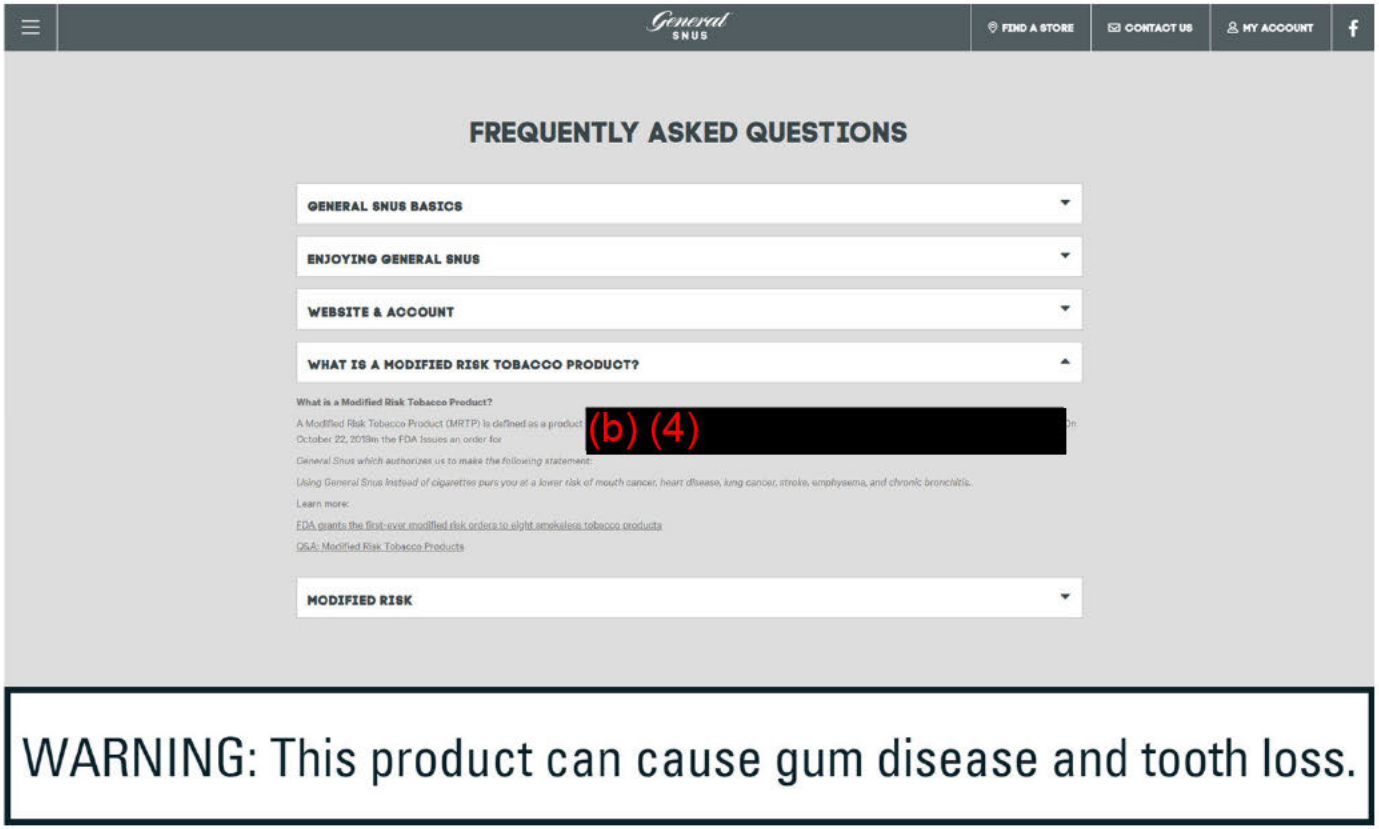
See FAQs on next page

WARNING: This product can cause gum disease and tooth loss.

FAQs – Website & Account Copy – Oct. 2020 – Oct. 2021

I forgot my password. What can I do?
Follow these steps and your password will be emailed to you.
Go to Forgot Password page
Enter your email address and hit submit
Check your inbox. A secure link will be sent for you to reset your password.
I've entered my login info but can't get into the site. What should I do?
If you receive a message saying that your email address/password has been entered incorrectly, try again.
If you still cannot log in, visit our Contact Us page and send us a message. We will get back to you shortly.
My age can't be verified. What can I do?
To register, you must be 21 years of age or meet the legal age requirements dictated by state or local law. Ensure the information you entered during registration is correct. If you're still having issues, follow the instructions on this PDF.
What if I don't own a computer?
Our site is accessible through public computers with internet access.
Can I opt out of receiving emails in the future?
Yes. There are three ways to opt out:
Go to My Account, then update your communication preferences by selecting "No" under the email section.
Send an email to info@smna.com. It may take 10 business days to process your request.
Send a written request to:
Swedish Match North Europe AB
PO Box 986
Owensboro, KY 42302
Provide your name and the email address to be removed from the mailing list in the request.
How is my privacy protected?
Visit our Privacy Policy for more information.
I'm having issues viewing images and messages on the site. What causes these issues?
If images are not appearing on the site, make sure you are viewing the site in one of the supported browsers:
Internet Explorer 11+ or Edge 12+ (WIN)
Firefox 40+ (WIN/MAC)
Safari 9+ (MAC)
Google Chrome 50+ (WIN/MAC)

FAQs (behind age gate) What is a Modified Risk Tobacco Product? Oct. 2020 – Oct. 2021



See FAQs on next page

FAQs (behind age gate) What is a Modified Risk Tobacco Product? Copy Oct. 2020 – Oct. 2021

What is a Modified Risk Tobacco Product?

A Modified Risk Tobacco Product (MRTP) is defined as a product (b) (4) (b) (4) On October 22, 2019m the FDA issues an order for *General Snus which authorizes us to make the following statement:*

Using General Snus instead of cigarettes puTs you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

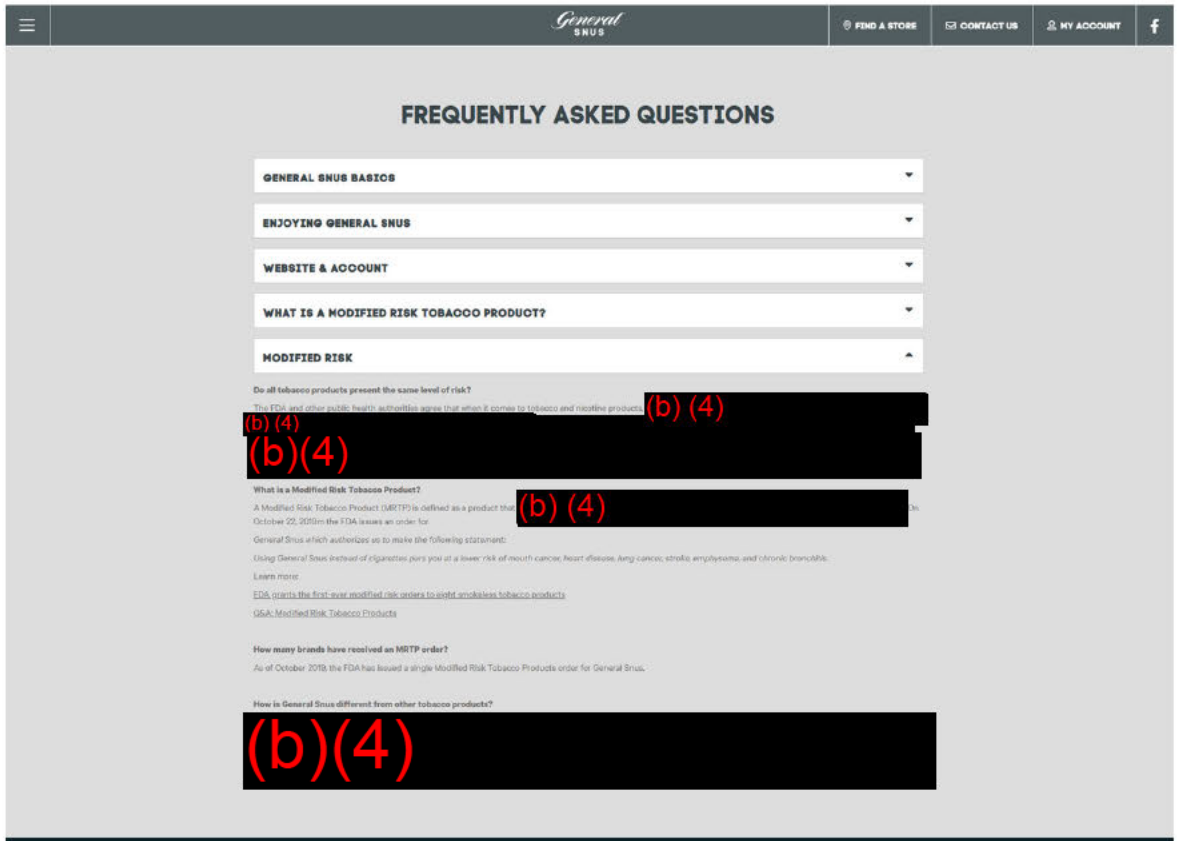
Learn more:

FDA grants the first-ever modified risk orders to eight smokeless tobacco products

Q&A: Modified Risk Tobacco Products

Swedish Match

FAQs (behind age gate) Modified Risk – Oct. 2020 – Oct. 2021



See FAQs on next page

WARNING: This product can cause gum disease and tooth loss.

FAQs (behind age gate) Modified Risk Copy – Oct. 2020 – Oct. 2021

Do all tobacco products present the same level of risk?
The FDA and other public health authorities agree that when it comes to tobacco and nicotine products, (b) (4)
(b) (4)
(b) (4)

What is a Modified Risk Tobacco Product?
A Modified Risk Tobacco Product (MRTP) is defined as a product (b) (4)
(b) (4) . On October 22, 2019m the FDA issues an order for
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Learn more:
FDA grants the first-ever modified risk orders to eight smokeless tobacco products
Q&A: Modified Risk Tobacco Products

How many brands have received an MRTP order?
As of October 2019, the FDA has issued a single Modified Risk Tobacco Products order for General Snus.

How is General Snus different from other tobacco products?
General Snus as a long history (b) (4) This is extremely apparent in Sweden and Norway. In Sweden, widespread use of snus in place of cigarettes has been tied to helping the country achieve the lowest lung and oral cancer rates in men in Europe, despite tobacco use rates being similar to other countries. In Norway, we saw snus rates among young woman increase to 13 percent since it was introduced in 2002. In the almost exact same time span, smoking rates among young women dropped from 30 percent to one percent. For more information, click here.

fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

fda.gov/tobacco-products/market-and-distribute-tobacco-product/qa-modified-risk-tobacco-products

Swedish Match

General Website Refresh
October 2021-today

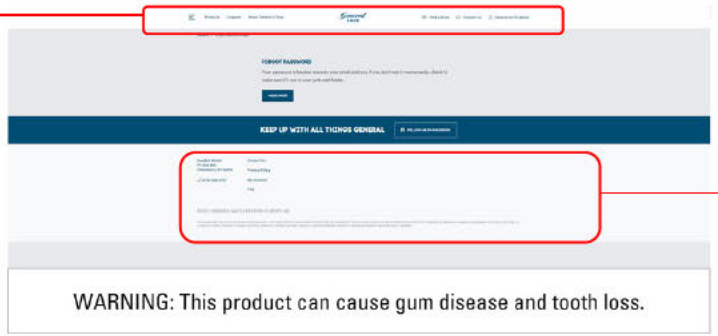
Warnings will automatically refresh to the appropriate warning at the beginning of the next quarter.
No new videos have been added to the website.

Swedish Match

GENERAL SNUS WEBSITE REFRESH (MRTP PAGES)
Outside Age Gate
October 2021 - current

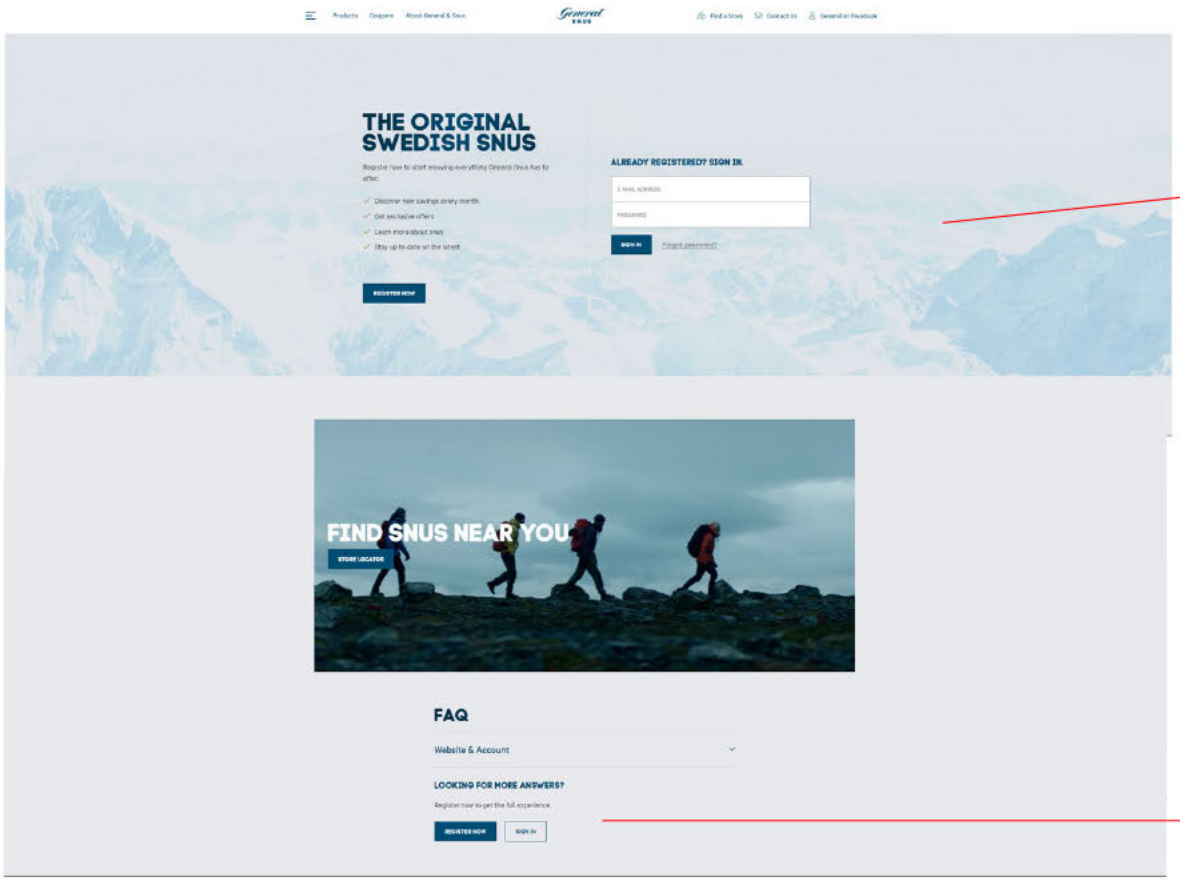
Swedish Match

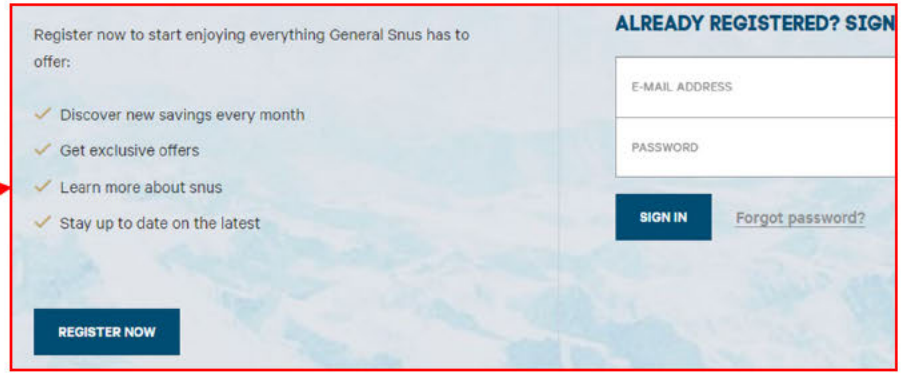
GENERAL WEBSITE REFRESH - *HEADER & FOOTER*
[OUTSIDE AGE GATE] Oct. 2021 - current

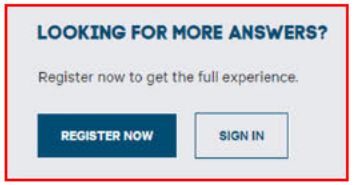


Swedish Match

GENERAL WEBSITE REFRESH –LANDING, *REGISTRATION / LOG-IN* [OUTSIDE AGE GATE] Oct. 2021 - current

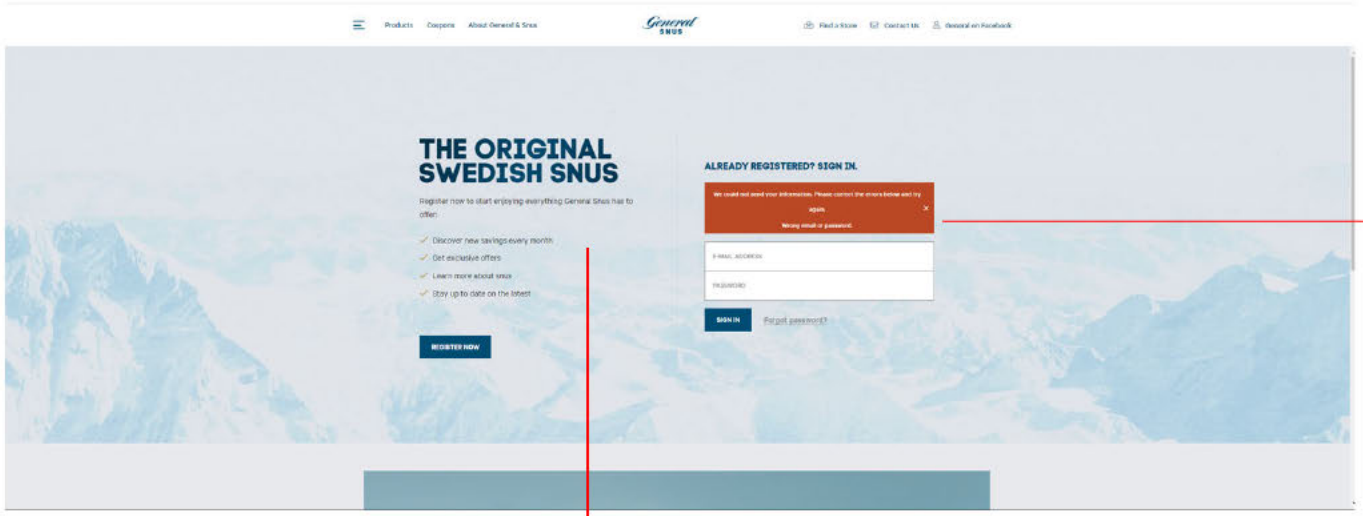


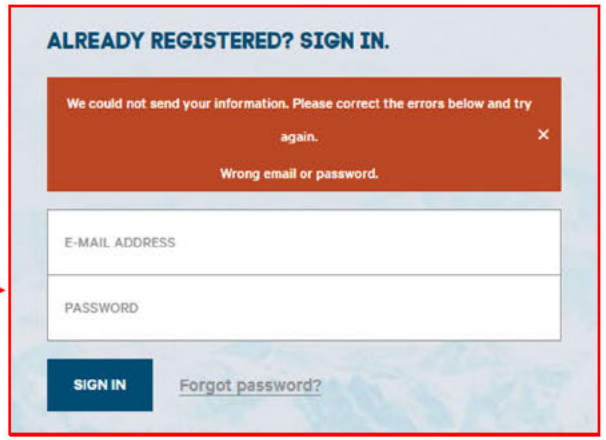




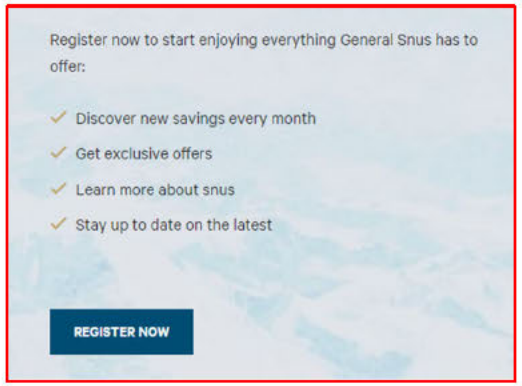
WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH - *FORGOT PASSWORD* [OUTSIDE AGE GATE] Oct. 2021 - current

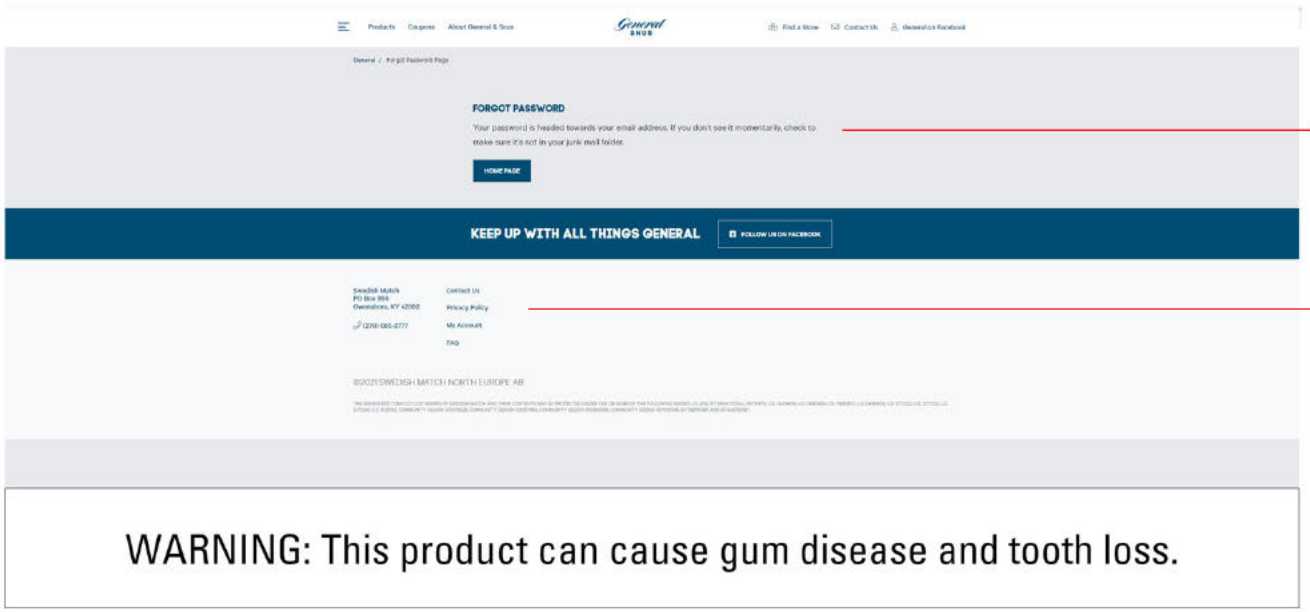


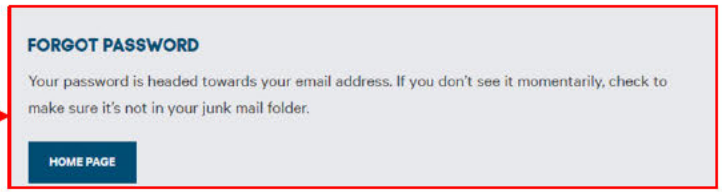


WARNING: This product can cause gum disease and tooth loss.



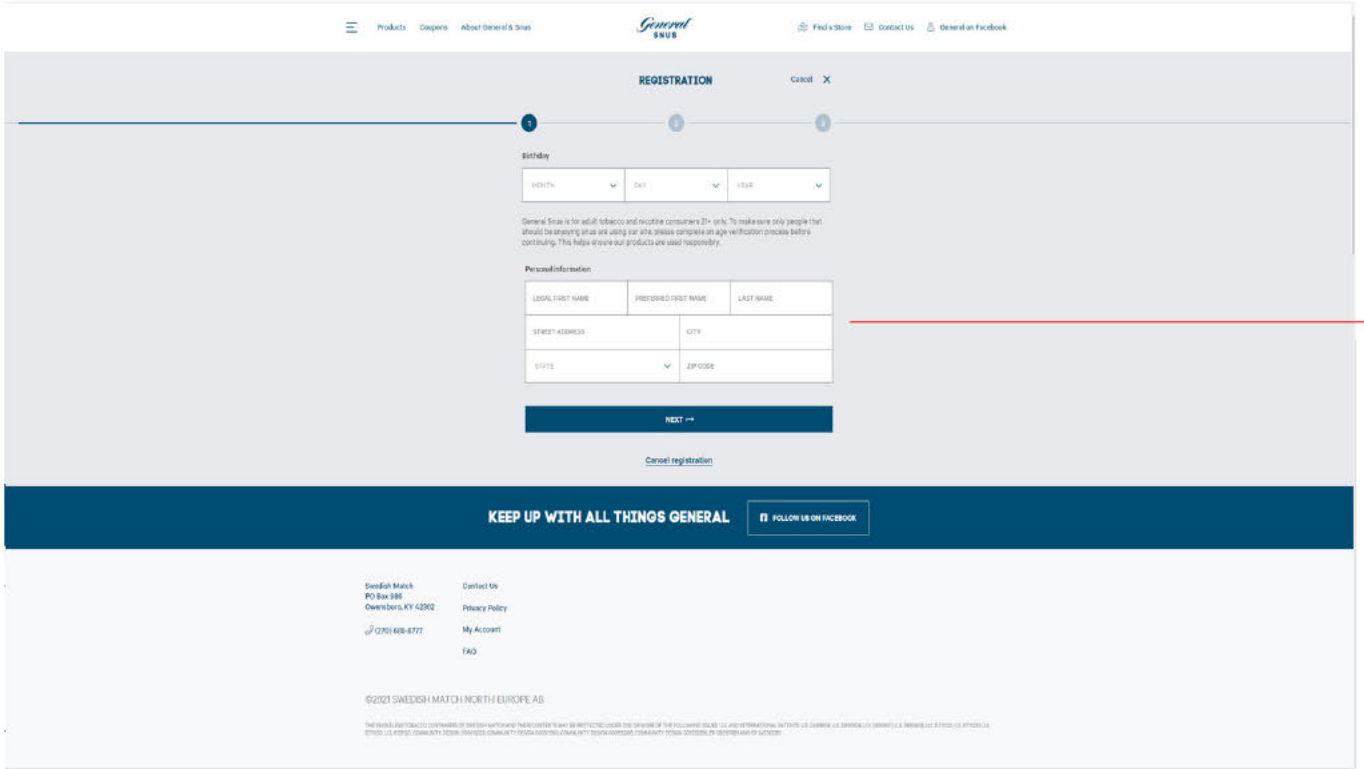
GENERAL WEBSITE REFRESH - *FORGOT PASSWORD: RESET ON THE WAY*
[OUTSIDE AGE GATE] Oct. 2021 - current

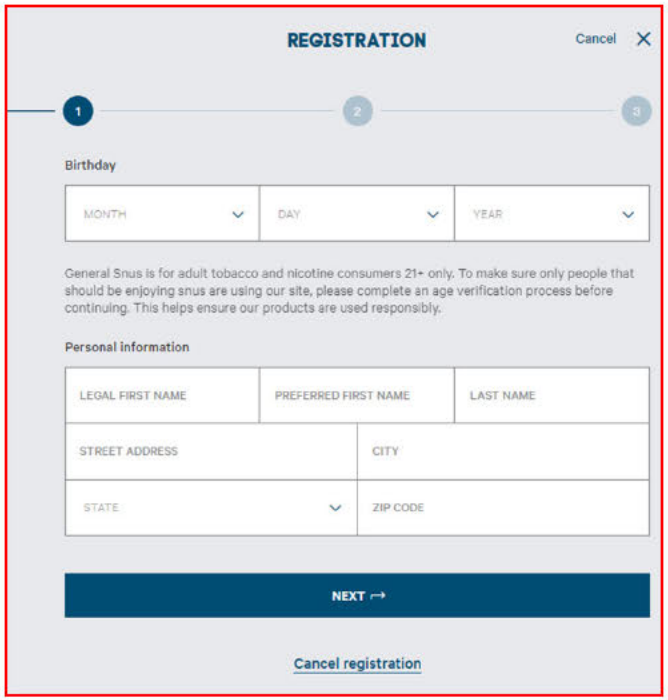




WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH – *REGISTRATION STEP 1*
[OUTSIDE AGE GATE]
Oct. 2021 - current



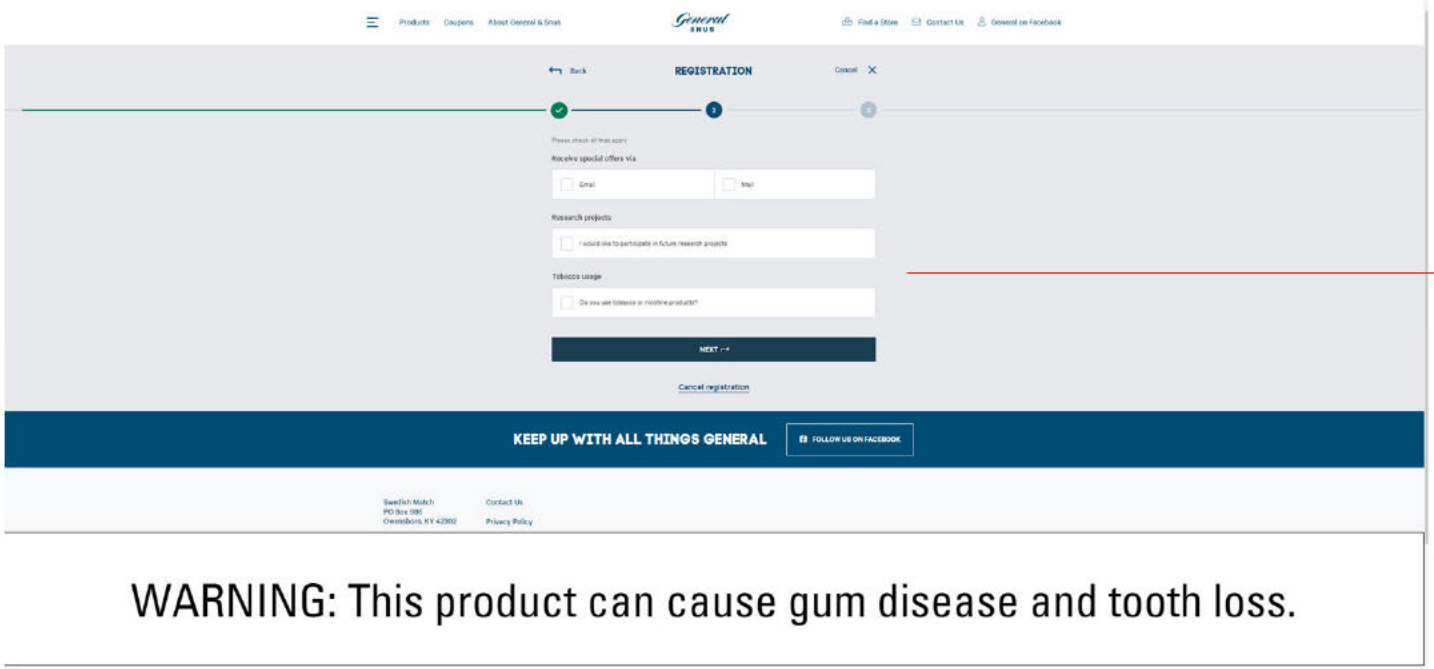


WARNING: This product can cause gum disease and tooth loss.

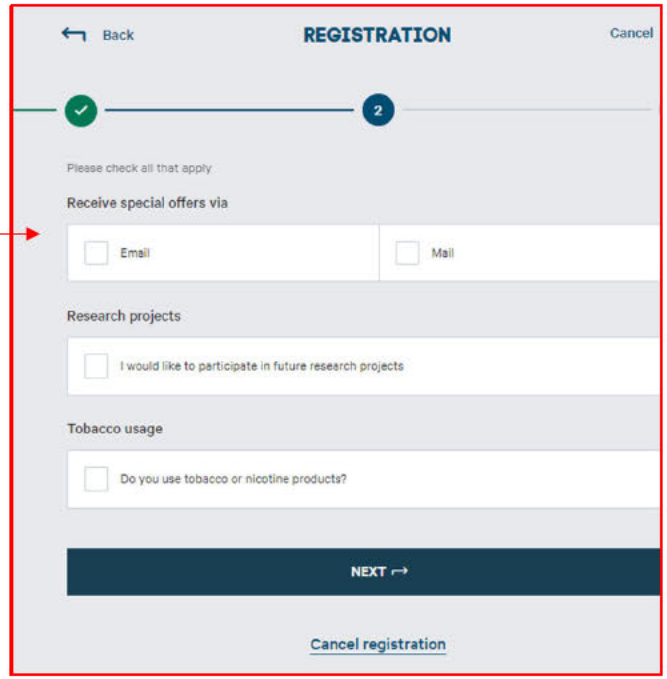
GENERAL WEBSITE REFRESH – *REGISTRATION STEP 2*

[OUTSIDE AGE GATE]

Oct. 2021 - current

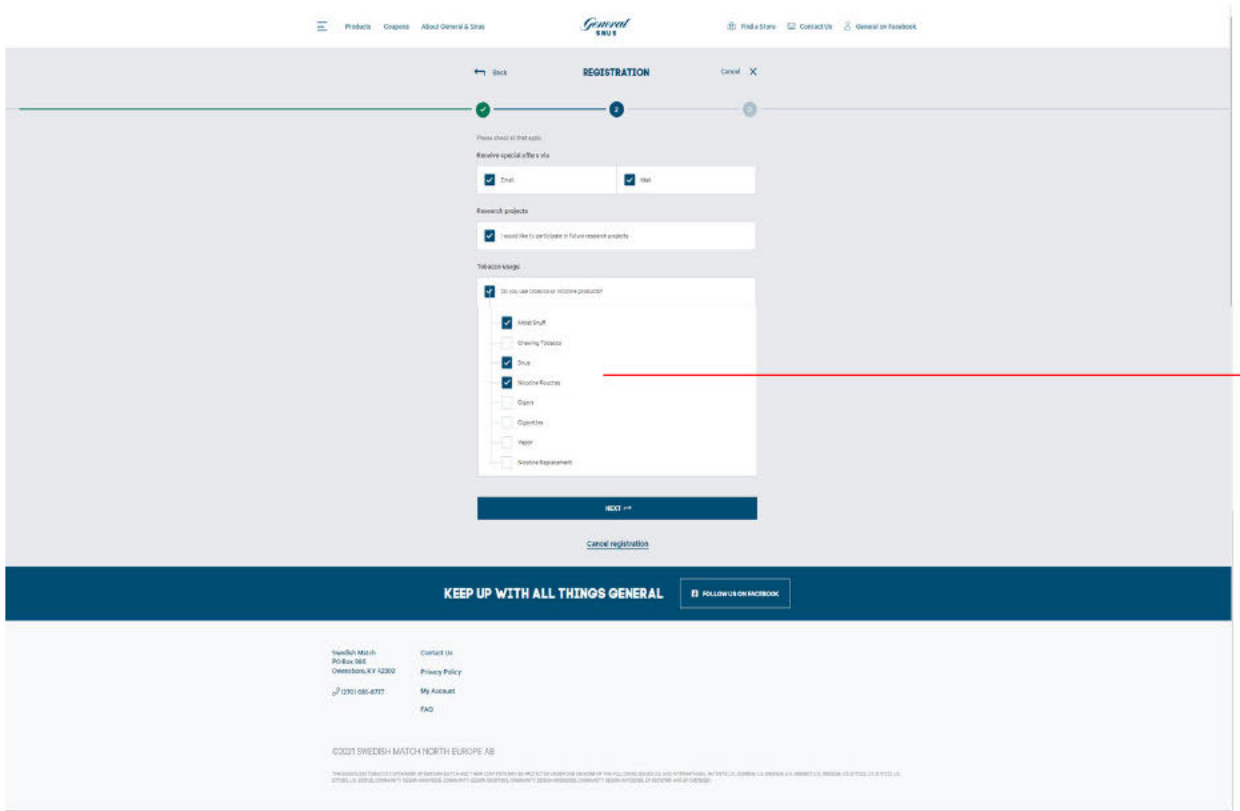


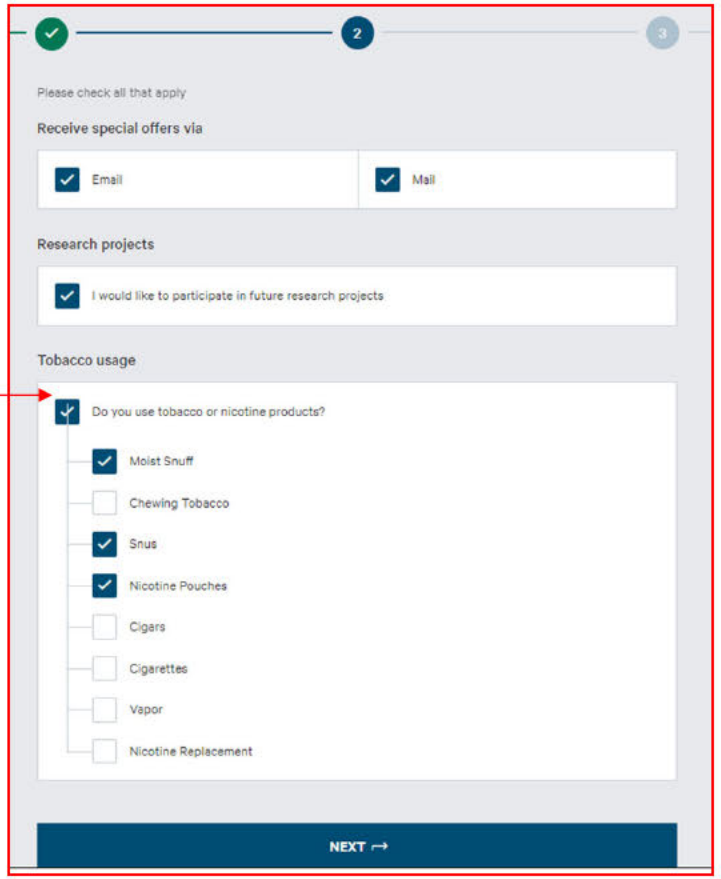
WARNING: This product can cause gum disease and tooth loss.



Swedish Match

GENERAL WEBSITE REFRESH – *REGISTRATION STEP 2 CON'T*
[OUTSIDE AGE GATE] Oct. 2021 - current

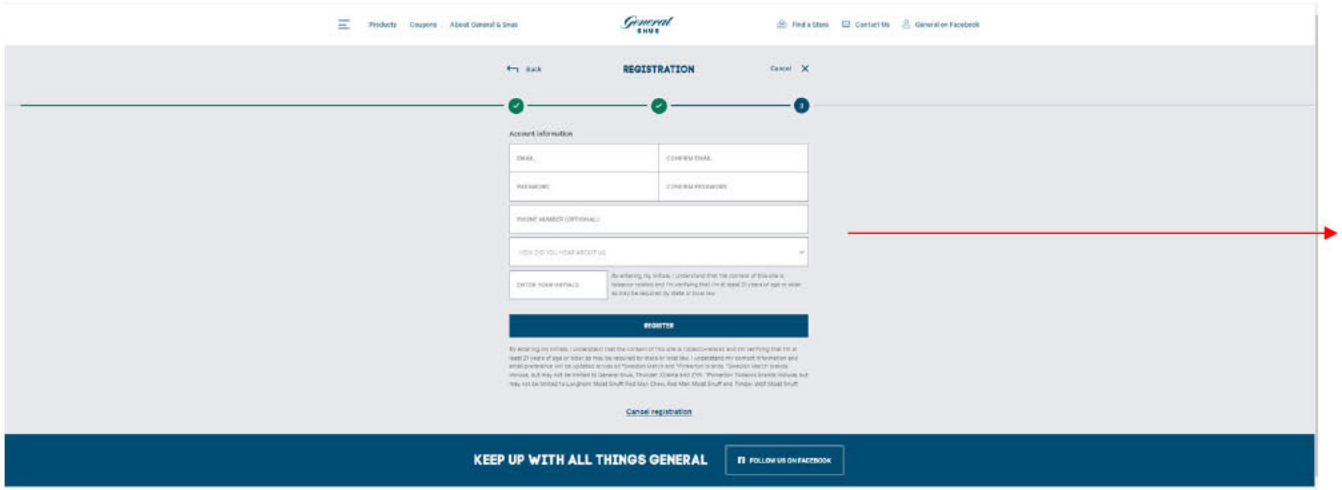




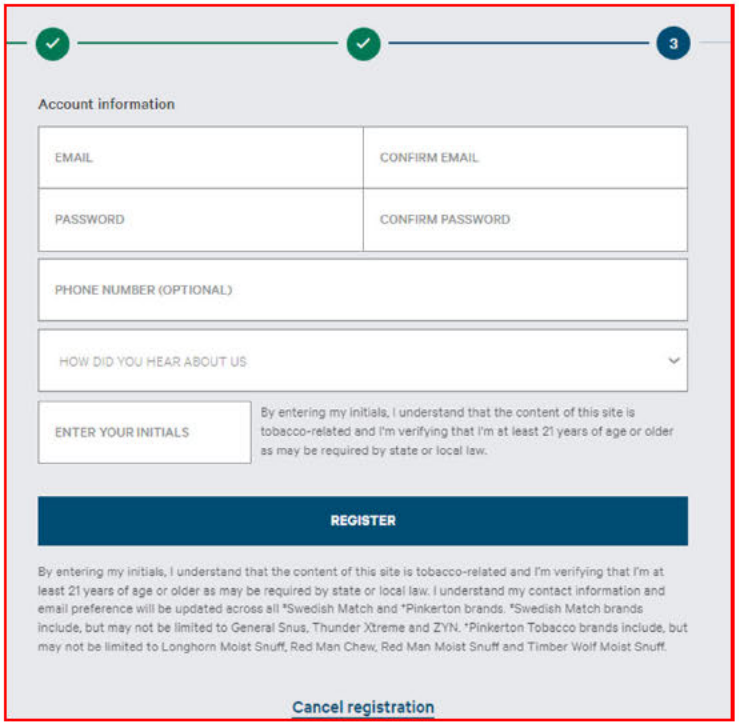
WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH – *REGISTRATION STEP 3*

[OUTSIDE AGE GATE] Oct. 2021 - current

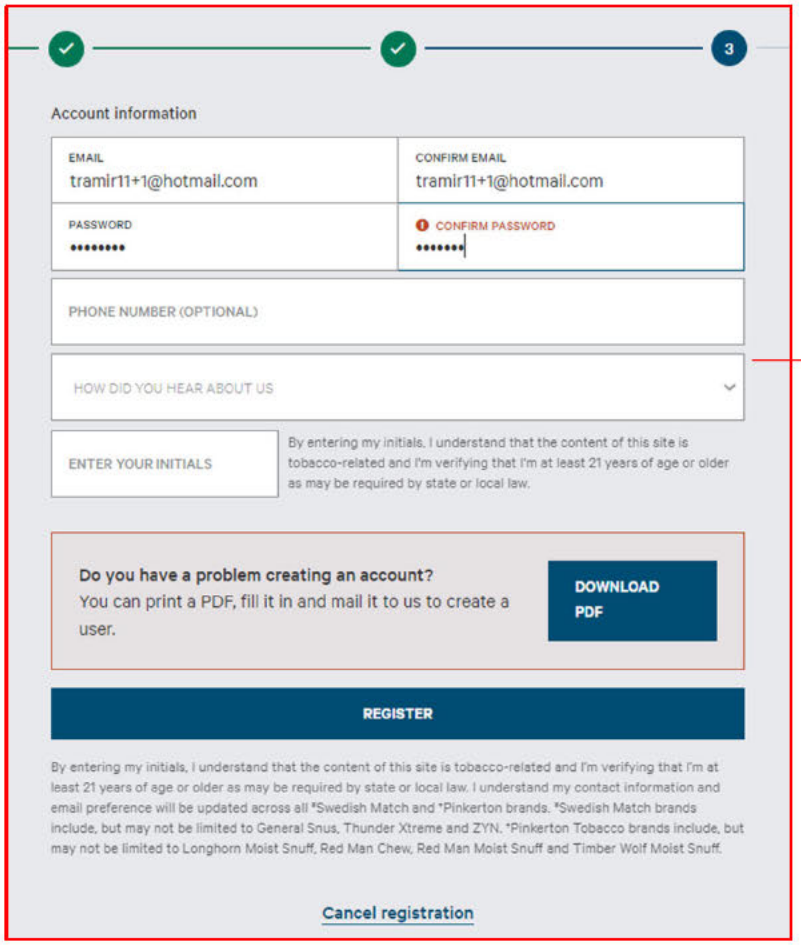


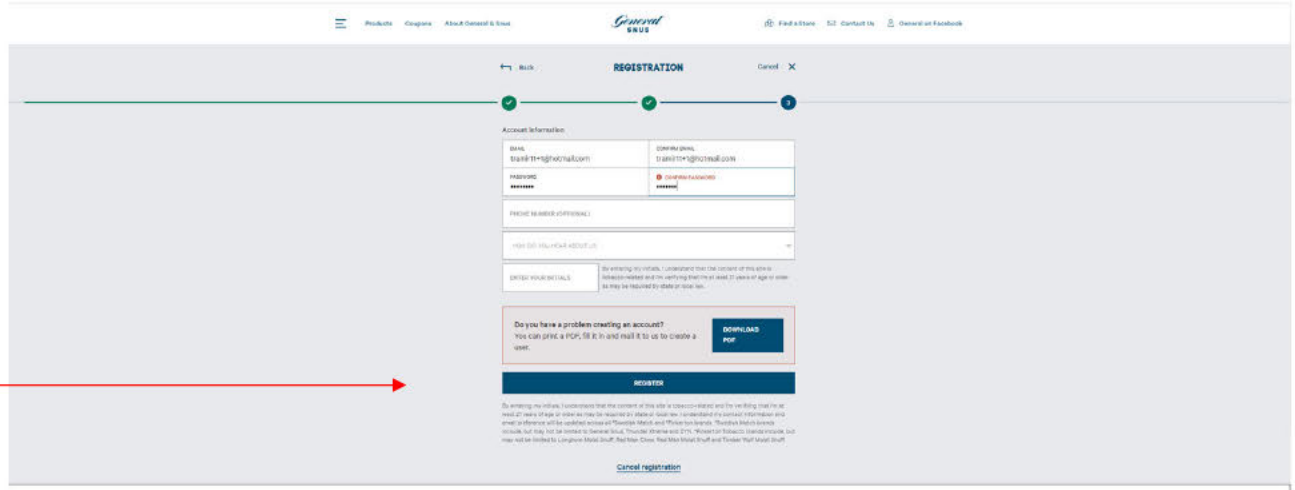
WARNING: This product can cause gum disease and tooth loss.



GENERAL WEBSITE REFRESH – *REGISTRATION STEP 3 ERROR MESSAGE* [OUTSIDE AGE GATE]

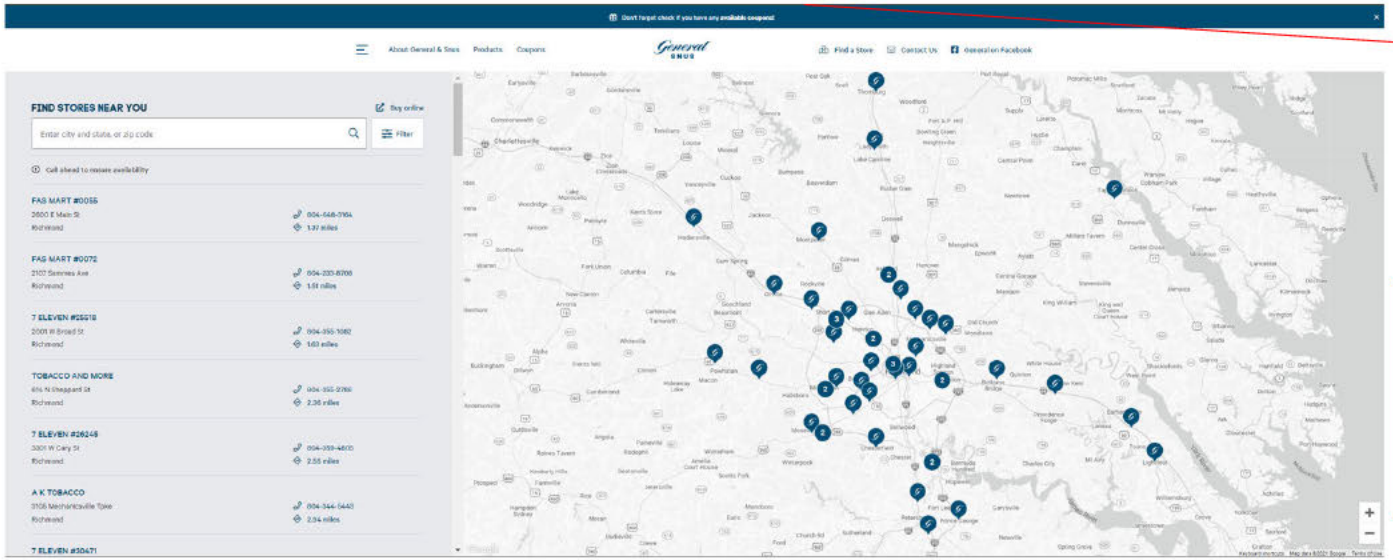
Oct. 2021 - current





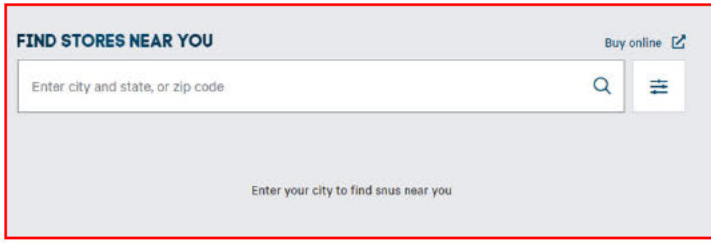
WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH - *WHERE TO BUY*
[OUTSIDE AGE GATE] Oct. 2021 - current



Don't forget check if you have any **available coupons!**

Links to Coupon page. If consumer is not already logged-in, it will first direct to Registration/Log-in then auto direct to the Coupon page.

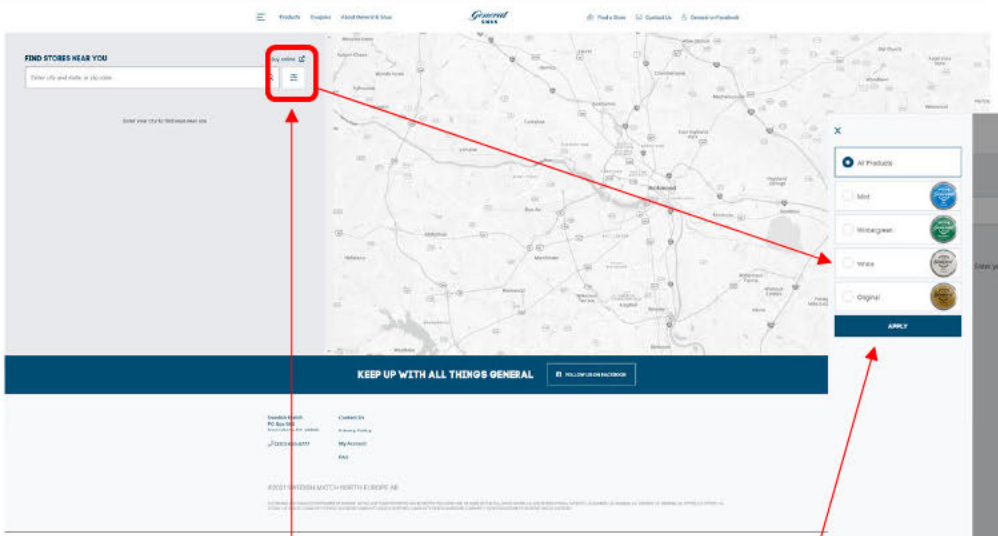


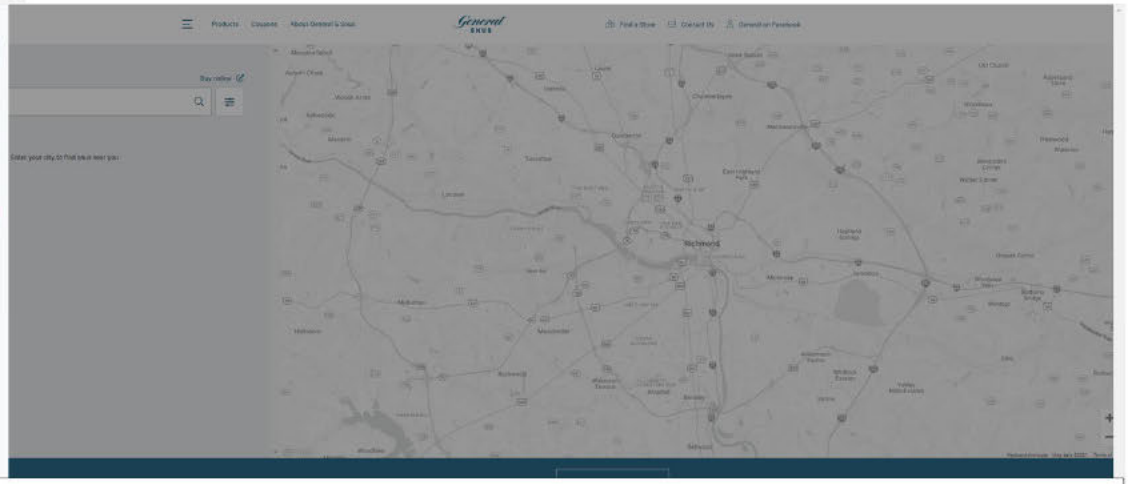
WARNING: This product is not a safe alternative to cigarettes.

Swedish Match

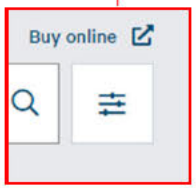
GENERAL WEBSITE REFRESH: *WHERE TO BUY – AFTER FILTERING PRODUCTS*

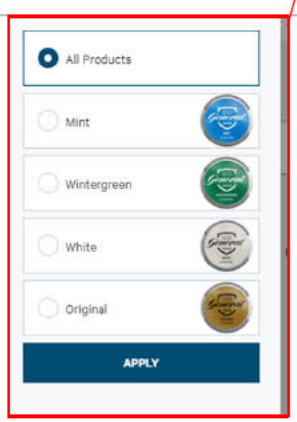
[OUTSIDE AGE GATE] Oct. 2021 - current





WARNING: This product can cause gum disease and tooth loss.

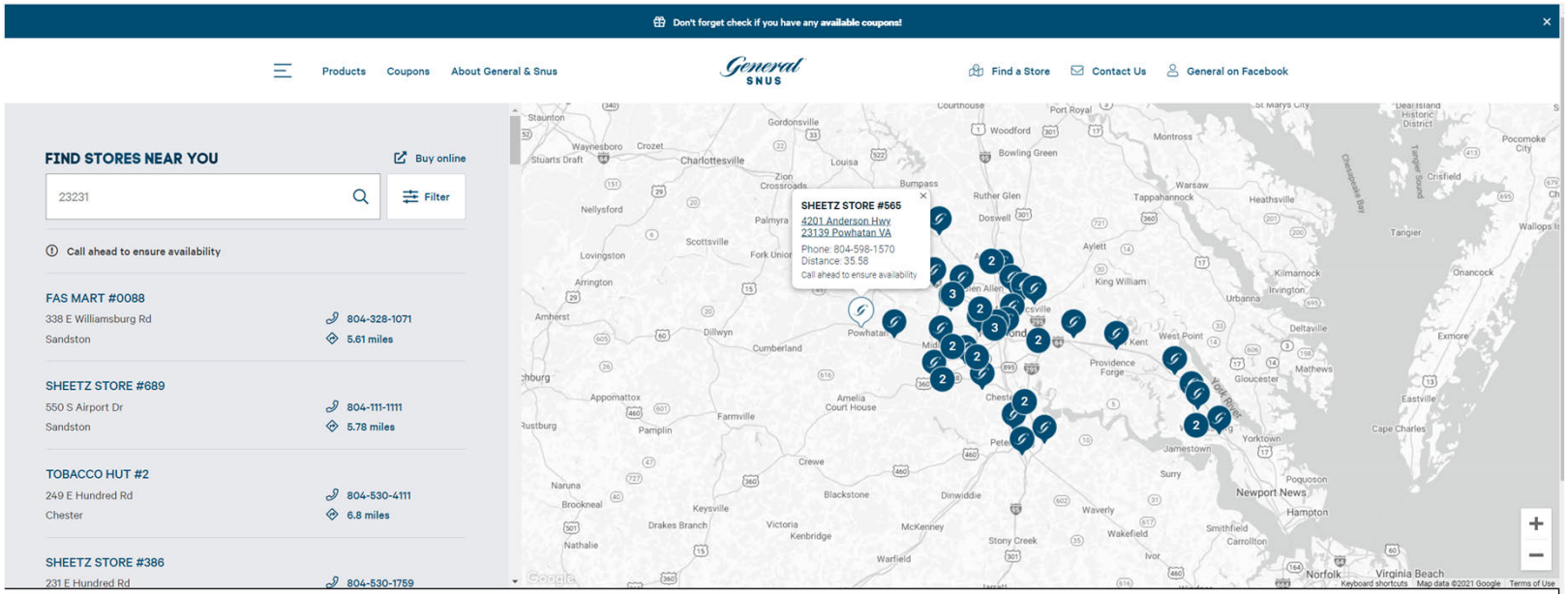




Swedish Match

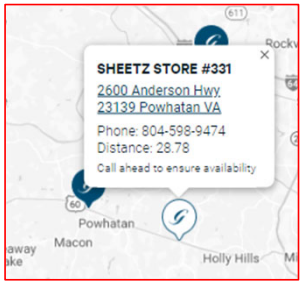
GENERAL WEBSITE REFRESH - *WHERE TO BUY – AFTER FILTERING PRODUCT*

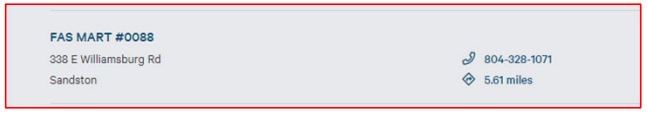
[OUTSIDE AGE GATE] Oct. 2021 - current



WARNING: This product can cause gum disease and tooth loss.

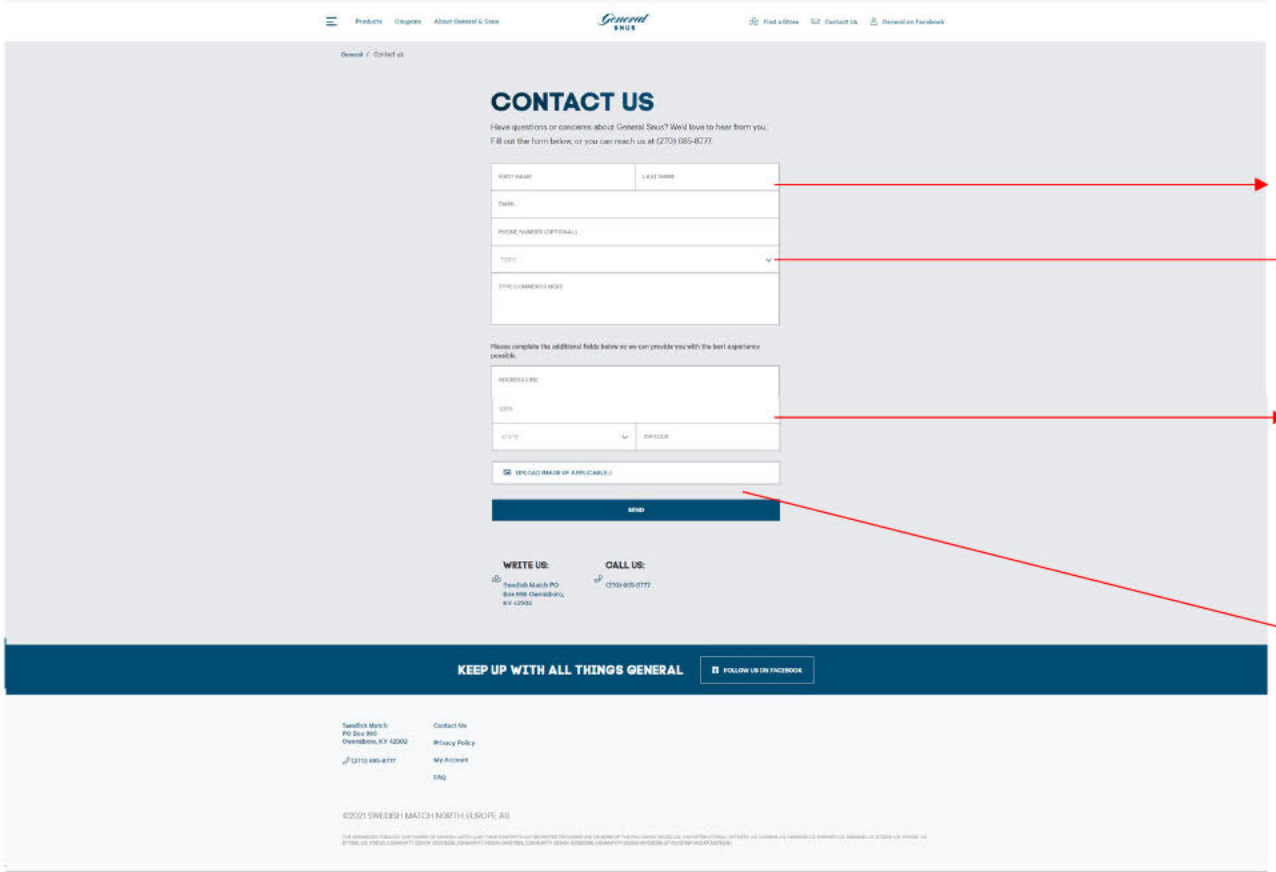
HOVER ON PIN

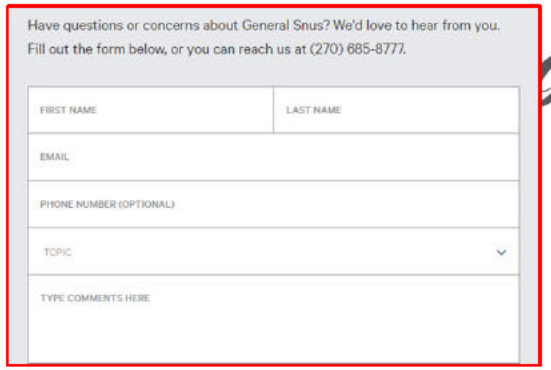


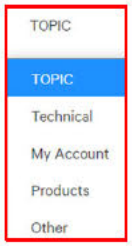


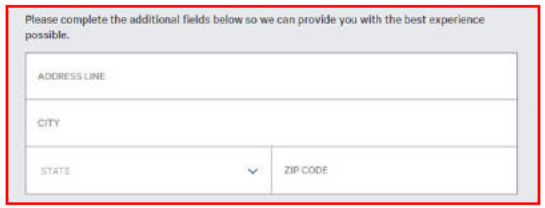
GENERAL WEBSITE REFRESH - *CONTACT US*

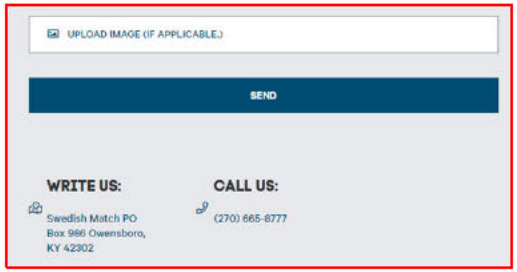
[OUTSIDE AGE GATE] Oct. 2021 - current







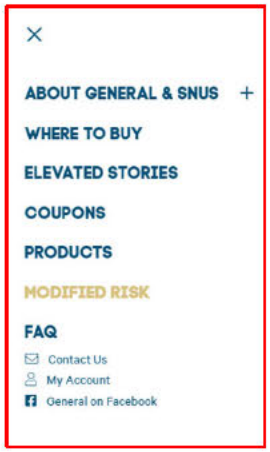




WARNING: This product can cause gum disease and tooth loss.

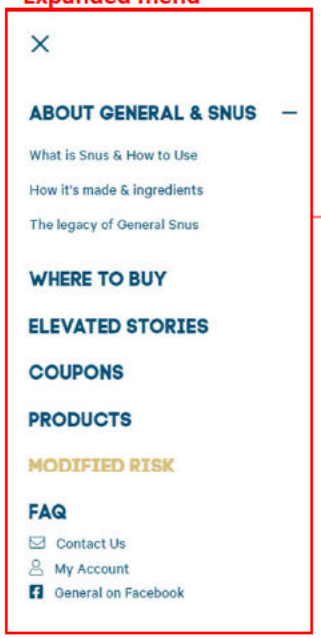
GENERAL WEBSITE REFRESH - *MENU: COLLAPSED & EXPANDED*

[OUTSIDE AGE GATE] Oct. 2021 - current



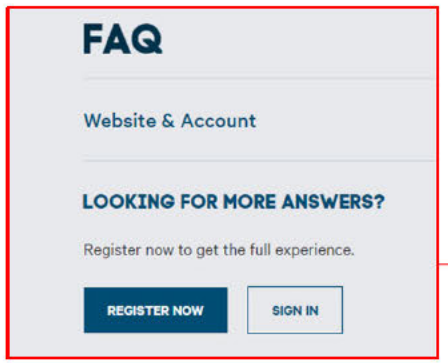
WARNING: This product is not a safe alternative to cigarettes.

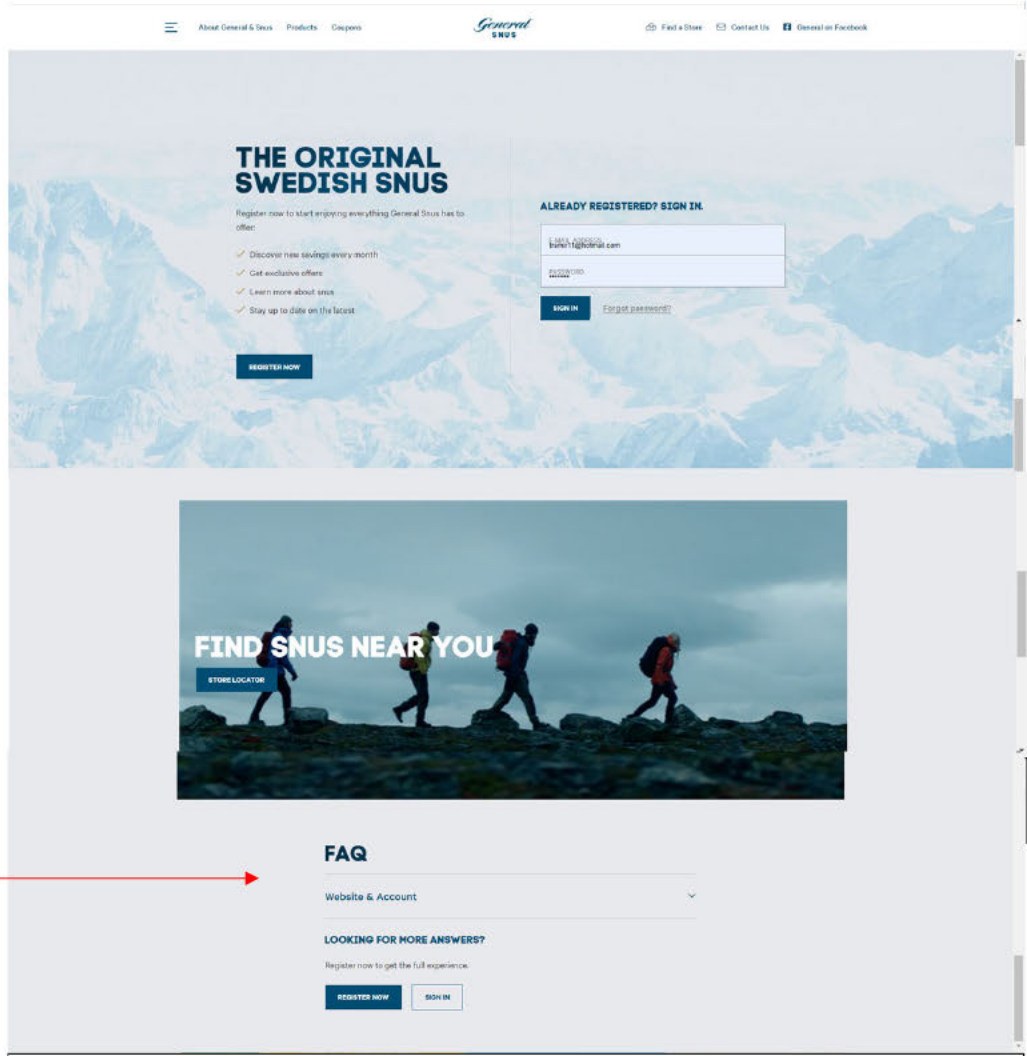
Expanded menu



WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH - *FAQS*
[OUTSIDE AGE GATE] Oct. 2021 - current

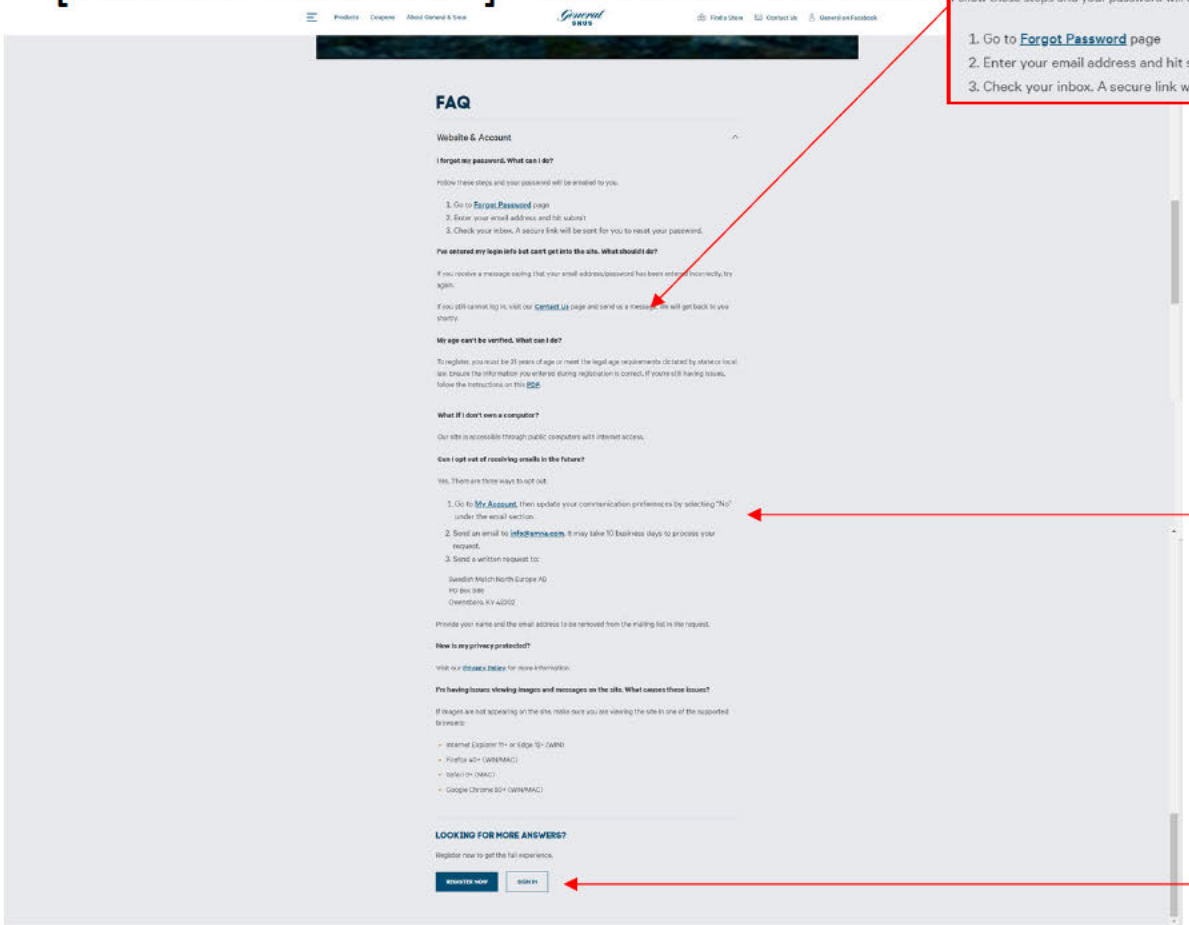




WARNING: This product is not a safe alternative to cigarettes.

Swedish Match

GENERAL WEBSITE REFRESH - *FAQS*
[OUTSIDE AGE GATE] Oct. 2021 - current



FAQ

Website & Account

I forgot my password. What can I do?

Follow these steps and your password will be emailed to you.

1. Go to Forgot Password page
2. Enter your email address and hit submit
3. Check your inbox. A secure link will be sent for you to reset your password.

I've entered my login info but can't get into the site. What should I do?

If you receive a message saying that your email address/password has been entered incorrectly, try again.

If you still cannot log in, visit our Contact Us page and send us a message. We will get back to you shortly.

My age can't be verified. What can I do?

To register, you must be 21 years of age or meet the legal age requirements dictated by state or local law. Ensure the information you entered during registration is correct. If you're still having issues, follow the instructions on this PDF.

What if I don't own a computer?

Our site is accessible through public computers with internet access.

Can I opt out of receiving emails in the future?

Yes. There are three ways to opt out:

1. Go to My Account, then update your communication preferences by selecting "No" under the email section.
2. Send an email to info@smna.com. It may take 10 business days to process your request.
3. Send a written request to:

Swedish Match North Europe AB
PO Box 986
Owensboro, KY 42302

Provide your name and the email address to be removed from the mailing list in the request.

How is my privacy protected?

Visit our Privacy Policy for more information.

I'm having issues viewing images and messages on the site. What causes these issues?

If images are not appearing on the site, make sure you are viewing the site in one of the supported browsers:

- Internet Explorer 11+ or Edge 12+ (WIN)
- Firefox 40+ (WIN/MAC)
- Safari 9+ (MAC)
- Google Chrome 50+ (WIN/MAC)

LOOKING FOR MORE ANSWERS?

Register now to get the full experience.

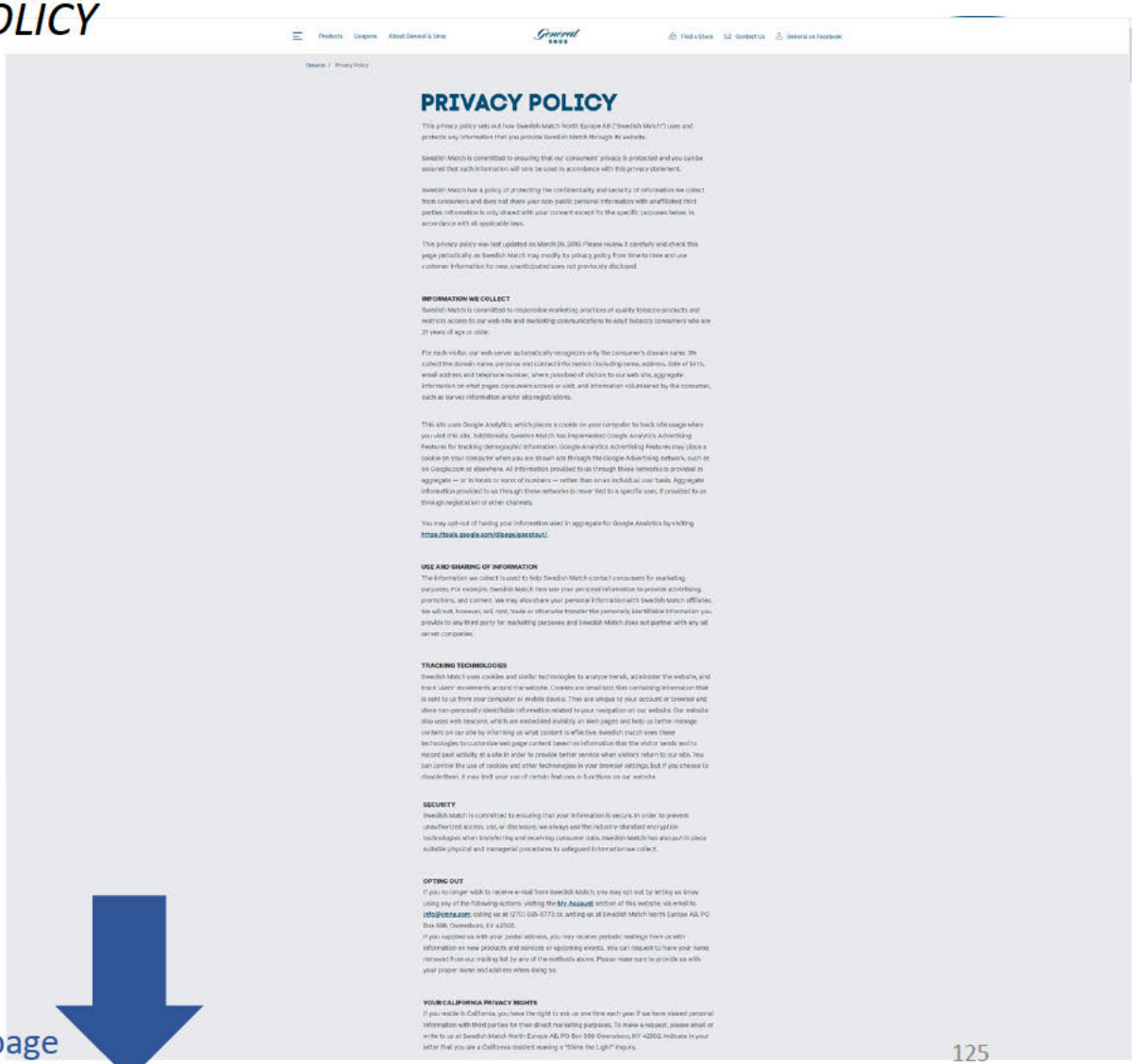
REGISTER NOW SIGN IN

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH – *PRIVACY POLICY* [OUTSIDE AGE GATE]

Oct. 2021 - current

See following two pages for copy detail.



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General / Privacy Policy

PRIVACY POLICY

This privacy policy sets out how Swedish Match North Europe AB ("Swedish Match") uses and protects any information that you provide Swedish Match through its website.

Swedish Match is committed to ensuring that our consumers' privacy is protected and you can be assured that such information will only be used in accordance with this privacy statement.

Swedish Match has a policy of protecting the confidentiality and security of information we collect from consumers and does not share your non-public personal information with unaffiliated third parties. Information is only shared with your consent except for the specific purposes below, in accordance with all applicable laws.

This privacy policy was last updated on March 26, 2015. Please review it carefully and check this page periodically, as Swedish Match may modify its privacy policy from time to time and use customer information for new, unanticipated uses not previously disclosed.

INFORMATION WE COLLECT

Swedish Match is committed to responsible marketing practices of quality tobacco products and restricts access to our web site and marketing communications to adult tobacco consumers who are 21 years of age or older.

For each visitor, our web server automatically recognizes only the consumer's domain name. We collect the domain name, personal and contact information (including name, address, date of birth, email address and telephone number, where possible) of visitors to our web site, aggregate information on what pages consumers access or visit, and information volunteered by the consumer, such as survey information and/or site registrations.

This site uses Google Analytics, which places a cookie on your computer to track site usage when you visit this site. Additionally, Swedish Match has implemented Google Analytics Advertising Features for tracking demographic information. Google Analytics Advertising Features may place a cookie on your computer when you are shown ads through the Google Advertising network, such as on Google.com or elsewhere. All information provided to us through these networks is provided in aggregate — or in totals or sums of numbers — rather than on an individual user basis. Aggregate information provided to us through these networks is never tied to a specific user, if provided to us through registration or other channels.

You may opt-out of having your information used in aggregate for Google Analytics by visiting https://tools.google.com/dlpage/gaoptout/.

USE AND SHARING OF INFORMATION

The information we collect is used to help Swedish Match contact consumers for marketing purposes. For example, Swedish Match may use your personal information to provide advertising, promotions, and content. We may also share your personal information with Swedish Match affiliates. We will not, however, sell, rent, trade or otherwise transfer the personally identifiable information you provide to any third party for marketing purposes and Swedish Match does not partner with any ad server companies.

TRACKING TECHNOLOGIES

Swedish Match uses cookies and similar technologies to analyze trends, administer the website, and track users' movements around the website. Cookies are small text files containing information that is sent to us from your computer or mobile device. They are unique to your account or browser and store non-personally identifiable information related to your navigation on our website. Our website also uses web beacons, which are embedded invisibly on Web pages and help us better manage content on our site by informing us what content is effective. Swedish match uses these technologies to customize web page content based on information that the visitor sends and to record past activity at a site in order to provide better service when visitors return to our site. You can control the use of cookies and other technologies in your browser settings, but if you choose to disable them, it may limit your use of certain features or functions on our website.

SECURITY

Swedish Match is committed to ensuring that your information is secure. In order to prevent unauthorized access, use, or disclosure, we always use the industry-standard encryption technologies when transferring and receiving consumer data. Swedish Match has also put in place suitable physical and managerial procedures to safeguard information we collect.

OPTING OUT

If you no longer wish to receive e-mail from Swedish Match, you may opt out by letting us know using any of the following options: visiting the My Account section of this website, via email to info@pmna.com, calling us at (270) 685-8770, or, writing us at Swedish Match North Europe AB, PO Box 888, Owensboro, KY 42302.

If you supplied us with your postal address, you may receive periodic mailings from us with information on new products and services or upcoming events. You can request to have your name removed from our mailing list by any of the methods above. Please make sure to provide us with your proper name and address when doing so.

YOUR CALIFORNIA PRIVACY RIGHTS

If you reside in California, you have the right to ask us one time each year if we have shared personal information with third parties for their direct marketing purposes. To make a request, please email or write to us at Swedish Match North Europe AB, PO Box 888 Owensboro, KY 42302. Indicate in your letter that you are a California resident making a "Shine the Light" inquiry.

Swedish Match

Continued on next page

GENERAL WEBSITE REFRESH – *PRIVACY POLICY CON'T*
[OUTSIDE AGE GATE] Oct. 2021 - current

PRIVACY POLICY FOR CALIFORNIA RESIDENTS

Effective Date: 1/1/2020
Last Reviewed on: 12/05/2019

This **Privacy Notice for California Residents** supplements the information contained in the Generalsnus.com Privacy Policy and applies solely to all visitors, users, and others who reside in the State of California ("consumers" or "you"). We adopt this notice to comply with the California Consumer Privacy Act of 2018 (**CCPA**) and terms defined in the **CCPA** have the same meaning when used in this notice.

INFORMATION WE COLLECT

Our website collects information that identifies, relates to, describes, references, is capable of being associated with, or could reasonably by linked, directly or indirectly, with a particular consumer or device (**"personal information"**). In particular, GENERALSNUS.COM has collected the following categories of personal information from its consumers within the last twelve (12) months:

CATEGORY	EXAMPLES	COLLECTED
A. Identifiers.	A real name, alias, postal address, unique personal identifier, online identifier, Internet Protocol address, email address, account name, driver's license number, passport number, or other similar identifiers.	YES
B. Personal information listed in the California Customer Records statute (Cal. Civ. Code § 1798.80(e)).	A name, signature, physical characteristics or description, address, telephone number, passport number, driver's license or state identification card number, education, employment or employment history. Some personal information in this category may overlap with other categories.	YES
C. Protected classification characteristics under California or federal law.	Age (40 years or older), race, color, ancestry, national origin, citizenship, religion or creed, marital status, medical condition, physical or mental disability, sex (including gender, gender identity, gender expression, pregnancy or childbirth and related medical conditions), sexual orientation, veteran or military status, genetic information (including familial genetic information).	NO
D. Commercial information.	Records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.	YES

See following page for copy detail.

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GENERAL WEBSITE REFRESH
PRIVACY POLICY CON'T
[OUTSIDE AGE GATE]
Oct. 2021 - current

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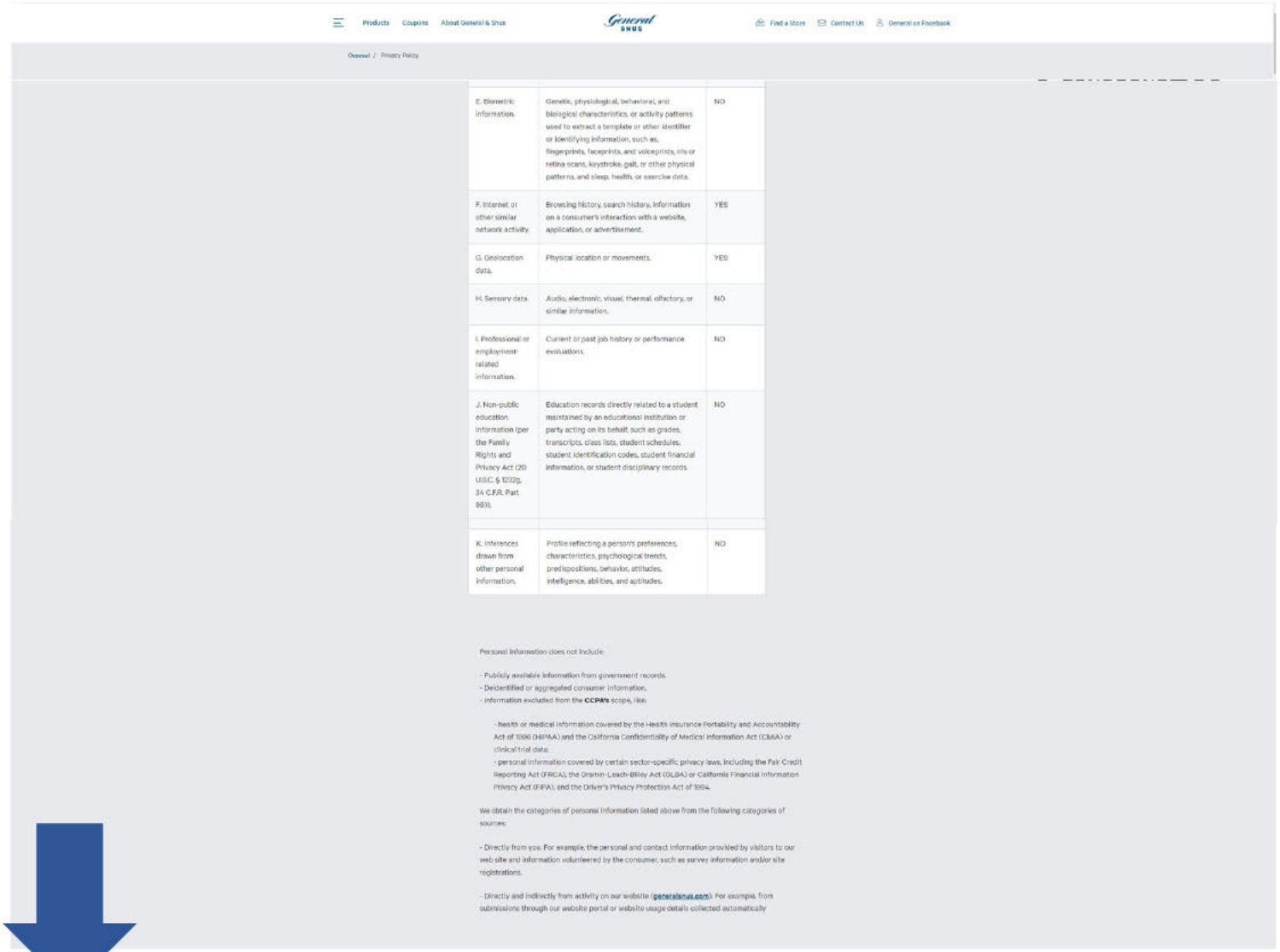

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General / Privacy Policy

E. Biometric information.	Genetic, physiological, behavioral, and biological characteristics, or activity patterns used to extract a template or other identifier or identifying information, such as, fingerprints, faceprints, and voiceprints, iris or retina scans, keystroke, gait, or other physical patterns, and sleep, health, or exercise data.	NO
F. Internet or other similar network activity.	Browsing history, search history, information on a consumer's interaction with a website, application, or advertisement.	YES
G. Geolocation data.	Physical location or movements.	YES
H. Sensory data.	Audio, electronic, visual, thermal, olfactory, or similar information.	NO
I. Professional or employment-related information.	Current or past job history or performance evaluations.	NO
J. Non-public education information (per the Family Rights and Privacy Act (20 U.S.C. § 1232g, 34 C.F.R. Part 99)).	Education records directly related to a student maintained by an educational institution or party acting on its behalf, such as grades, transcripts, class lists, student schedules, student identification codes, student financial information, or student disciplinary records.	NO
K. Inferences drawn from other personal information.	Profile reflecting a person's preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.	NO

Personal Information does not include:

- Publicly available information from government records.
- Deidentified or aggregated consumer information.
- Information excluded from the **CCPA's** scope, like:

  - health or medical information covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the California Confidentiality of Medical Information Act (CMIA) or clinical trial data;
  - personal information covered by certain sector-specific privacy laws, including the Fair Credit Reporting Act (FRCA), the Gramm-Leach-Bliley Act (GLBA) or California Financial Information Privacy Act (FIPA), and the Driver's Privacy Protection Act of 1994.

We obtain the categories of personal information listed above from the following categories of sources:

- Directly from you. For example, the personal and contact information provided by visitors to our web site and information volunteered by the consumer, such as survey information and/or site registrations.

- Directly and indirectly from activity on our website (generalsnus.com). For example, from submissions through our website portal or website usage details collected automatically

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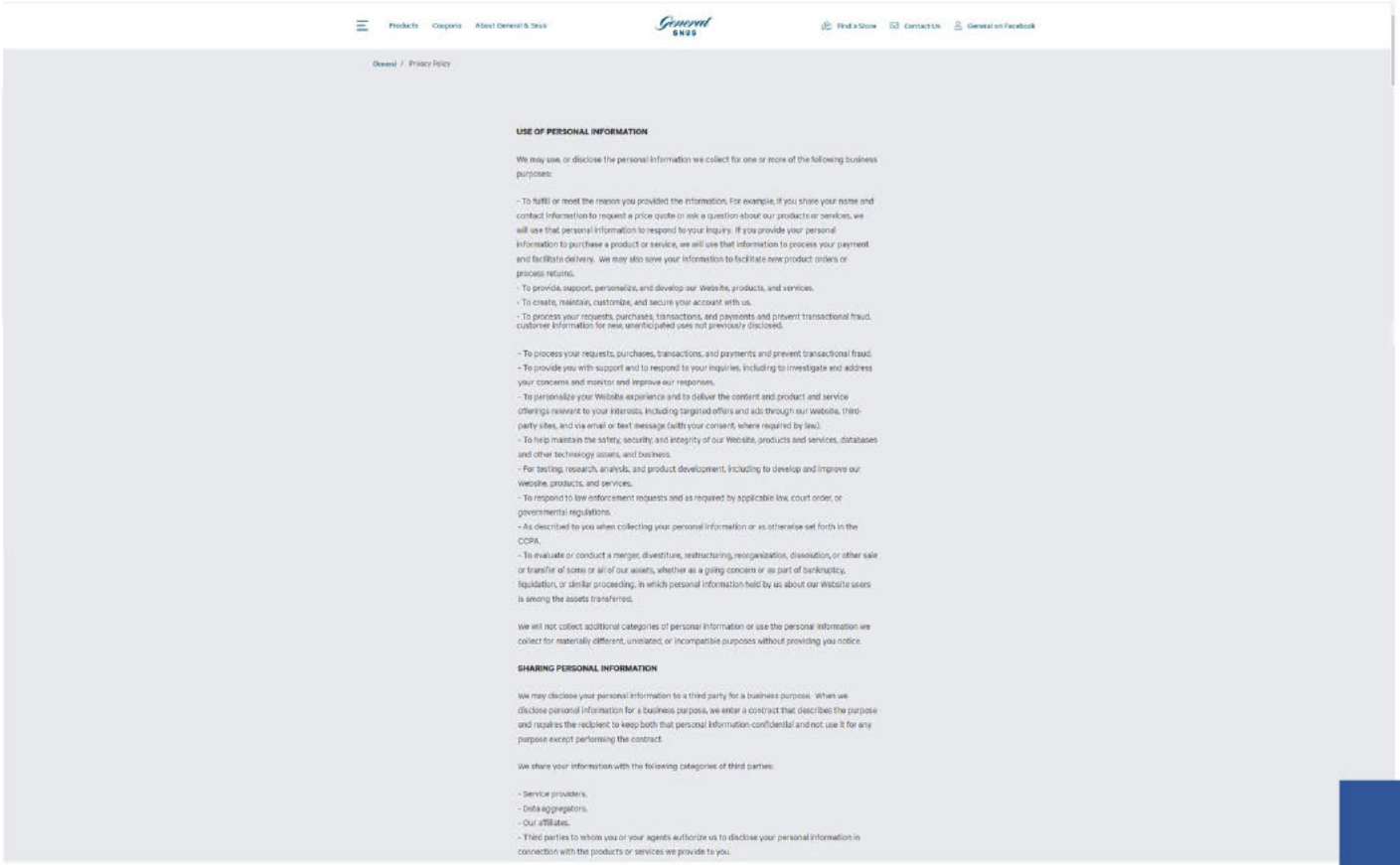
[OUTSIDE AGE GATE] Oct. 2021 - current



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General / Privacy Policy

USE OF PERSONAL INFORMATION

We may use, or disclose the personal information we collect for one or more of the following business purposes:

- To fulfill or meet the reason you provided the information. For example, if you share your name and contact information to request a price quote or ask a question about our products or services, we will use that personal information to respond to your inquiry. If you provide your personal information to purchase a product or service, we will use that information to process your payment and facilitate delivery. We may also save your information to facilitate new product orders or process returns.
- To provide, support, personalize, and develop our Website, products, and services.
- To create, maintain, customize, and secure your account with us.
- To process your requests, purchases, transactions, and payments and prevent transactional fraud.
customer information for new, unanticipated uses not previously disclosed.

- To process your requests, purchases, transactions, and payments and prevent transactional fraud.
- To provide you with support and to respond to your inquiries, including to investigate and address your concerns and monitor and improve our responses.
- To personalize your Website experience and to deliver the content and product and service offerings relevant to your interests, including targeted offers and ads through our Website, third-party sites, and via email or text message (with your consent, where required by law).
- To help maintain the safety, security, and integrity of our Website, products and services, databases and other technology assets, and business.
- For testing, research, analysis, and product development, including to develop and improve our Website, products, and services.
- To respond to law enforcement requests and as required by applicable law, court order, or governmental regulations.
- As described to you when collecting your personal information or as otherwise set forth in the CCPA.
- To evaluate or conduct a merger, divestiture, restructuring, reorganization, dissolution, or other sale or transfer of some or all of our assets, whether as a going concern or as part of bankruptcy, liquidation, or similar proceeding, in which personal information held by us about our Website users is among the assets transferred.

We will not collect additional categories of personal information or use the personal information we collect for materially different, unrelated, or incompatible purposes without providing you notice.

SHARING PERSONAL INFORMATION

We may disclose your personal information to a third party for a business purpose. When we disclose personal information for a business purpose, we enter a contract that describes the purpose and requires the recipient to keep both that personal information confidential and not use it for any purpose except performing the contract.

We share your information with the following categories of third parties:

- Service providers.
- Data aggregators.
- Our affiliates.
- Third parties to whom you or your agents authorize us to disclose your personal information in connection with the products or services we provide to you.

See following page for copy detail.

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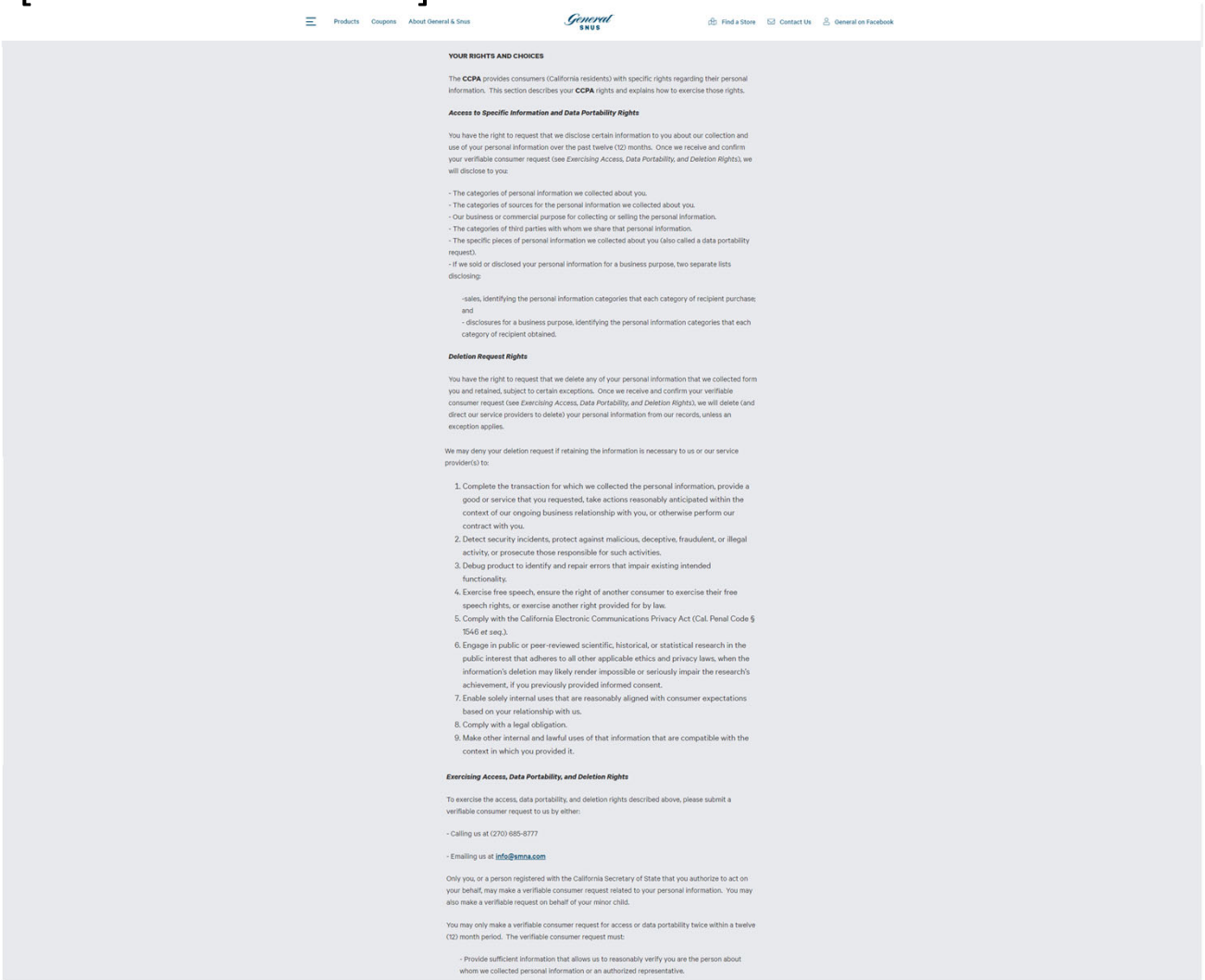
GENERAL WEBSITE REFRESH – *PRIVACY POLICY CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current



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YOUR RIGHTS AND CHOICES

The **CCPA** provides consumers (California residents) with specific rights regarding their personal information. This section describes your **CCPA** rights and explains how to exercise those rights.

Access to Specific Information and Data Portability Rights

You have the right to request that we disclose certain information to you about our collection and use of your personal information over the past twelve (12) months. Once we receive and confirm your verifiable consumer request (see *Exercising Access, Data Portability, and Deletion Rights*), we will disclose to you:

- The categories of personal information we collected about you.
- The categories of sources for the personal information we collected about you.
- Our business or commercial purpose for collecting or selling the personal information.
- The categories of third parties with whom we share that personal information.
- The specific pieces of personal information we collected about you (also called a data portability request).
- If we sold or disclosed your personal information for a business purpose, two separate lists disclosing:

  -sales, identifying the personal information categories that each category of recipient purchase; and
  - disclosures for a business purpose, identifying the personal information categories that each category of recipient obtained.

Deletion Request Rights

You have the right to request that we delete any of your personal information that we collected form you and retained, subject to certain exceptions. Once we receive and confirm your verifiable consumer request (see *Exercising Access, Data Portability, and Deletion Rights*), we will delete (and direct our service providers to delete) your personal information from our records, unless an exception applies.

We may deny your deletion request if retaining the information is necessary to us or our service provider(s) to:

1. Complete the transaction for which we collected the personal information, provide a good or service that you requested, take actions reasonably anticipated within the context of our ongoing business relationship with you, or otherwise perform our contract with you.
2. Detect security incidents, protect against malicious, deceptive, fraudulent, or illegal activity, or prosecute those responsible for such activities.
3. Debug product to identify and repair errors that impair existing intended functionality.
4. Exercise free speech, ensure the right of another consumer to exercise their free speech rights, or exercise another right provided for by law.
5. Comply with the California Electronic Communications Privacy Act (Cal. Penal Code § 1546 *et seq.*).
6. Engage in public or peer-reviewed scientific, historical, or statistical research in the public interest that adheres to all other applicable ethics and privacy laws, when the information's deletion may likely render impossible or seriously impair the research's achievement, if you previously provided informed consent.
7. Enable solely internal uses that are reasonably aligned with consumer expectations based on your relationship with us.
8. Comply with a legal obligation.
9. Make other internal and lawful uses of that information that are compatible with the context in which you provided it.

Exercising Access, Data Portability, and Deletion Rights

To exercise the access, data portability, and deletion rights described above, please submit a verifiable consumer request to us by either:

- Calling us at (270) 685-8777

- Emailing us at info@smna.com

Only you, or a person registered with the California Secretary of State that you authorize to act on your behalf, may make a verifiable consumer request related to your personal information. You may also make a verifiable request on behalf of your minor child.

You may only make a verifiable consumer request for access or data portability twice within a twelve (12) month period. The verifiable consumer request must:

- Provide sufficient information that allows us to reasonably verify you are the person about whom we collected personal information or an authorized representative.

See following page for copy detail.

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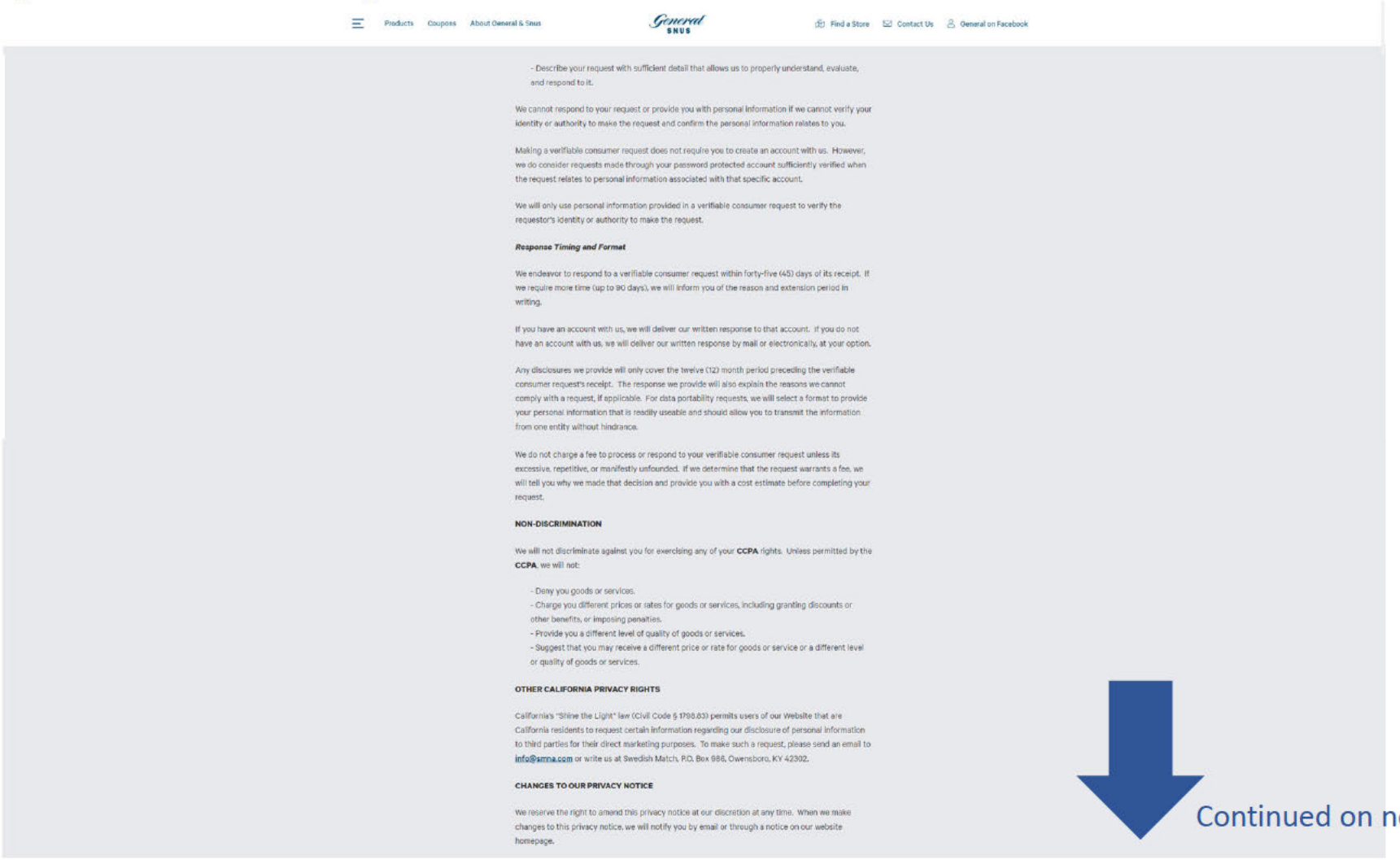
GENERAL WEBSITE REFRESH – *PRIVACY POLICY CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current



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- Describe your request with sufficient detail that allows us to properly understand, evaluate, and respond to it.

We cannot respond to your request or provide you with personal information if we cannot verify your identity or authority to make the request and confirm the personal information relates to you.

Making a verifiable consumer request does not require you to create an account with us. However, we do consider requests made through your password protected account sufficiently verified when the request relates to personal information associated with that specific account.

We will only use personal information provided in a verifiable consumer request to verify the requestor's identity or authority to make the request.

Response Timing and Format

We endeavor to respond to a verifiable consumer request within forty-five (45) days of its receipt. If we require more time (up to 90 days), we will inform you of the reason and extension period in writing.

If you have an account with us, we will deliver our written response to that account. If you do not have an account with us, we will deliver our written response by mail or electronically, at your option.

Any disclosures we provide will only cover the twelve (12) month period preceding the verifiable consumer request's receipt. The response we provide will also explain the reasons we cannot comply with a request, if applicable. For data portability requests, we will select a format to provide your personal information that is readily useable and should allow you to transmit the information from one entity without hindrance.

We do not charge a fee to process or respond to your verifiable consumer request unless its excessive, repetitive, or manifestly unfounded. If we determine that the request warrants a fee, we will tell you why we made that decision and provide you with a cost estimate before completing your request.

NON-DISCRIMINATION

We will not discriminate against you for exercising any of your **CCPA** rights. Unless permitted by the **CCPA**, we will not:

- Deny you goods or services.
- Charge you different prices or rates for goods or services, including granting discounts or other benefits, or imposing penalties.
- Provide you a different level of quality of goods or services.
- Suggest that you may receive a different price or rate for goods or service or a different level or quality of goods or services.

OTHER CALIFORNIA PRIVACY RIGHTS

California's "Shine the Light" law (Civil Code § 1798.83) permits users of our Website that are California residents to request certain information regarding our disclosure of personal information to third parties for their direct marketing purposes. To make such a request, please send an email to info@smna.com or write us at Swedish Match, P.O. Box 988, Owensboro, KY 42302.

CHANGES TO OUR PRIVACY NOTICE

We reserve the right to amend this privacy notice at our discretion at any time. When we make changes to this privacy notice, we will notify you by email or through a notice on our website homepage.

See following page for copy detail.

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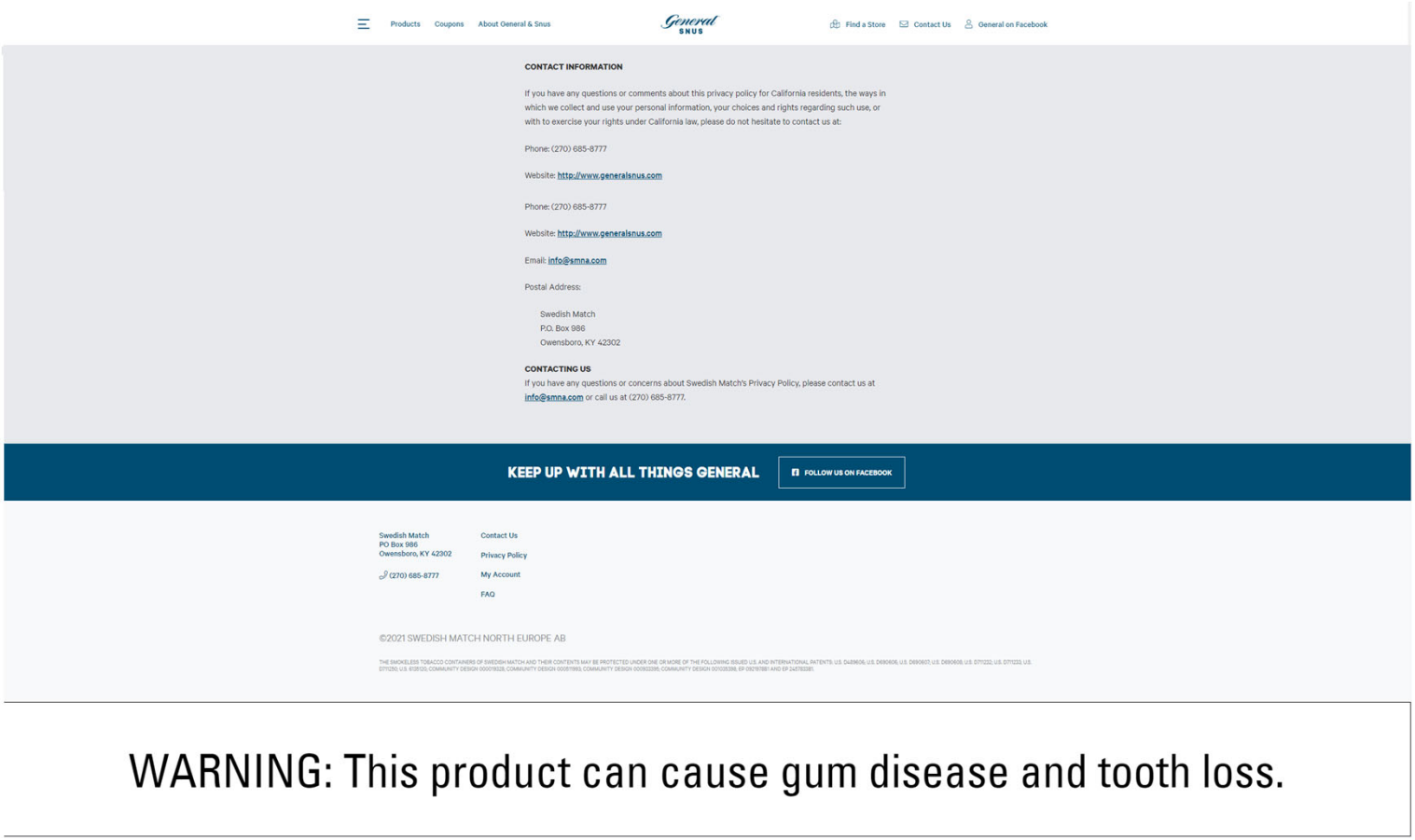
GENERAL WEBSITE REFRESH – *PRIVACY POLICY CON'T*
[OUTSIDE AGE GATE] Oct. 2021 - current



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GENERAL WEBSITE REFRESH - *PRIVACY POLICY, COPY DETAIL CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current

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If you supplied us with your postal address, you may receive periodic mailings from us with information on new products and services or upcoming events. You can request to have your name removed from our mailing list by any of the methods above. Please make sure to provide us with your proper name and address when doing so.

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B. Personal information listed in the California Customer Records statute (Cal. Civ. Code § 1798.80(e)).	A name, signature, physical characteristics or description, address, telephone number, passport number, driver's license or state identification card number, education, employment or employment history. Some personal information in this category may overlap with other categories.	YES
C. Protected classification characteristics under California or federal law.	Age (40 years or older), race, color, ancestry, national origin, citizenship, religion or creed, marital status, medical condition, physical or mental disability, sex (including gender, gender identity, gender expression, pregnancy or childbirth and related medical conditions), sexual orientation, veteran or military status, genetic information (including familiar genetic information).	NO
D. Commercial information.	Records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.	YES

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GENERAL WEBSITE REFRESH – *PRIVACY POLICY, COPY DETAIL CON'T*
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Oct. 2021 - current

E. Biometric information.	Genetic, physiological, behavioral, and biological characteristics, or activity patterns used to extract a template or other identifier or identifying information, such as, fingerprints, faceprints, and voiceprints, iris or retina scans, keystroke, gait, or other physical patterns, and sleep, health, or exercise data.	NO
F. Internet or other similar network activity.	Browsing history, search history, information on a consumer's interaction with a website, application, or advertisement.	YES
G. Geolocation data.	Physical location or movements.	YES
H. Sensory data.	Audio, electronic, visual, thermal, olfactory, or similar information.	NO
I. Professional or employment-related information.	Current or past job history or performance evaluations.	NO
J. Non-public education information (per the Family Rights and Privacy Act (20 U.S.C. § 1232g, 34 C.F.R. Part 99)).	Education records directly related to a student maintained by an educational institution or party acting on its behalf, such as grades, transcripts, class lists, student schedules, student identification codes, student financial information, or student disciplinary records.	NO
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- To provide, support, personalize, and develop our Website, products, and services.
- To create, maintain, customize, and secure your account with us.
- To process your requests, purchases, transactions, and payments and prevent transactional fraud.
- To provide you with support and to respond to your inquiries, including to investigate and address your concerns and monitor and improve our responses.
- To personalize your Website experience and to deliver the content and product and service offerings relevant to your interests, including targeted offers and ads through our Website, third-party sites, and via email or text message (with your consent, where required by law).
- To help maintain the safety, security, and integrity of our Website, products and services, databases and other technology assets, and business.
- For testing, research, analysis, and product development, including to develop and improve our Website, products, and services.
- To respond to law enforcement requests and as required by applicable law, court order, or governmental regulations.
- As described to you when collecting your personal information or as otherwise set forth in the CCPA.
- To evaluate or conduct a merger, divestiture, restructuring, reorganization, dissolution, or other sale or transfer of some or all of our assets, whether as a going concern or as part of bankruptcy, liquidation, or similar proceeding, in which personal information held by us about our Website users is among the assets transferred.

We will not collect additional categories of personal information or use the personal information we collect for materially different, unrelated, or incompatible purposes without providing you notice.

SHARING PERSONAL INFORMATION

We may disclose your personal information to a third party for a business purpose. When we disclose personal information for a business purpose, we enter a contract that describes the purpose and requires the recipient to keep both that personal information confidential and not use it for any purpose except performing the contract.

We share your information with the following categories of third parties:

- Service providers.
- Data aggregators.
- Our affiliates.
- Third parties to whom you or your agents authorize us to disclose your personal information in connection with the products or services we provide to you.

Continued on next page

GENERAL WEBSITE REFRESH – *PRIVACY POLICY, COPY DETAIL CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current

YOUR RIGHTS AND CHOICES

The **CCPA** provides consumers (California residents) with specific rights regarding their personal information. This section describes your **CCPA** rights and explains how to exercise those rights.

Access to Specific Information and Data Portability Rights

You have the right to request that we disclose certain information to you about our collection and use of your personal information over the past twelve (12) months. Once we receive and confirm your verifiable consumer request (see *Exercising Access, Data Portability, and Deletion Rights*), we will disclose to you:

- The categories of personal information we collected about you.
- The categories of sources for the personal information we collected about you.
- Our business or commercial purpose for collecting or selling the personal information.
- The categories of third parties with whom we share that personal information.
- The specific pieces of personal information we collected about you (also called a data portability request).
- If we sold or disclosed your personal information for a business purpose, two separate lists disclosing:

  -sales, identifying the personal information categories that each category of recipient purchase; and
  - disclosures for a business purpose, identifying the personal information categories that each category of recipient obtained.

Deletion Request Rights

You have the right to request that we delete any of your personal information that we collected form you and retained, subject to certain exceptions. Once we receive and confirm your verifiable consumer request (see *Exercising Access, Data Portability, and Deletion Rights*), we will delete (and direct our service providers to delete) your personal information from our records, unless an exception applies.

We may deny your deletion request if retaining the information is necessary to us or our service provider(s) to:

1. Complete the transaction for which we collected the personal information, provide a good or service that you requested, take actions reasonably anticipated within the context of our ongoing business relationship with you, or otherwise perform our contract with you.
2. Detect security incidents, protect against malicious, deceptive, fraudulent, or illegal activity, or prosecute those responsible for such activities.
3. Debug product to identify and repair errors that impair existing intended functionality.
4. Exercise free speech, ensure the right of another consumer to exercise their free speech rights, or exercise another right provided for by law.
5. Comply with the California Electronic Communications Privacy Act (Cal. Penal Code § 1546 *et seq.*).
6. Engage in public or peer-reviewed scientific, historical, or statistical research in the public interest that adheres to all other applicable ethics and privacy laws, when the information's deletion may likely render impossible or seriously impair the research's achievement, if you previously provided informed consent.
7. Enable solely internal uses that are reasonably aligned with consumer expectations based on your relationship with us.
8. Comply with a legal obligation.
9. Make other internal and lawful uses of that information that are compatible with the context in which you provided it.

Exercising Access, Data Portability, and Deletion Rights

To exercise the access, data portability, and deletion rights described above, please submit a verifiable consumer request to us by either:

- Calling us at (270) 685-8777

- Emailing us at info@smna.com

Only you, or a person registered with the California Secretary of State that you authorize to act on your behalf, may make a verifiable consumer request related to your personal information. You may also make a verifiable request on behalf of your minor child.

You may only make a verifiable consumer request for access or data portability twice within a twelve (12) month period. The verifiable consumer request must:

- Provide sufficient information that allows us to reasonably verify you are the person about whom we collected personal information or an authorized representative.

Continued on next page

GENERAL WEBSITE REFRESH – *PRIVACY POLICY, COPY DETAIL CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current

- Describe your request with sufficient detail that allows us to properly understand, evaluate, and respond to it.

We cannot respond to your request or provide you with personal information if we cannot verify your identity or authority to make the request and confirm the personal information relates to you.

Making a verifiable consumer request does not require you to create an account with us. However, we do consider requests made through your password protected account sufficiently verified when the request relates to personal information associated with that specific account.

We will only use personal information provided in a verifiable consumer request to verify the requestor's identity or authority to make the request.

Response Timing and Format

We endeavor to respond to a verifiable consumer request within forty-five (45) days of its receipt. If we require more time (up to 90 days), we will inform you of the reason and extension period in writing.

If you have an account with us, we will deliver our written response to that account. If you do not have an account with us, we will deliver our written response by mail or electronically, at your option.

Any disclosures we provide will only cover the twelve (12) month period preceding the verifiable consumer request's receipt. The response we provide will also explain the reasons we cannot comply with a request, if applicable. For data portability requests, we will select a format to provide your personal information that is readily useable and should allow you to transmit the information from one entity without hindrance.

We do not charge a fee to process or respond to your verifiable consumer request unless its excessive, repetitive, or manifestly unfounded. If we determine that the request warrants a fee, we will tell you why we made that decision and provide you with a cost estimate before completing your request.

NON-DISCRIMINATION

We will not discriminate against you for exercising any of your **CCPA** rights. Unless permitted by the **CCPA**, we will not:

- Deny you goods or services.
- Charge you different prices or rates for goods or services, including granting discounts or other benefits, or imposing penalties.
- Provide you a different level of quality of goods or services.
- Suggest that you may receive a different price or rate for goods or service or a different level or quality of goods or services.

OTHER CALIFORNIA PRIVACY RIGHTS

California's "Shine the Light" law (Civil Code § 1798.83) permits users of our Website that are California residents to request certain information regarding our disclosure of personal information to third parties for their direct marketing purposes. To make such a request, please send an email to info@smna.com or write us at Swedish Match, P.O. Box 986, Owensboro, KY 42302.

CHANGES TO OUR PRIVACY NOTICE

We reserve the right to amend this privacy notice at our discretion at any time. When we make changes to this privacy notice, we will notify you by email or through a notice on our website homepage.

Continued on next page

GENERAL WEBSITE REFRESH – *PRIVACY POLICY, COPY DETAIL CON'T*

[OUTSIDE AGE GATE] Oct. 2021 - current

CONTACT INFORMATION

If you have any questions or comments about this privacy policy for California residents, the ways in which we collect and use your personal information, your choices and rights regarding such use, or with to exercise your rights under California law, please do not hesitate to contact us at:

Phone: (270) 685-8777

Website: http://www.generalsnus.com

Email: info@smna.com

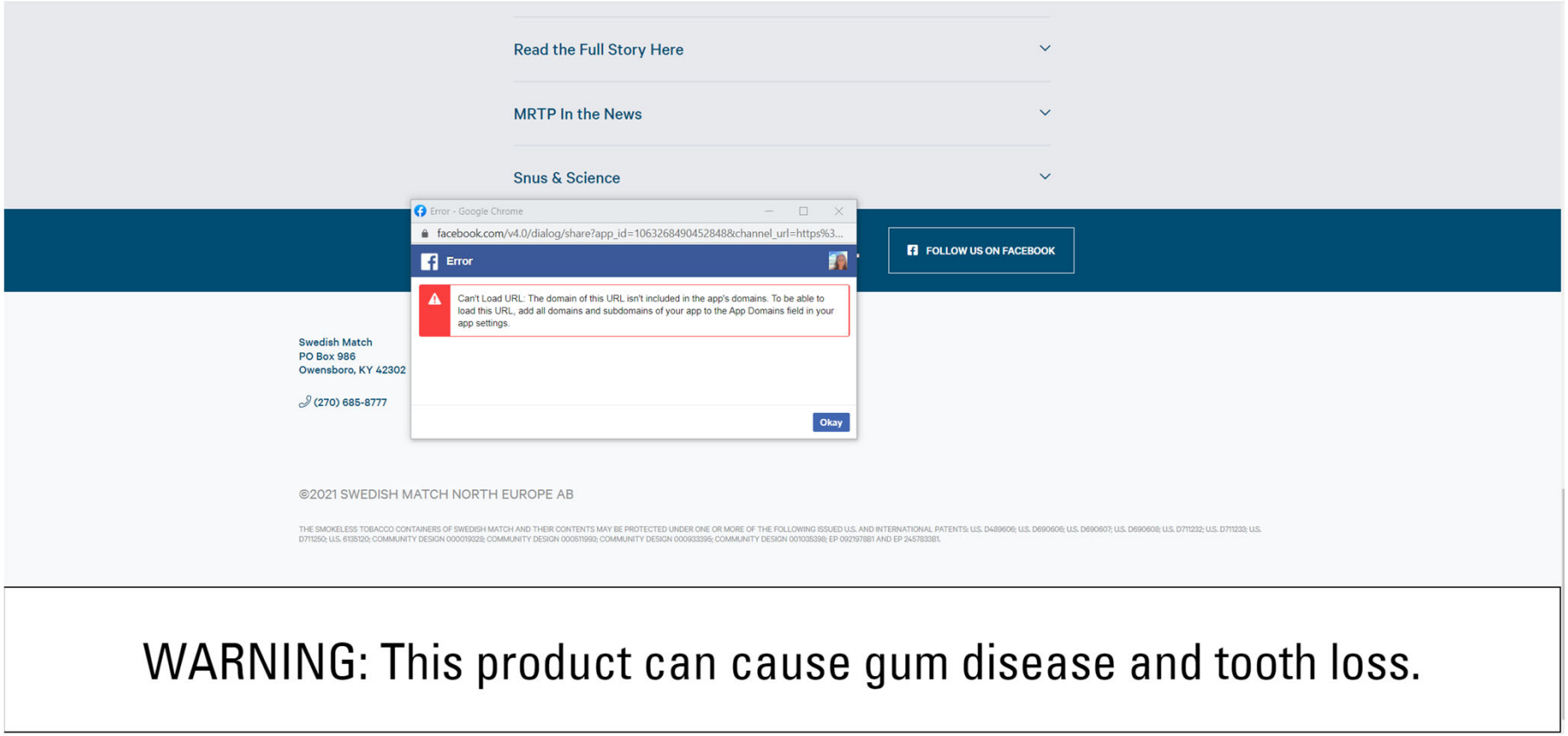
Postal Address:

Swedish Match
P.O. Box 986
Owensboro, KY 42302

CONTACTING US

If you have any questions or concerns about Swedish Match's Privacy Policy, please contact us at info@smna.com or call us at (270) 685-8777.

GENERAL SNUS WEBSITE REFRESH - *FOOTER FACEBOOK LINK*
[OUTSIDE AGE GATE] Oct. 2021 - current

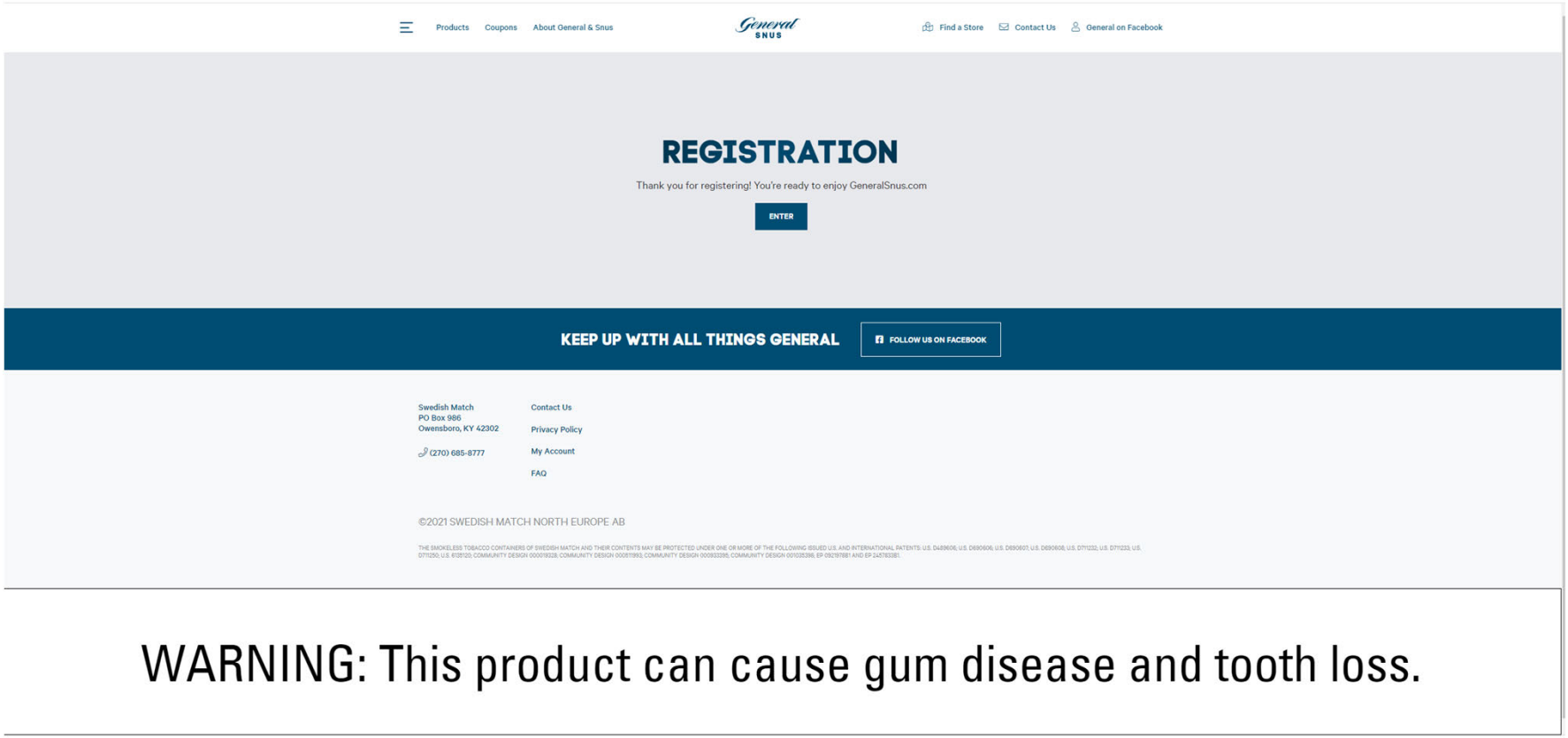


GENERAL SNUS WEBSITE REFRESH (MRTP PAGES)
Behind Age Gate
October 2021 - current

Swedish Match

GENERAL WEBSITE REFRESH – *REGISTRATION CONFIRMATION*

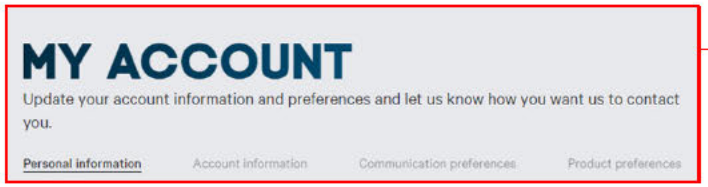
[BEHIND AGE GATE] Oct. 2021 - current

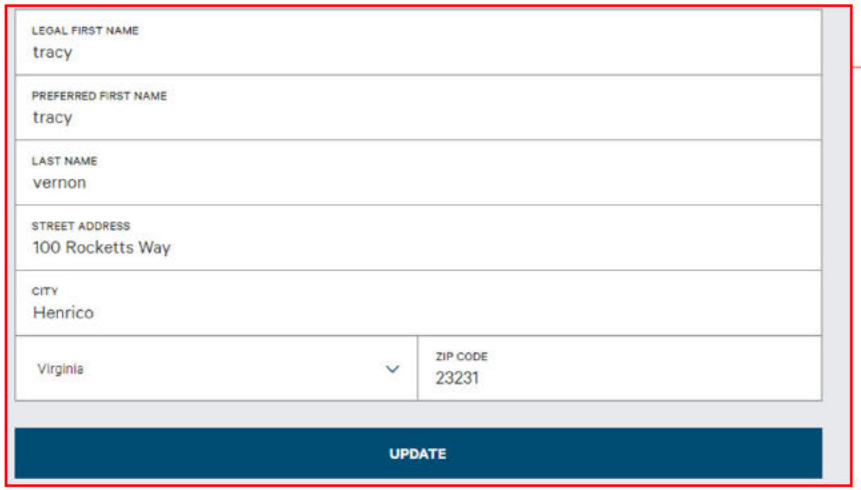


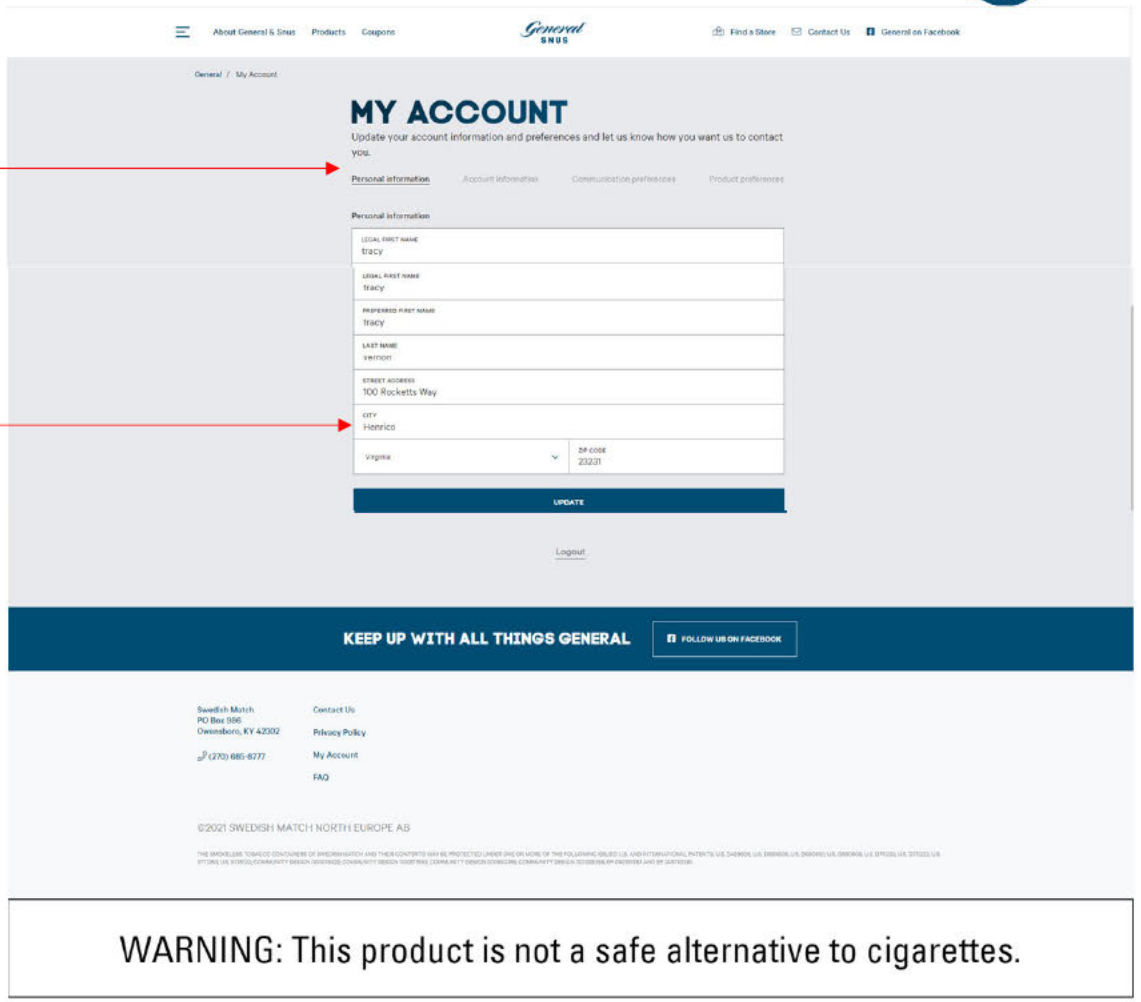
GENERAL WEBSITE REFRESH – MY ACCOUNT, *PERSONAL INFORMATION*

[BEHIND AGE GATE]

Oct. 2021 - current

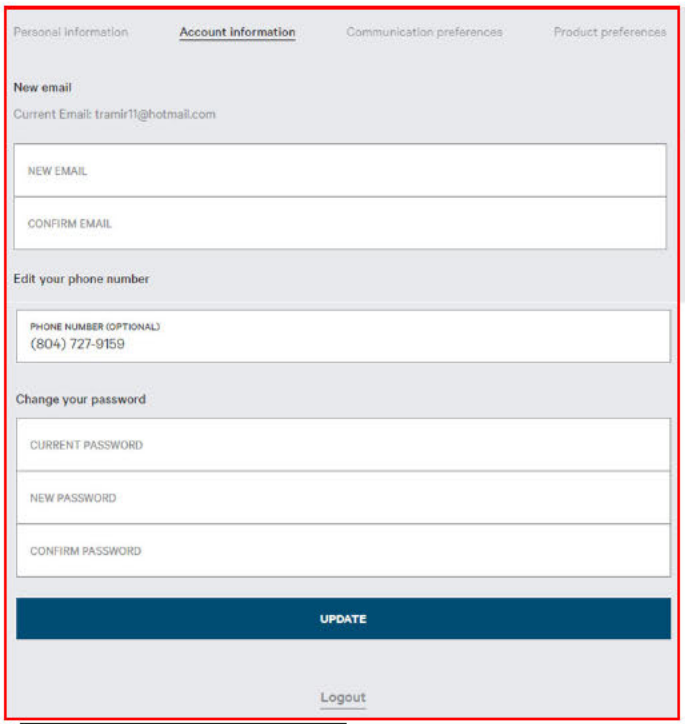


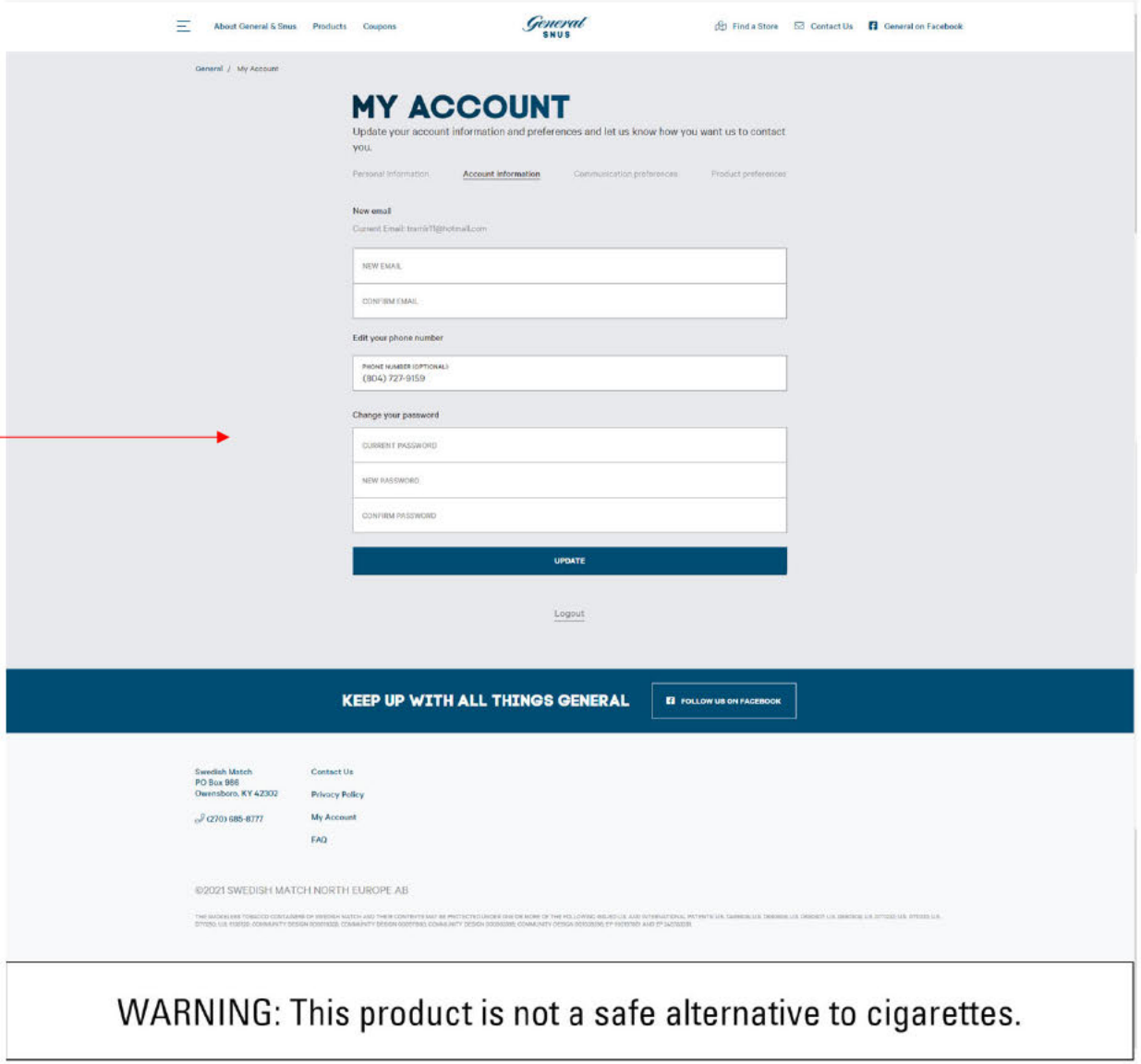




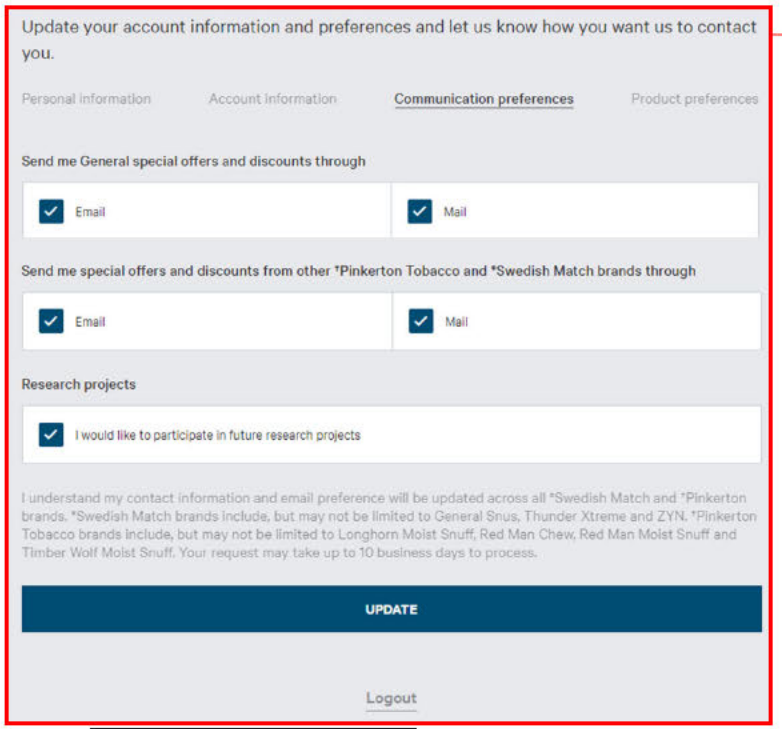
WARNING: This product is not a safe alternative to cigarettes.

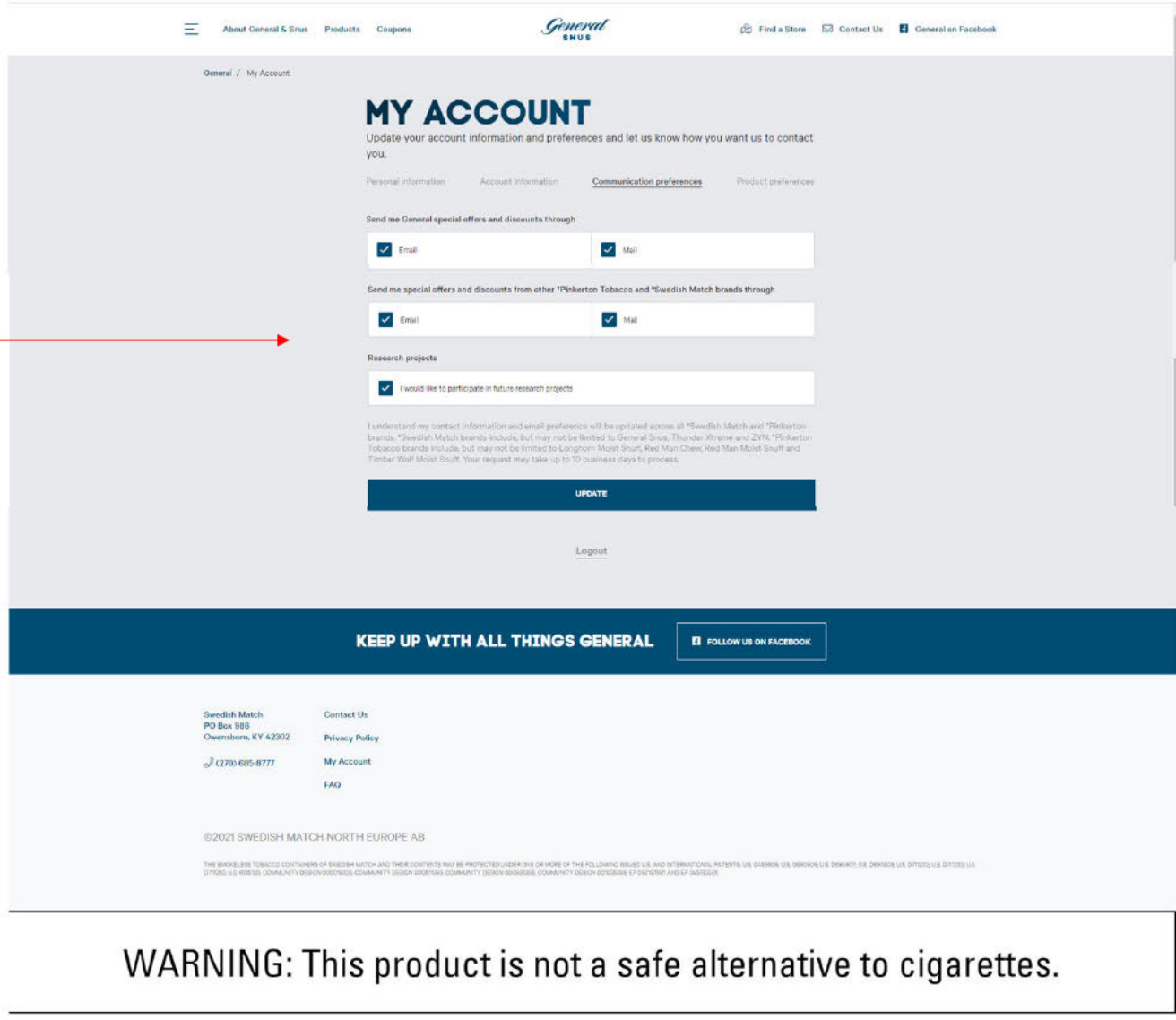
GENERAL WEBSITE REFRESH
MY ACCOUNT,
ACCOUNT INFORMATION
[BEHIND AGE GATE]
Oct. 2021 - current





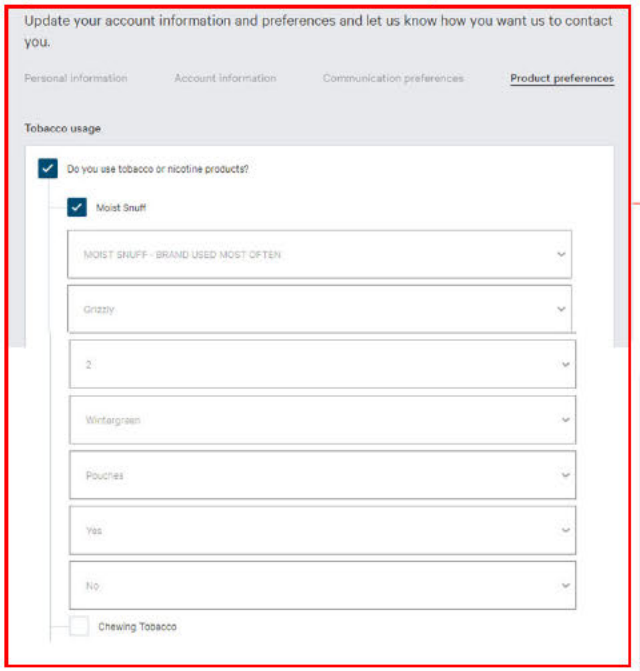
GENERAL WEBSITE REFRESH
MY ACCOUNT,
COMMUNICATION PREFERENCES
[BEHIND AGE GATE]
Oct. 2021 - current

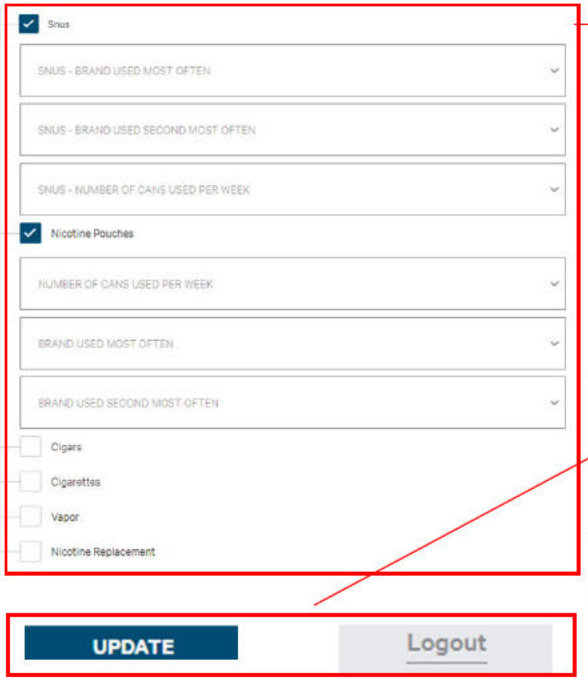


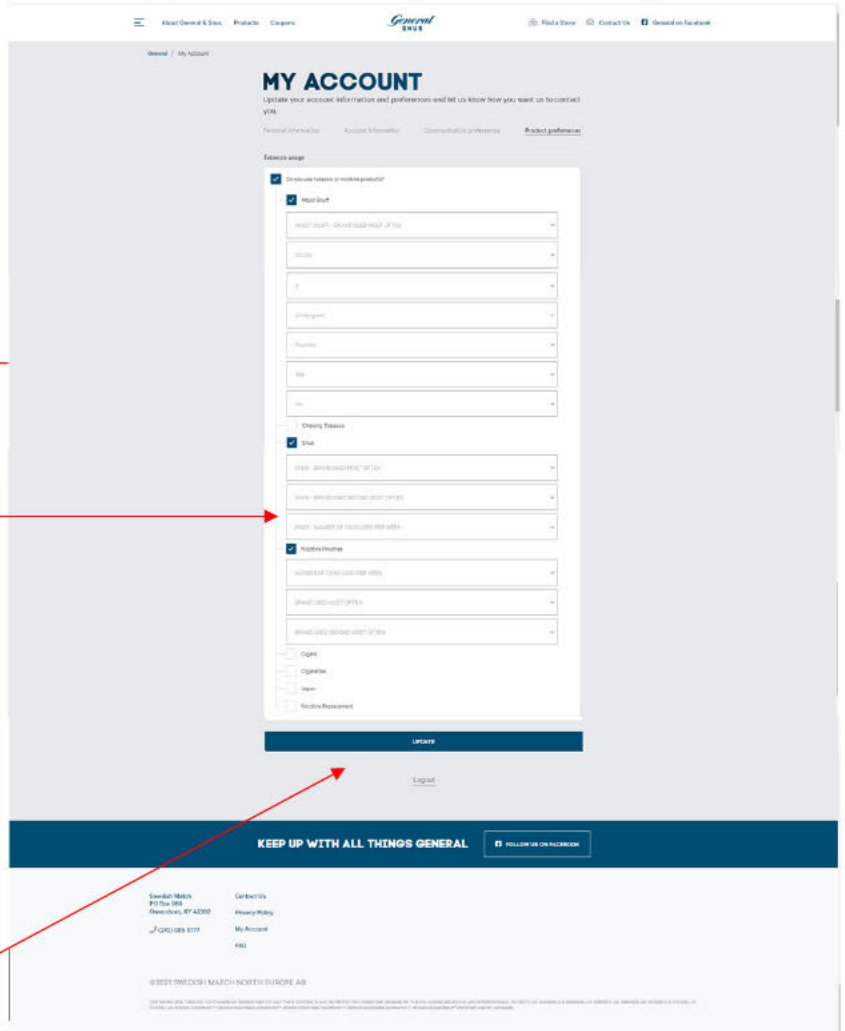


WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH: MY ACCOUNT, *PRODUCT PREFERENCES* [BEHIND AGE GATE] Oct. 2021 - current



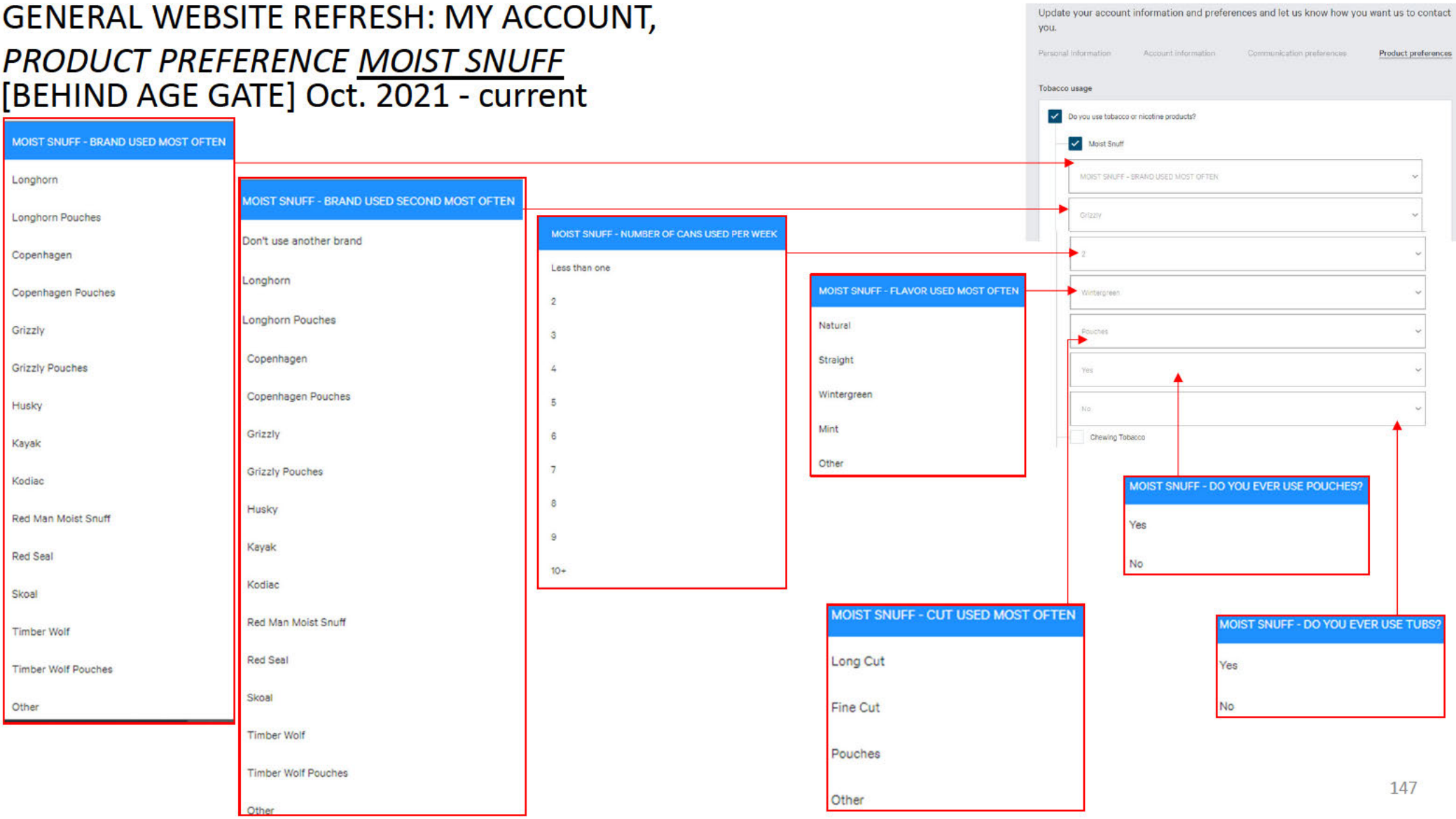




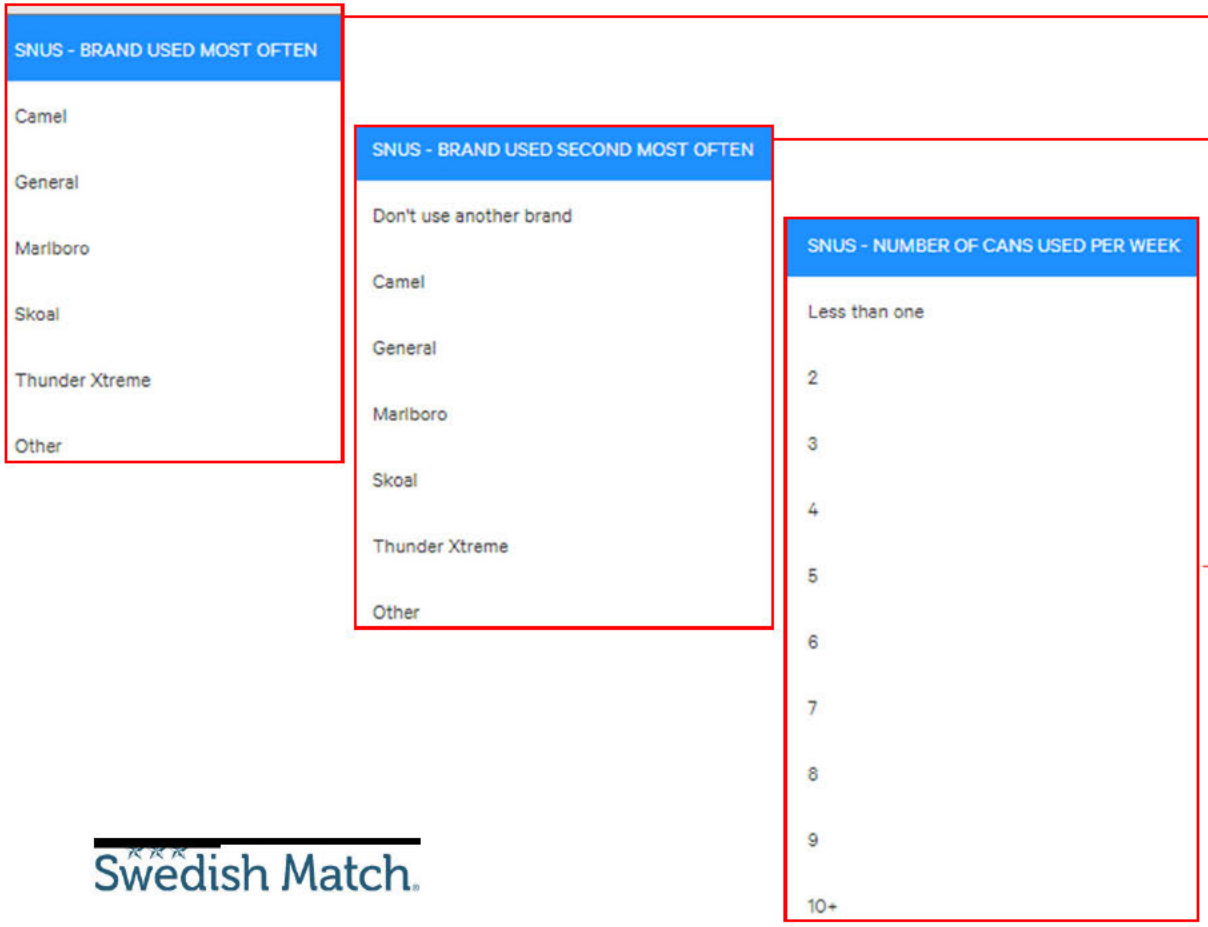
WARNING: This product is not a safe alternative to cigarettes.

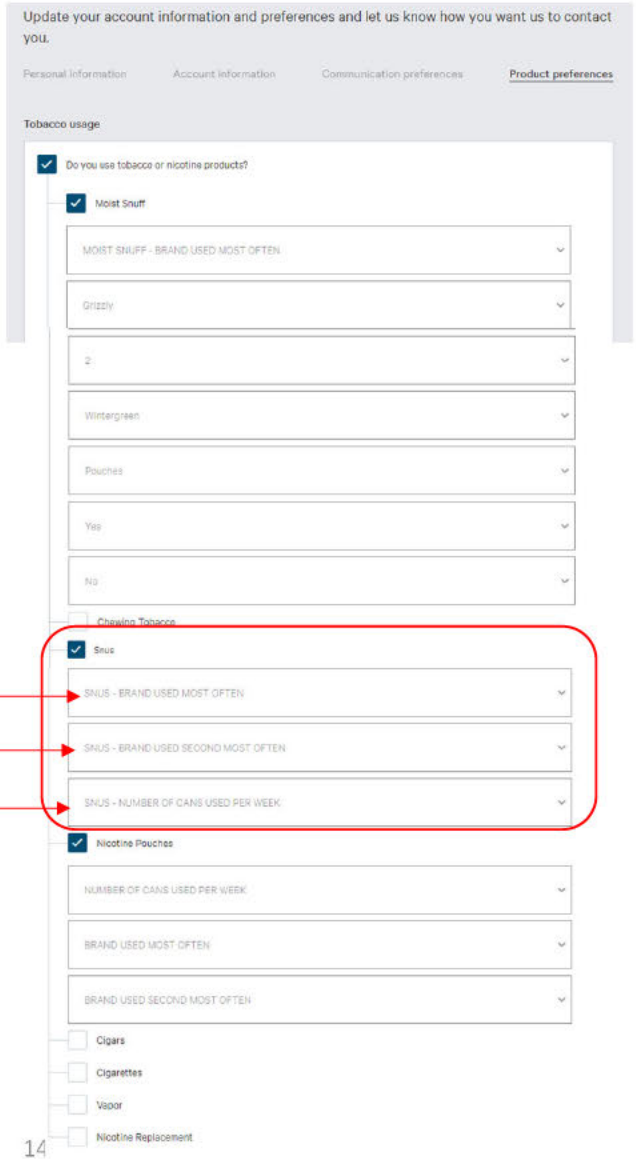
Swedish Match

GENERAL WEBSITE REFRESH: MY ACCOUNT, *PRODUCT PREFERENCE MOIST SNUFF* [BEHIND AGE GATE] Oct. 2021 - current



GENERAL WEBSITE REFRESH: MY ACCOUNT, *PRODUCT PREFERENCES, SNUS* [BEHIND AGE GATE] Oct. 2021 - current

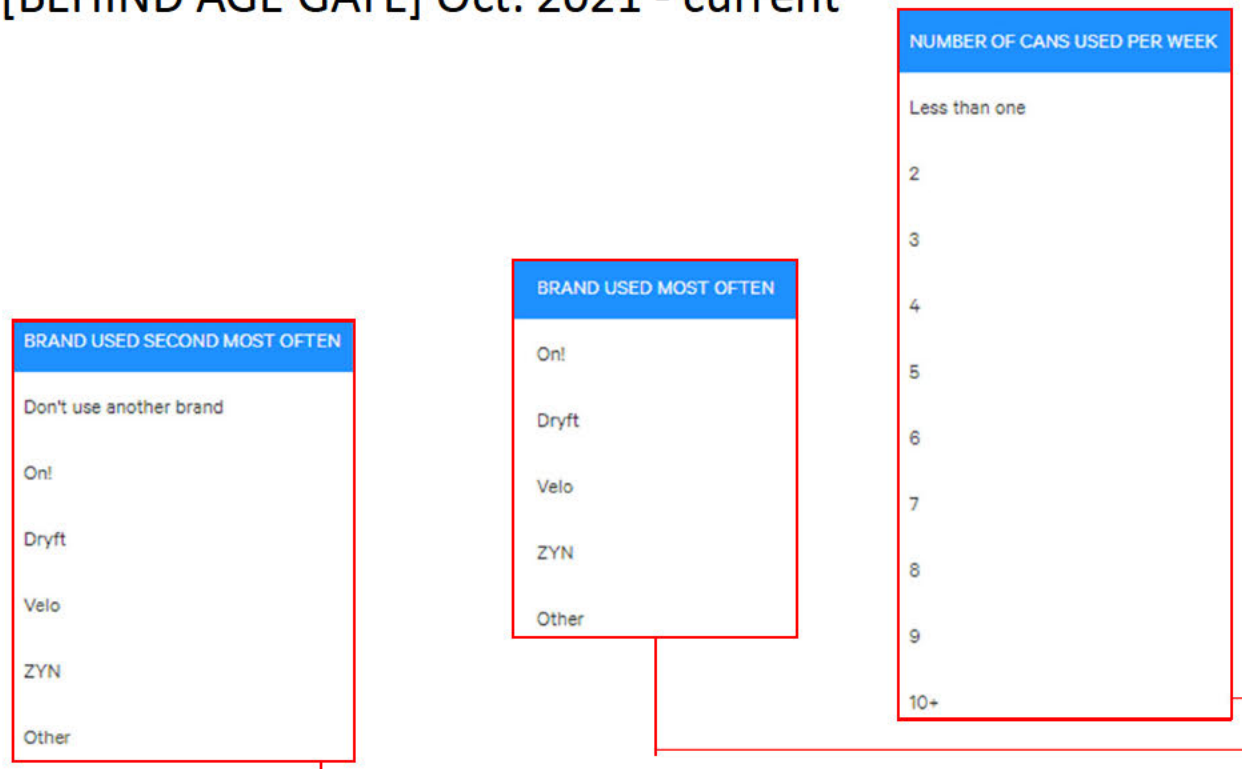


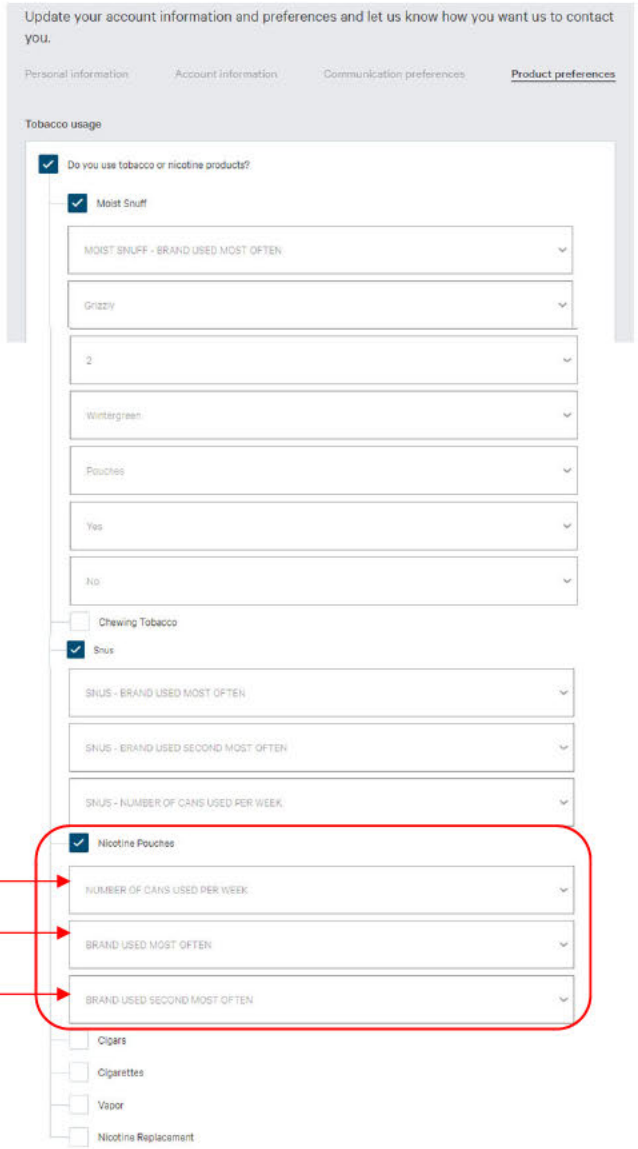


Swedish Match

GENERAL WEBSITE REFRESH: MY ACCOUNT, *PRODUCT PREFERENCES, NICOTINE POUCHES*

[BEHIND AGE GATE] Oct. 2021 - current

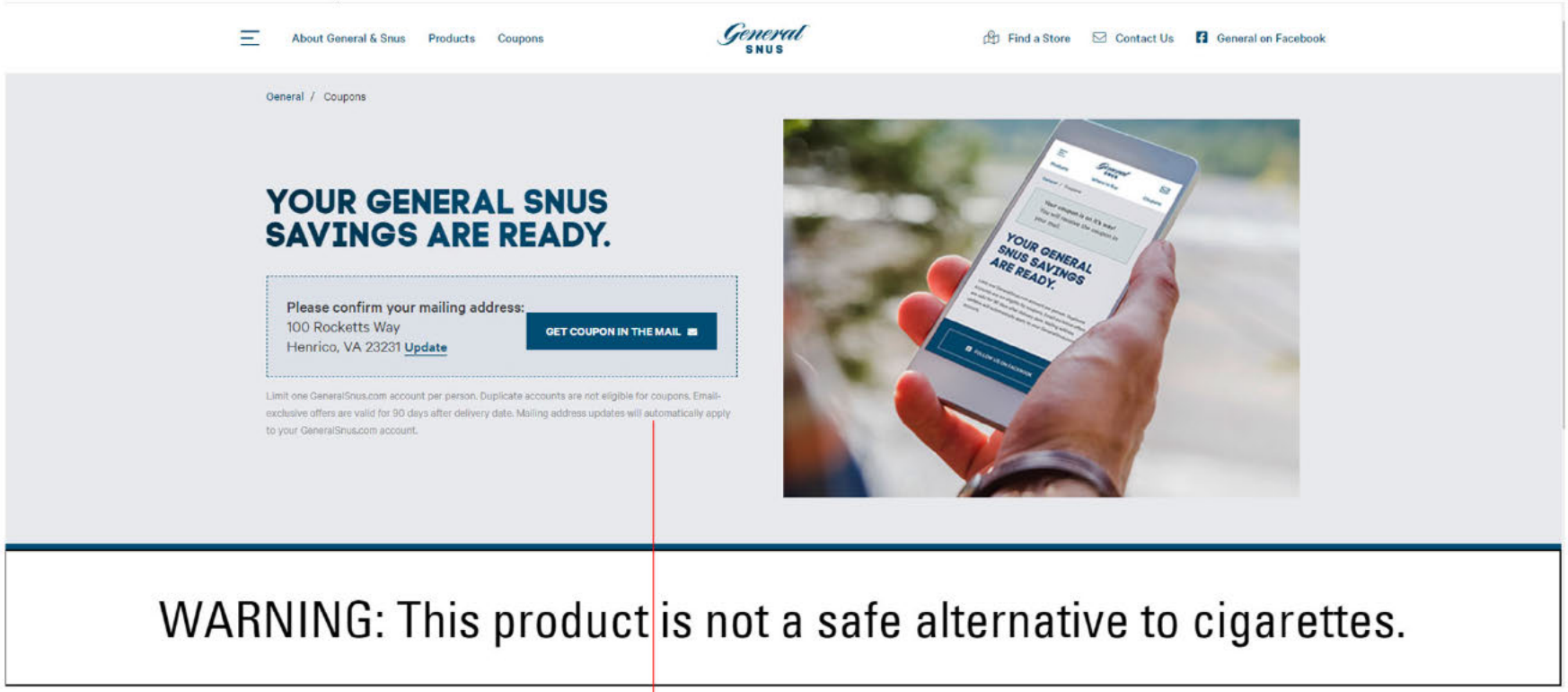




Swedish Match

GENERAL WEBSITE REFRESH – *COUPONS ARE AVAILABLE*

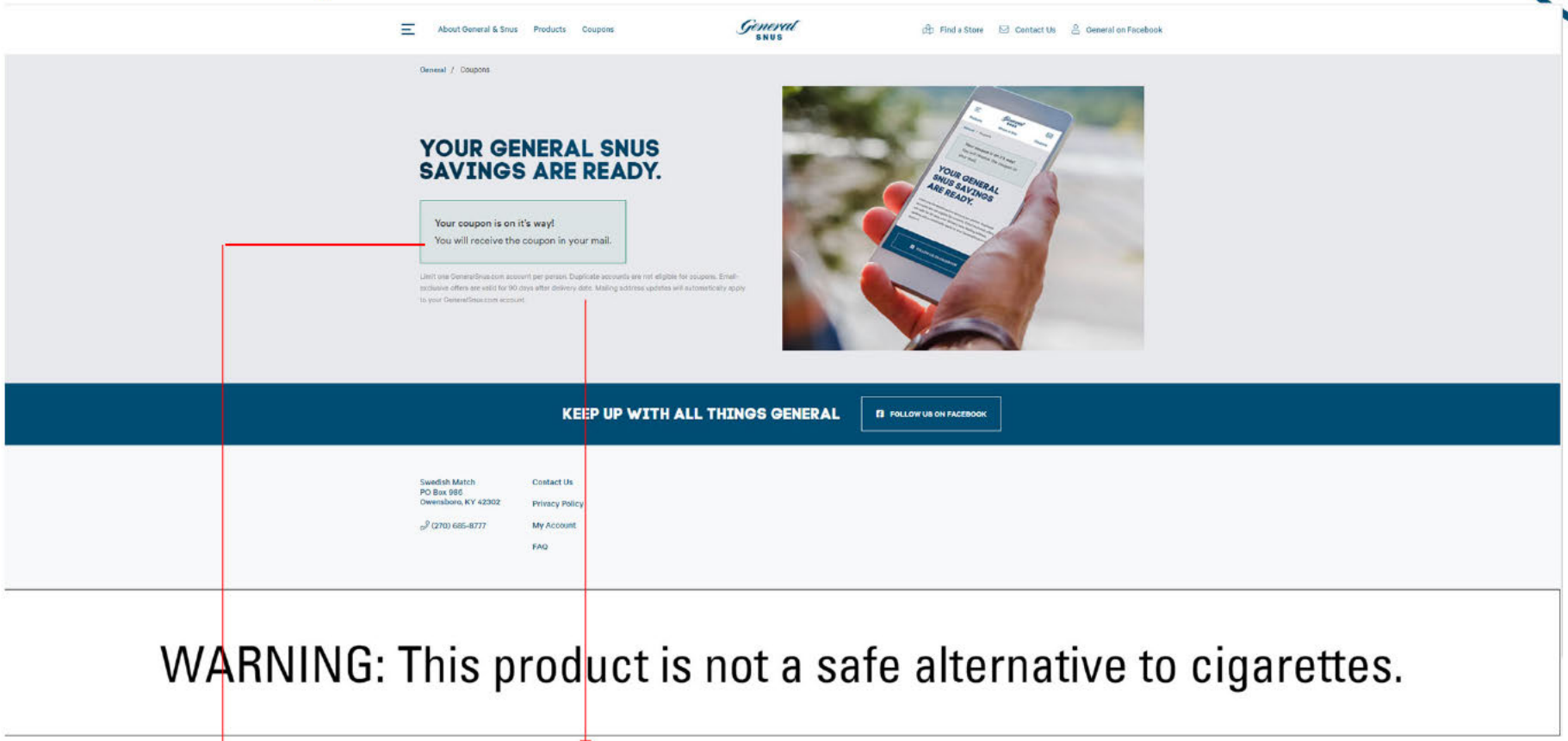
[BEHIND AGE GATE] Oct. 2021 - current



Limit one GeneralSnus.com account per person. Duplicate accounts are not eligible for coupons. Email-exclusive offers are valid for 90 days after delivery date. Mailing address updates will automatically apply to your GeneralSnus.com account.

GENERAL WEBSITE REFRESH - *COUPONS: ON THEIR WAY*

[BEHIND AGE GATE] Oct. 2021 - current



Your coupon is on it's way!
You will receive the coupon in your mail.

Limit one GeneralSnus.com account per person. Duplicate accounts are not eligible for coupons. Email-exclusive offers are valid for 90 days after delivery date. Mailing address updates will automatically apply to your GeneralSnus.com account.

GENERAL WEBSITE REFRESH - *HOME*

[BEHIND AGE GATE] Oct. 2021 - current

WHAT IS SNUS & HOW TO USE

Learn more about how to use Swedish Snus.

WHAT IS SNUS

Explore what goes into snus, how it's made, and the centuries-old story of a tobacco product that changed the world.

READ MORE

Links to 'About General & Snus' page

Links to 'Find a Store' page

FIND SNUS NEAR YOU

STORE LOCATOR

Links to 'Coupons' page

EXCLUSIVE SAVINGS

Enjoy monthly coupons for your favorite varieties of General Snus, redeemable anywhere adventure takes you.

VIEW AVAILABLE COUPONS

Links to 'Products' page

PRODUCTS

The original General Snus combines premium tobacco with natural and artificial flavors for an authentic snus experience unlinke any other. Discover your favorite today.

EXPLORE PRODUCTS

Links to 'Modified Risk' page

FIRST EVER

General Snus received the first-ever Modified Risk Tobacco Product (MRTP) order from the FDA. Learn more about what this means for you.

LEARN MORE

ELEVATE YOUR FALL BBQ GAME

We've got a recipe + tips that will take your fall barbeque to the next level.

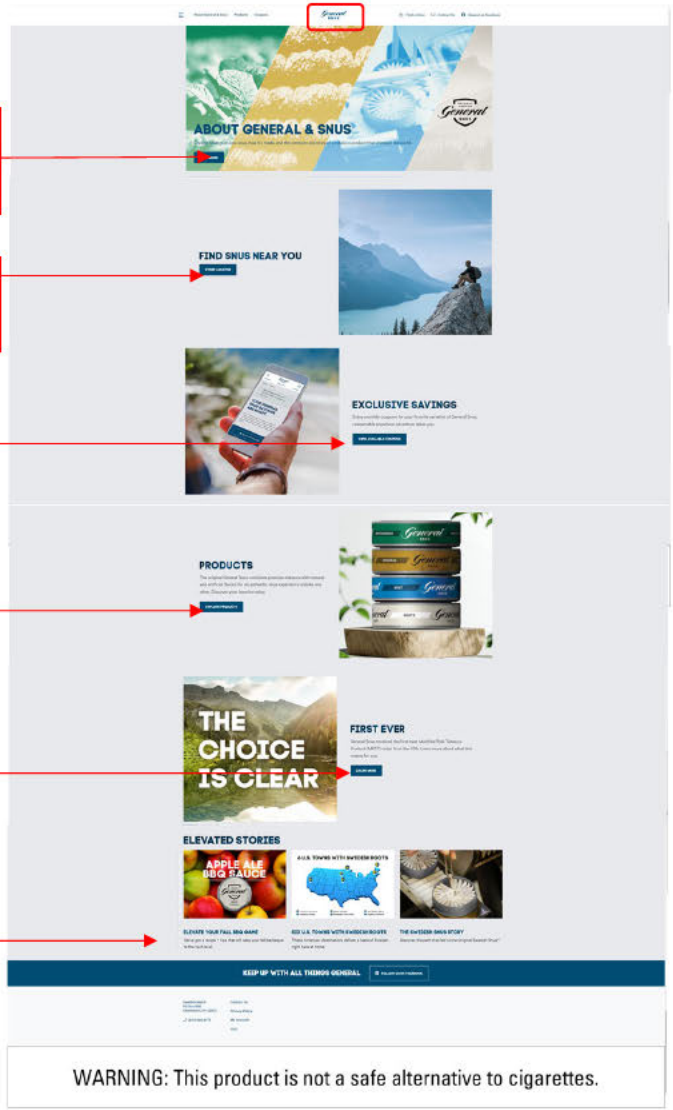
SIX U.S. TOWNS WITH SWEDISH ROOTS

These American destinations deliver a taste of Sweden right here at home.

THE SWEDISH SNUS STORY

Discover the path that led to the Original Swedish Snus™

Links to 'Elevated Stories' page



WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH – *ABOUT GENERAL & SNUS*
[BEHIND AGE GATE] Oct. 2021 - current

WHAT IS SNUS & HOW TO USE

Learn more about how to use Swedish Snus.

WHAT IS SNUS

HOW IT'S MADE

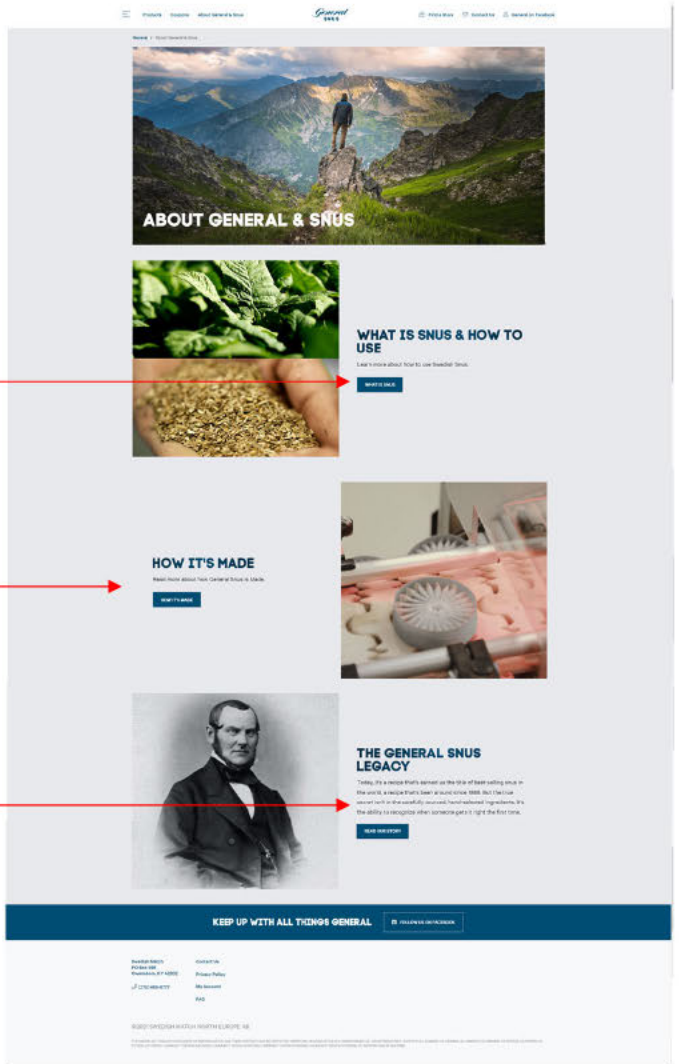
Read more about how General Snus is Made.

HOW IT'S MADE

THE GENERAL SNUS LEGACY

Today, it's a recipe that's earned us the title of best-selling snus in the world, a recipe that's been around since 1866. But the true secret isn't in the carefully sourced, hand-selected ingredients. It's the ability to recognize when someone gets it right the first time.

READ OUR STORY



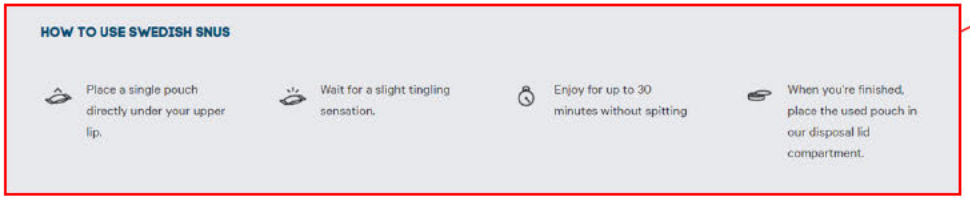
WARNING: This product can cause gum disease and tooth loss.

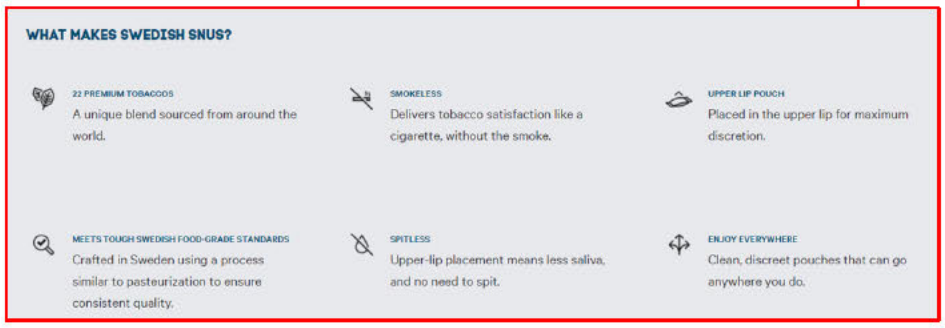
Swedish Match

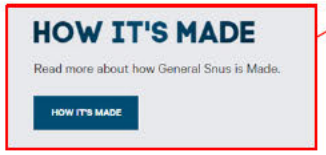
GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: WHAT IS SNUS & HOW TO USE

[BEHIND AGE GATE] Oct. 2021 - current





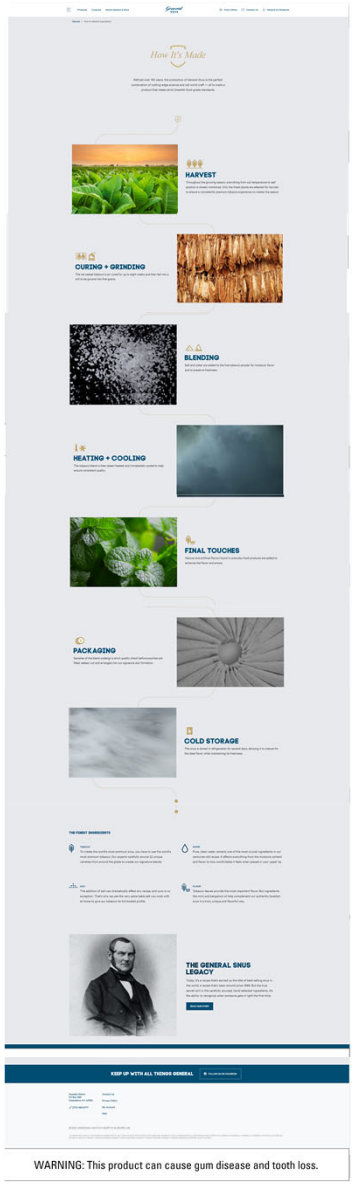


GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: HOW IT'S MADE

[BEHIND AGE GATE] Oct. 2021 - current

See next two pages for detail



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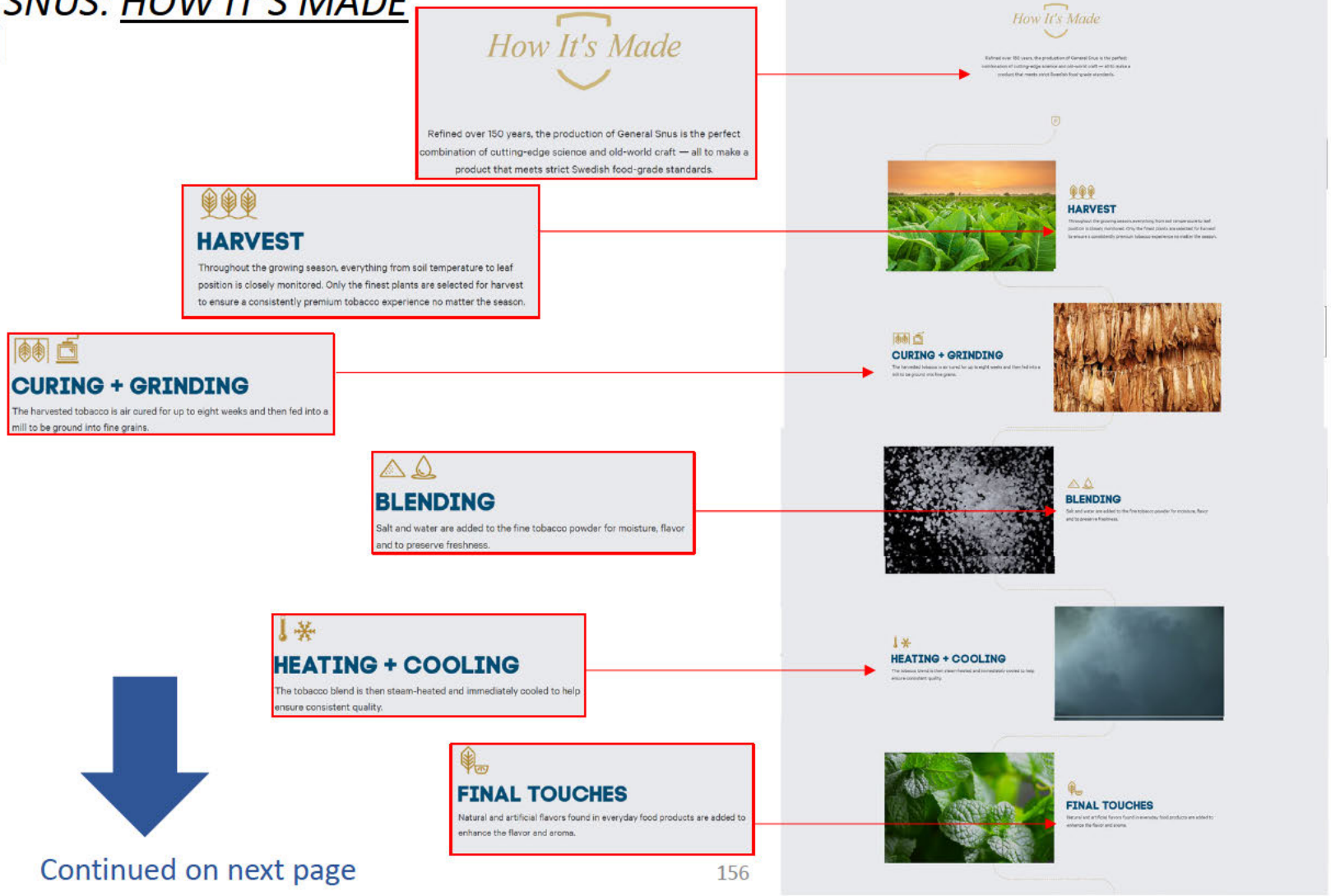
GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: HOW IT'S MADE

[BEHIND AGE GATE]

Oct. 2021 - current



Swedish Match

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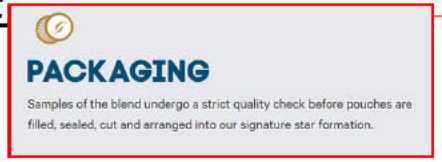
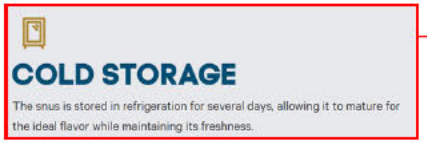
GENERAL WEBSITE REFRESH

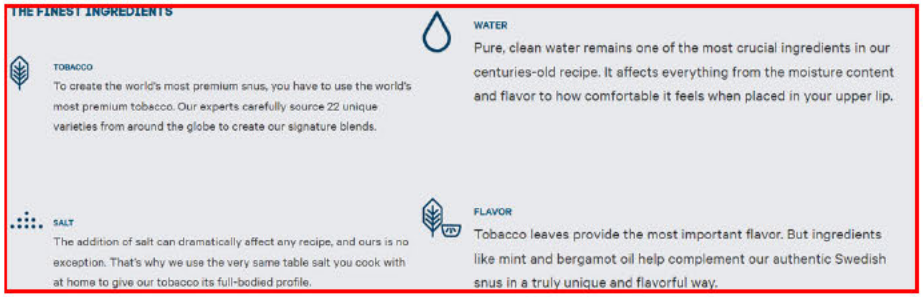
ABOUT GENERAL & SNUS: HOW IT'S MADE

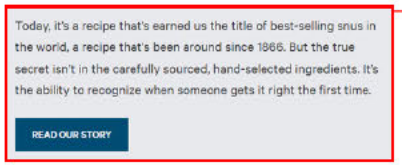
[BEHIND AGE GATE]

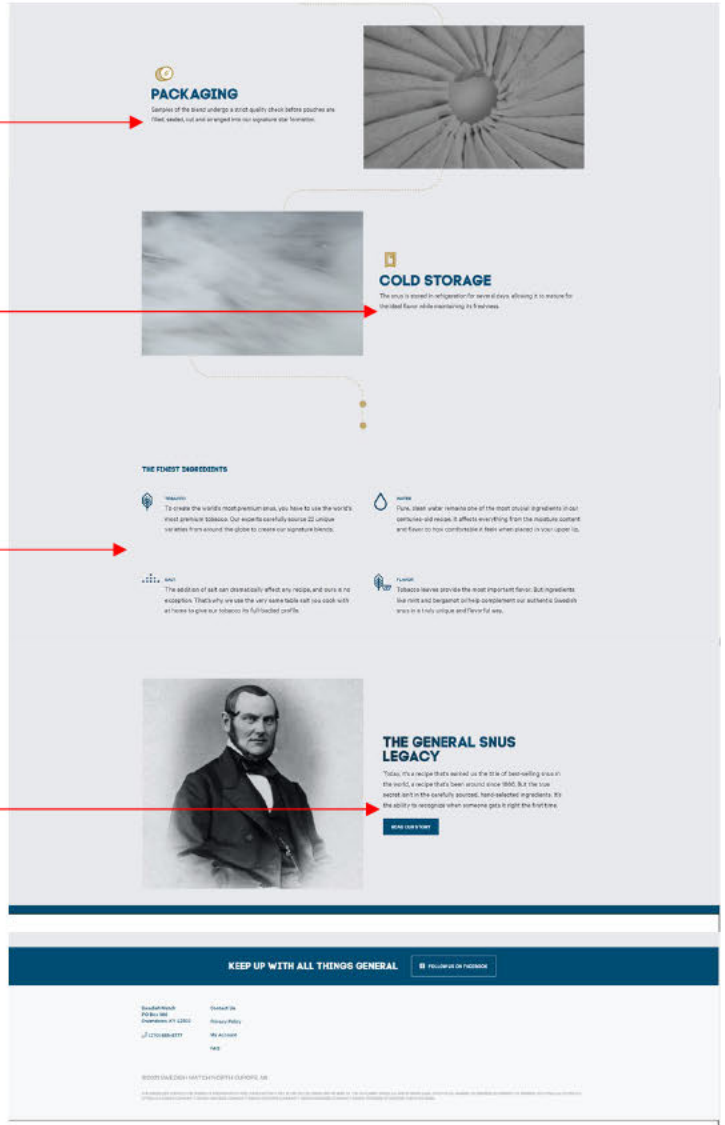
Oct. 2021 - current











Swedish Match

CONTINUED ON THE RIGHT

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY

[BEHIND AGE GATE] Oct. 2021 - current

See following two pages for detail

Swedish Match

GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY

[BEHIND AGE GATE] Oct. 2021 - current

This is a centuries-old story of a tobacco that changed the world, and the way people experienced it. A tale of potential, and what it means to see it and make the most of it, at every possible turn. This is the story of elevating every experience.

Unsatisfied with the tobacco of his time, revered Swedish craftsman Johan A. Boman sets out to craft a higher quality product.

After four years of painstakingly crafting his recipe, Boman introduces an elevated tobacco experience to his home country. Crafted using only the finest ingredients, it was an upper-lip snus unlike anything seen before.

Snus becomes an identifying mark for the millions of Swedes immigrating to America. Main streets in Swedish neighborhoods even earn the name "Snus Boulevard."

The first portion-packed pouch is developed in Sweden, making snus convenient and more appealing to the broader public.

Swedish Match introduces the Gothiatek Standard, which guarantees that every can of General Snus exceeds even the toughest Swedish food-grade requirements. It also promises to ensure every can meets our standards through a quality-controlled process, starting with the very soil where the tobacco seed is planted.

General Snus is the first to take cleanliness to the next level by introducing "white portions" – a new process that delivers cleaner, white pouches that are still sold today in wintergreen, white and mint.

Swedish Match

Continued on next page

GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY

[BEHIND AGE GATE]
Oct. 2021 - current

General develops a new type of can with a unique disposal compartment that holds used portions of snus.

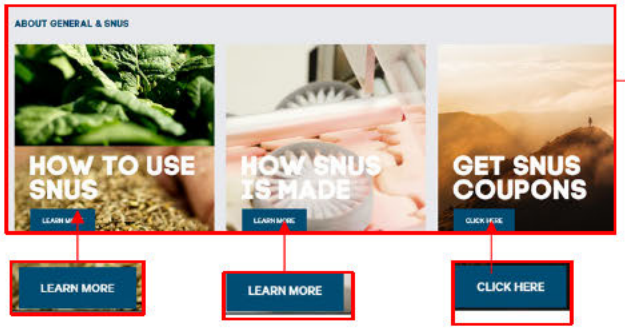
General's signature Star Formation makes its first appearance in select cans. Not only does it maximize the number of portions per can, but each pouch is shaped to fit more comfortably under the upper lip.

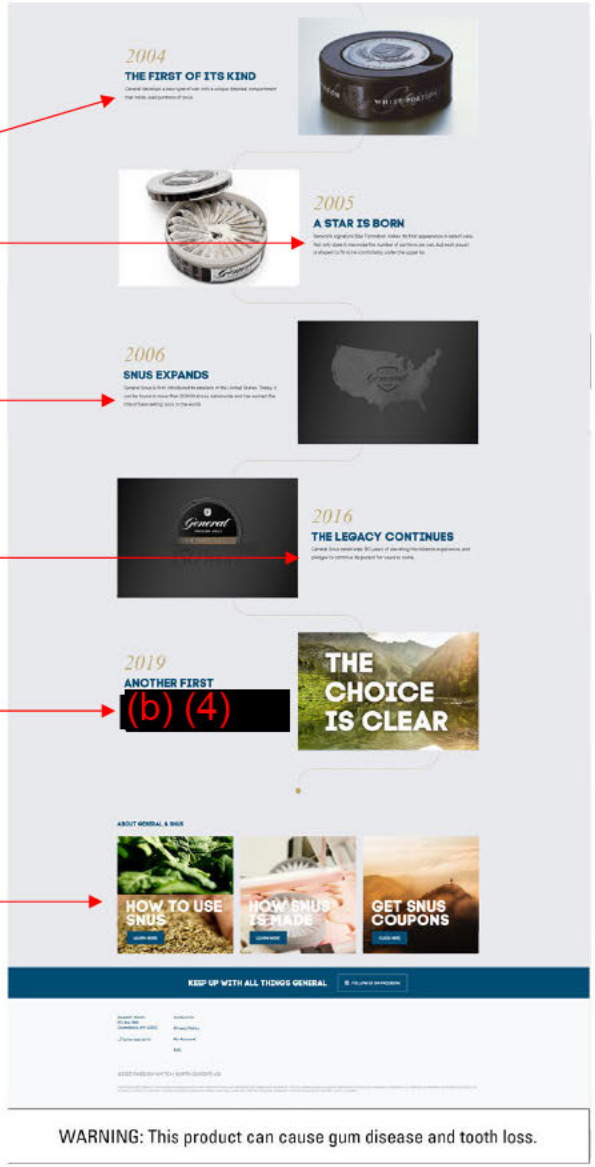
General Snus is first introduced to retailers in the United States. Today, it can be found in more than 20,000 stores nationwide and has earned the title of best-selling snus in the world.

General Snus celebrates 150 years of elevating the tobacco experience, and pledges to continue its pursuit for years to come.

The FDA issues the first-ever Modified Risk Tobacco Product (MRTP) order for General Snus. An MRTP is defined as a product that (b) (4)

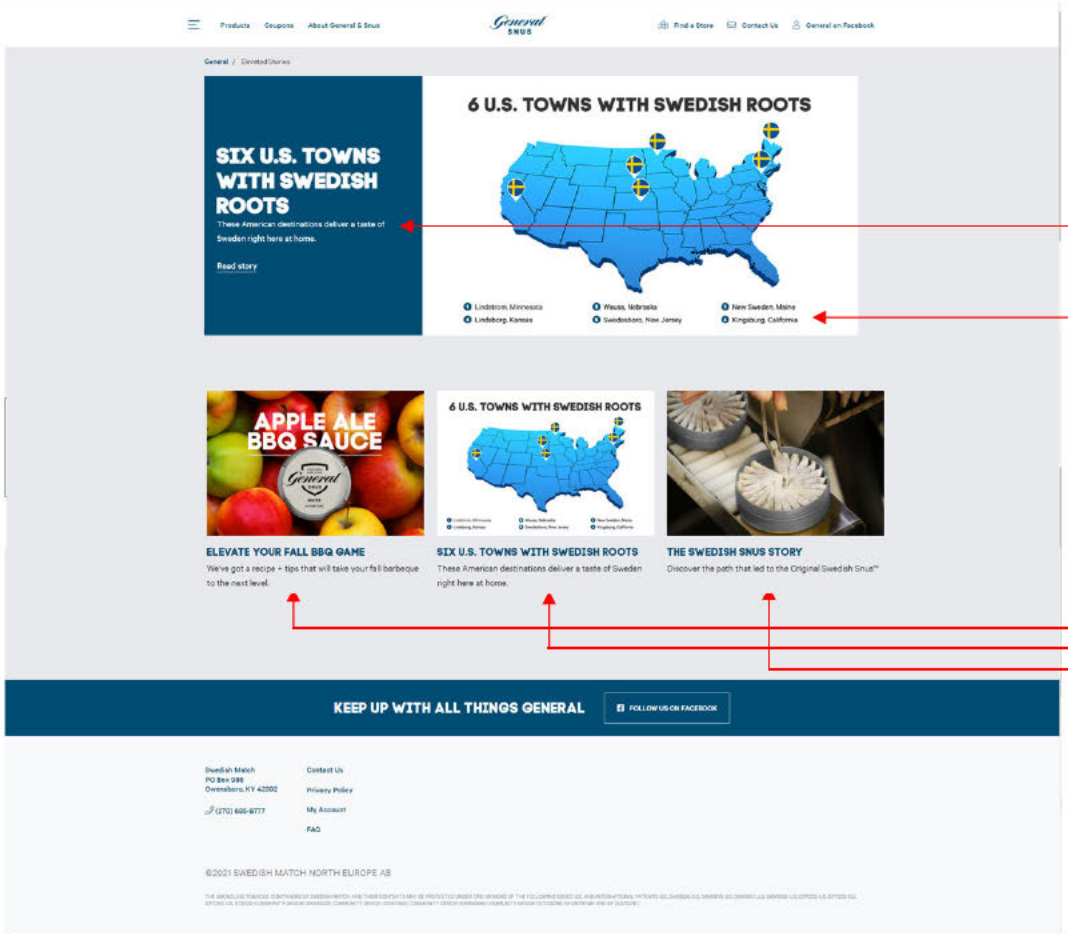
(b) (4)





Swedish Match

GENERAL WEBSITE REFRESH - *ABOUT GENERAL & SNUS: ELEVATED STORIES*
[BEHIND AGE GATE] Oct. 2021 - current



These American destinations deliver a taste of Sweden right here at home.

Read story

1 Lindstrom, Minnesota
2 Wausa, Nebraska
3 New Sweden, Maine
4 Lindsborg, Kansas
5 Swedesboro, New Jersey
6 Kingsburg, California

We've got a recipe + tips that will take your fall barbeque to the next level.

These American destinations deliver a taste of Sweden right here at home.

Discover the path that led to the Original Swedish Snus™

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH - *ELEVATED STORIES: SIX SWEDISH U.S. TOWNS*

[BEHIND AGE GATE]
Oct. 2021 - current

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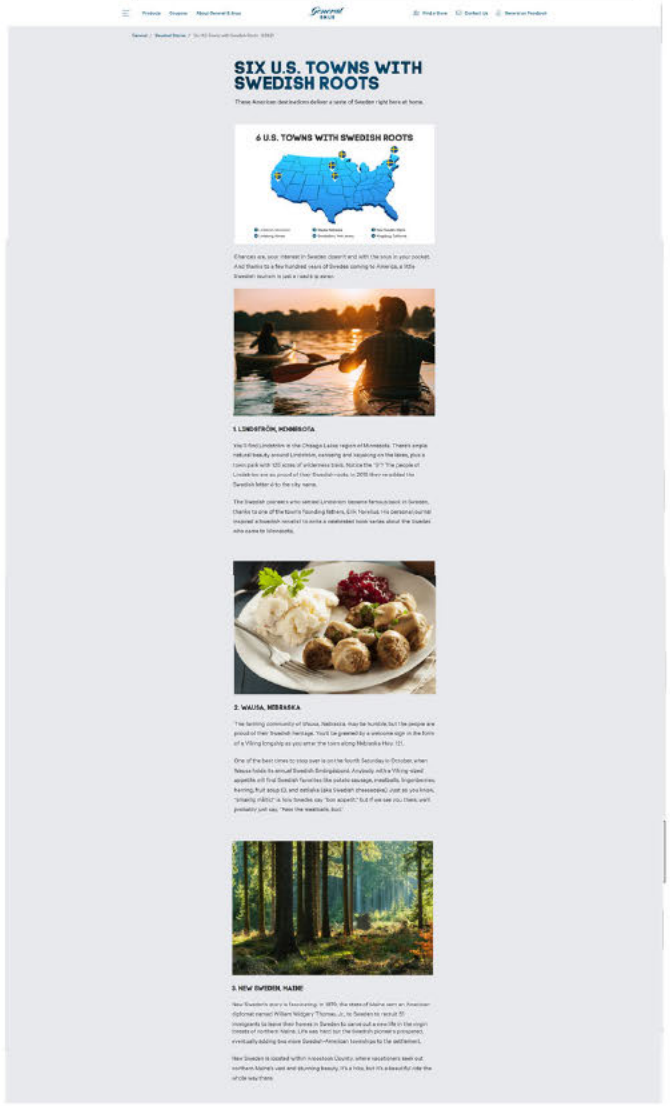
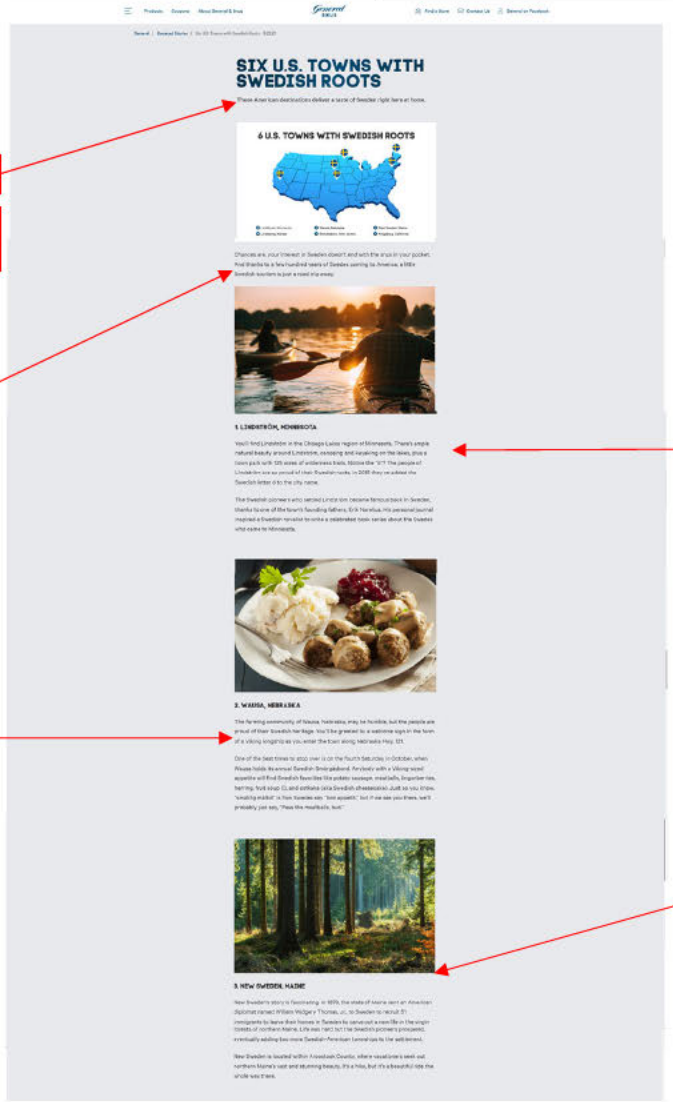


GENERAL WEBSITE REFRESH - *ELEVATED STORIES: SIX SWEDISH U.S. TOWNS*

[BEHIND AGE GATE]

Oct. 2021 - current



These American destinations deliver a taste of Sweden right here at home.

1. Lindstrom, Minnesota
2. Lindsborg, Kansas
3. Wausa, Nebraska
4. Swedesboro, New Jersey
5. New Sweden, Maine
6. Kingsburg, California

Chances are, your interest in Sweden doesn't end with the snus in your pocket. And thanks to a few hundred years of Swedes coming to America, a little Swedish tourism is just a road trip away.

1. LINDSTRÖM, MINNESOTA

You'll find Lindström in the Chicago Lakes region of Minnesota. There's ample natural beauty around Lindström, canoeing and kayaking on the lakes, plus a town park with 125 acres of wilderness trails. Notice the "ö"? The people of Lindström are so proud of their Swedish roots, in 2015 they re-added the Swedish letter ö to the city name.

The Swedish pioneers who settled Lindström became famous back in Sweden, thanks to one of the town's founding fathers, Erik Norelius. His personal journal inspired a Swedish novelist to write a celebrated book series about the Swedes who came to Minnesota.

2. WAUSA, NEBRASKA

The farming community of Wausa, Nebraska, may be humble, but the people are proud of their Swedish heritage. You'll be greeted by a welcome sign in the form of a Viking longship as you enter the town along Nebraska Hwy. 121.

One of the best times to stop over is on the fourth Saturday in October, when Wausa holds its annual Swedish Smörgåsbord. Anybody with a Viking-sized appetite will find Swedish favorites like potato sausage, meatballs, lingonberries, herring, fruit soup (!), and ostkaka (aka Swedish cheesecake). Just so you know, "smaklig måltid" is how Swedes say "bon appetit," but if we see you there, we'll probably just say, "Pass the meatballs, bud."

3. NEW SWEDEN, MAINE

New Sweden's story is fascinating. In 1870, the state of Maine sent an American diplomat named William Widgery Thomas, Jr., to Sweden to recruit 51 immigrants to leave their homes in Sweden to carve out a new life in the virgin forests of northern Maine. Life was hard but the Swedish pioneers prospered, eventually adding two more Swedish-American townships to the settlement.

New Sweden is located within Aroostook County, where vacationers seek out northern Maine's vast and stunning beauty. It's a hike, but it's a beautiful ride the whole way there.

Swedish Match

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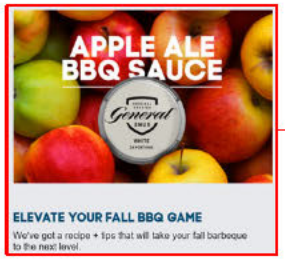
GENERAL WEBSITE REFRESH - *ELEVATED STORIES: SIX SWEDISH U.S. TOWNS*

[BEHIND AGE GATE]
Oct. 2021 - current



4. LINDSBORG, KANSAS

Lindsborg, Kansas, was settled by Swedish immigrants over 150 years ago and immediately thrived thanks to the arrival of the railroad. Thirty percent of its current residents have Swedish ancestors.

Lindsborg truly earns its nickname, "Little Sweden USA." The town holds the Svensk Hyllningsfest, a celebration of Swedish heritage, every other year. The town symbol is the Dala Horse, a traditional carved, painted wooden statue of a horse originating in the Swedish province of Dalarna. And Lindsborg was even the site of a royal visit — Swedish King Carl XVI Gustaf visited this modest Kansas town during his royal tour of the United States.

5. KINGSBURG, CALIFORNIA

Kingsburg, California, calls itself Central California's Swedish Village, and it's easy to see why. Swedish natives began to arrive in the 1870s, and within 50 years, over 90% of the population was Swedish-American. Today, the buildings in town are detailed with Swedish-inspired architecture.

But the big draw is the Kingsburg Swedish Festival. It's always held during the third weekend in May, and it features a traditional Swedish breakfast, a smorgasbord dinner, a 2K and 10K run, the crowning of a festival queen, folk dancing, a parade, live entertainment, and — yes — a Pea Soup and Pancake Dinner. It all sounds maybe a little silly, but thousands of visitors attend every year, and it's proud to be a family-friendly event.

6. SWEDESBORO, NEW JERSEY

Swedesboro, New Jersey, 20 minutes south of Philadelphia, was founded by Swedes and Finns in 1638 as part of the American colony of New Sweden, which would become parts of New Jersey and Delaware.

Swedesboro's churches, cemeteries and landmarks tell stories of early American history. The oldest remaining log cabin in the U.S. was built in Swedesboro around 1640. It's listed on the National Register of Historic Places, as is Trinity Episcopal "Old Swedes" Church. So it's no surprise King Carl XVI Gustaf also visited Swedesboro during his American tour. But Swedesboro isn't all history lesson. You'll find a small winery and a microbrewery in the city limits. We recommend you arrive thirsty.

Swedish Match

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH

ELEVATED STORIES: THE SWEDISH SNUS STORY

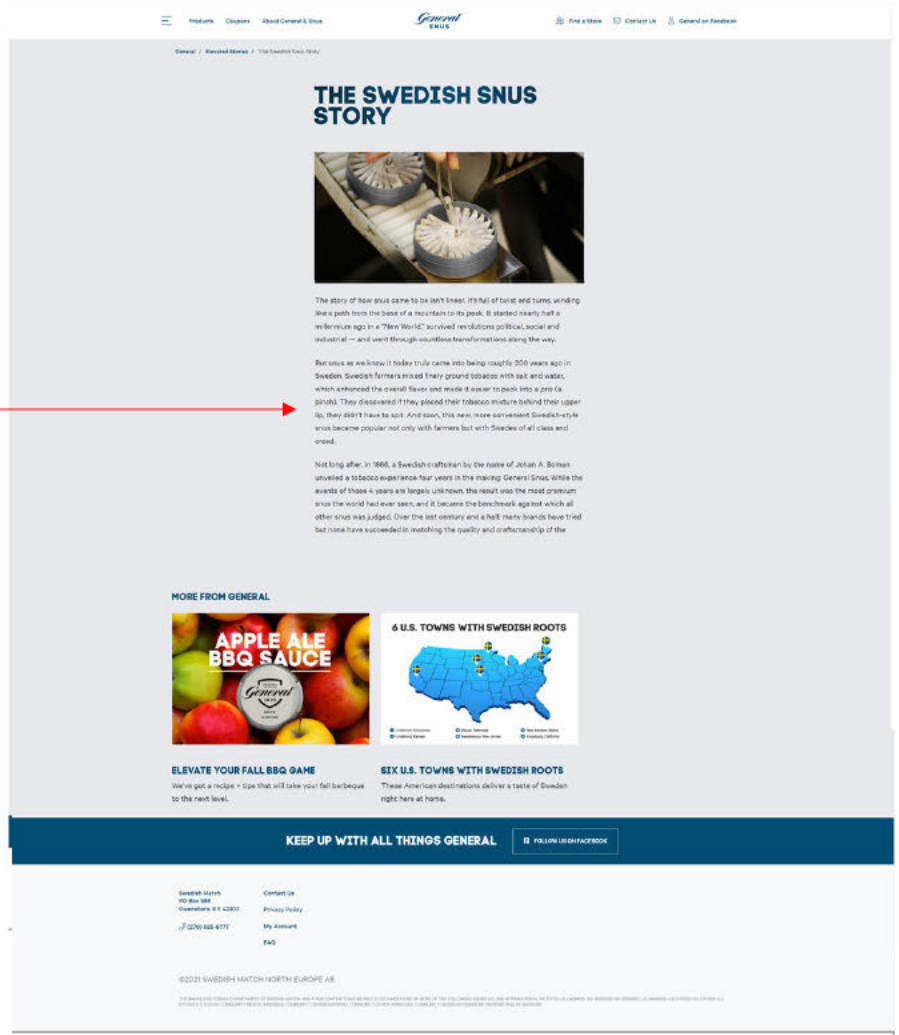
[BEHIND AGE GATE]

Oct. 2021 - current

The story of how snus came to be isn't linear. It's full of twist and turns, winding like a path from the base of a mountain to its peak. It started nearly half a millennium ago in a "New World," survived revolutions political, social and industrial — and went through countless transformations along the way.

But snus as we know it today truly came into being roughly 200 years ago in Sweden. Swedish farmers mixed finely ground tobacco with salt and water, which enhanced the overall flavor and made it easier to pack into a *pris* (a pinch). They discovered if they placed their tobacco mixture behind their upper lip, they didn't have to spit. And soon, this new, more convenient *Swedish-style* snus became popular not only with farmers but with Swedes of all class and creed.

Not long after, in 1866, a Swedish craftsman by the name of Johan A. Boman unveiled a tobacco experience four years in the making: General Snus. While the events of those 4 years are largely unknown, the result was the most premium snus the world had ever seen, and it became the benchmark against which all other snus was judged. Over the last century and a half, many brands have tried but none have succeeded in matching the quality and craftsmanship of the Original Swedish Snus™.



WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH - *ELEVATED STORIES: APPLE BBQ SAUCE*

[BEHIND AGE GATE]
Oct. 2021 - current

When crisp air comes, grills and smokers fire up again. We've got a sauce recipe that will make your cookout the envy of the neighborhood. It goes great with everything—but especially pork chops or a pork shoulder. And it's built around a seasonal favorite: apple ale. Plus, check out our 7 Fall BBQ Tips & Tricks below to make sure you and your guests have an easy, fun time.

APPLE ALE BARBECUE SAUCE: ONE OF OUR FALL FAVORITES

Ingredients:

1 cup apple ale (apple beer will work, too)
4 teaspoons butter
1 clove garlic, minced
1 small onion, diced
2 cups ketchup
4 teaspoons sugar
4 teaspoons barbecue sauce
1/3 cup cider vinegar
2 teaspoons Dijon mustard
Freshly ground black pepper

Directions:

1. In a large pot, melt butter and cook onions and garlic until soft.
2. Add remaining ingredients and stir until blended.
3. Blend further in a food processor until smooth.
4. Taste test and adjust ingredients if needed. Makes about 4 cups of sauce.

Leftovers?
Allow sauce to cool and store in an airtight container such as a mason jar for up to 2 weeks.

Source: *Beerbistro (Toronto) & winemag.com*

WARNING: This product is not a safe alternative to cigarettes.

Swedish Match

Continued on next page

GENERAL WEBSITE REFRESH - *ELEVATED STORIES: APPLE BBQ SAUCE*

[BEHIND AGE GATE]
Oct. 2021 - current

7 FALL BBQ TIPS & TRICKS

1. **Sear autumn vegetables:**
   Summer standbys are fine, but you can elevate your cookout by grilling or searing cauliflower, brussels sprouts or butternut squash.
2. **Try potluck:**
   A week before your barbecue, start a text thread with suggested side dishes and ask your guests to bring one side each.
3. **Gather game options:**
   Think outdoors AND indoors: cornhole or a wiffle ball set, but also jenga or board games.
4. **Stage from the fridge:**
   Clean out your refrigerator before the event to make sure you have enough space for uncooked meats and vegetables, cold salads and condiments.
5. **Have a bug plan:**
   Non-toxic or natural repellents help everyone enjoy your outdoor space without distraction (or bites). For example, mosquitoes hate citrus, and you can stage your table with halved lemons or limes to keep them away. You'll find dozens of recipes for natural bug repellent online.
6. **Fall beverages:**
   Seasonal beer is big in October, but also offer the designated drivers non-alcohol options like sparkling cider.
7. **Ice, ice, baby:**
   The weather may be coolish, but you can never have enough ice. Stock up!

MORE FROM GENERAL

THE SWEDISH SNUS STORY
Discover the path that led to the Original Swedish Snus™

SIX U.S. TOWNS WITH SWEDISH ROOTS
These American destinations deliver a taste of Sweden right here at home.

WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH - *OUR PRODUCTS*

[BEHIND AGE GATE] Oct. 2021 - current

For more than 150 years, General has crafted the original Swedish snus using a blend of 22 premium tobaccos from around the globe to ensure each portion elevates your tobacco experience.

EXPLORE OUR FLAVORS

GENERAL WINTERGREEN

Our most invigorating blend starts with an earthy tobacco flavor and ends with a subtly satisfying wintergreen finish. General Wintergreen also features traces of rich leather and wood smoke to give you an unforgettable tobacco experience in every portion.

Ingredients +

FIND WINTERGREEN NEAR YOU

GENERAL WHITE

This vibrant blend features a complex, spicy tobacco taste that's perfect for elevating any occasion.

Ingredients +

FIND WHITE NEAR YOU

GENERAL MINT

With its distinctly cool peppermint notes and well-balanced blend of premium tobaccos, General Mint delivers uniquely fresh and long-lasting tobacco satisfaction. It's the perfect partner to elevate any occasion.

Ingredients +

FIND MINT NEAR YOU

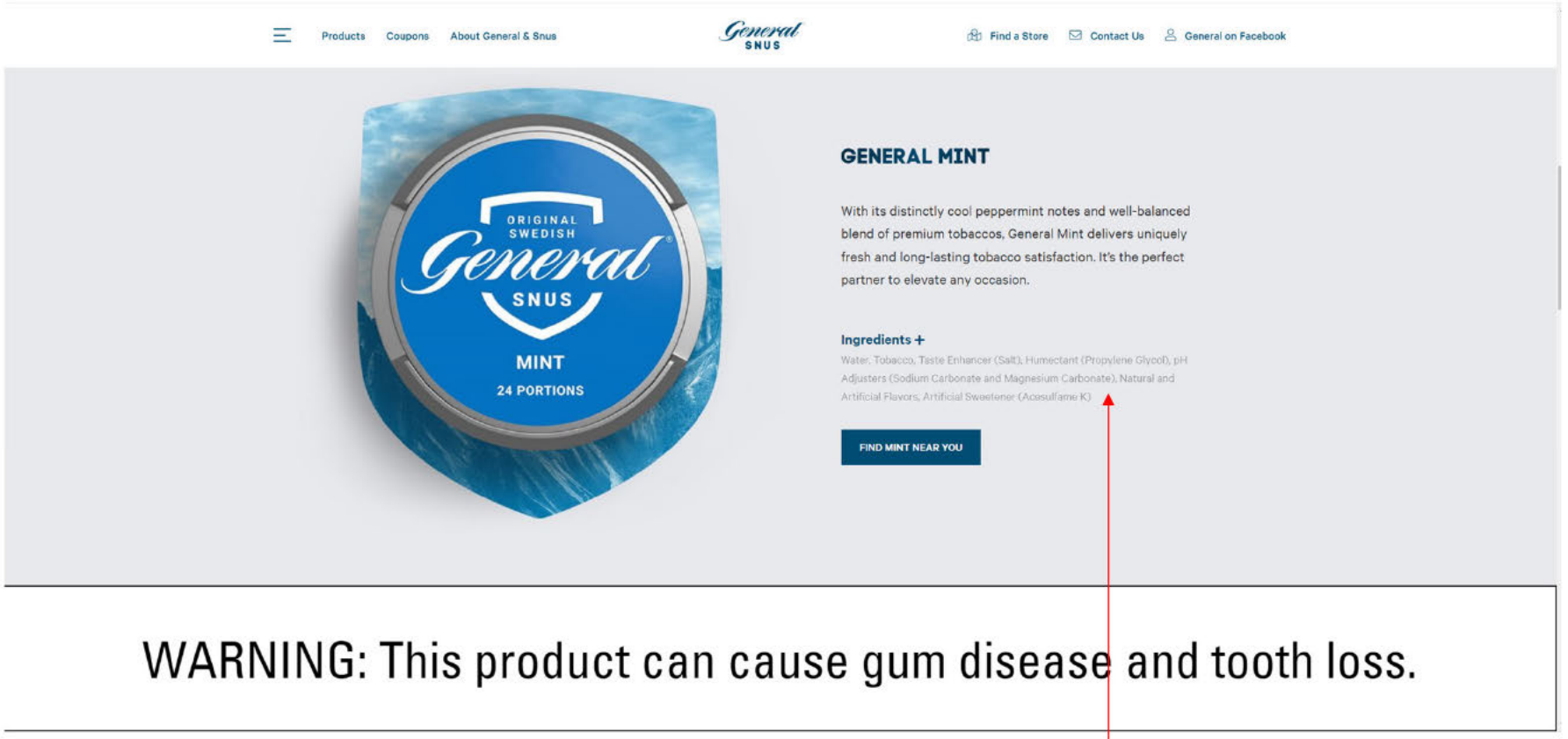
GENERAL ORIGINAL

The snus that started it all. General Original's unique blend of 22 tobaccos offers you a rich natural experience. And with its fast-release pouches, it's ready when you are.

Ingredients +

FIND ORIGINAL NEAR YOU

GENERAL WEBSITE REFRESH – *OUR PRODUCTS: MINT*
[BEHIND AGE GATE] Oct. 2021 - current



Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate and Magnesium Carbonate), Natural and Artificial Flavors, Artificial Sweetener (Acesulfame K)

Swedish Match

GENERAL WEBSITE REFRESH – *OUR PRODUCTS, WINTERGREEN*

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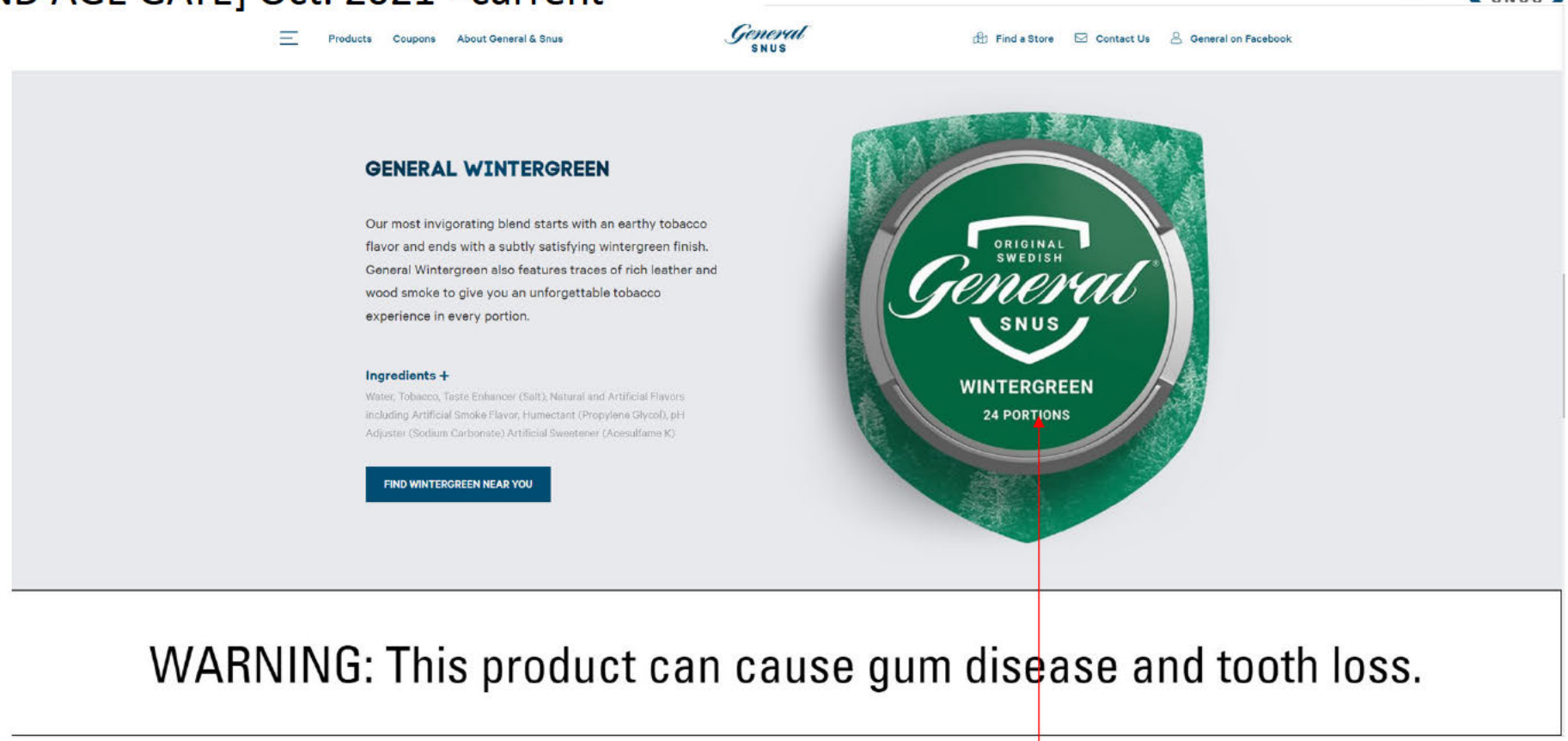
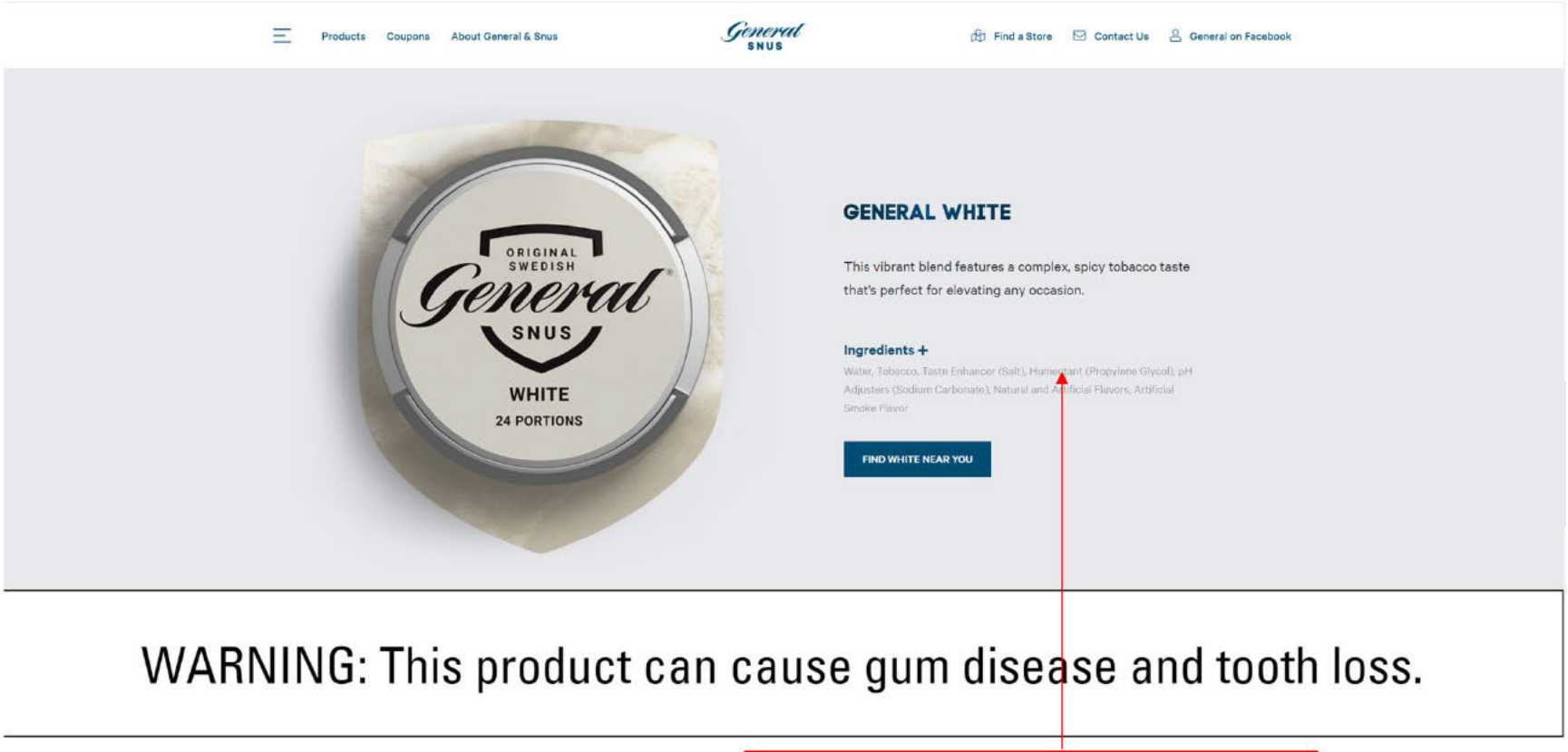


Ingredients +

Water, Tobacco, Taste Enhancer (Salt), Natural and Artificial Flavors including Artificial Smoke Flavor, Humectant (Propylene Glycol), pH Adjuster (Sodium Carbonate) Artificial Sweetener (Acesulfame K)

Swedish Match

GENERAL WEBSITE REFRESH – *OUR PRODUCTS, WHITE*
[BEHIND AGE GATE] Oct. 2021 - current

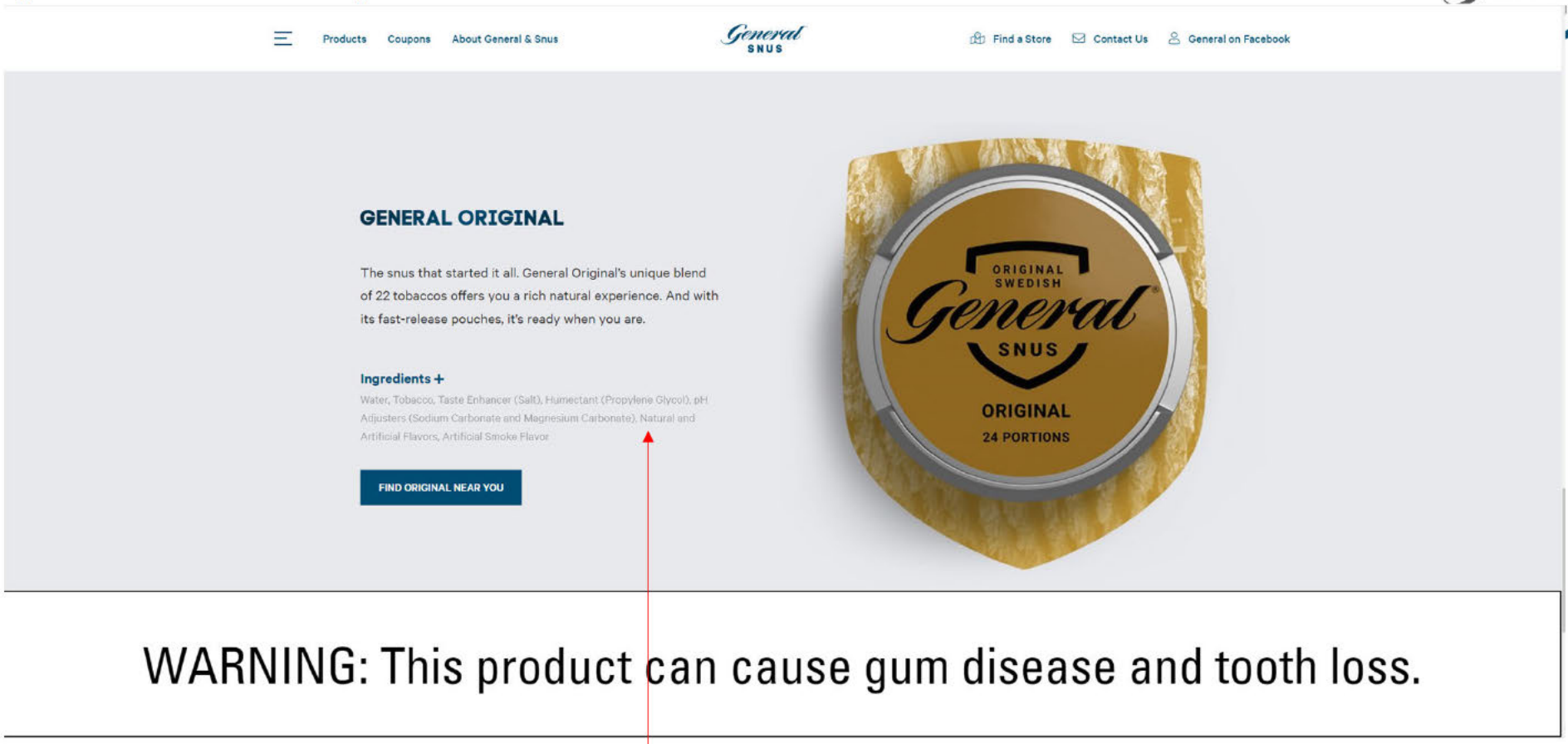


Ingredients +

Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate), Natural and Artificial Flavors, Artificial Smoke Flavor

Swedish Match

GENERAL WEBSITE REFRESH – *OUR PRODUCTS, ORIGINAL*
[BEHIND AGE GATE] Oct. 2021 - current



WARNING: This product can cause gum disease and tooth loss.

Ingredients +

Water, Tobacco, Taste Enhancer (Salt), Humectant (Propylene Glycol), pH Adjusters (Sodium Carbonate and Magnesium Carbonate), Natural and Artificial Flavors, Artificial Smoke Flavor

Swedish Match

GENERAL WEBSITE REFRESH – *MODIFIED RISK*

[BEHIND AGE GATE] Oct. 2021 - current

The U.S. Food and Drug Administration (FDA) has stated (b) (4)

(b) (4)

On October 22, 2019 General Snus received the first-ever Modified Risk Tobacco Product (MRTP) order, which allows us to say:

A Modified Risk Tobacco Product (MRTP) is defined as a product that (b) (4)

(b) (4) (GEN website FAQ)

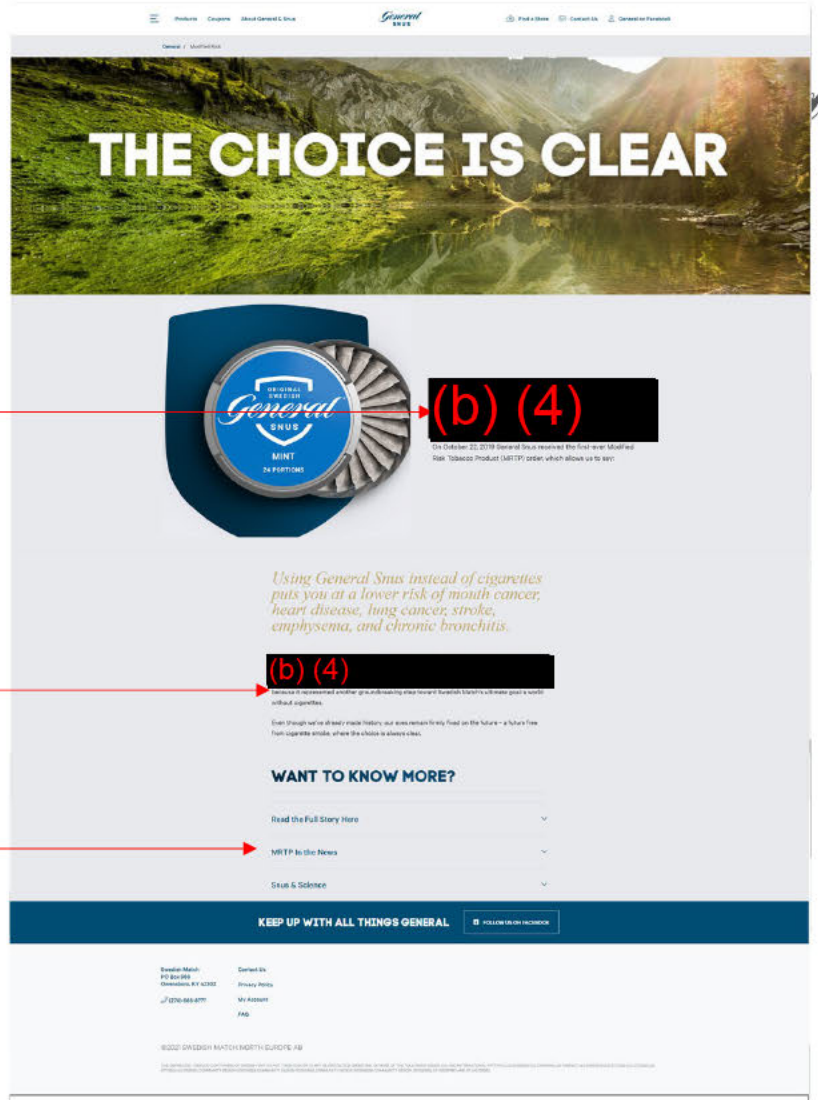
General Snus obtaining an MRTP order wasn't just historic because it was the first-ever, but also because it represented another groundbreaking step toward Swedish Match's ultimate goal: a world without cigarettes.

Even though we've already made history, our eyes remain firmly fixed on the future – a future free from cigarette smoke, where the choice is always clear.

Read the Full Story Here

MRTP In the News

Snus & Science



WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH - *MODIFIED RISK: WANT TO KNOW MORE? FULL STORY.*

[BEHIND AGE GATE]
Oct. 2021 - current

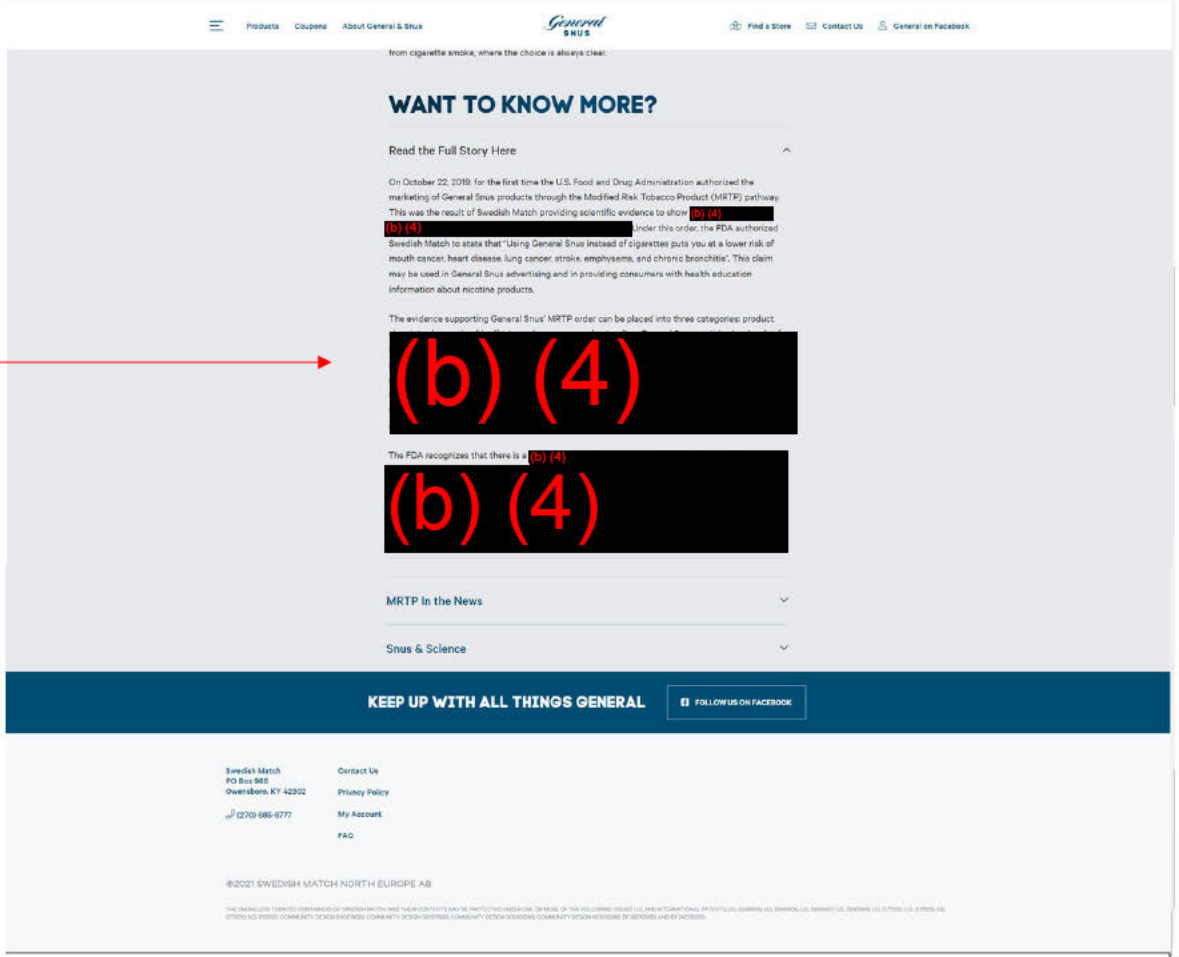
On October 22, 2019, for the first time the U.S. Food and Drug Administration authorized the marketing of General Snus products through the Modified Risk Tobacco Product (MRTP) pathway. This was the result of Swedish Match providing scientific evidence to show (b) (4) (b) (4) Under this order, the FDA authorized Swedish Match to state that "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis". This claim may be used in General Snus advertising and in providing consumers with health education information about nicotine products.

The evidence supporting General Snus' MRTP order can be placed into three categories: product

(b) (4)

The FDA recognizes that (b) (4)

(b) (4)

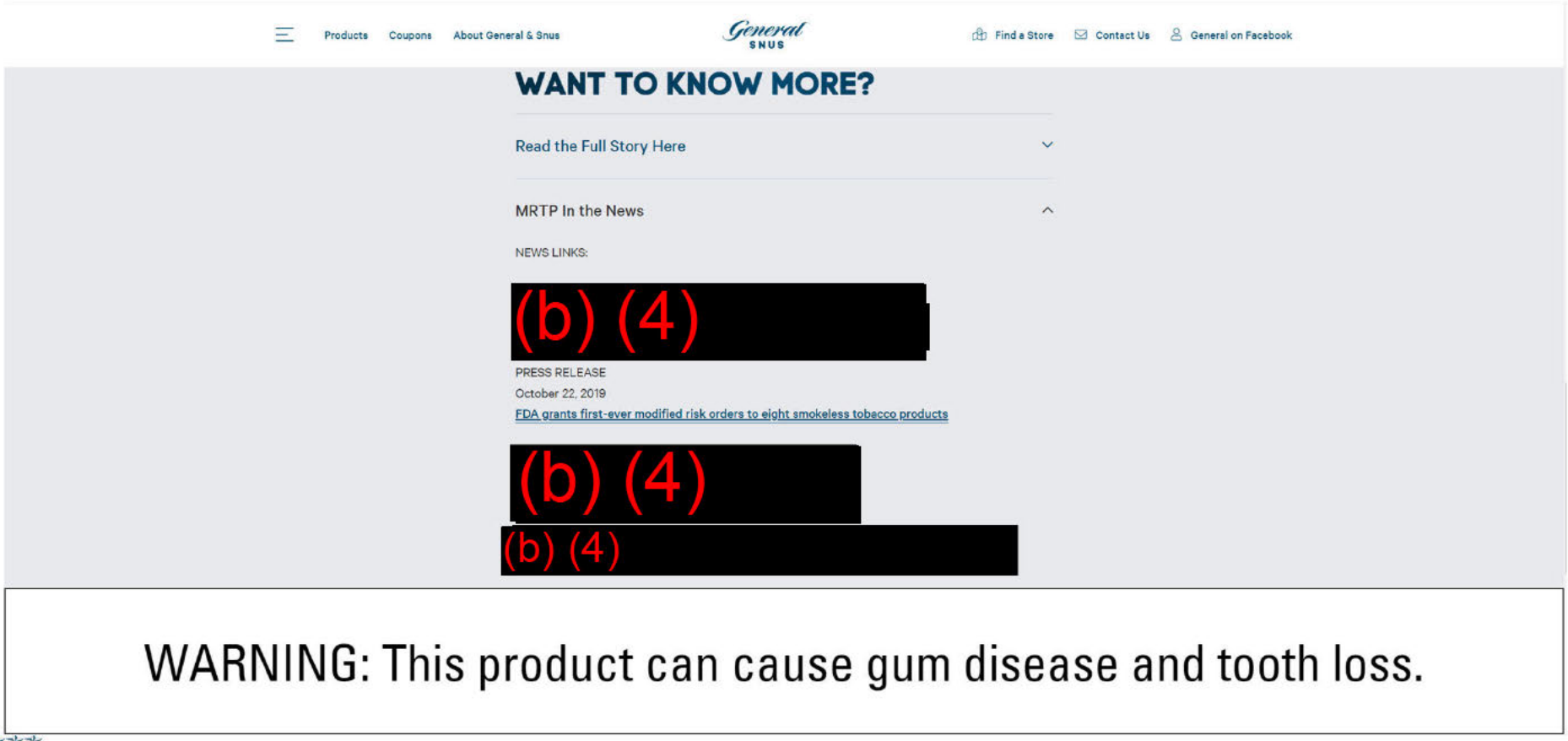


WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH - *MODIFIED RISK: WANT TO KNOW MORE? MRTP IN THE NEWS*

[BEHIND AGE GATE] Oct. 2021 - current



Swedish Match

GENERAL WEBSITE REFRESH - *MODIFIED RISK: WANT TO KNOW MORE? SNUS & SCIENCE*

[BEHIND AGE GATE]
Oct. 2021 - current

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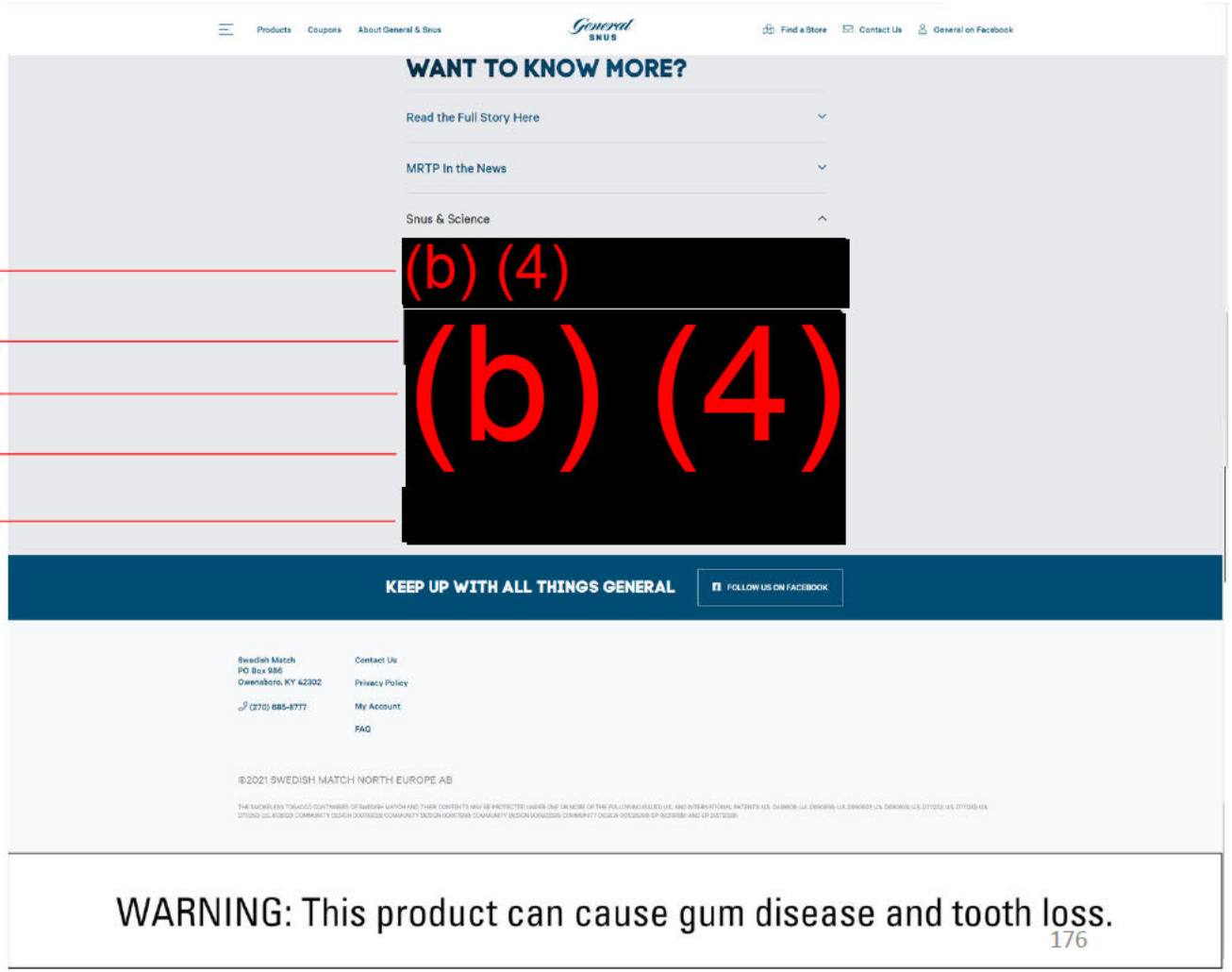
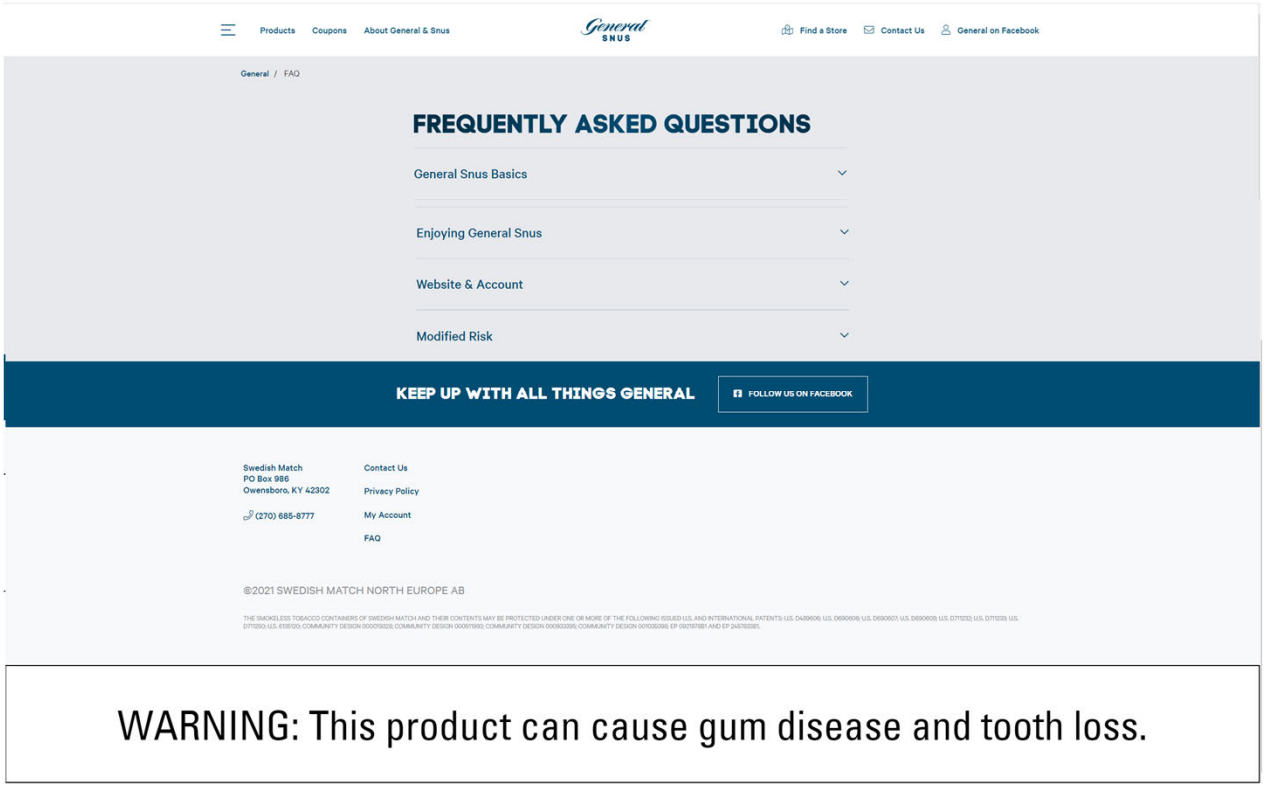


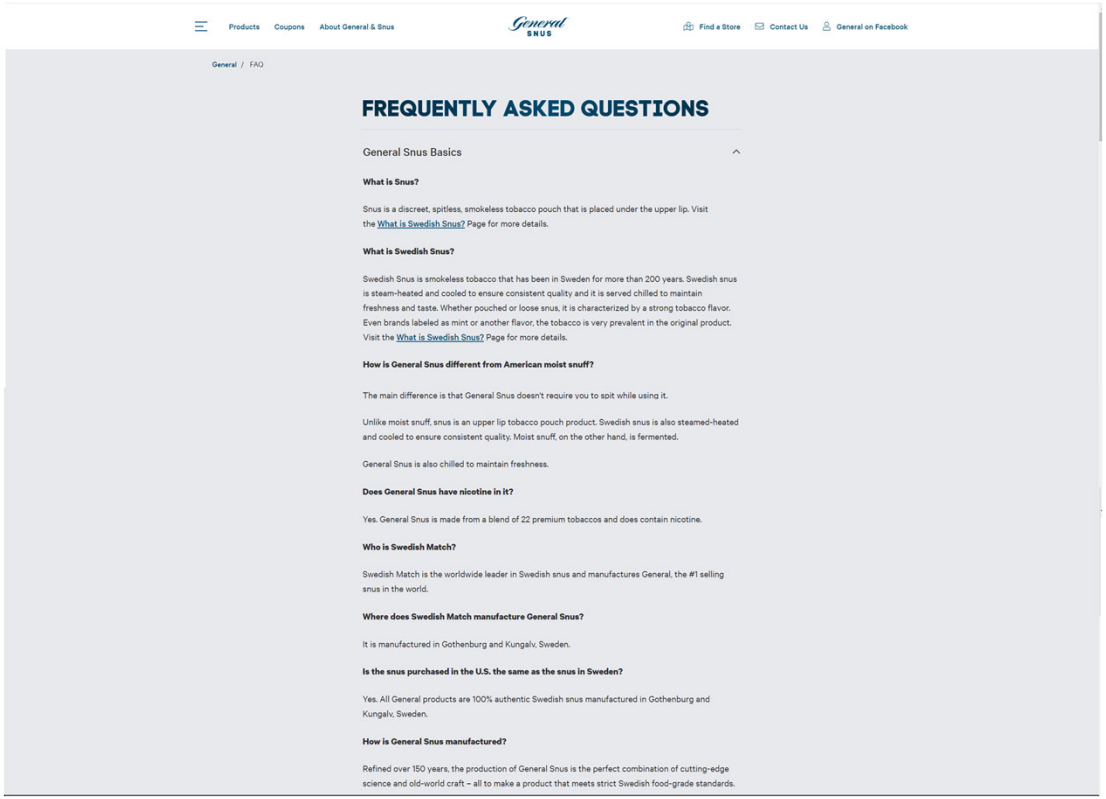
Swedish Match

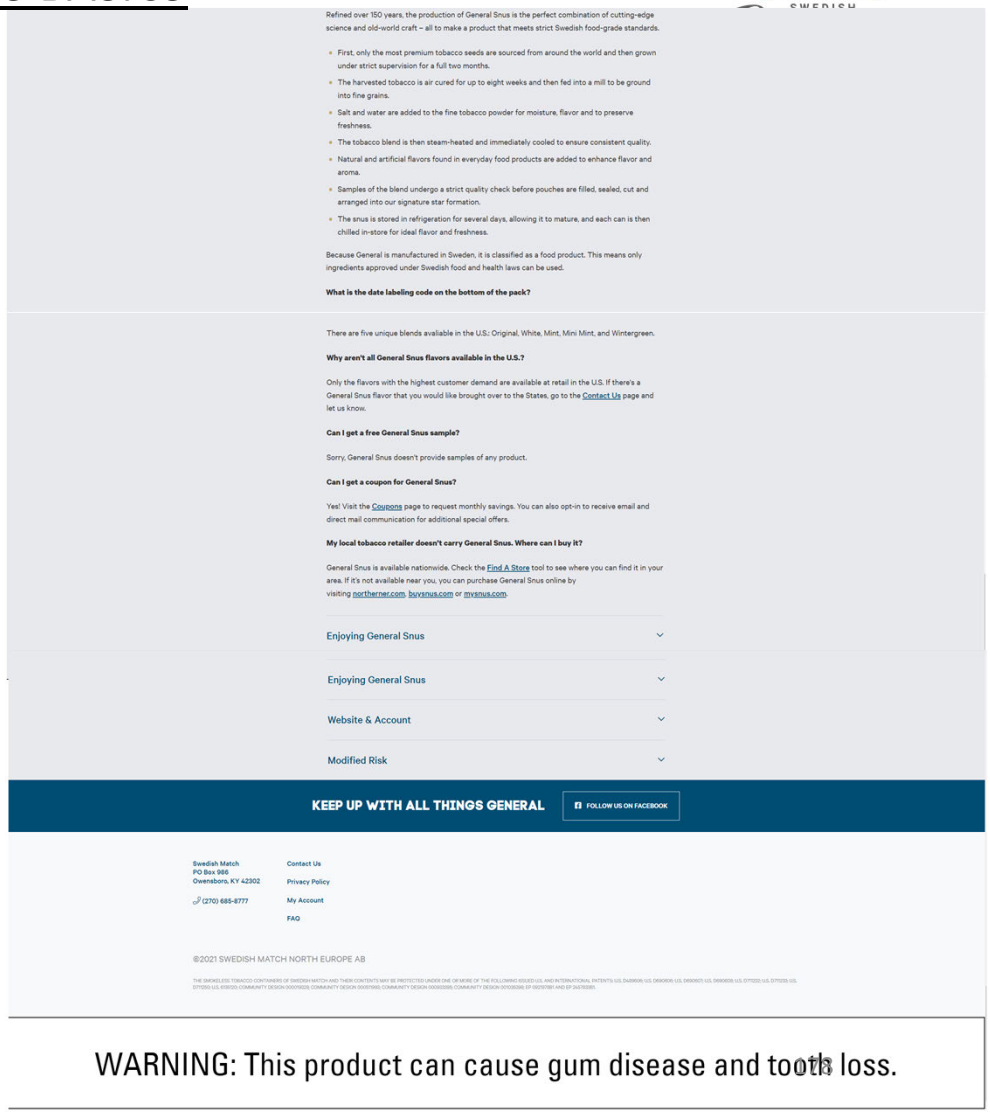
GENERAL WEBSITE REFRESH – *FAQS, TRUNCATED* [BEHIND AGE GATE]
Oct. 2021 - current



GENERAL WEBSITE REFRESH - *FAQS: GENERAL SNUS BASICS* [BEHIND AGE GATE]

Oct. 2021 - current





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GENERAL WEBSITE REFRESH - *FAQS: GENERAL SNUS BASICS COPY DETAIL*
[BEHIND AGE GATE] Oct. 2021 - current

FREQUENTLY ASKED QUESTIONS

General Snus Basics

What is Snus?

Snus is a discreet, spitless, smokeless tobacco pouch that is placed under the upper lip. Visit the What is Swedish Snus? Page for more details.

What is Swedish Snus?

Swedish Snus is smokeless tobacco that has been in Sweden for more than 200 years. Swedish snus is steam-heated and cooled to ensure consistent quality and it is served chilled to maintain freshness and taste. Whether pouched or loose snus, it is characterized by a strong tobacco flavor. Even brands labeled as mint or another flavor, the tobacco is very prevalent in the original product. Visit the What is Swedish Snus? Page for more details.

How is General Snus different from American moist snuff?

The main difference is that General Snus doesn't require you to spit while using it.

Unlike moist snuff, snus is an upper lip tobacco pouch product. Swedish snus is also steamed-heated and cooled to ensure consistent quality. Moist snuff, on the other hand, is fermented.

General Snus is also chilled to maintain freshness.

Does General Snus have nicotine in it?

Yes. General Snus is made from a blend of 22 premium tobaccos and does contain nicotine.

Who is Swedish Match?

Swedish Match is the worldwide leader in Swedish snus and manufactures General, the #1 selling snus in the world.

Where does Swedish Match manufacture General Snus?

It is manufactured in Gothenburg and Kungalv, Sweden.

Is the snus purchased in the U.S. the same as the snus in Sweden?

Yes. All General products are 100% authentic Swedish snus manufactured in Gothenburg and Kungalv, Sweden.

How is General Snus manufactured?

Refined over 150 years, the production of General Snus is the perfect combination of cutting-edge science and old-world craft – all to make a product that meets strict Swedish food-grade standards.

- First, only the most premium tobacco seeds are sourced from around the world and then grown under strict supervision for a full two months.
- The harvested tobacco is air cured for up to eight weeks and then fed into a mill to be ground into fine grains.
- Salt and water are added to the fine tobacco powder for moisture, flavor and to preserve freshness.
- The tobacco blend is then steam-heated and immediately cooled to ensure consistent quality.
- Natural and artificial flavors found in everyday food products are added to enhance flavor and aroma.
- Samples of the blend undergo a strict quality check before pouches are filled, sealed, cut and arranged into our signature star formation.
- The snus is stored in refrigeration for several days, allowing it to mature, and each can is then chilled in-store for ideal flavor and freshness.

Because General is manufactured in Sweden, it is classified as a food product. This means only ingredients approved under Swedish food and health laws can be used.

What is the date labeling code on the bottom of the pack?

This is the "Best Before" date.

What types of General Snus are available in the U.S.?

There are five unique blends avaliable in the U.S.: Original, White, Mint, Mini Mint, and Wintergreen.

Why aren't all General Snus flavors available in the U.S.?

Only the flavors with the highest customer demand are available at retail in the U.S. If there's a General Snus flavor that you would like brought over to the States, go to the Contact Us page and let us know.

Can I get a free General Snus sample?

Sorry, General Snus doesn't provide samples of any product.

Can I get a coupon for General Snus?

Yes! Visit the Coupons page to request monthly savings. You can also opt-in to receive email and direct mail communication for additional special offers.

My local tobacco retailer doesn't carry General Snus. Where can I buy it?

General Snus is available nationwide. Check the Find A Store tool to see where you can find it in your area. If it's not available near you, you can purchase General Snus online by visiting northerner.com, buysnus.com or mysnus.com.

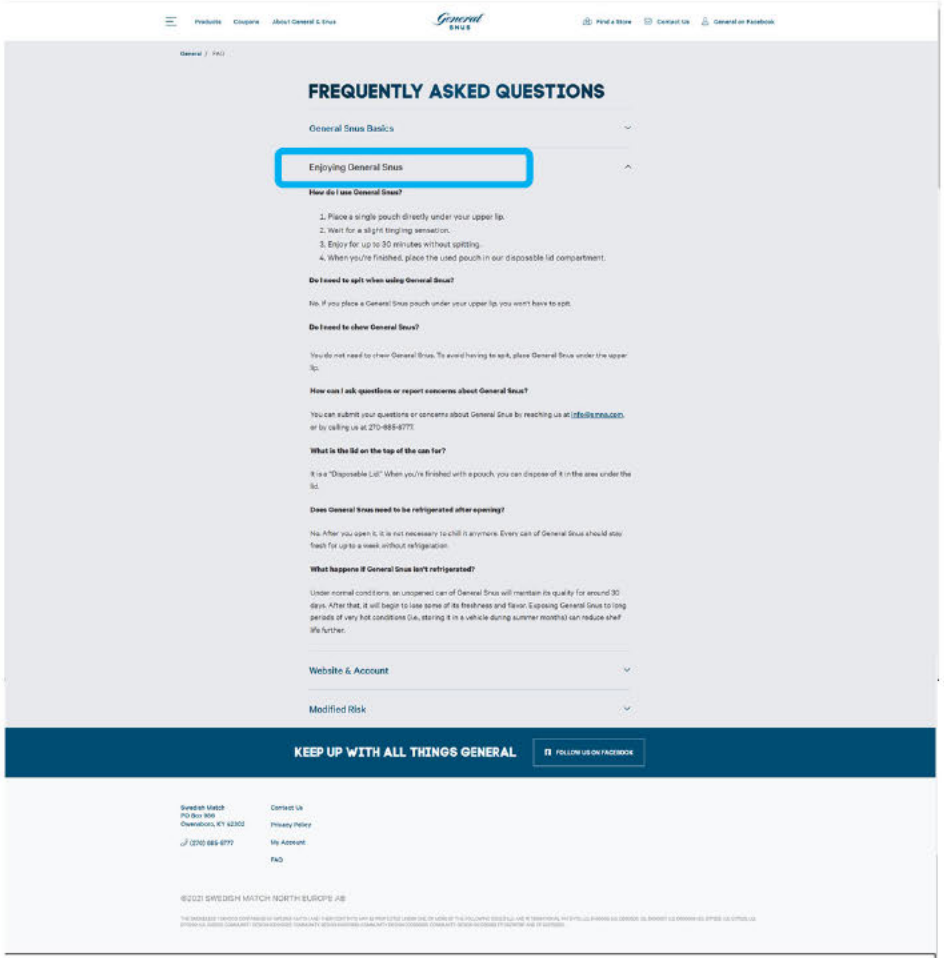
Enjoying General Snus

Website & Account

Modified Risk

GENERAL WEBSITE REFRESH - *FAQS: ENJOYING GENERAL SNUS*

[BEHIND AGE GATE] Oct. 2021 - current



FREQUENTLY ASKED QUESTIONS

General Snus Basics

Enjoying General Snus

How do I use General Snus?

1. Place a single pouch directly under your upper lip.
2. Wait for a slight tingling sensation.
3. Enjoy for up to 30 minutes without spitting.
4. When you're finished, place the used pouch in our disposable lid compartment.

Do I need to spit when using General Snus?

No. If you place a General Snus pouch under your upper lip, you won't have to spit.

Do I need to chew General Snus?

You do not need to chew General Snus. To avoid having to spit, place General Snus under the upper lip.

How can I ask questions or report concerns about General Snus?

You can submit your questions or concerns about General Snus by reaching us at info@smna.com, or by calling us at 270-685-8777.

What is the lid on the top of the can for?

It is a "Disposable Lid." When you're finished with a pouch, you can dispose of it in the area under the lid.

Does General Snus need to be refrigerated after opening?

No. After you open it, it is not necessary to chill it anymore. Every can of General Snus should stay fresh for up to a week without refrigeration.

What happens if General Snus isn't refrigerated?

Under normal conditions, an unopened can of General Snus will maintain its quality for around 30 days. After that, it will begin to lose some of its freshness and flavor. Exposing General Snus to long periods of very hot conditions (i.e., storing it in a vehicle during summer months) can reduce shelf life further.

Website & Account

Modified Risk

KEEP UP WITH ALL THINGS GENERAL

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Swedish Match
PO Box 906
Owensboro, KY 42302
(270) 685-8777

Contact Us
Privacy Policy
My Account
FAQ

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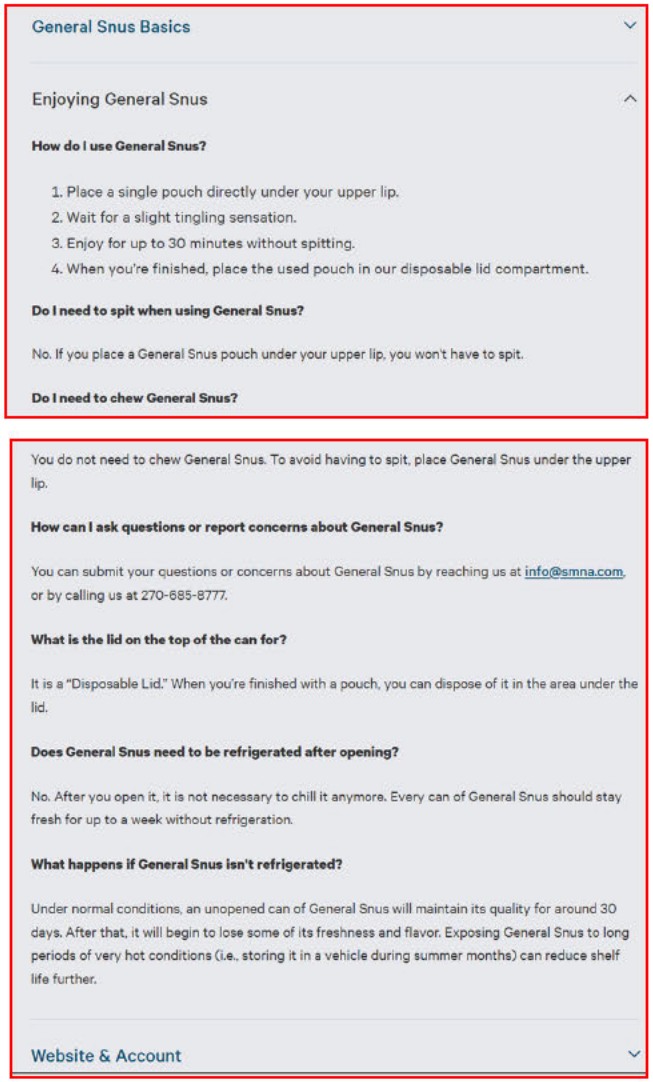
WARNING: This product can cause gum disease and tooth loss.



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Website & Account

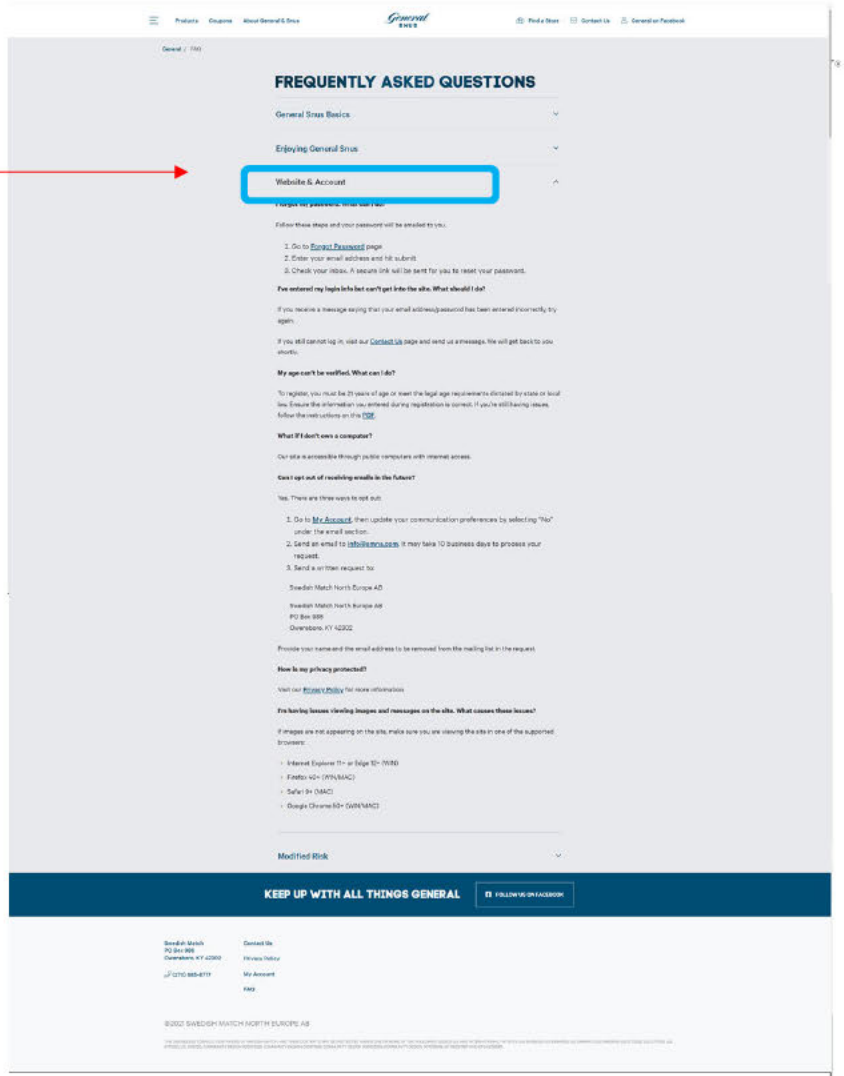
GENERAL WEBSITE REFRESH

FAQS – <u>WEBSITE & ACCOUNT</u>

[OUTSIDE & BEHIND AGE GATE]

Oct. 2021 - current

Website & Account



See following page for copy detail.

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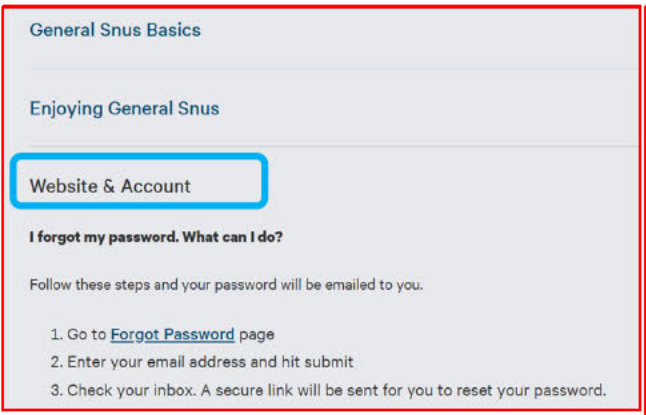
GENERAL WEBSITE REFRESH
FAQS – WEBSITE & ACCOUNT
[OUTSIDE & BEHIND AGE GATE] COPY DETAIL
Oct. 2021 - current



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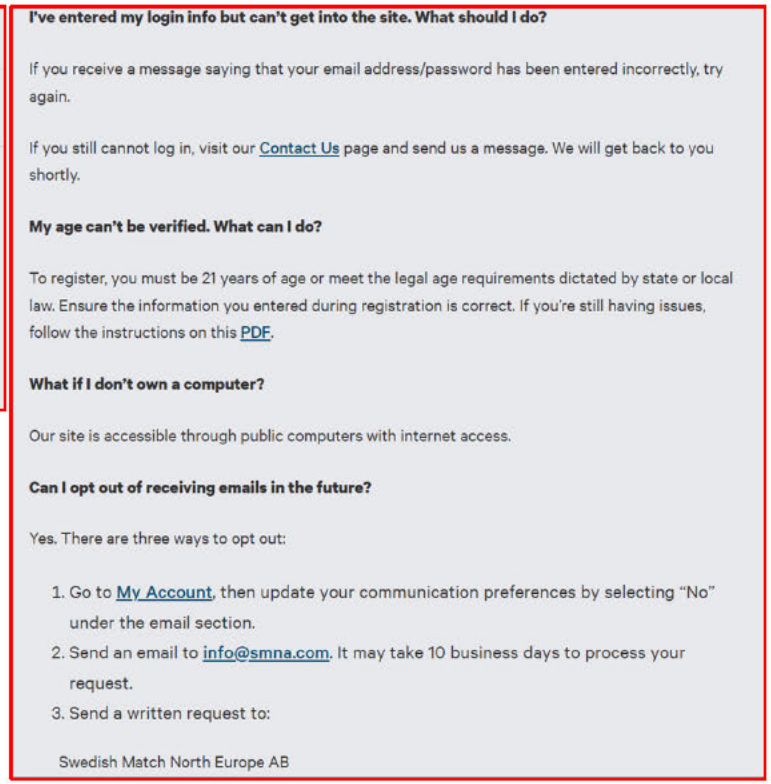

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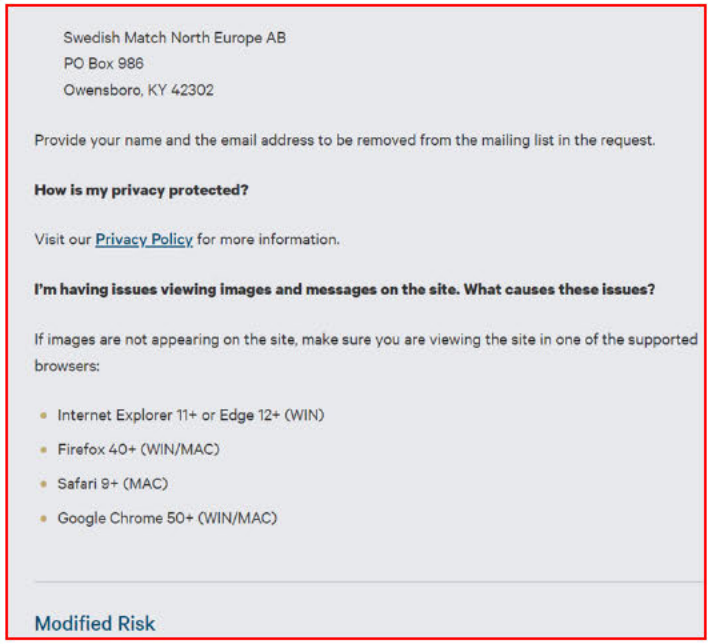
Swedish Match North Europe AB



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Modified Risk

GENERAL WEBSITE REFRESH

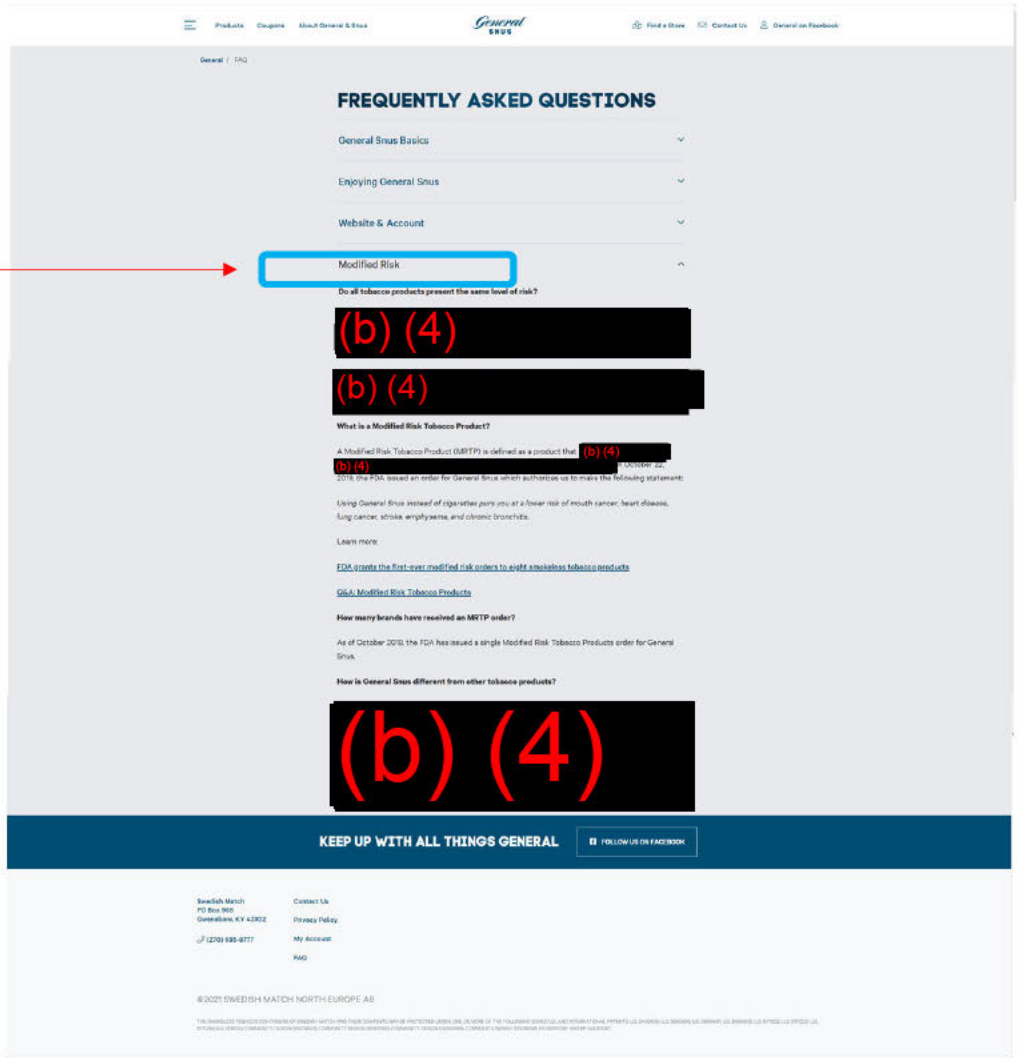
FAQS: MODIFIED RISK

[BEHIND AGE GATE]

Oct. 2021 - current

Modified Risk

See following page for copy detail.



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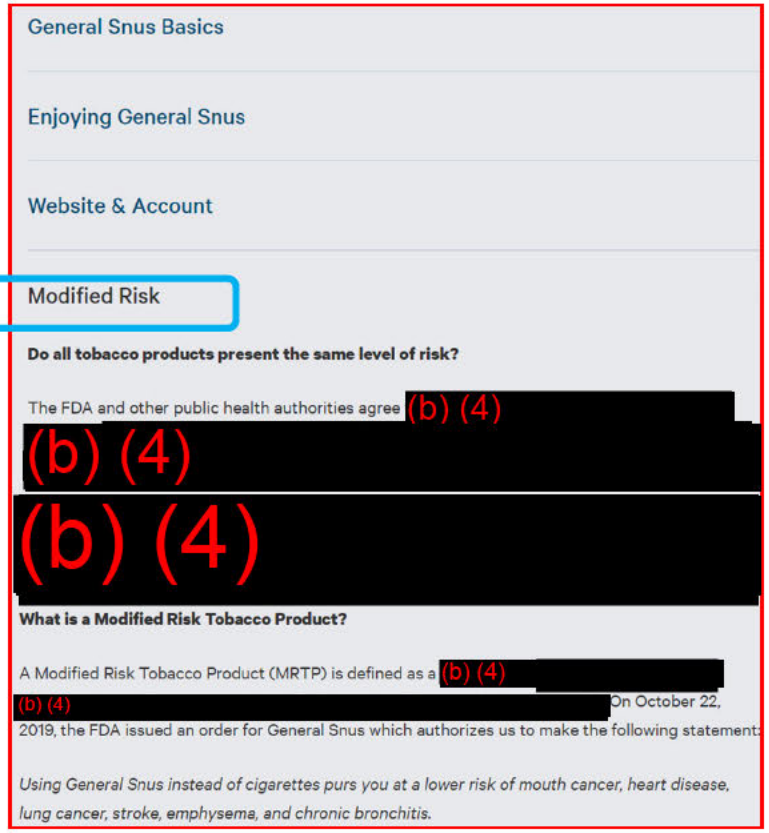
[BEHIND AGE GATE] Oct. 2021 - current



General Snus Basics

Enjoying General Snus

Website & Account

Modified Risk

Do all tobacco products present the same level of risk?

The FDA and other public health authorities agree (b) (4)

(b) (4)

(b) (4)

What is a Modified Risk Tobacco Product?

A Modified Risk Tobacco Product (MRTP) is defined as a (b) (4)

(b) (4) On October 22, 2019, the FDA issued an order for General Snus which authorizes us to make the following statement:

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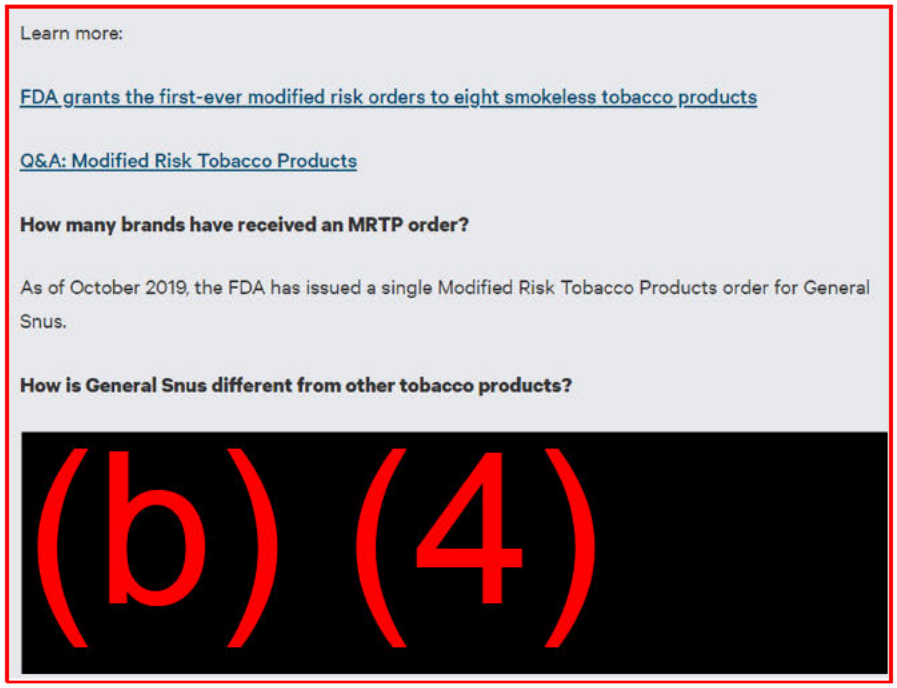


Learn more:

FDA grants the first-ever modified risk orders to eight smokeless tobacco products

Q&A: Modified Risk Tobacco Products

How many brands have received an MRTP order?

As of October 2019, the FDA has issued a single Modified Risk Tobacco Products order for General Snus.

How is General Snus different from other tobacco products?

(b) (4)

Swedish Match

Appendix 2: MRTP Website Pages

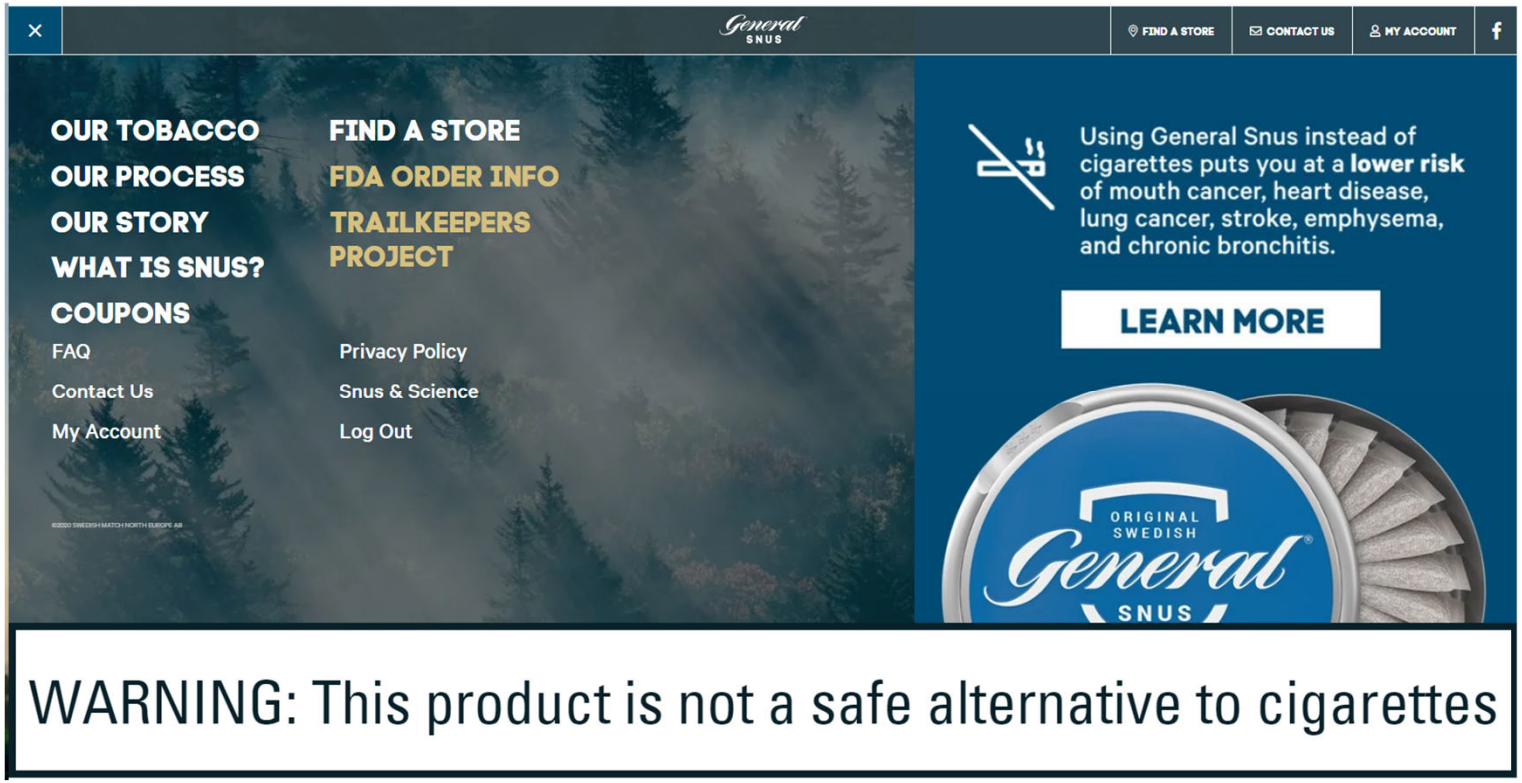
CATEGORY: SNUS
BRAND: GENERAL SNUS
Annual Report
October 2020 – October 2021

Swedish Match

WEBSITE
(MRTP PAGES)
Outside Age Gate

Swedish Match

MENU (outside age gate)
Oct. 2020 – Dec. 2020



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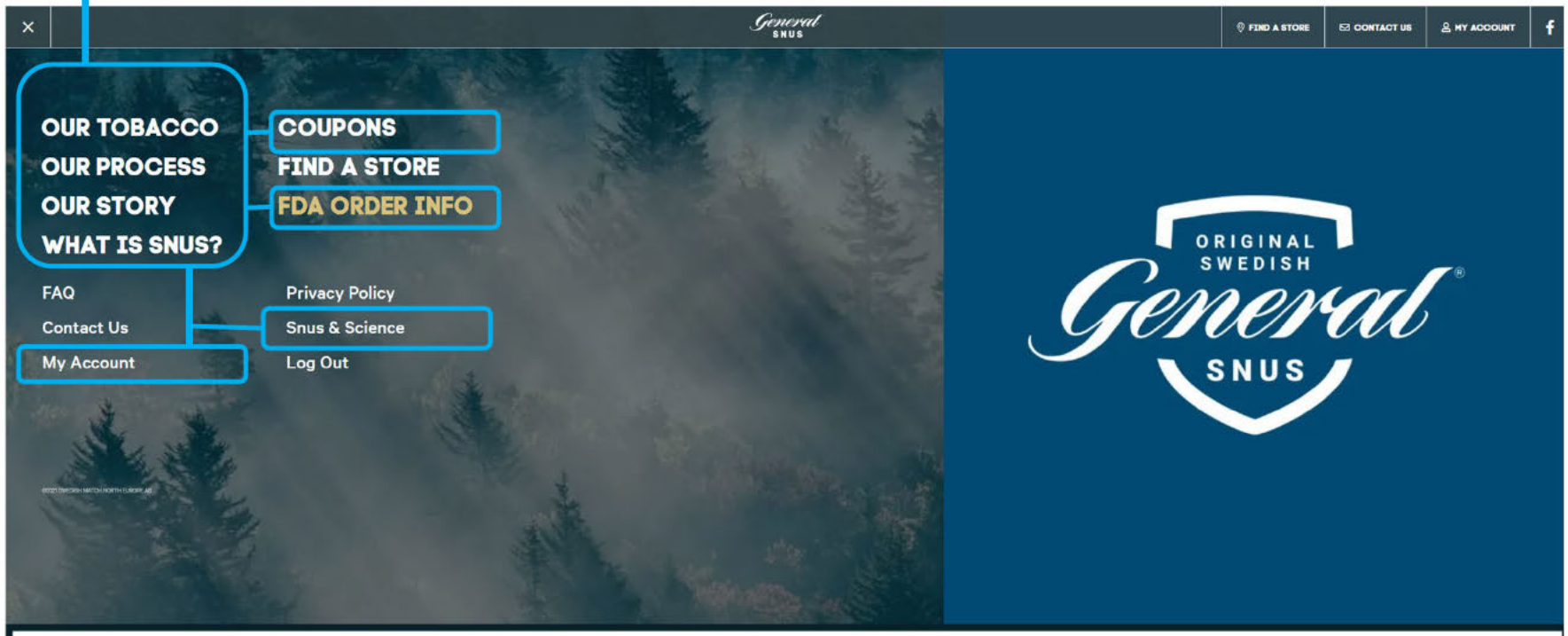
MENU (outside age gate) Dec. 2020 – Oct. 2021

Removed can image, revised menu copy

Behind Age-Gate



WARNING: This product is not a safe alternative to cigarettes

LANDING PAGE (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020

generalsnus.com/StoreLocator/

generalsnus.com/Contact/

LINKS TO LOG-IN/REGISTRATION PAGE
(my account is behind age gate)

facebook.com/GeneralSnus

LINKS TO MRTP NEWS (outside age gate)

Swedish Match

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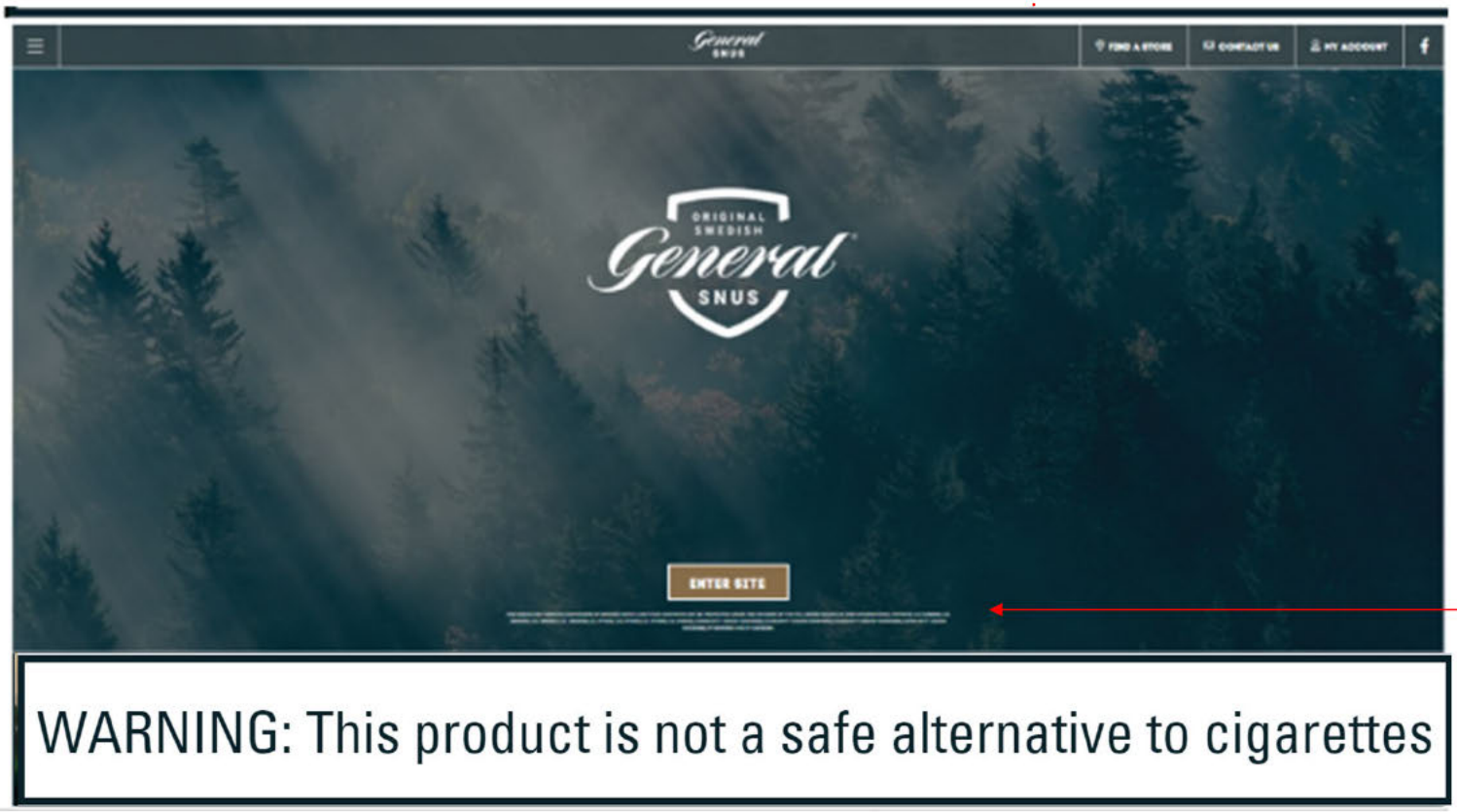
LANDING PAGE (outside age gate) Dec. 2020 – Oct. 2021



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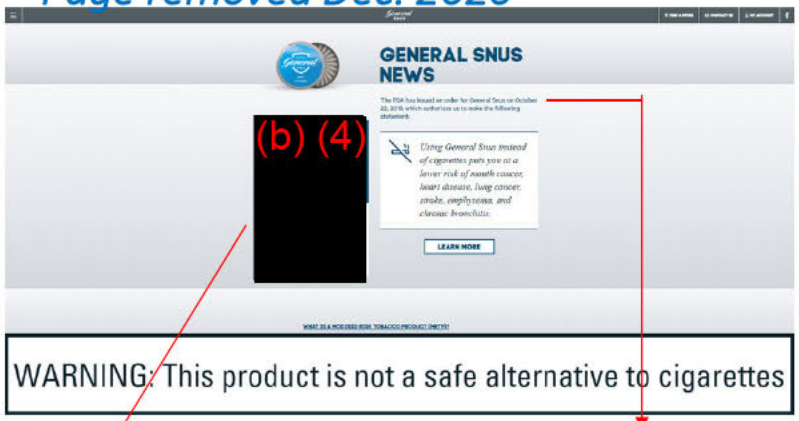
Swedish Match

MRTP NEWS PAGE (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020



The FDA has issued an order for General Snus on October 22, 2019, which authorizes us to make the following statement:

(b) (4)

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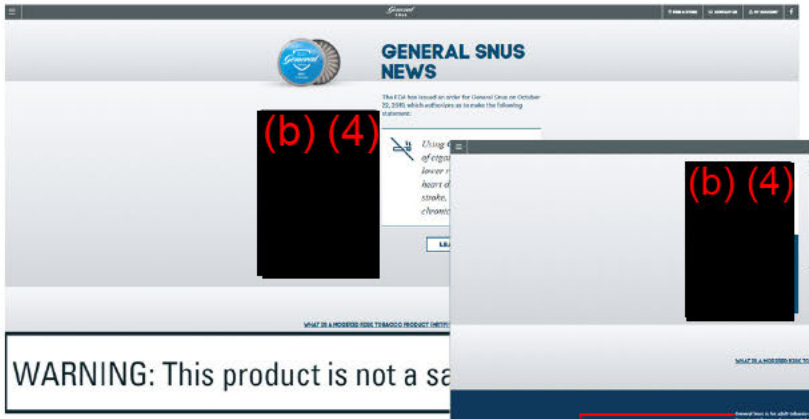
fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

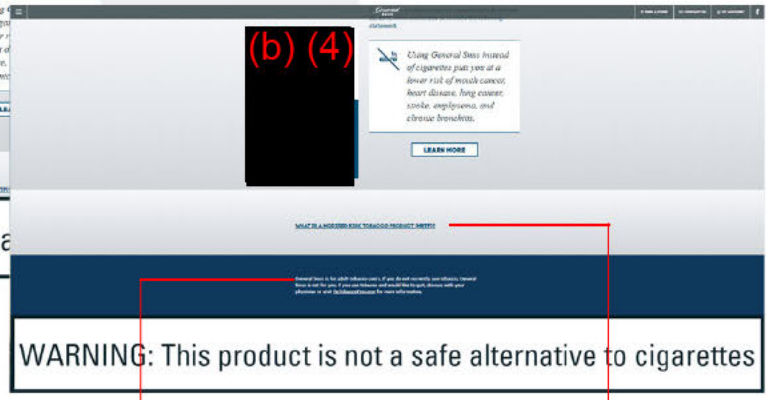
(b) (4)

(b) (4)

fda.gov/tobacco-products/market-and-distribute-tobacco-product/qa-modified-risk-tobacco-products

(b) (4)





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Q&A: Modified Risk Tobacco Products

General Snus is for adult-tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit (b) (4)

(b) (4)

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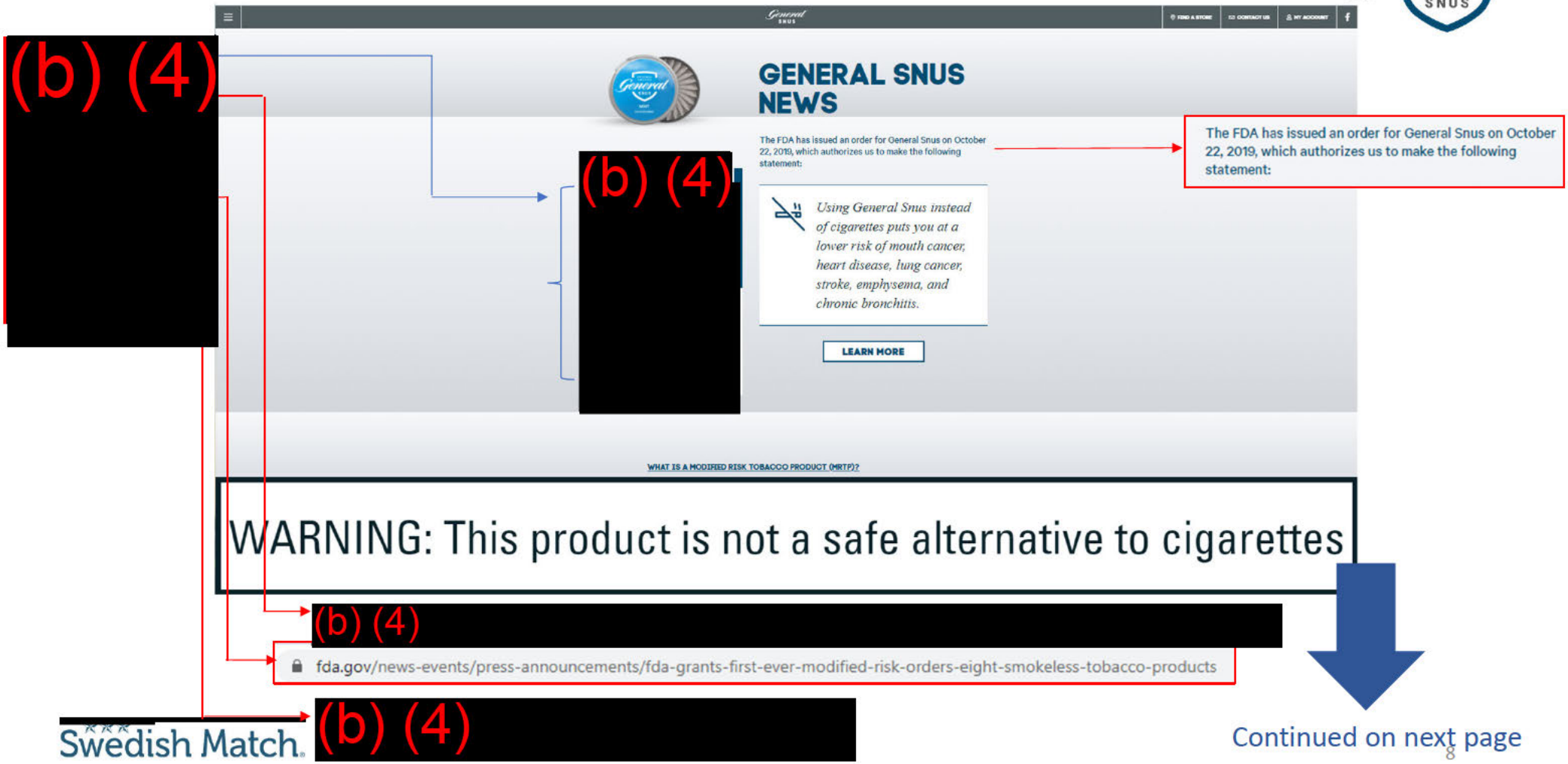
MRTP NEWS PAGE CON'T (outside age gate) Oct. 2020 – Dec. 2020

Page removed Dec. 2020



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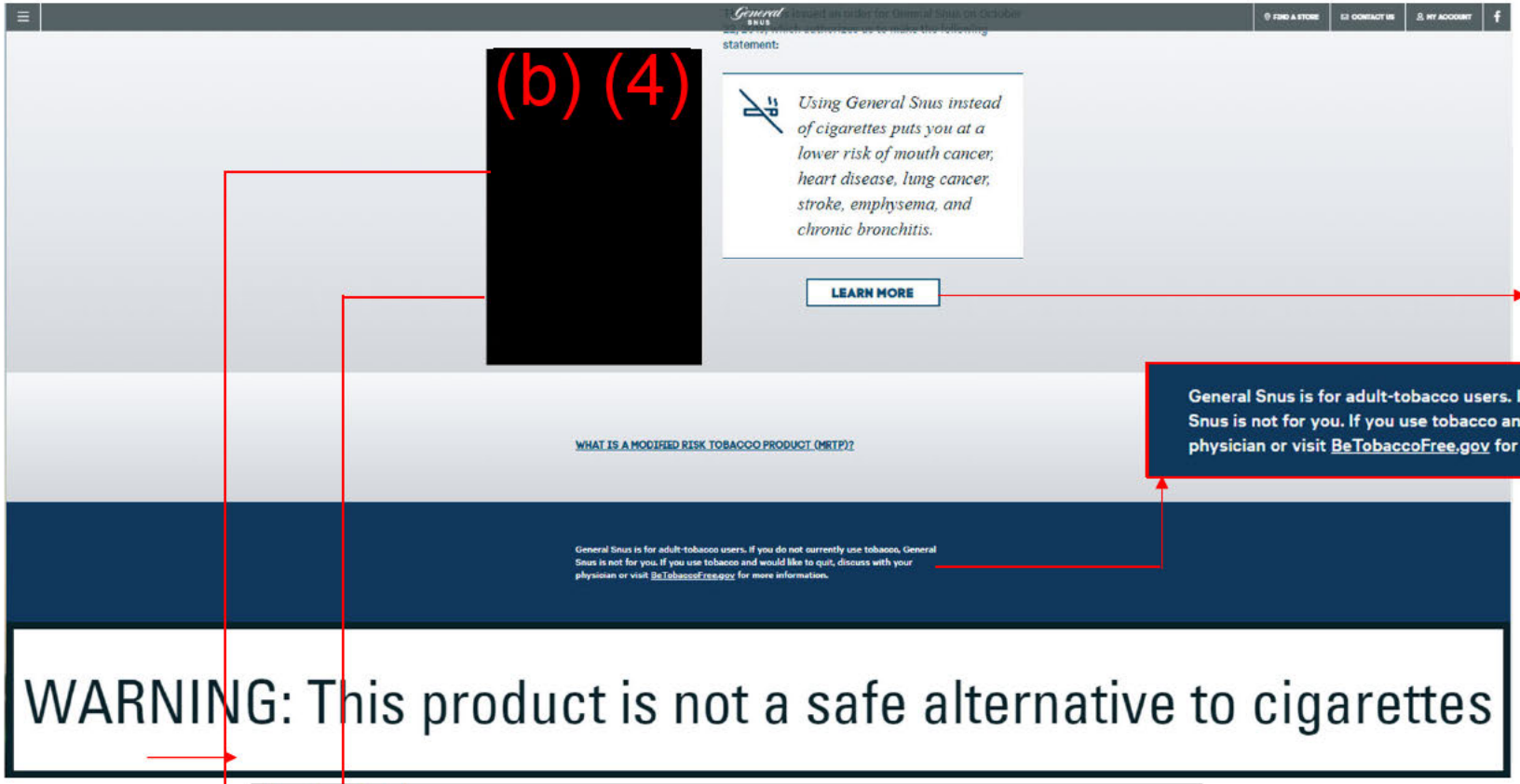

Links to MRTP Experience Like No Other Page (behind age gate)

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Continued on next page

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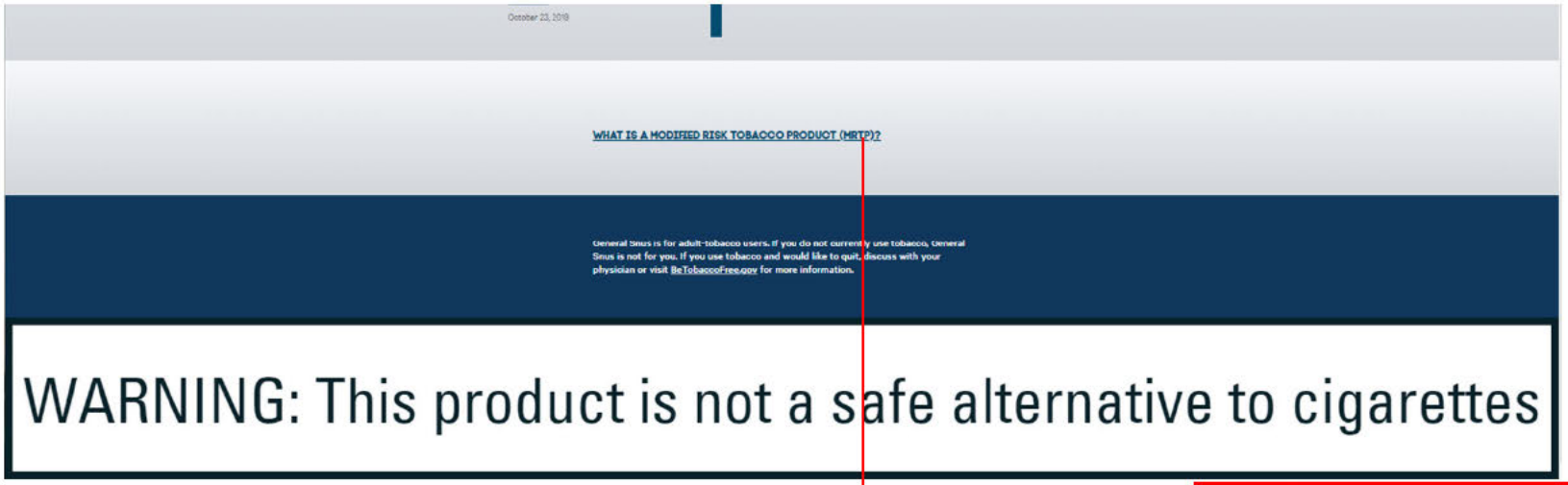

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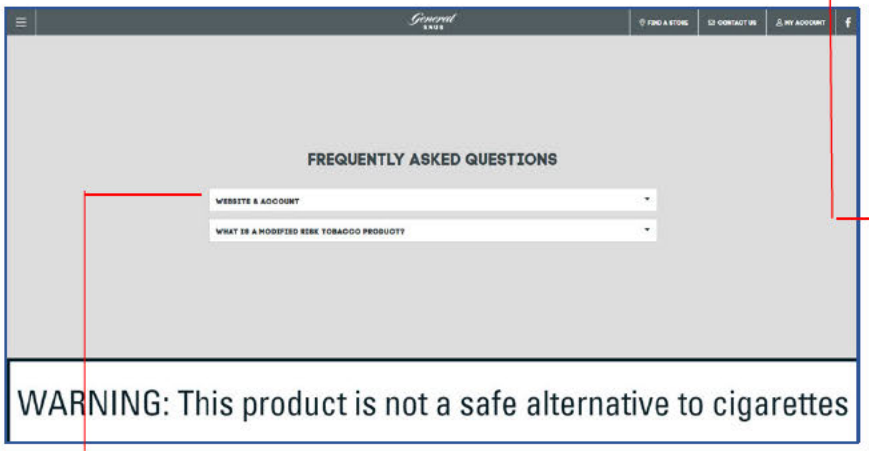
Continued on next page

FAQ PAGE: WEBSITE & ACCOUNT (outside age gate)
Oct. 2020 – Dec. 2020

MRTP content removed from outside age gate Dec. 2020

See My Account Page [behind age-gate]



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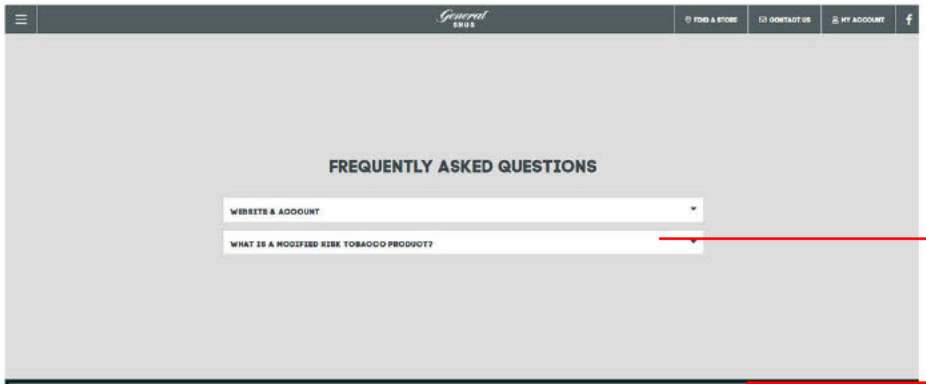

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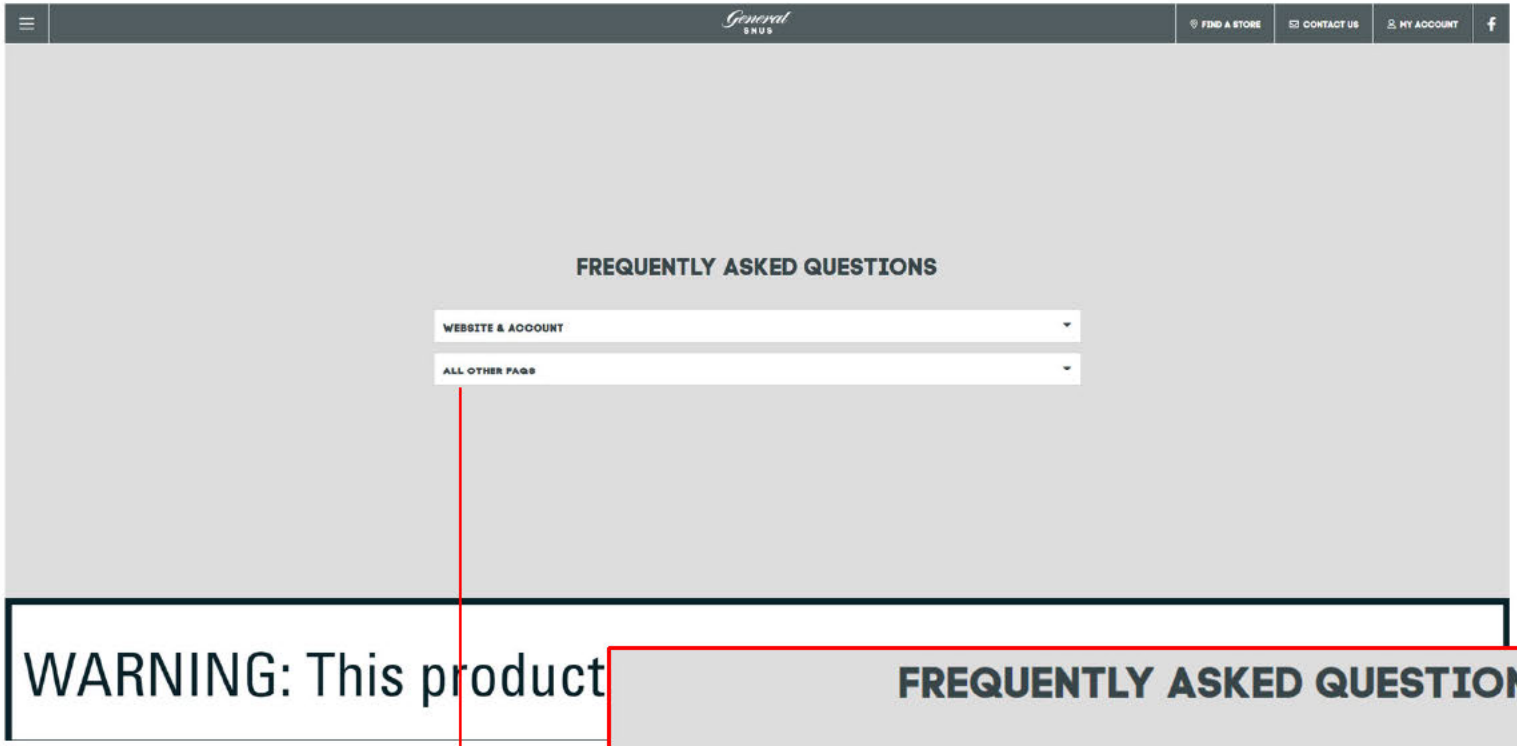
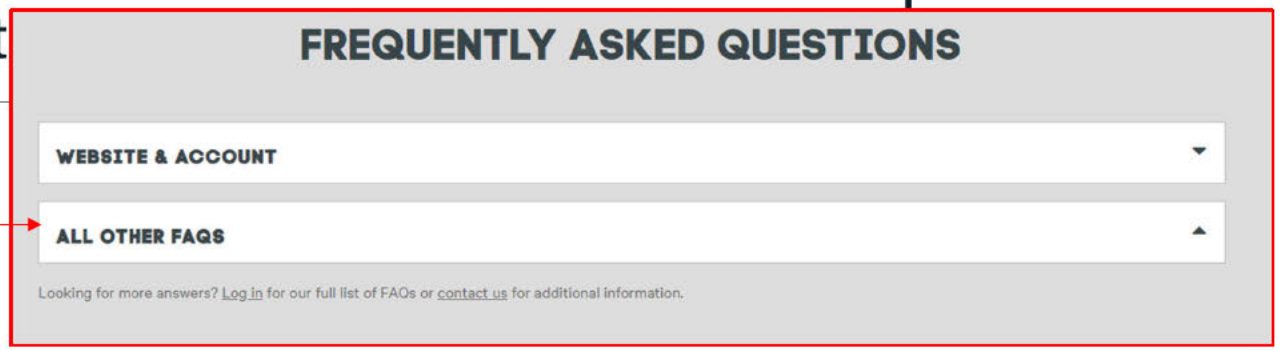
Dec. 2020 – Oct. 2021

Removed all FAQs related to MRTP or brand





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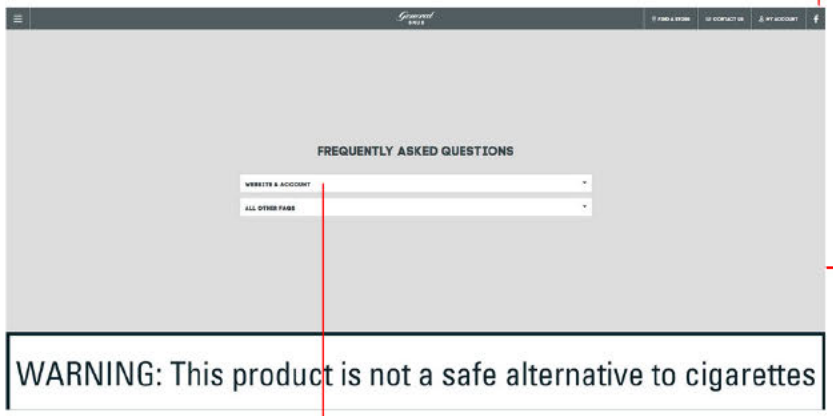
See My Account Page [behind age-gate]



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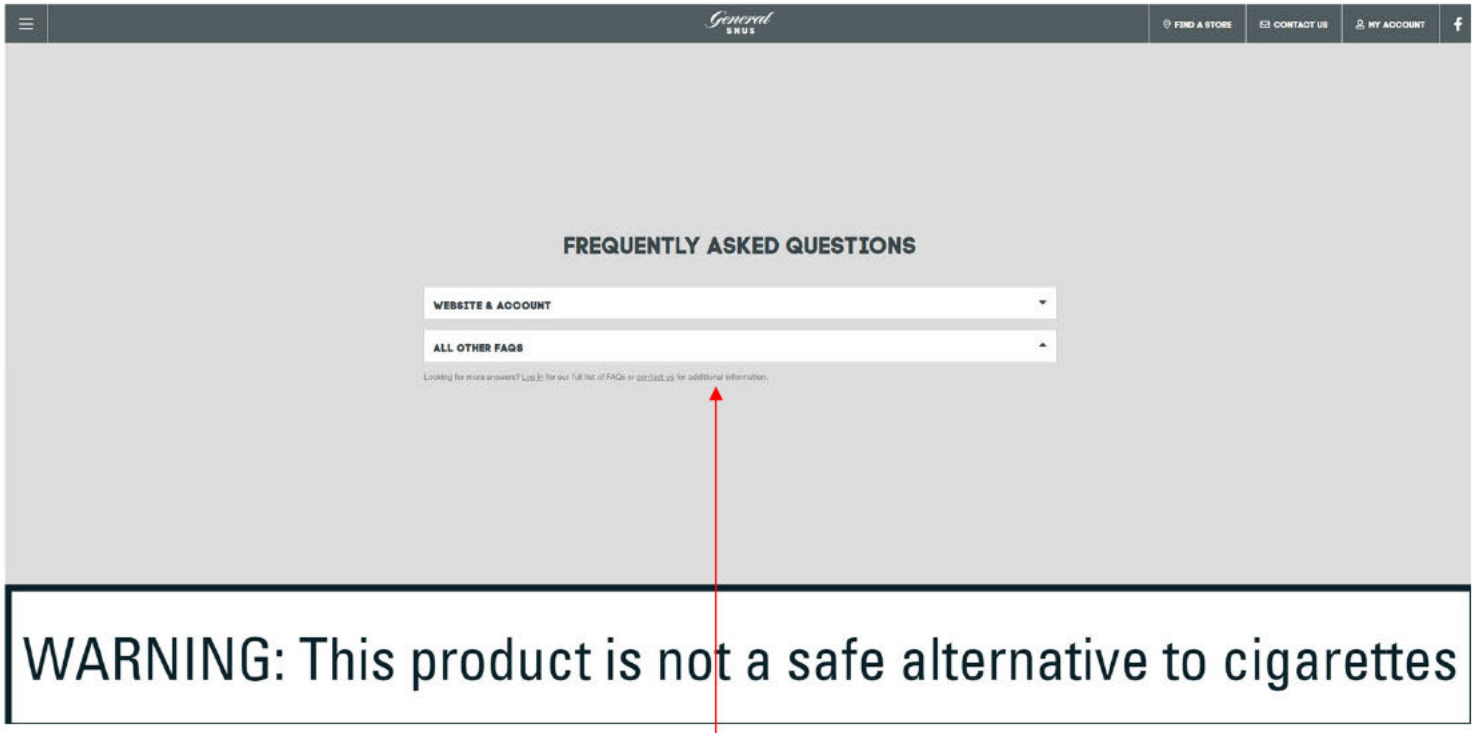


WEBSITE
(MRTP PAGES)
Behind Age Gate

Swedish Match

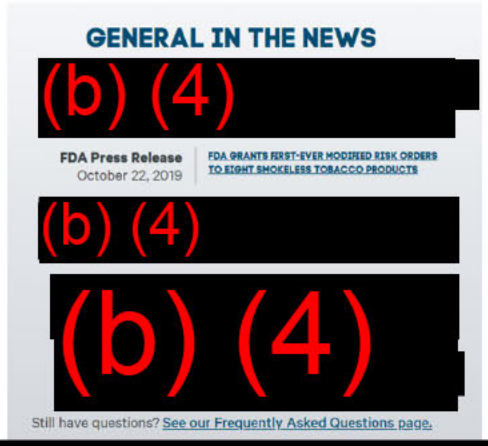
Home Page (behind age gate): Oct. 2020 – Oct. 2021

See file (behind age gate):

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

Links to 'FDA Order Info' (behind age gate)

MRTP Experience Like No Other Page (behind age gate) Oct. 2020 – Oct. 2021



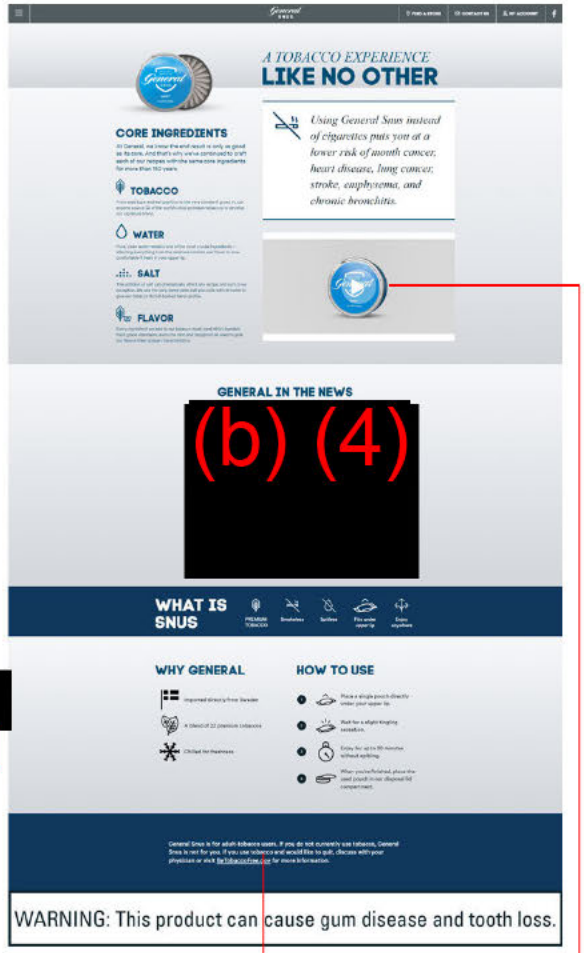
Links:

(b) (4)

fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

(b) (4)

See FAQ Page



betobaccofree.hhs.gov

General Snus is for adult-tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

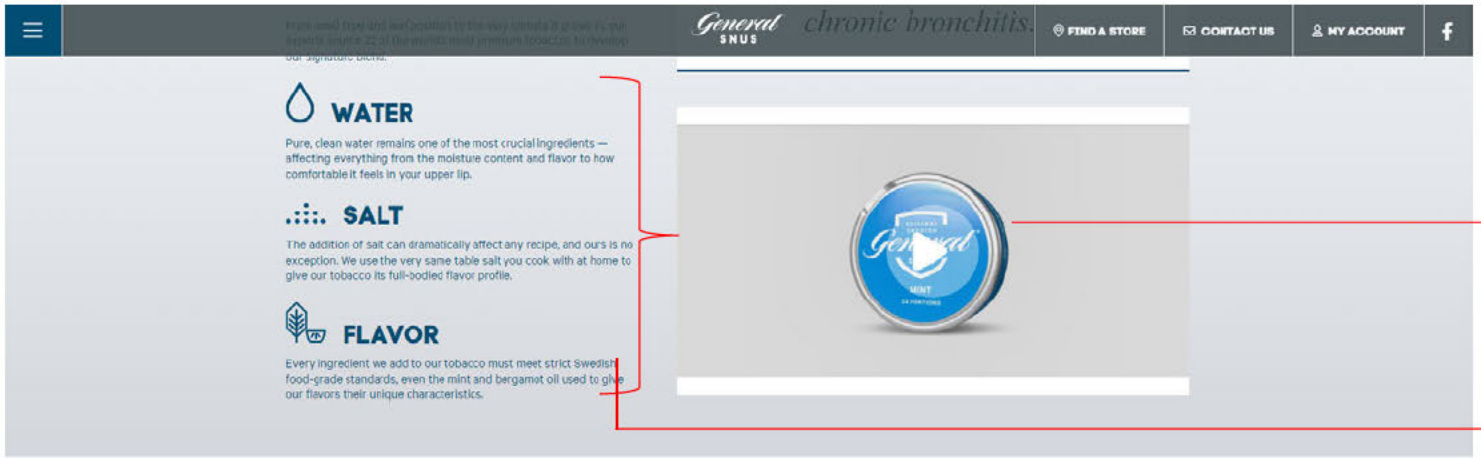
Landing, MRTP Experience Like No Other Page (behind age gate)
Oct. 2020 – Oct. 2021

TOBACCO

From seed type and leaf position to the very climate it grows in, our experts source 22 of the world's most premium tobaccos to develop our signature blend.

Continued on next page

MRTP Experience Like No Other Page (behind age gate)
Oct. 2020 – Oct. 2021



See file:

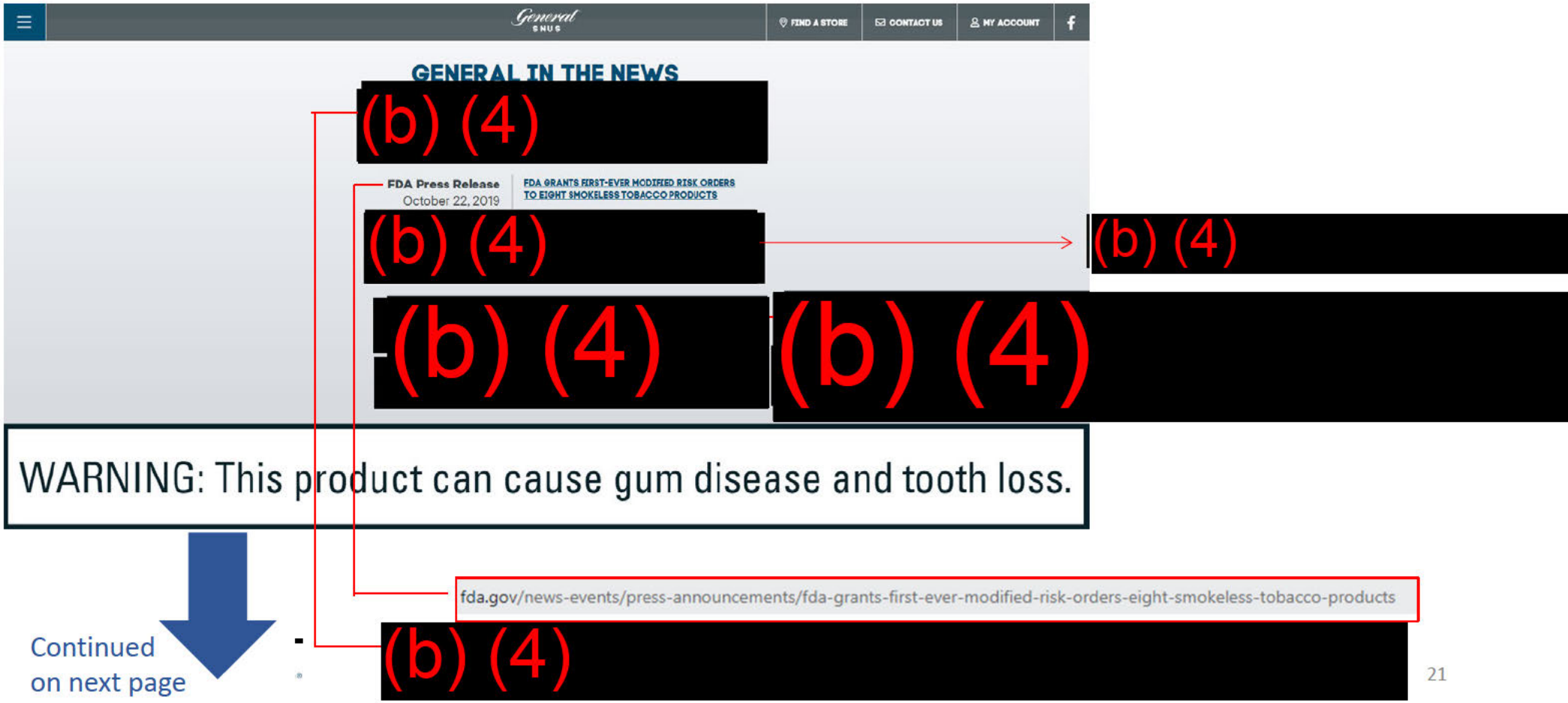
GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

GENERAL IN THE NEWS

WARNING: This product can cause gum disease and tooth loss.

Continued on next page

MRTP Experience Like No Other Page (behind age gate)
Oct. 2020 – Oct. 2021



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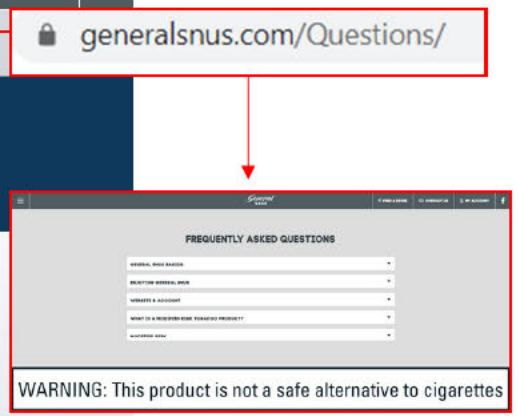
MRTP Experience Like No Other Page (behind age gate)
Oct. 2020 – Oct. 2021



See FAQ Page (behind age gate, page)

Swedish Match

Continued on next page

MRTP Experience Like No Other Page (behind age gate)
Oct. 2020 – Oct. 2021

betobaccofree.hhs.gov

Video Storyboards for MRTP Video
Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

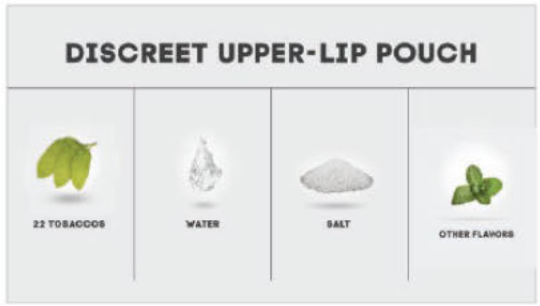
Audio Voice Over	
"Since 1866, General Snus, the Original Swedish Snus, has continued to create a tobacco experience like no other.	 01
Smokeless, spitless, and chilled for freshness,	 02
General's discreet upper-lip pouch is made with only the best:	 03

Continued on next page

Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

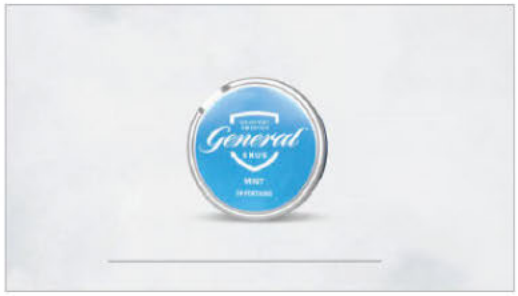
Audio Voice Over	
	 04
A blend of 22 air-dried tobaccos, pure, clean water, a hint of salt, and other natural and artificial flavors found in everyday food items.	 05
	 06

Continued on next page

Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

Audio Voice Over	
But the true difference is in our process.	07
General's blend is steam-heated and cooled,	 08
making a product that meets tough Swedish food-grade standards.	09

Continued on next page

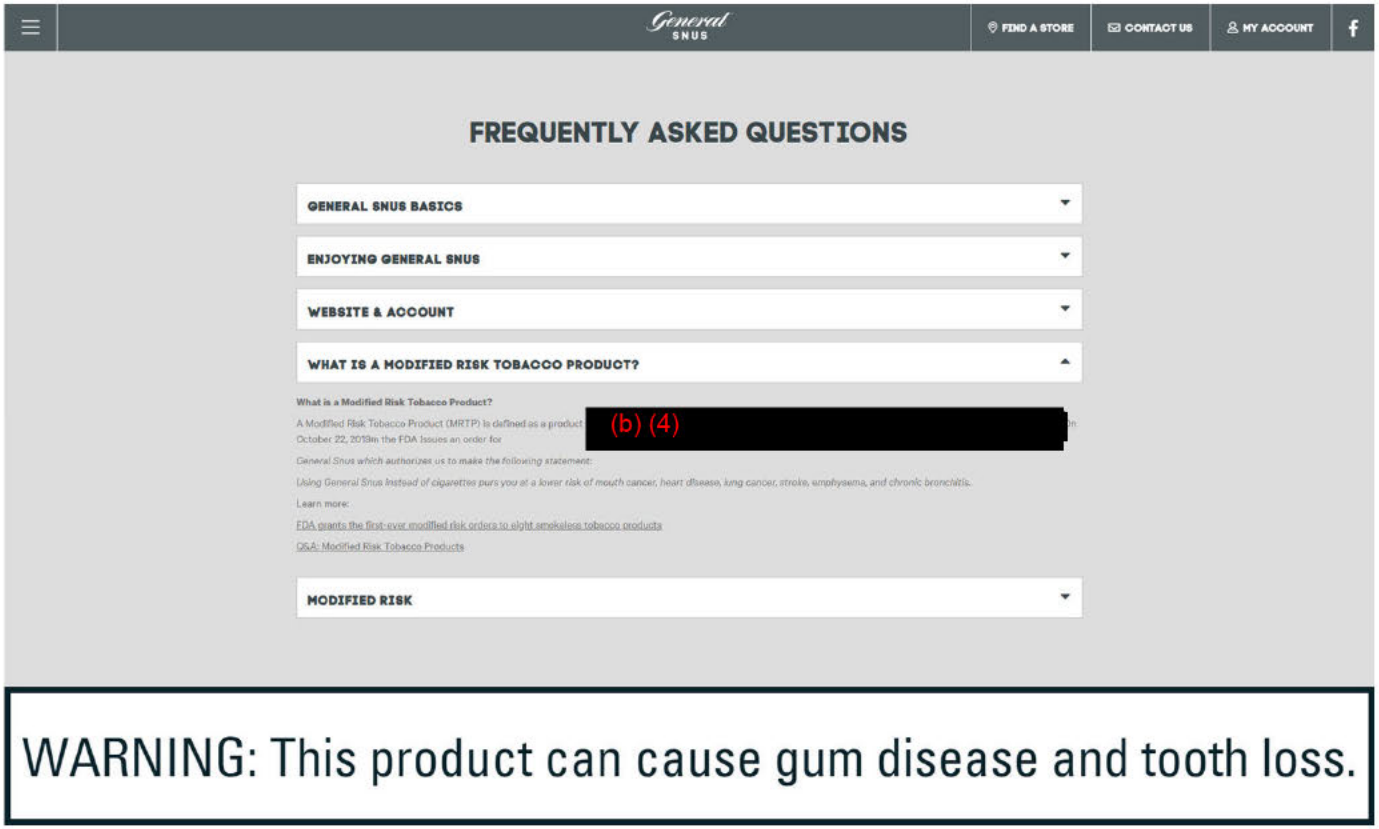
Video Storyboards (cont.) – Oct. 2020 – Oct. 2021

See file:

GeneralSnus_MRTP_2019_Q3_WebVideo.mp4

Audio Voice Over	
Learn more at GeneralSnus.com.	13
WARNING: Smokeless tobacco is addictive.	14

FAQs (behind age gate) What is a Modified Risk Tobacco Product? Oct. 2020 – Oct. 2021



See FAQs on next page

FAQs (behind age gate) What is a Modified Risk Tobacco Product? Copy Oct. 2020 – Oct. 2021

What is a Modified Risk Tobacco Product?

A Modified Risk Tobacco Product (MRTP) is defined as a product that (b) (4) [redacted] (b) (4) [redacted] On October 22, 2019m the FDA issues an order for *General Snus which authorizes us to make the following statement:*

Using General Snus instead of cigarettes puTs you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

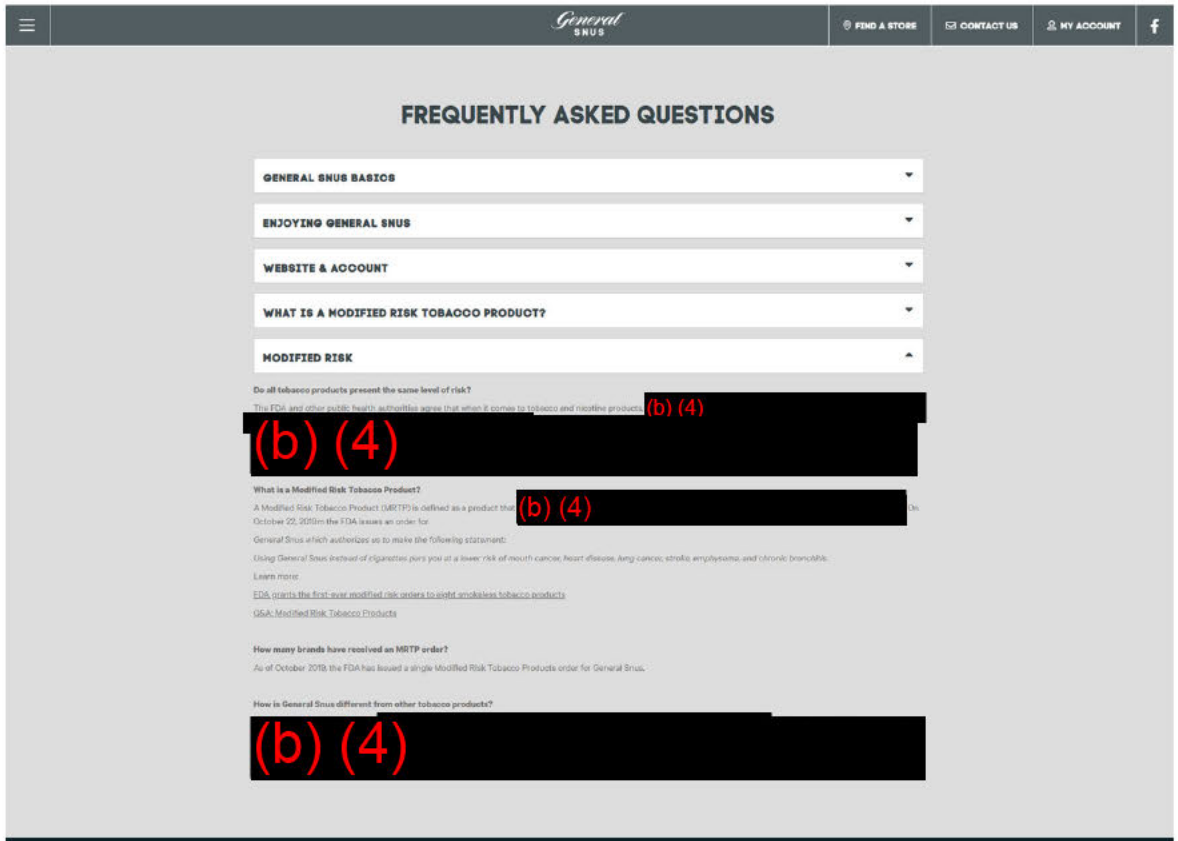
Learn more:

FDA grants the first-ever modified risk orders to eight smokeless tobacco products

Q&A: Modified Risk Tobacco Products

Swedish Match

FAQs (behind age gate) Modified Risk
Oct. 2020 – Oct. 2021



See FAQs on next page

WARNING: This product can cause gum disease and tooth loss.

FAQs (behind age gate) Modified Risk Copy
Oct. 2020 – Oct. 2021

Do all tobacco products present the same level of risk?
The FDA and other public health authorities agree that when it comes to tobacco and nicotine products, (b) (4)
(b) (4)

What is a Modified Risk Tobacco Product?
A Modified Risk Tobacco Product (MRTP) is defined as a product that (b) (4)
(b) (4) On October 22, 2019m the FDA issues an order for
General Snus which authorizes us to make the following statement:
Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
Learn more:
FDA grants the first-ever modified risk orders to eight smokeless tobacco products
Q&A: Modified Risk Tobacco Products

How many brands have received an MRTP order?
As of October 2019, the FDA has issued a single Modified Risk Tobacco Products order for General Snus.

How is General Snus different from other tobacco products?
(b) (4)
(b)(4)
(b)(4)

fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products

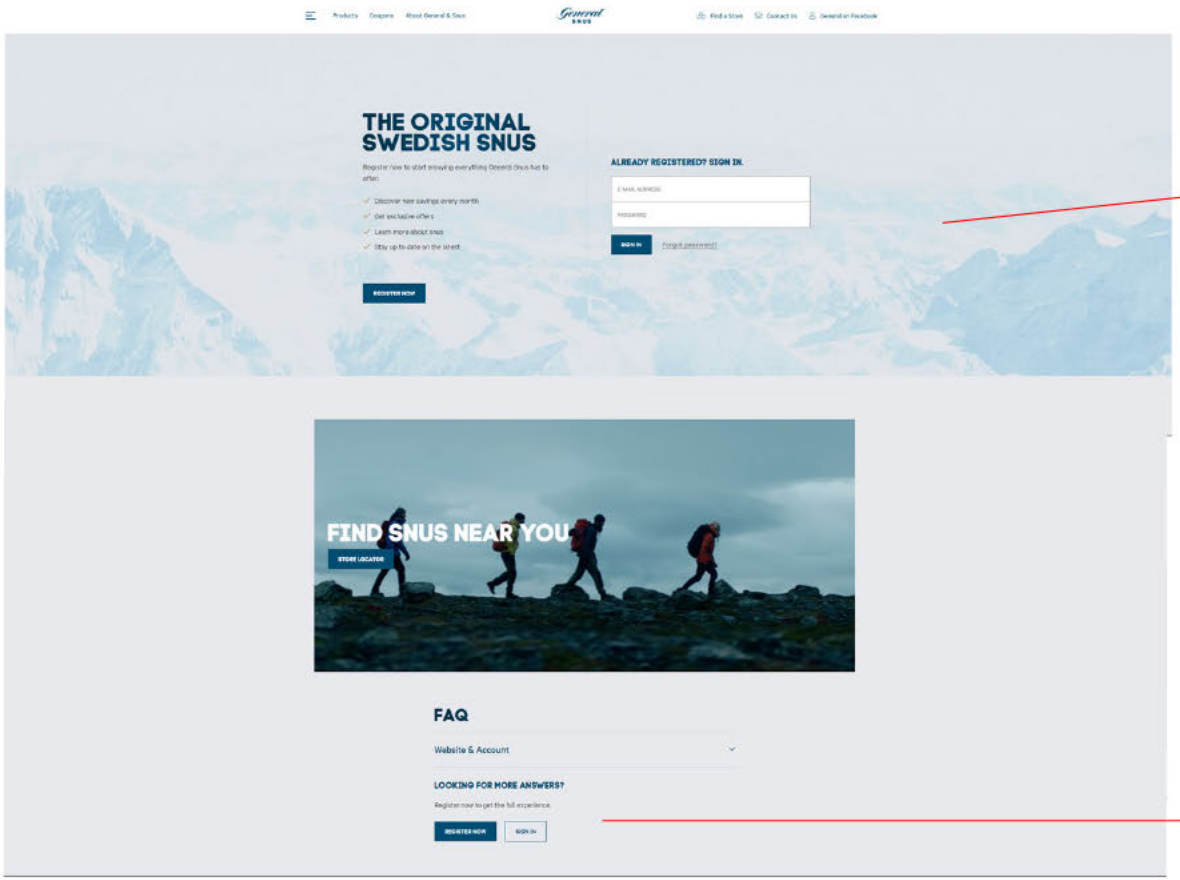
fda.gov/tobacco-products/market-and-distribute-tobacco-product/qa-modified-risk-tobacco-products

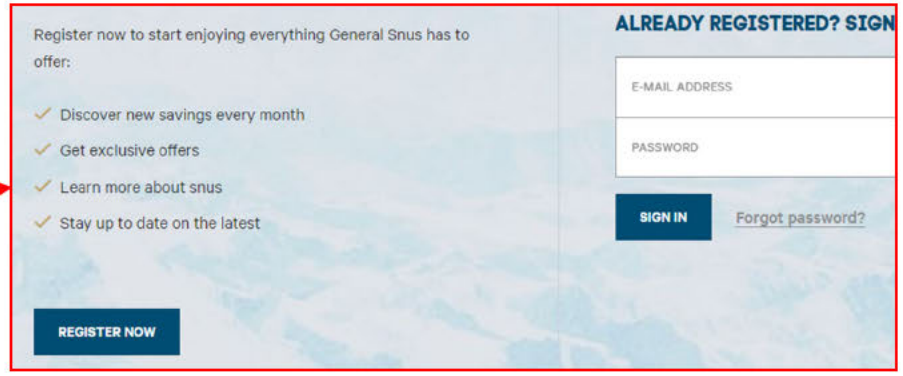
Swedish Match

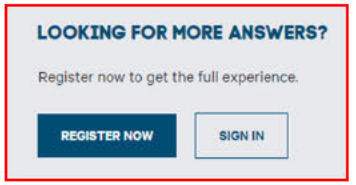
GENERAL SNUS WEBSITE REFRESH (MRTP PAGES)
Outside Age Gate
October 2021 - current

Swedish Match

GENERAL WEBSITE REFRESH –LANDING, *REGISTRATION / LOG-IN* [OUTSIDE AGE GATE] Oct. 2021 - current



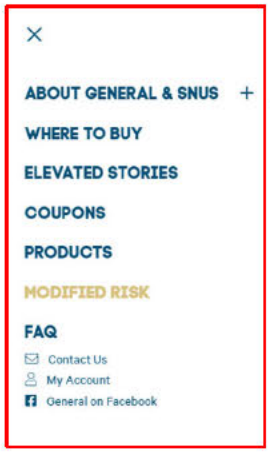




WARNING: This product can cause gum disease and tooth loss.

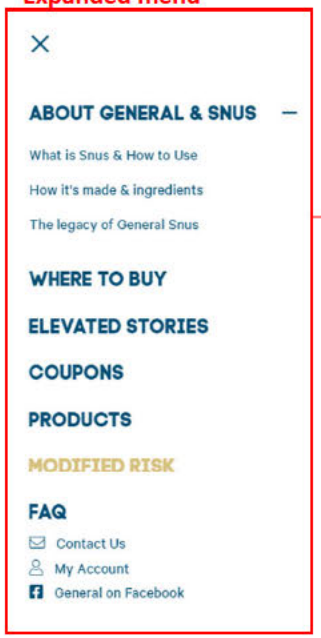
GENERAL WEBSITE REFRESH - *MENU: COLLAPSED & EXPANDED*

[OUTSIDE AGE GATE] Oct. 2021 - current



WARNING: This product is not a safe alternative to cigarettes.

Expanded menu

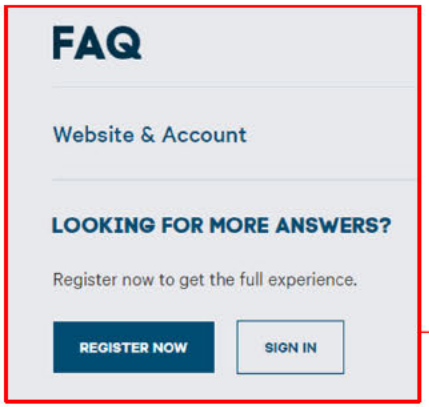


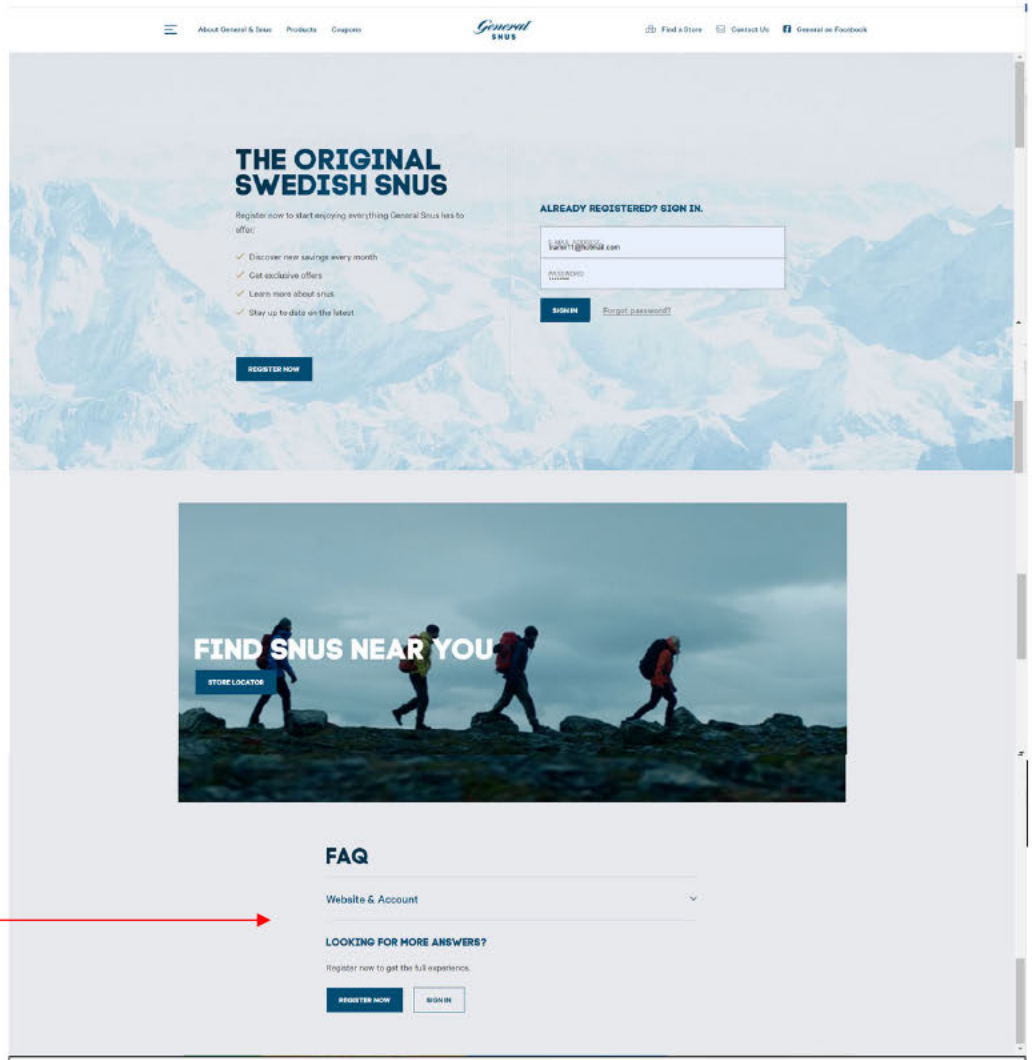
WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH – *FAQs*

[OUTSIDE AGE GATE] Oct. 2021 - current

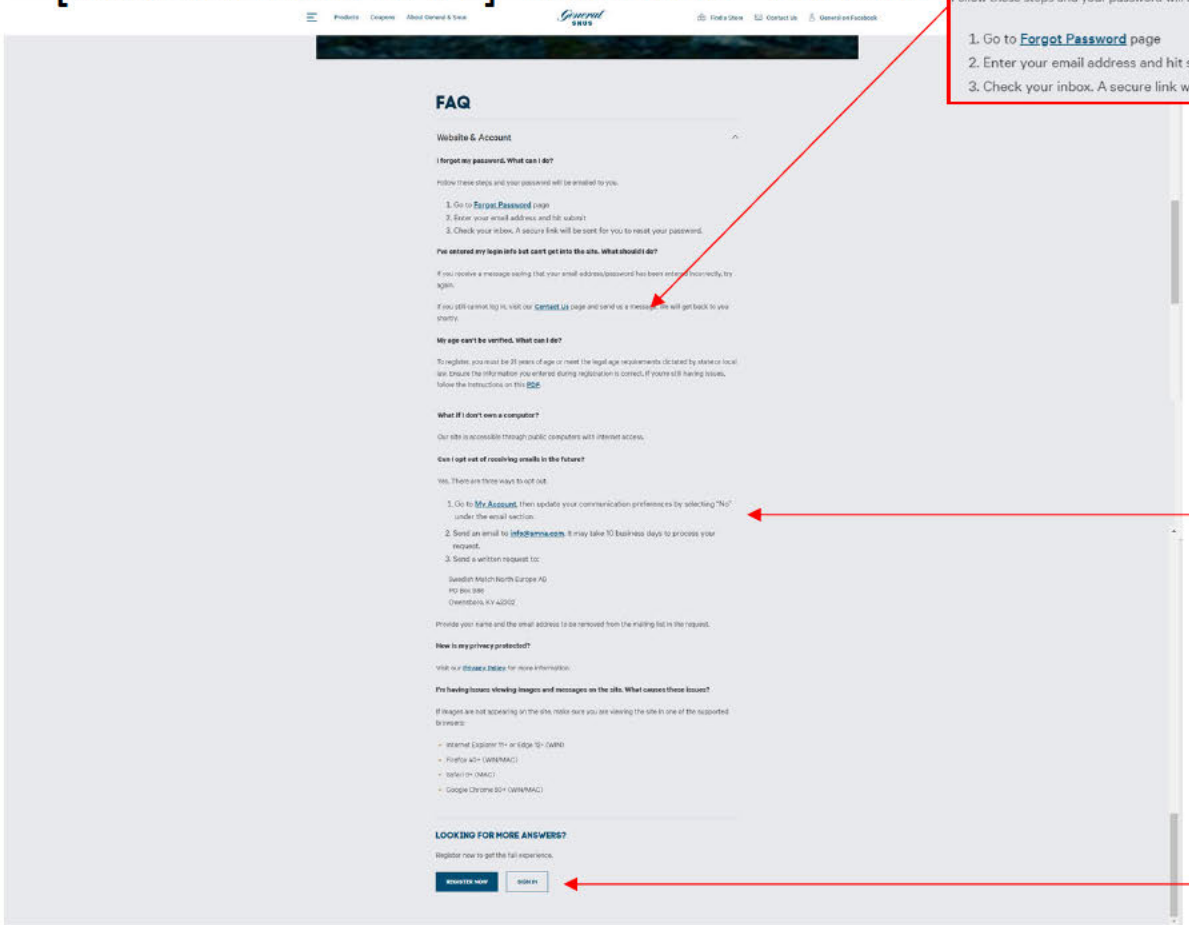
No MRTP-related FAQs can be accessed outside age gate





WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH - *FAQS*
[OUTSIDE AGE GATE] Oct. 2021 - current



Website & Account

I forgot my password. What can I do?

Follow these steps and your password will be emailed to you.

1. Go to Forgot Password page
2. Enter your email address and hit submit
3. Check your inbox. A secure link will be sent for you to reset your password.

I've entered my login info but can't get into the site. What should I do?

If you receive a message saying that your email address/password has been entered incorrectly, try again.

If you still cannot log in, visit our Contact Us page and send us a message. We will get back to you shortly.

My age can't be verified. What can I do?

To register, you must be 21 years of age or meet the legal age requirements dictated by state or local law. Ensure the information you entered during registration is correct. If you're still having issues, follow the instructions on this PDF.

What if I don't own a computer?

Our site is accessible through public computers with internet access.

What if I don't own a computer?

Our site is accessible through public computers with internet access.

Can I opt out of receiving emails in the future?

Yes. There are three ways to opt out:

1. Go to My Account, then update your communication preferences by selecting "No" under the email section.
2. Send an email to info@smna.com. It may take 10 business days to process your request.
3. Send a written request to:

Swedish Match North Europe AB
PO Box 986
Owensboro, KY 42302

Provide your name and the email address to be removed from the mailing list in the request.

How is my privacy protected?

Visit our Privacy Policy for more information.

I'm having issues viewing images and messages on the site. What causes these issues?

If images are not appearing on the site, make sure you are viewing the site in one of the supported browsers:

- Internet Explorer 11+ or Edge 12+ (WIN)
- Firefox 40+ (WIN/MAC)
- Safari 9+ (MAC)
- Google Chrome 50+ (WIN/MAC)

LOOKING FOR MORE ANSWERS?

Register now to get the full experience.

REGISTER NOW SIGN IN

WARNING: This product can cause gum disease and tooth loss.

GENERAL SNUS WEBSITE REFRESH (MRTP PAGES)
Behind Age Gate
October 2021 - current

Swedish Match

GENERAL WEBSITE REFRESH - *HOME*

[BEHIND AGE GATE] Oct. 2021 - current

WHAT IS SNUS & HOW TO USE

Learn more about how to use Swedish Snus.

WHAT IS SNUS

Explore what goes into snus, how it's made, and the centuries-old story of a tobacco product that changed the world.

READ MORE

Links to 'About General & Snus' page

Links to 'Find a Store' page

FIND SNUS NEAR YOU

STORE LOCATOR

Links to 'Coupons' page

EXCLUSIVE SAVINGS

Enjoy monthly coupons for your favorite varieties of General Snus, redeemable anywhere adventure takes you.

VIEW AVAILABLE COUPONS

Links to 'Products' page

PRODUCTS

The original General Snus combines premium tobacco with natural and artificial flavors for an authentic snus experience unlinke any other. Discover your favorite today.

EXPLORE PRODUCTS

Links to 'Modified Risk' page

FIRST EVER

General Snus received the first-ever Modified Risk Tobacco Product (MRTP) order from the FDA. Learn more about what this means for you.

LEARN MORE

ELEVATE YOUR FALL BBQ GAME

We've got a recipe + tips that will take your fall barbeque to the next level.

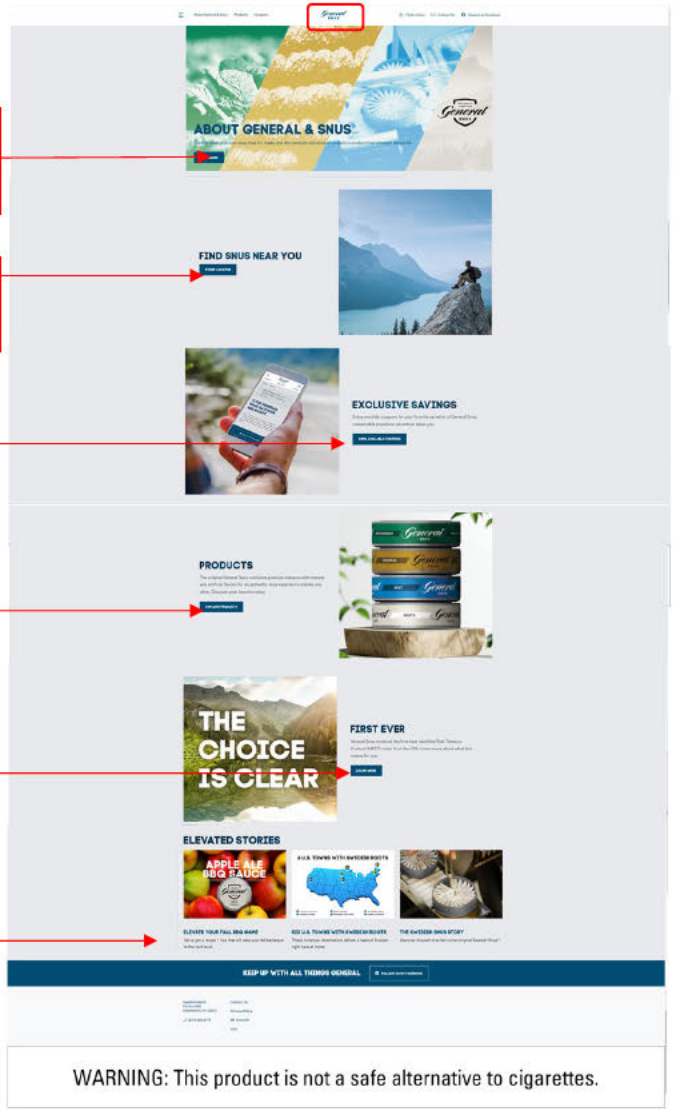
SIX U.S. TOWNS WITH SWEDISH ROOTS

These American destinations deliver a taste of Sweden right here at home.

THE SWEDISH SNUS STORY

Discover the path that led to the Original Swedish Snus™

Links to 'Elevated Stories' page



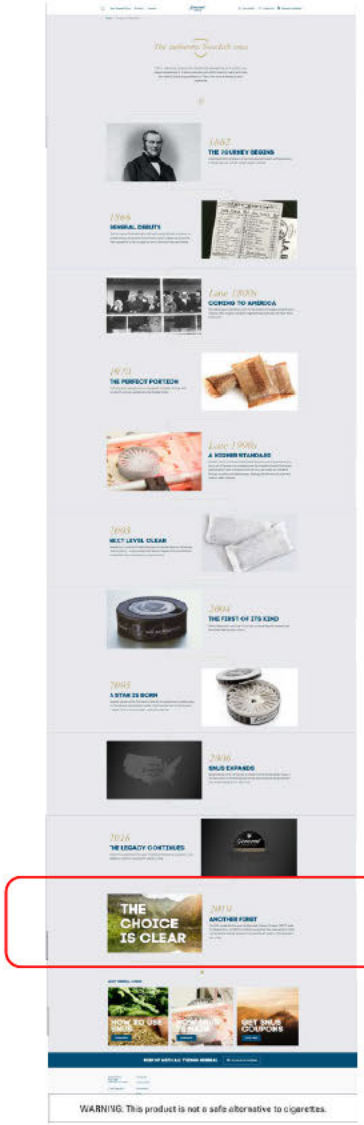
WARNING: This product is not a safe alternative to cigarettes.

GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY

[BEHIND AGE GATE] Oct. 2021 - current

See following two pages for detail



Swedish Match

GENERAL WEBSITE REFRESH - *ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY*

[BEHIND AGE GATE] Oct. 2021 - current

This is a centuries-old story of a tobacco that changed the world, and the way people experienced it. A tale of potential, and what it means to see it and make the most of it, at every possible turn. This is the story of elevating every experience.

Unsatisfied with the tobacco of his time, revered Swedish craftsman Johan A. Boman sets out to craft a higher quality product.

After four years of painstakingly crafting his recipe, Boman introduces an elevated tobacco experience to his home country. Crafted using only the finest ingredients, it was an upper-lip snus unlike anything seen before.

Snus becomes an identifying mark for the millions of Swedes immigrating to America. Main streets in Swedish neighborhoods even earn the name "Snus Boulevard."

The first portion-packed pouch is developed in Sweden, making snus convenient and more appealing to the broader public.

Swedish Match introduces the Gothiatek Standard, which guarantees that every can of General Snus exceeds even the toughest Swedish food-grade requirements. It also promises to ensure every can meets our standards through a quality-controlled process, starting with the very soil where the tobacco seed is planted.

General Snus is the first to take cleanliness to the next level by introducing "white portions" – a new process that delivers cleaner, white pouches that are still sold today in wintergreen, white and mint.

Continued on next page

GENERAL WEBSITE REFRESH

ABOUT GENERAL & SNUS: GENERAL SNUS LEGACY

[BEHIND AGE GATE]

Oct. 2021 - current

General develops a new type of can with a unique disposal compartment that holds used portions of snus.

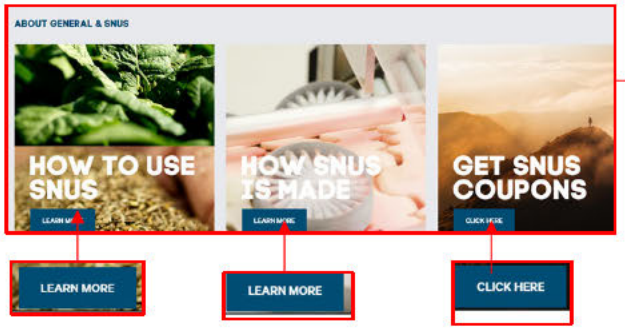
General's signature Star Formation makes its first appearance in select cans. Not only does it maximize the number of portions per can, but each pouch is shaped to fit more comfortably under the upper lip.

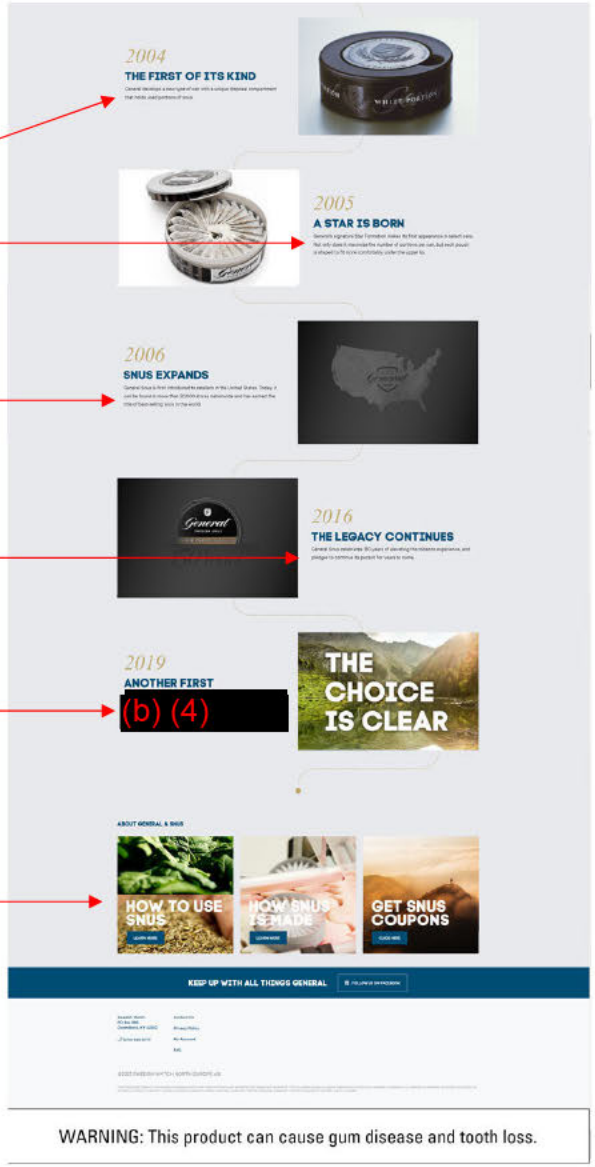
General Snus is first introduced to retailers in the United States. Today, it can be found in more than 20,000 stores nationwide and has earned the title of best-selling snus in the world.

General Snus celebrates 150 years of elevating the tobacco experience, and pledges to continue its pursuit for years to come.

The FDA issues the first-ever Modified Risk Tobacco Product (MRTP) order for General Snus. An MRTP is defined as a product that (b) (4)

(b) (4)





Swedish Match

GENERAL WEBSITE REFRESH – *MODIFIED RISK*

[BEHIND AGE GATE] Oct. 2021 - current

(b) (4)

On October 22, 2019 General Snus received the first-ever Modified Risk Tobacco Product (MRTP) order, which allows us to say:

A Modified Risk Tobacco Product (MRTP) is defined as a product that (b) (4)

(b) (4) (GEN website FAQ)

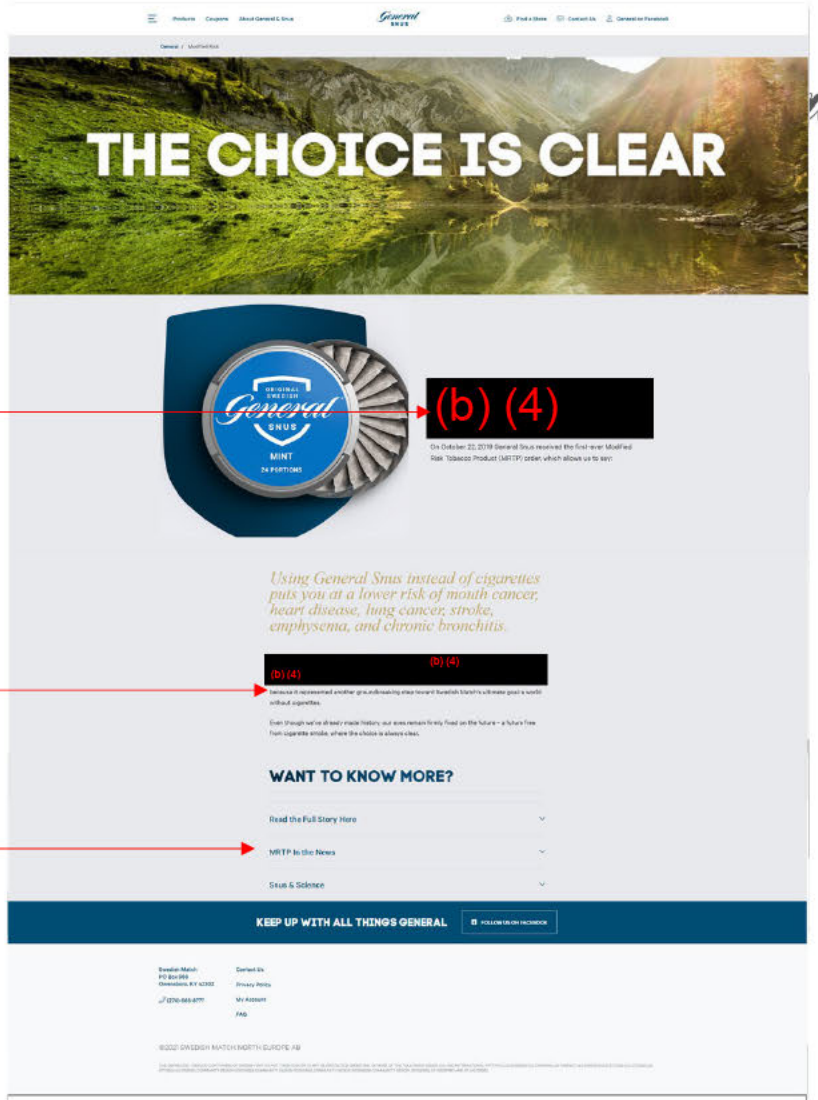
General Snus obtaining an MRTP order wasn't just historic because it was the first-ever, but also because it represented another groundbreaking step toward Swedish Match's ultimate goal: a world without cigarettes.

Even though we've already made history, our eyes remain firmly fixed on the future – a future free from cigarette smoke, where the choice is always clear.

Read the Full Story Here

MRTP In the News

Snus & Science



WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH - *MODIFIED RISK: <u>WANT TO KNOW MORE? FULL STORY.</u>*

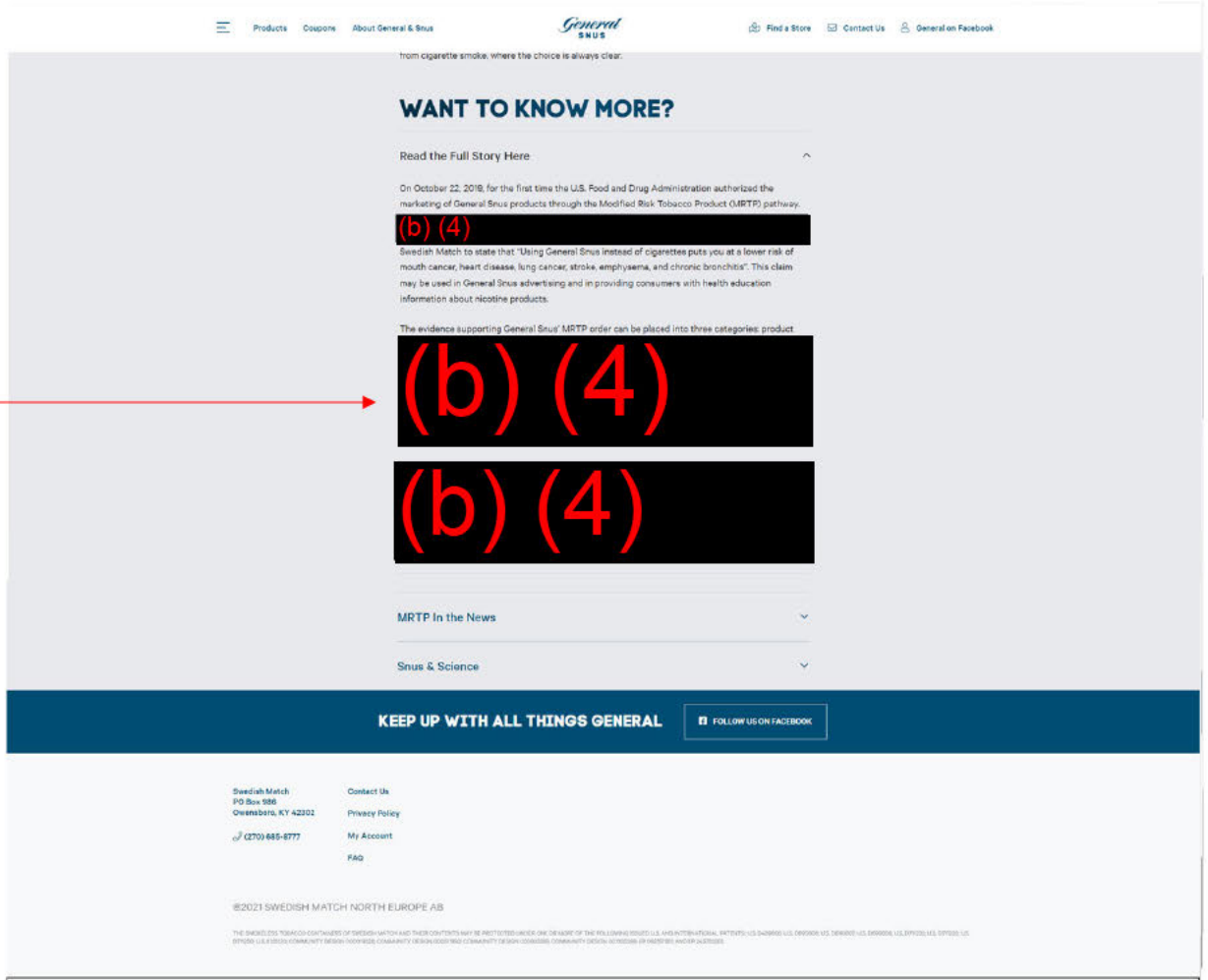
[BEHIND AGE GATE]
Oct. 2021 - current

On October 22, 2019, for the first time the U.S. Food and Drug Administration authorized the marketing of General Snus products through the Modified Risk Tobacco Product (MRTP) pathway.
(b) (4)
(b) (4) Under this order, the FDA authorized Swedish Match to state that "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis". This claim may be used in General Snus advertising and in providing consumers with health education information about nicotine products.

The evidence supporting General Snus' MRTP order can be placed into three categories: product

(b) (4)

(b) (4)



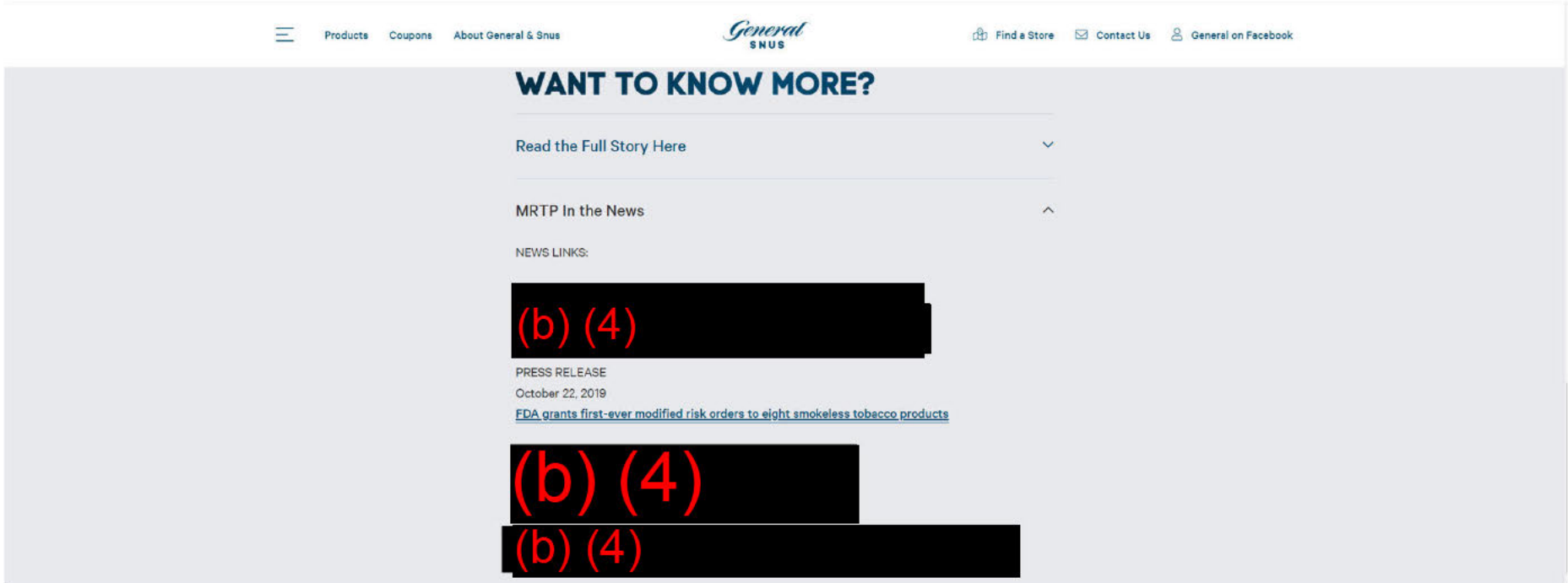
WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH

MODIFIED RISK: WANT TO KNOW MORE? MRTP IN THE NEWS

[BEHIND AGE GATE] Oct. 2021 - current



WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH - *MODIFIED RISK: WANT TO KNOW MORE? SNUS & SCIENCE*

[BEHIND AGE GATE]

Oct. 2021 - current

(b) (4)

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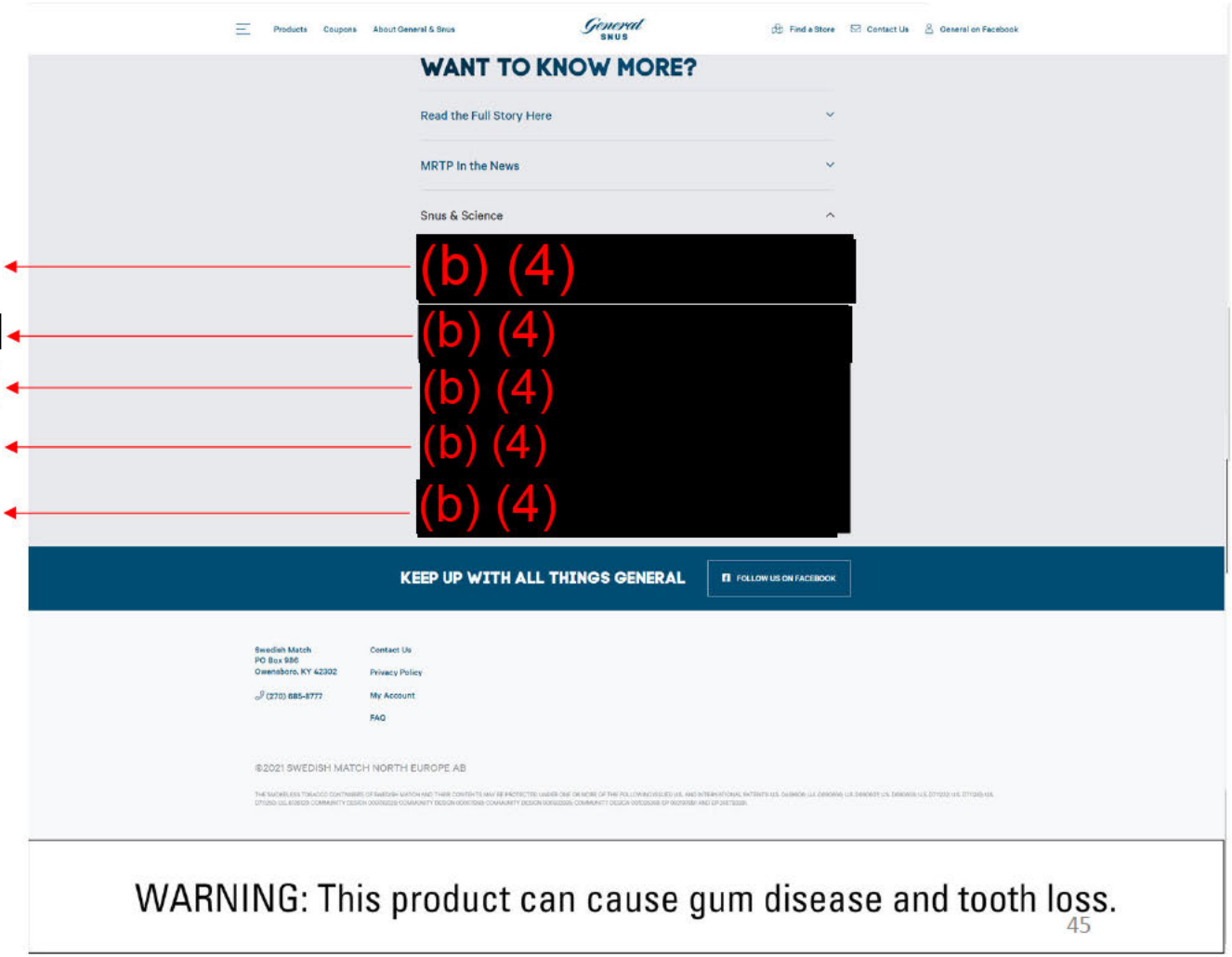
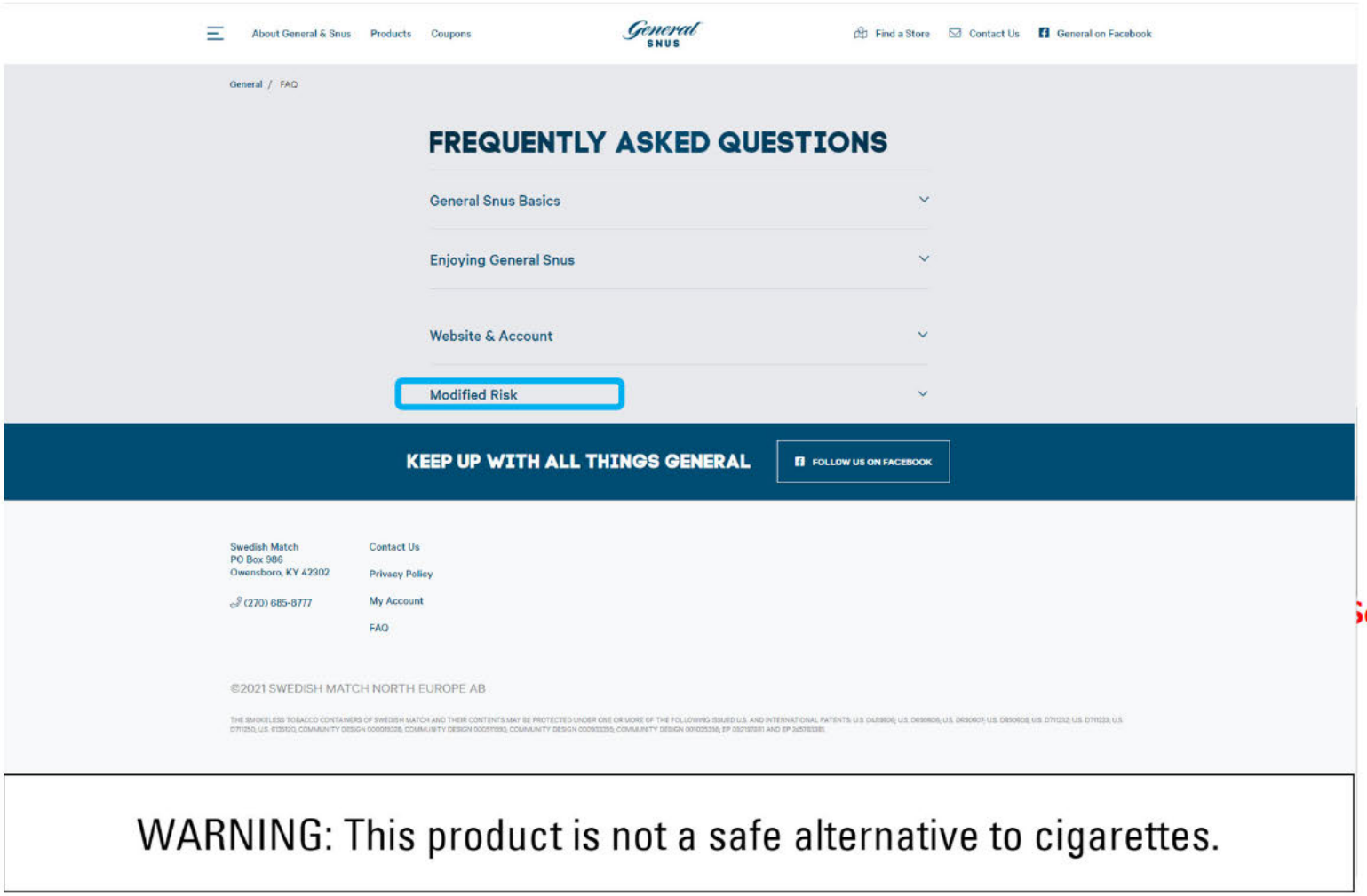


WARNING: This product can cause gum disease and tooth loss.

Swedish Match

GENERAL WEBSITE REFRESH – *FAQS: MODIFIED RISK* [BEHIND AGE GATE]

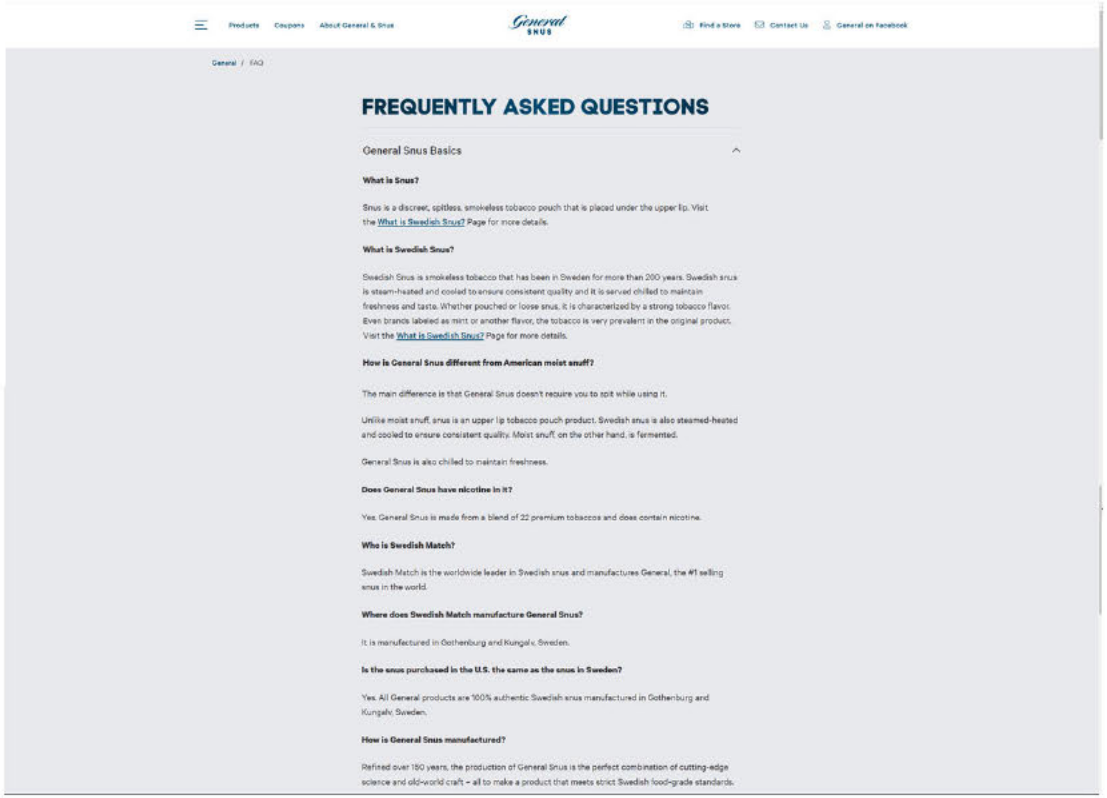
Oct. 2021 - current



WARNING: This product is not a safe alternative to cigarettes.

See following page for copy detail.

GENERAL WEBSITE REFRESH – *FAQS: GENERAL SNUS BASICS*
[BEHIND AGE GATE]
Oct. 2021 - current



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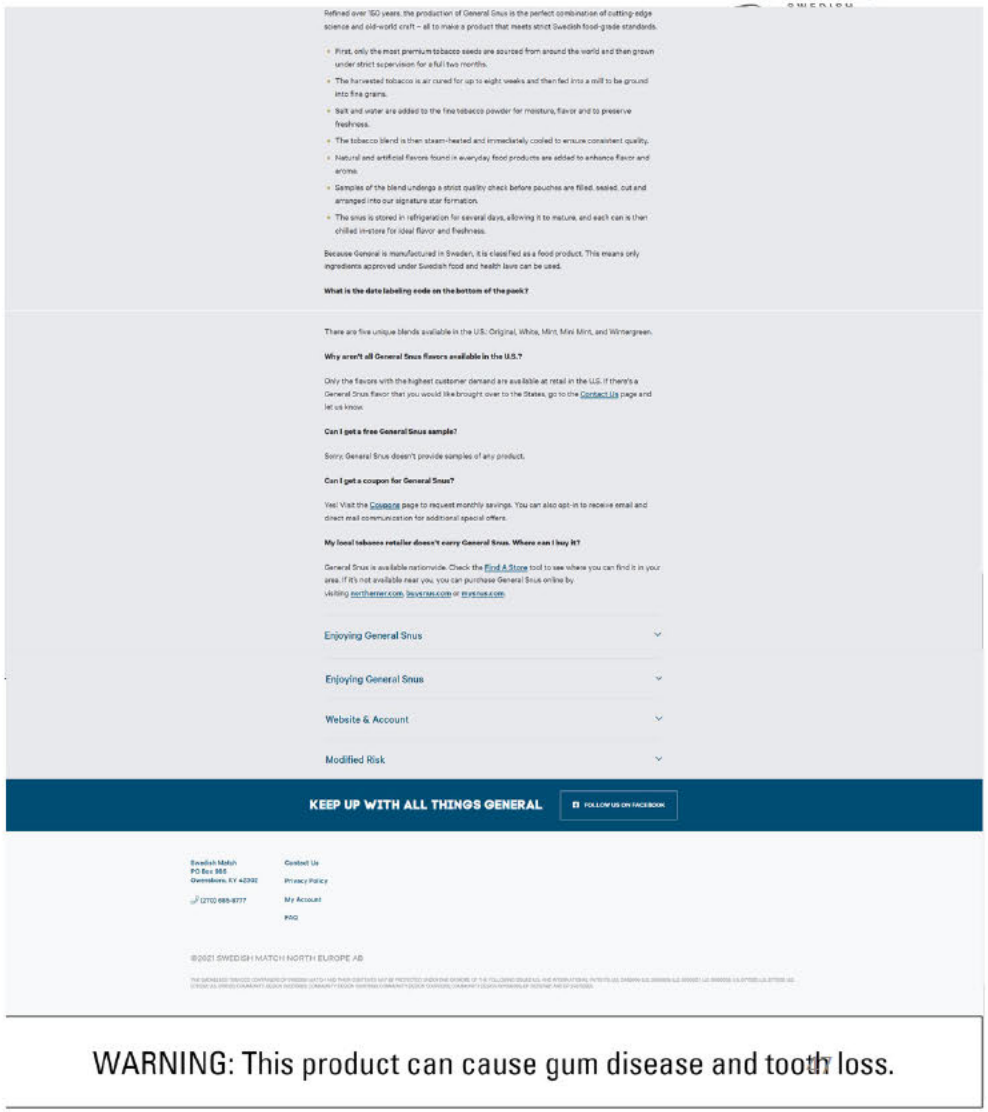


Swedish Match

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH – *FAQS: GENERAL SNUS BASICS COPY DETAIL*
[BEHIND AGE GATE] Oct. 2021 - current

FREQUENTLY ASKED QUESTIONS

General Snus Basics

What is Snus?

Snus is a discreet, spitless, smokeless tobacco pouch that is placed under the upper lip. Visit the What is Swedish Snus? Page for more details.

What is Swedish Snus?

Swedish Snus is smokeless tobacco that has been in Sweden for more than 200 years. Swedish snus is steam-heated and cooled to ensure consistent quality and it is served chilled to maintain freshness and taste. Whether pouched or loose snus, it is characterized by a strong tobacco flavor. Even brands labeled as mint or another flavor, the tobacco is very prevalent in the original product. Visit the What is Swedish Snus? Page for more details.

How is General Snus different from American moist snuff?

The main difference is that General Snus doesn't require you to spit while using it.

Unlike moist snuff, snus is an upper lip tobacco pouch product. Swedish snus is also steamed-heated and cooled to ensure consistent quality. Moist snuff, on the other hand, is fermented.

General Snus is also chilled to maintain freshness.

Does General Snus have nicotine in it?

Yes. General Snus is made from a blend of 22 premium tobaccos and does contain nicotine.

Who is Swedish Match?

Swedish Match is the worldwide leader in Swedish snus and manufactures General, the #1 selling snus in the world.

Where does Swedish Match manufacture General Snus?

It is manufactured in Gothenburg and Kungalv, Sweden.

Is the snus purchased in the U.S. the same as the snus in Sweden?

Yes. All General products are 100% authentic Swedish snus manufactured in Gothenburg and Kungalv, Sweden.

How is General Snus manufactured?

Refined over 150 years, the production of General Snus is the perfect combination of cutting-edge science and old-world craft – all to make a product that meets strict Swedish food-grade standards.

- First, only the most premium tobacco seeds are sourced from around the world and then grown under strict supervision for a full two months.
- The harvested tobacco is air cured for up to eight weeks and then fed into a mill to be ground into fine grains.
- Salt and water are added to the fine tobacco powder for moisture, flavor and to preserve freshness.
- The tobacco blend is then steam-heated and immediately cooled to ensure consistent quality.
- Natural and artificial flavors found in everyday food products are added to enhance flavor and aroma.
- Samples of the blend undergo a strict quality check before pouches are filled, sealed, cut and arranged into our signature star formation.
- The snus is stored in refrigeration for several days, allowing it to mature, and each can is then chilled in-store for ideal flavor and freshness.

Because General is manufactured in Sweden, it is classified as a food product. This means only ingredients approved under Swedish food and health laws can be used.

What is the date labeling code on the bottom of the pack?

This is the "Best Before" date.

What types of General Snus are available in the U.S.?

There are five unique blends avaliable in the U.S.: Original, White, Mint, Mini Mint, and Wintergreen.

Why aren't all General Snus flavors available in the U.S.?

Only the flavors with the highest customer demand are available at retail in the U.S. If there's a General Snus flavor that you would like brought over to the States, go to the Contact Us page and let us know.

Can I get a free General Snus sample?

Sorry, General Snus doesn't provide samples of any product.

Can I get a coupon for General Snus?

Yes! Visit the Coupons page to request monthly savings. You can also opt-in to receive email and direct mail communication for additional special offers.

My local tobacco retailer doesn't carry General Snus. Where can I buy it?

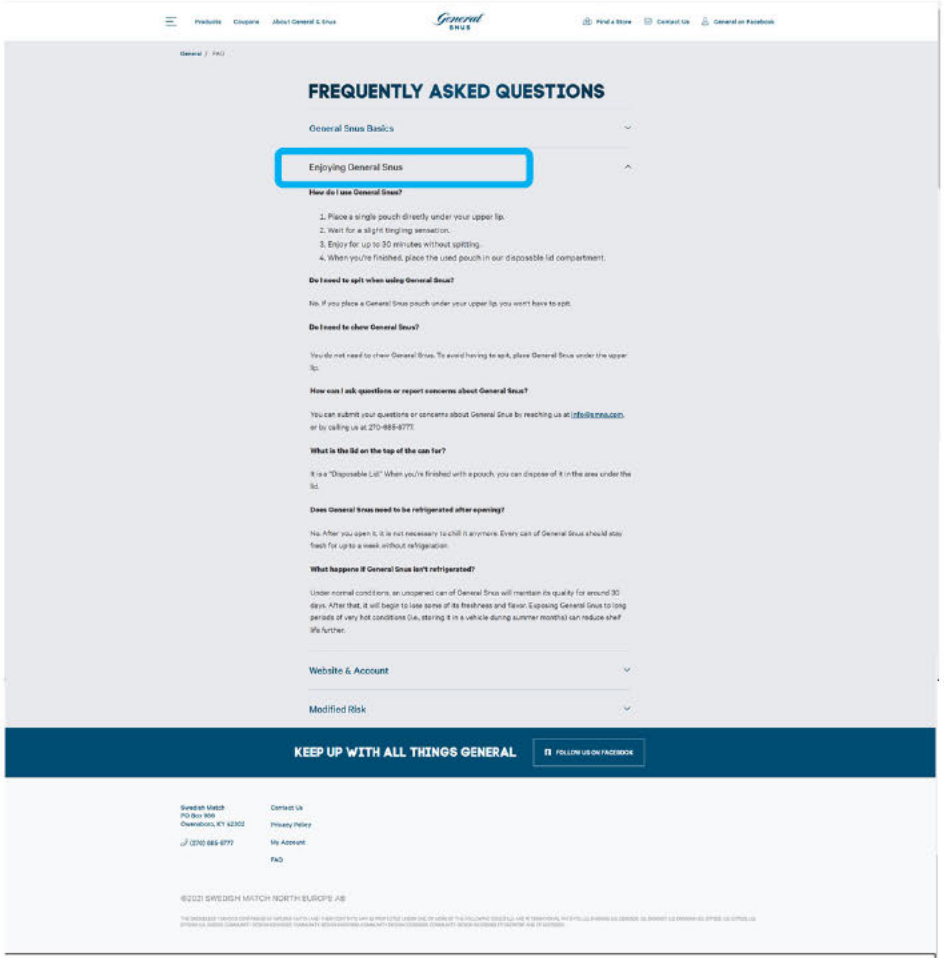
General Snus is available nationwide. Check the Find A Store tool to see where you can find it in your area. If it's not available near you, you can purchase General Snus online by visiting northerner.com, buysnus.com or mysnus.com.

Enjoying General Snus

Website & Account

Modified Risk

GENERAL WEBSITE REFRESH – *FAQS: ENJOYING GENERAL SNUS*
[BEHIND AGE GATE] Oct. 2021 - current



WARNING: This product can cause gum disease and tooth loss.

General Snus Basics

Enjoying General Snus

How do I use General Snus?

1. Place a single pouch directly under your upper lip.
2. Wait for a slight tingling sensation.
3. Enjoy for up to 30 minutes without spitting.
4. When you're finished, place the used pouch in our disposable lid compartment.

Do I need to spit when using General Snus?

No. If you place a General Snus pouch under your upper lip, you won't have to spit.

Do I need to chew General Snus?

You do not need to chew General Snus. To avoid having to spit, place General Snus under the upper lip.

How can I ask questions or report concerns about General Snus?

You can submit your questions or concerns about General Snus by reaching us at info@smna.com, or by calling us at 270-685-8777.

What is the lid on the top of the can for?

It is a "Disposable Lid." When you're finished with a pouch, you can dispose of it in the area under the lid.

Does General Snus need to be refrigerated after opening?

No. After you open it, it is not necessary to chill it anymore. Every can of General Snus should stay fresh for up to a week without refrigeration.

What happens if General Snus isn't refrigerated?

Under normal conditions, an unopened can of General Snus will maintain its quality for around 30 days. After that, it will begin to lose some of its freshness and flavor. Exposing General Snus to long periods of very hot conditions (i.e., storing it in a vehicle during summer months) can reduce shelf life further.

Website & Account

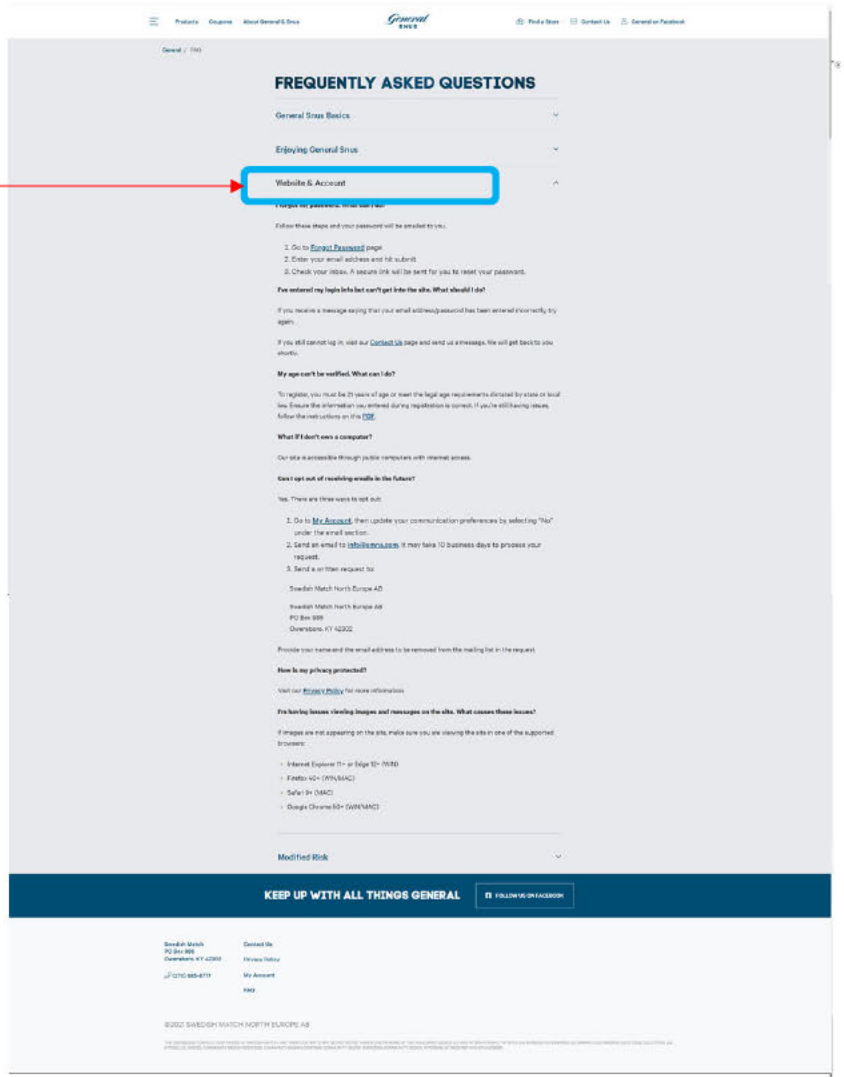
GENERAL WEBSITE REFRESH

FAQS: WEBSITE & ACCOUNT

[OUTSIDE & BEHIND AGE GATE]

Oct. 2021 - current

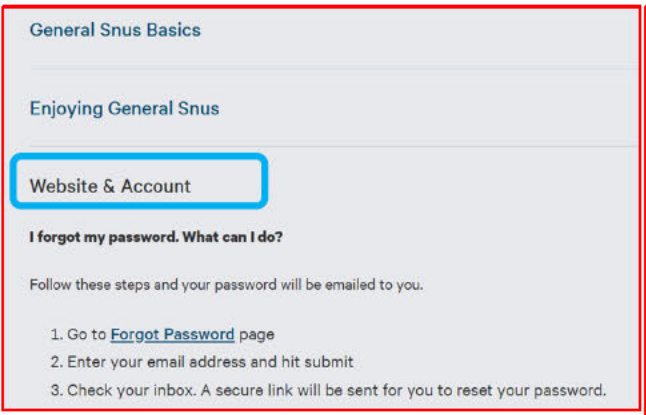
Website & Account



See following page for copy detail.

WARNING: This product can cause gum disease and tooth loss.

GENERAL WEBSITE REFRESH – *FAQS: WEBSITE & ACCOUNT* [OUTSIDE & BEHIND AGE GATE] COPY DETAIL Oct. 2021 - current



General Snus Basics

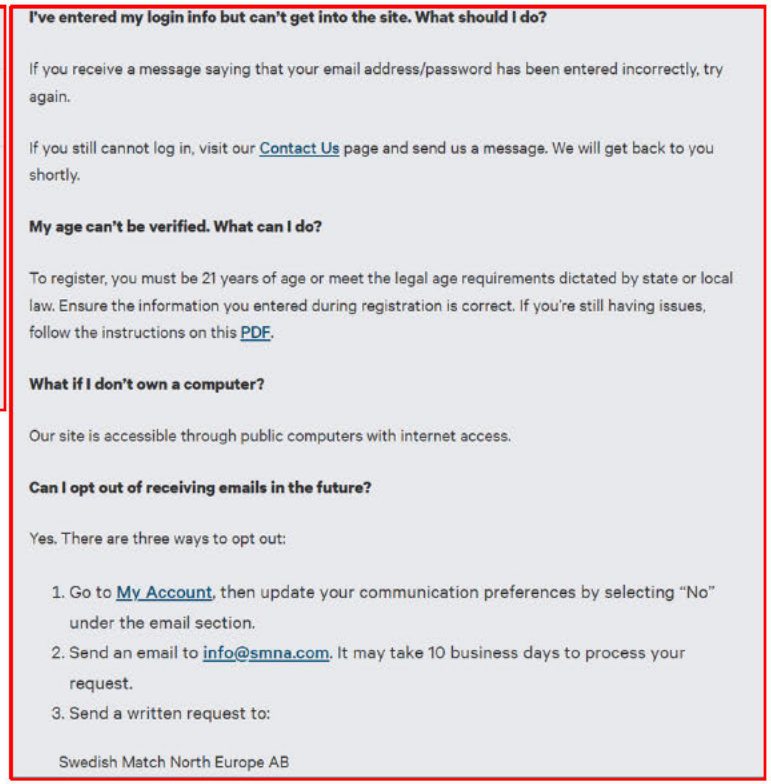
Enjoying General Snus

Website & Account

I forgot my password. What can I do?

Follow these steps and your password will be emailed to you.

1. Go to Forgot Password page
2. Enter your email address and hit submit
3. Check your inbox. A secure link will be sent for you to reset your password.



I've entered my login info but can't get into the site. What should I do?

If you receive a message saying that your email address/password has been entered incorrectly, try again.

If you still cannot log in, visit our Contact Us page and send us a message. We will get back to you shortly.

My age can't be verified. What can I do?

To register, you must be 21 years of age or meet the legal age requirements dictated by state or local law. Ensure the information you entered during registration is correct. If you're still having issues, follow the instructions on this PDF.

What if I don't own a computer?

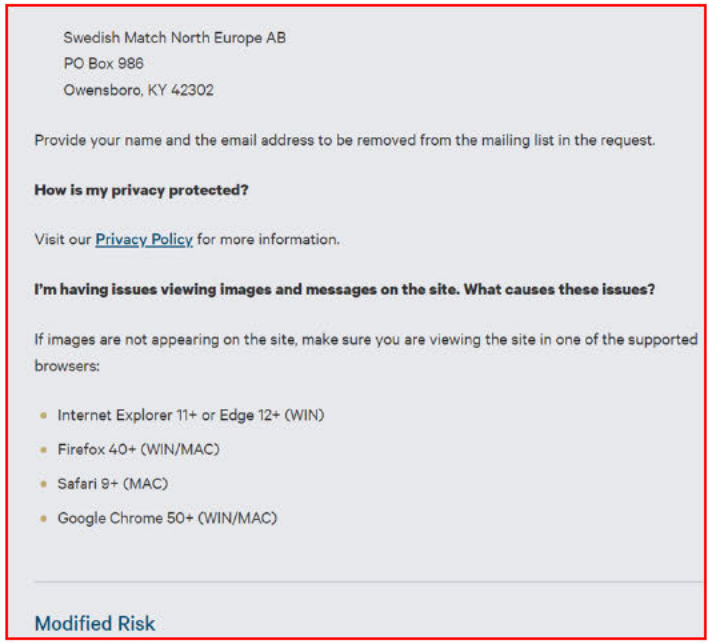
Our site is accessible through public computers with internet access.

Can I opt out of receiving emails in the future?

Yes. There are three ways to opt out:

1. Go to My Account, then update your communication preferences by selecting "No" under the email section.
2. Send an email to info@smna.com. It may take 10 business days to process your request.
3. Send a written request to:

Swedish Match North Europe AB



Swedish Match North Europe AB
PO Box 986
Owensboro, KY 42302

Provide your name and the email address to be removed from the mailing list in the request.

How is my privacy protected?

Visit our Privacy Policy for more information.

I'm having issues viewing images and messages on the site. What causes these issues?

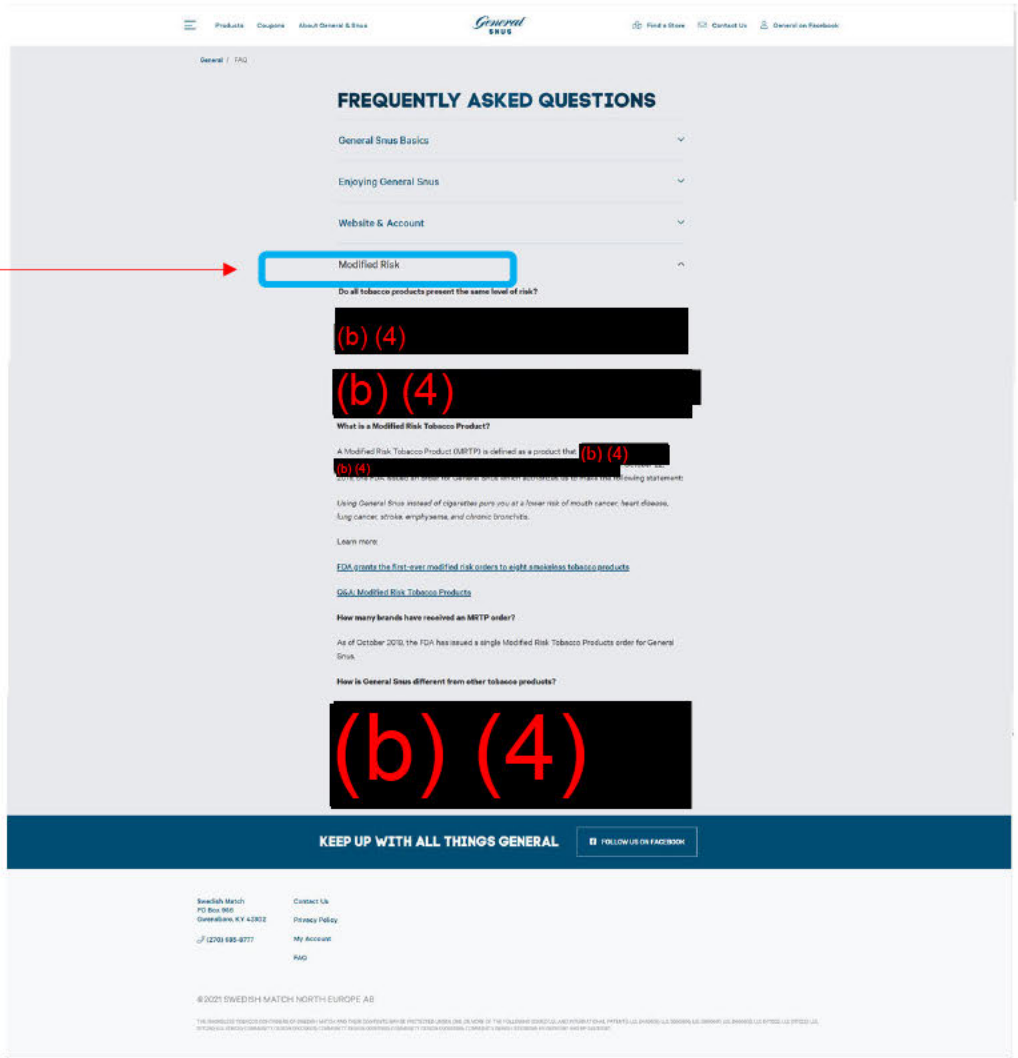
If images are not appearing on the site, make sure you are viewing the site in one of the supported browsers:

- Internet Explorer 11+ or Edge 12+ (WIN)
- Firefox 40+ (WIN/MAC)
- Safari 9+ (MAC)
- Google Chrome 50+ (WIN/MAC)

Modified Risk

GENERAL WEBSITE REFRESH –
FAQS: MODIFIED RISK
[BEHIND AGE GATE] Oct. 2021 - current

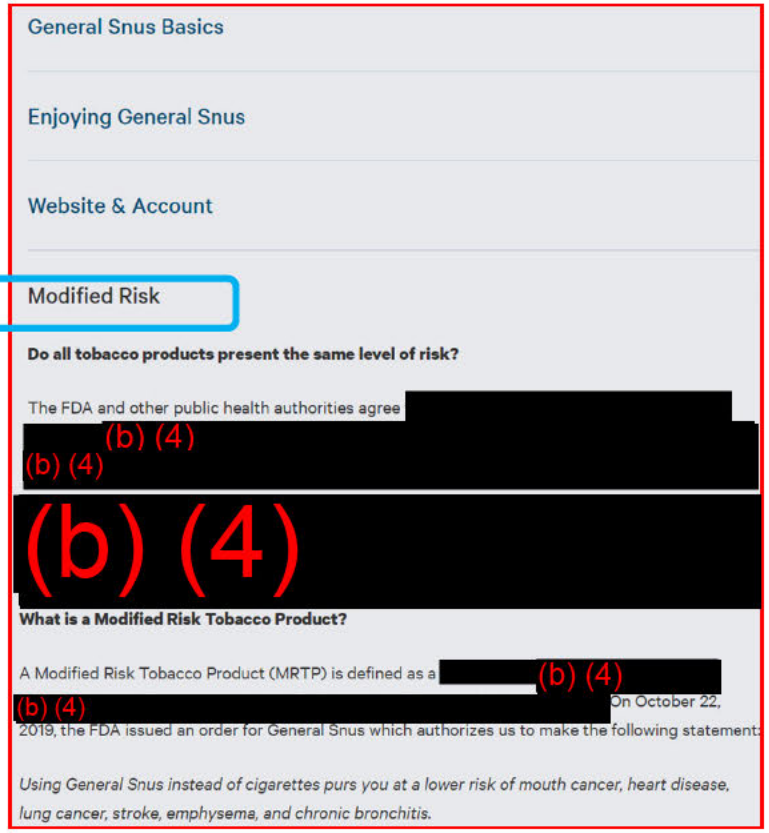
Modified Risk



See following page for copy detail.

Swedish Match

GENERAL WEBSITE REFRESH – *FAQS: MODIFIED RISK*
[BEHIND AGE GATE] Oct. 2021 - current



General Snus Basics

Enjoying General Snus

Website & Account

Modified Risk

Do all tobacco products present the same level of risk?

The FDA and other public health authorities agree (b) (4)

(b) (4)

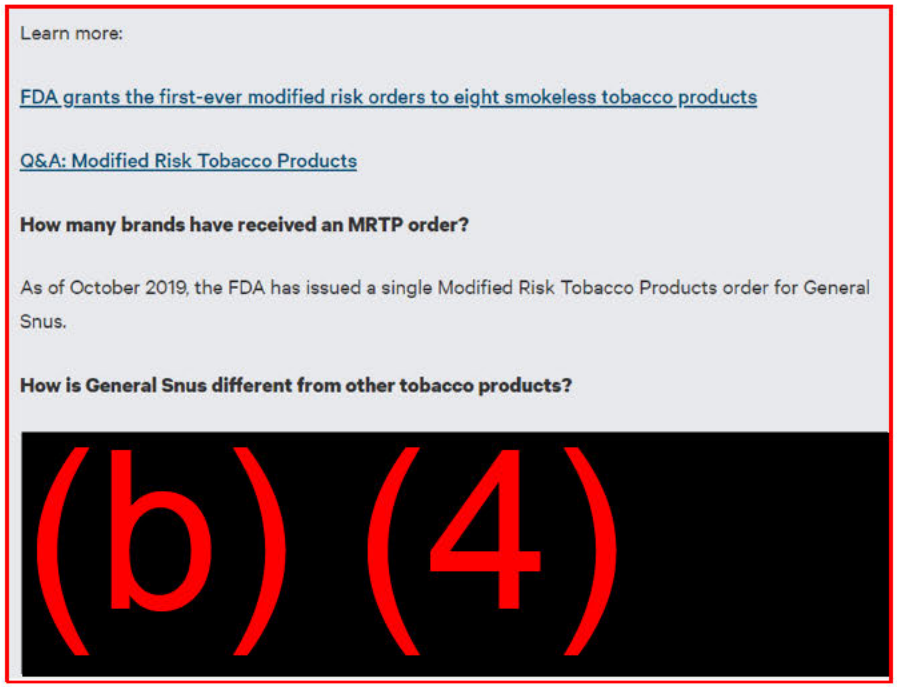
(b) (4)

What is a Modified Risk Tobacco Product?

A Modified Risk Tobacco Product (MRTP) is defined as a (b) (4)

(b) (4) On October 22, 2019, the FDA issued an order for General Snus which authorizes us to make the following statement:

Using General Snus instead of cigarettes purs you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.



Learn more:

FDA grants the first-ever modified risk orders to eight smokeless tobacco products

Q&A: Modified Risk Tobacco Products

How many brands have received an MRTP order?

As of October 2019, the FDA has issued a single Modified Risk Tobacco Products order for General Snus.

How is General Snus different from other tobacco products?

(b) (4)

Swedish Match

Appendix 3: Advertising

CATEGORY: SNUS

BRAND: GENERAL SNUS

Annual Report

October 2020 – October 2021

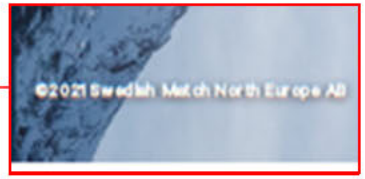
GENERAL SNUS CONSUMER ADVERTISING

[redacted]

General Snus SACC LA PRINT ADS:

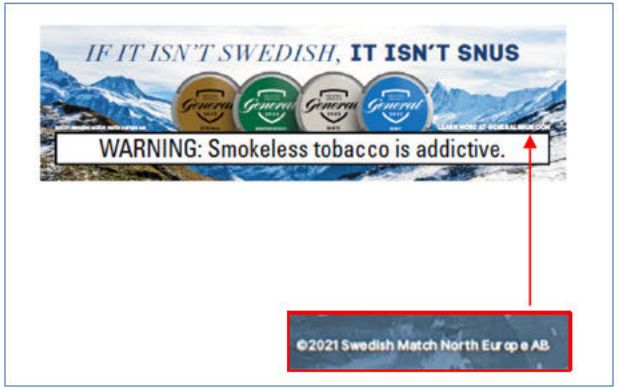
More than 20 years ago, we introduced the Gothiatek Standard: a self-imposed quality standard that every can of General Snus must meet, which exceeds even the toughest Swedish food-grade requirements. Because to craft a tobacco experience unlike any other, you can't play by the same rules as everyone else.

Learn more at GeneralSnus.com.



[redacted]

General Snus Nordic Reach Print & Digital Ads



Maybe it's the attention to detail. Or the fact that it's made with only the finest ingredients. Or maybe you can taste just a hint of the clean air and fresh water of home. Whatever it is, there's no mistaking any other tobacco for the Original Swedish Snus.

Learn more at GeneralSnus.com.

Discover the premium tobacco experience that's distinctly Swedish at GeneralSnus.com.

Swedish Match

General Snus Digital Ads: Display, Animated – Multi Frame 300 x 250

Swedish Match

General Snus Digital Ads: Display, Animated – Multi Frame 300 x 600

GEN_Flavor Like No Other_Digital_Ads_300X600-StoreLocator.mp4

[redacted]

General Snus Digital Ads: Display, Animated – Multi Frame 160 x 600

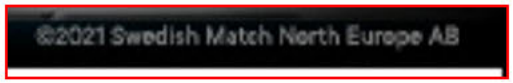
Slide 1

Slide 2

Slide 3

Slide 4

160 X 600



[redacted]

GEN_Flavor Like No Other_Digital_Ads_160X600-StoreLocator.mp4

General Snus Digital Ads: Display, Animated – Multi Frame

Slide 1

Slide 2

Slide 3

Slide 4

728 X 90

©2021 Swedish Match North Europe AB

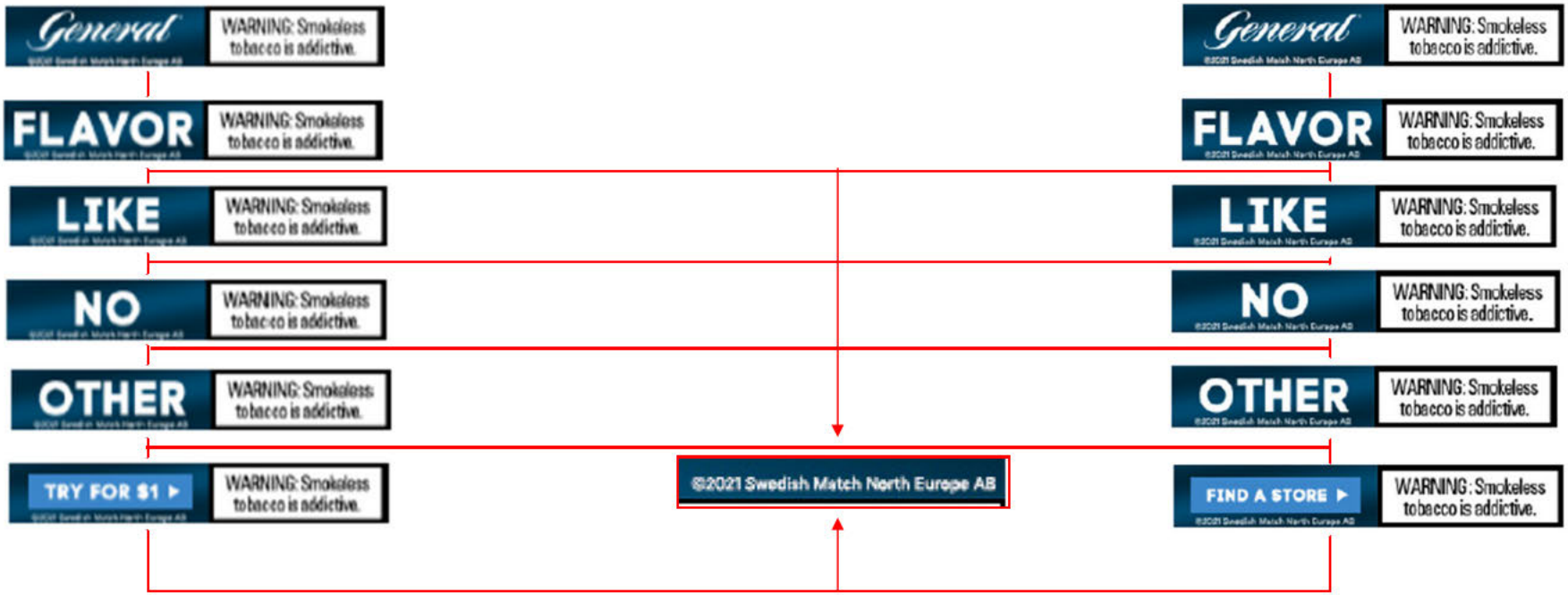
[redacted]

GEN_Flavor Like No Other_Digital_Ads_728x90-StoreLocator.mp4

General Snus Digital Ads: Display, Animated – Multi Frame 320 x 50

States “General, flavor like no other” with a call-to-action to click through to Generalsnus.com and login/register to request a coupon. 0:09

States “General, flavor like no other” with a call-to-action to click through to Generalsnus.com to find product via the store locator. 0:09



GEN_Flavor Like No Other_Digital_Ads_320x50-Coupon.mp4

GEN_Flavor Like No Other_Digital_Ads_320x50-StoreLocator.mp4

General Snus Digital Ads: Display, Static 300 x 250

Primary – Store

Alt – Coupon

300 X 250

[redacted]

General Snus Digital Ads: Display, Static 728 x 90

Primary – Store

Alt – Coupon

728 X 90

[redacted]

General Snus Digital Ads: Display, Static 160 x 600

Primary – Store

Alt – Coupon

160 X 600

[redacted]

General Snus Digital Ads: Display, Static 300 x 600

Primary – Store

Alt – Coupon

300 X 600

[redacted]

©2021 Swedish Match North Europe AB

General Snus Digital Ads: Display, Static 320 x 50

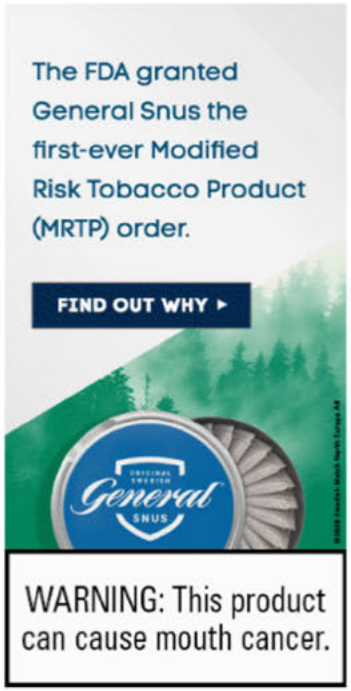
320 X 50 (mobile)

[redacted]

General Snus Digital Ads: Display – Animated, Multi-Frame 300 x 600

Slide 1

Slide 2



300 X 600

GEN_First Ever.Banner_Ads_300x600_2.mp4

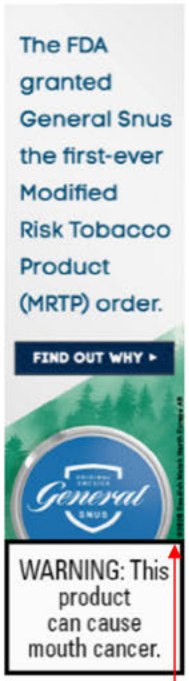
Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 160 x 600

Slide 1

160 X 600

Slide 2



Swedish Match

GEN_First Ever.Banner_Ads_160x600_2.mp4

General Snus Digital Ads: Display – Animated, Multi-Frame 728 x 90

Slide 1

728 X 90

Slide 2

GEN_First Ever.Banner_Ads_728x90_2.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 320 x 50

Slide 1

320 X 50

Slide 2

GEN_First Ever.Banner_Ads_320x50_2.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 300 x 250

Slide 1

300 X 250

Slide 2

GEN_First Ever.Banner_Ads_300x250_2.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 300 x 600

Slide 1

300 X 600

Slide 2

300 X 600

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Swedish Match

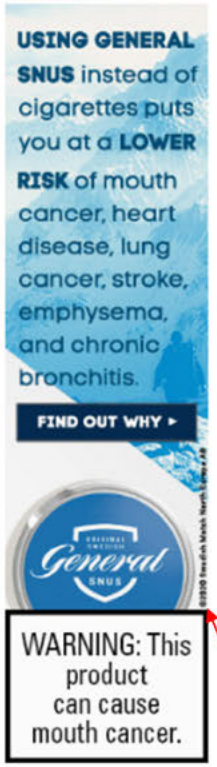
GEN_The Choice Is Clear.Banner_Ads_300x600_1.mp4

General Snus Digital Ads: Display – Animated, Multi-Frame 160 x 600

Slide 1

160 X 600

Slide 2



GEN_The Choice Is Clear_Banner_Ads_160x600_1.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 728 x 90

©2021 Swedish Match North Europe AB

Slide 1

728 X 90

Slide 2

©2021 Swedish Match North Europe AB

GEN_The Choice Is Clear.Banner_Ads_728x90_1.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 320 x 50

Slide 1

Slide 2

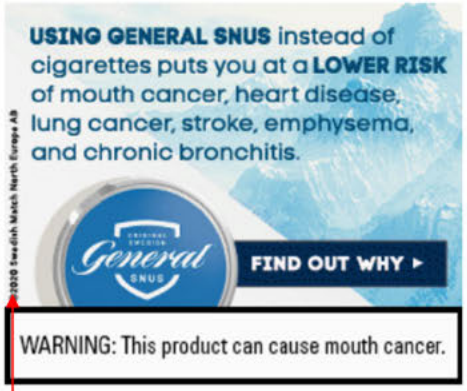
GEN_The Choice Is Clear.Banner_Ads_320x50_1.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame 300 x 250

Slide 1

Slide 2



GEN_The Choice Is Clear.Banner_Ads_300x250_1.mp4

Swedish Match

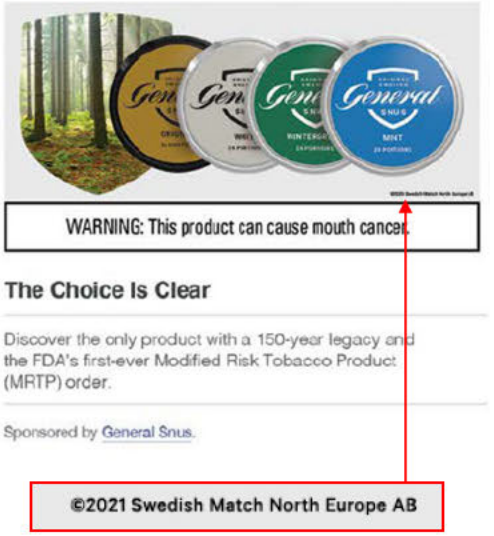
General Snus Digital Ads: Native - Static

1200 x 628

600 x 600

800 x 600

As seen online



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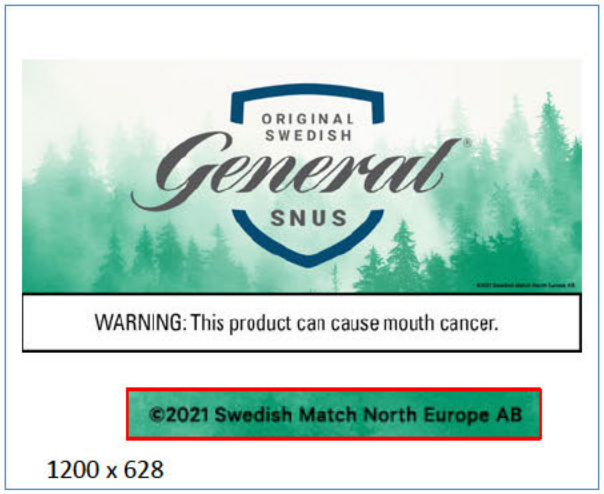
General Snus Digital Ads: Native - Static

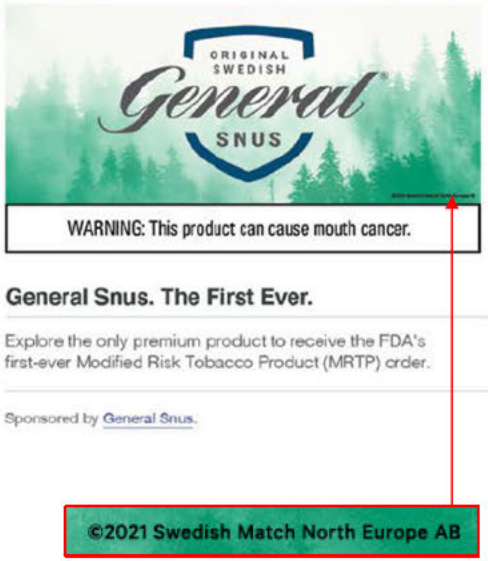


1200 x 628

800 x 600

600 x 600

As seen online

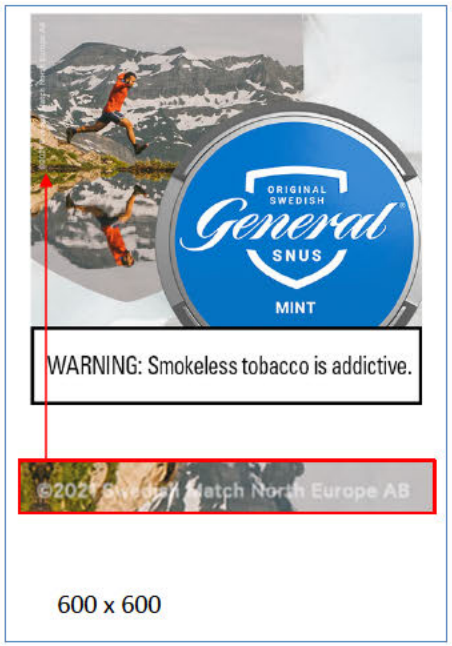


[redacted]

General Snus Digital Ads: Native - Static

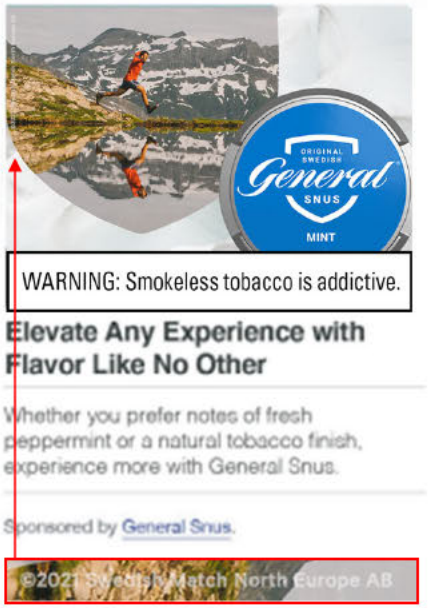
1200 x 628

800 x 600



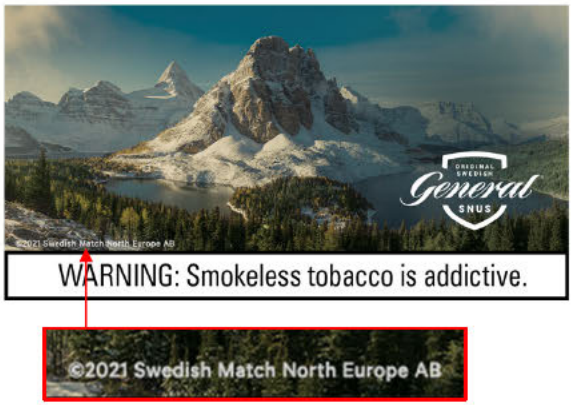
600 x 600

As seen online



[redacted]

General Snus Digital Ads: Native - Static



1200 x 628

800 x 600

600 x 600

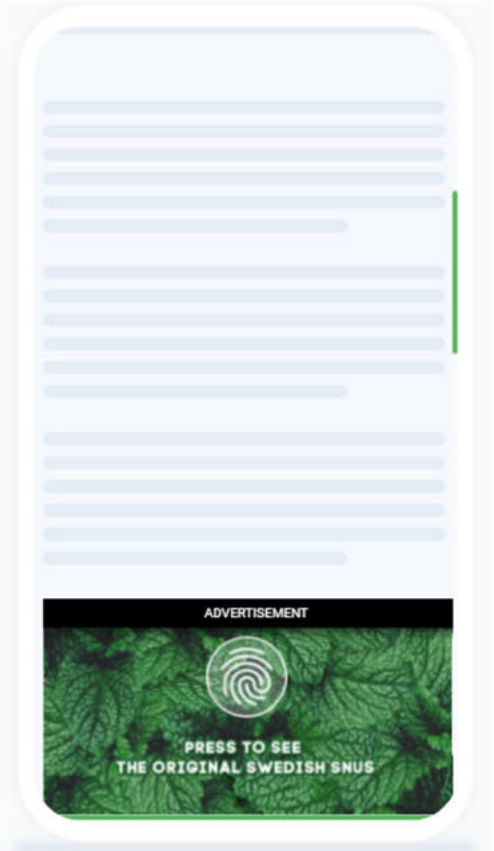
As seen online

[redacted]

General Snus Digital Ads: Interactive, Pad Squad - Animated

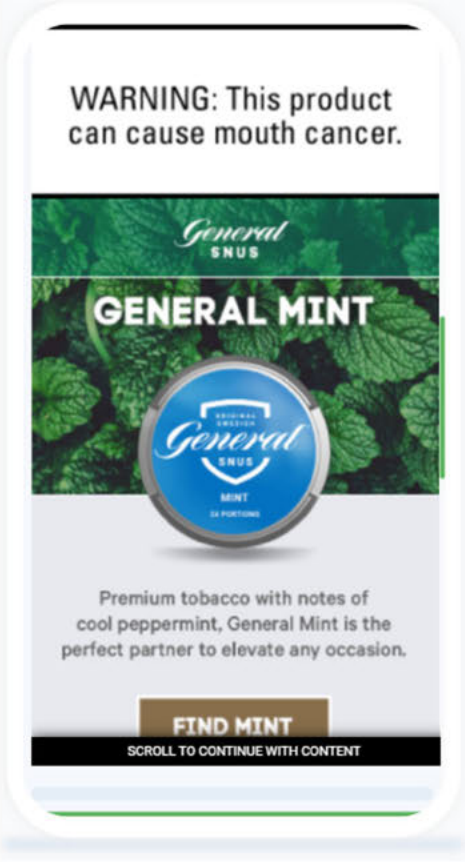
Animation 1

Animation 2



Animation 3

Animation 4



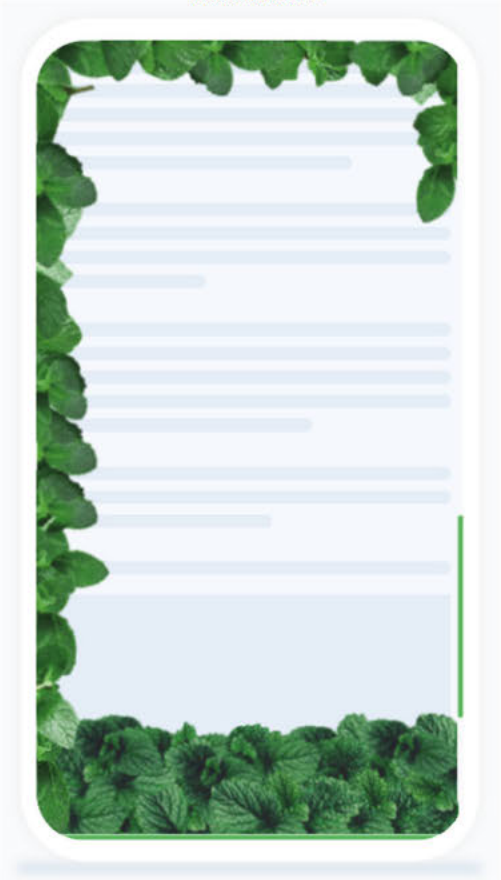
Swedish Match

General Snus MINT Press&Hold Duo.mp4

General Snus Digital Ads: Interactive, Pad Squad - Animated

Animation 1

Animation 2



Animation 3

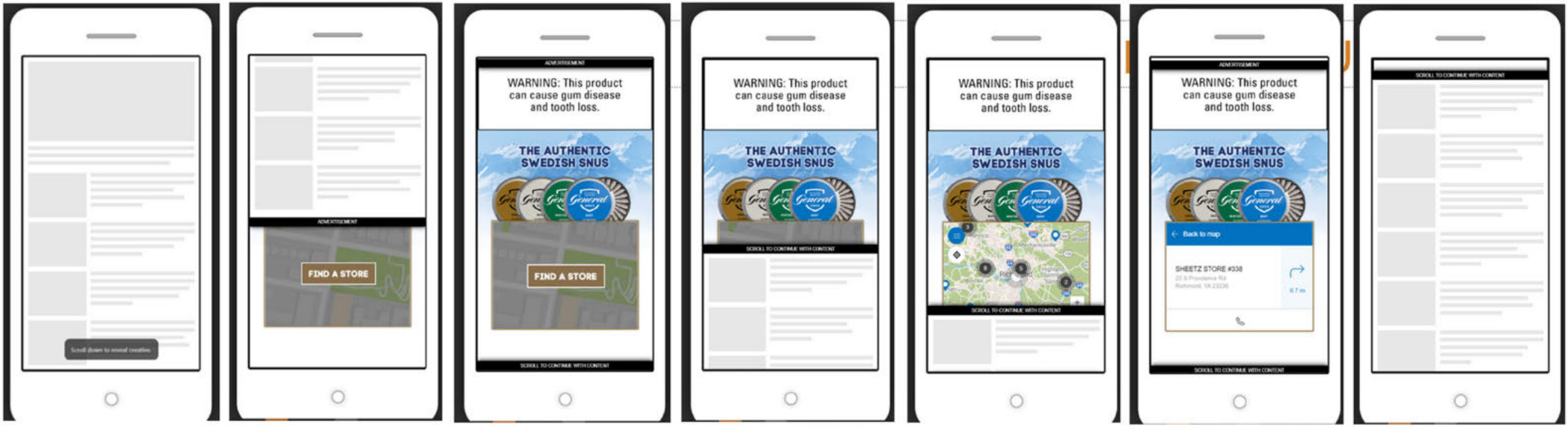
Animation 4

[redacted]

General Snus MINT Superscape.mp4

General Snus Digital Ads: Interactive, Pad Squad - Animated

Appears when scrolling on the screen.



General Snus Tap to Map Scroller Q3 2021 Digital Ad.mp4

[redacted]

General Snus Digital Ads: Native

Don't Get Fooled by Fake Snus

Authentic Swedish snus offers a premium tobacco experience. But fake snus is easy to spot when you know the differences.

800 x 600

600 x 600

1200 x 628

©2021 Swedish Match North Europe AB

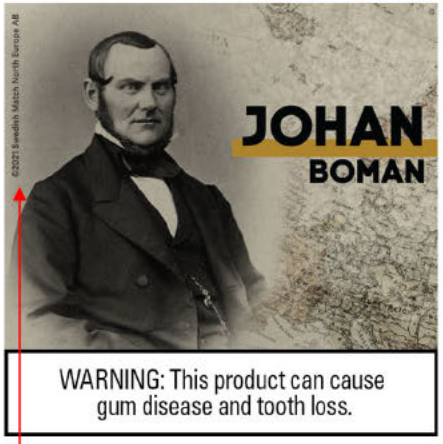
[redacted]

General Snus Digital Ads: Native

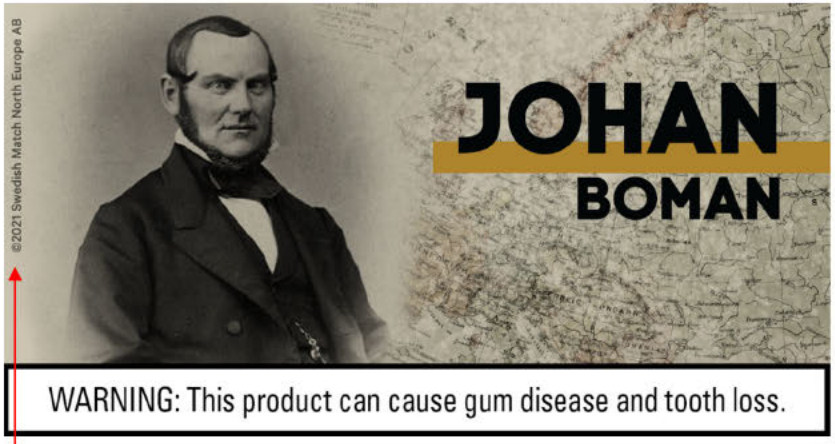
He Created the World's Most Storied Tobacco Brand

Johan Boman invented a better tobacco experience. Today General Snus meets Sweden's food-grade standards and more.

800 x 600



600 x 600



200 x 628

©2021 Swedish Match North Europe AB

[redacted]

General Snus Digital Ads: Native

Meet a Community of Tobacco Enthusiasts Like No Other

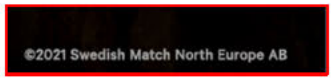
General Snus—the world's #1 selling snus—inspires loyalty and love from its fans. Find out what makes them different.

800 x 600

600 x 600

1200 x 628

[redacted]



General Snus Digital Ads: Native

Only One Tobacco Experience Meets All These Standards

General Snus meets strict quality Swedish food grade standards. Learn what makes it the world's #1 selling snus.

800 x 600

600 x 600

1200 x 628

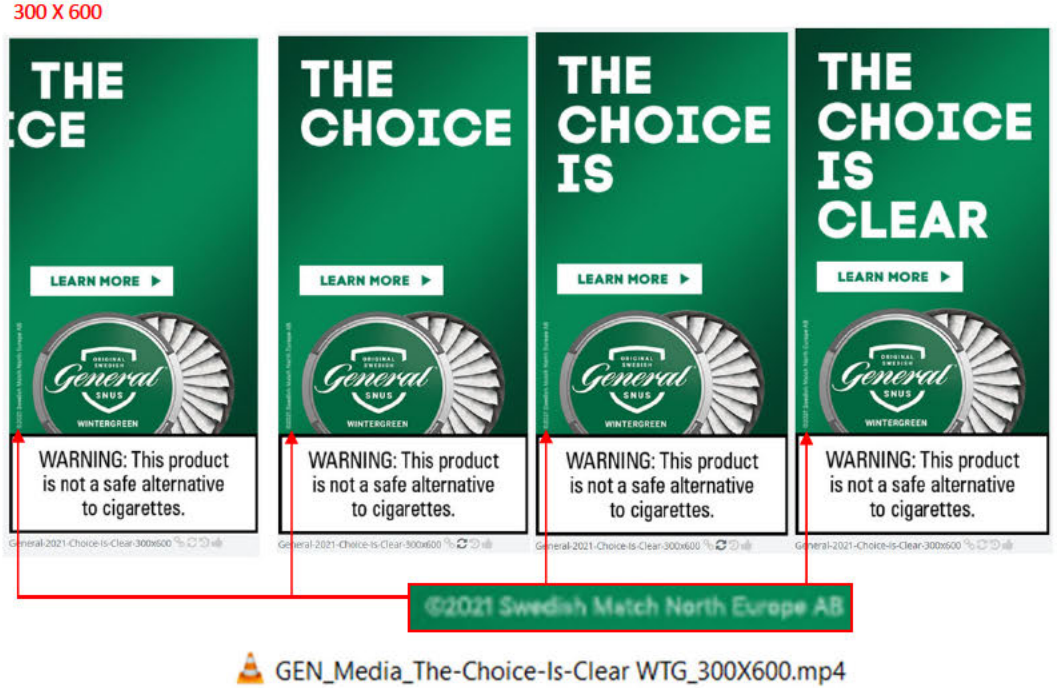
[redacted]

©2021 Swedish Match North Europe AB

General Snus Digital Ads: Display – Animated, Multi-Frame
'THE CHOICE IS CLEAR': 160 X 600 / 300 X 600

160 X 600

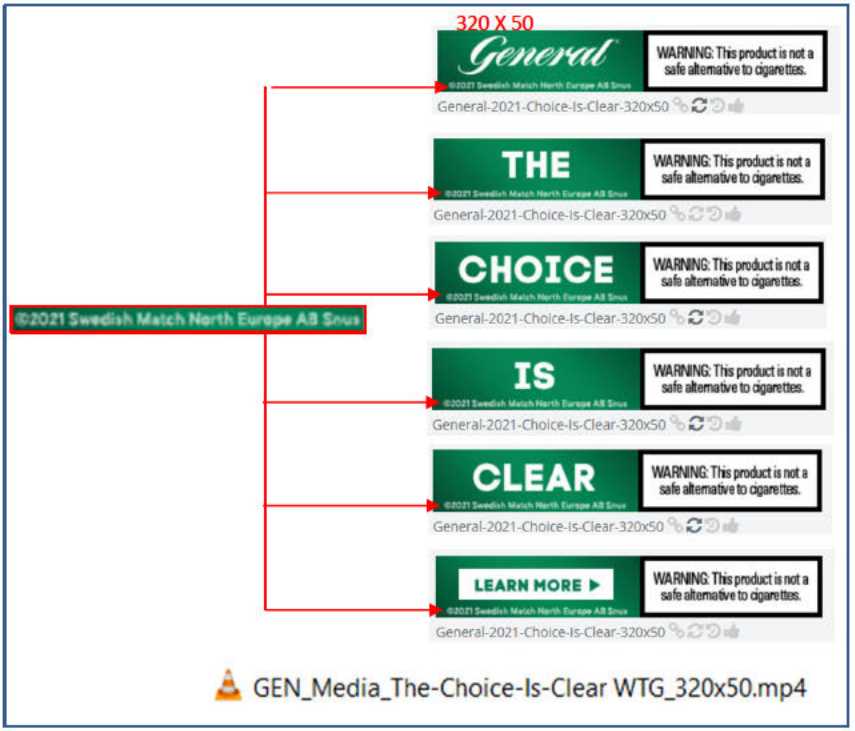
300 X 600



Swedish Match

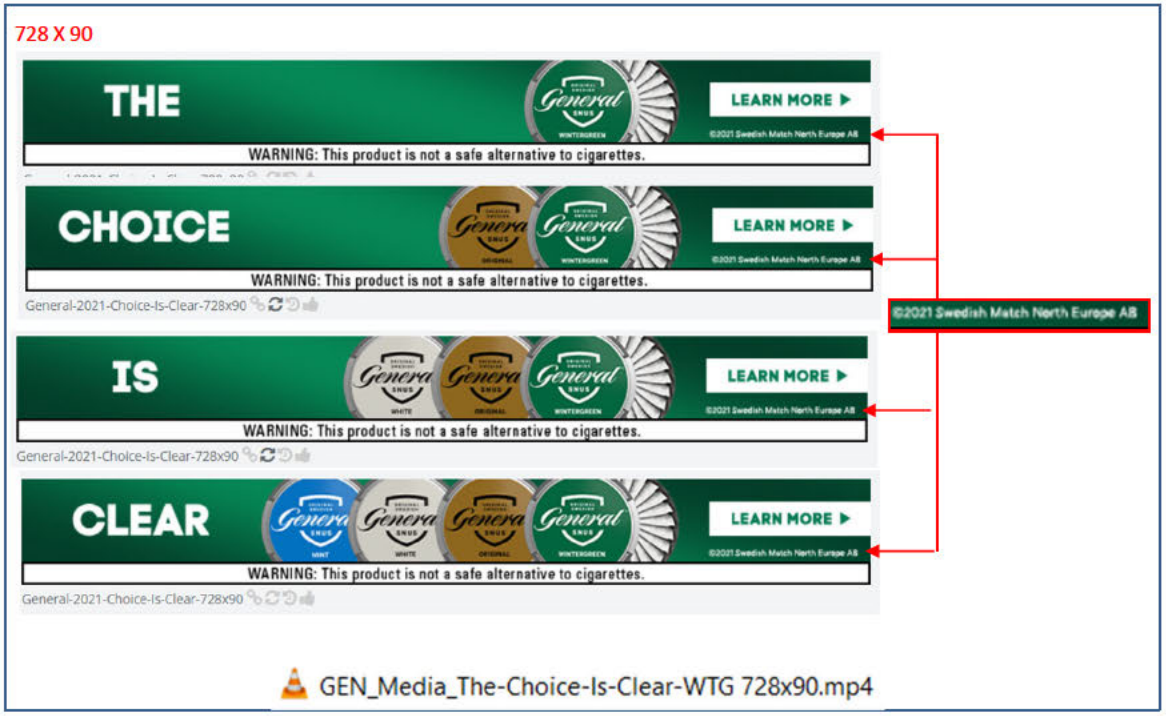
General Snus Digital Ads: Display – Animated, Multi-Frame
'THE CHOICE IS CLEAR': 320 X 50 / 728 X 90

320 X 50



GEN_Media_The-Choice-Is-Clear WTG_320x50.mp4

728 X 90

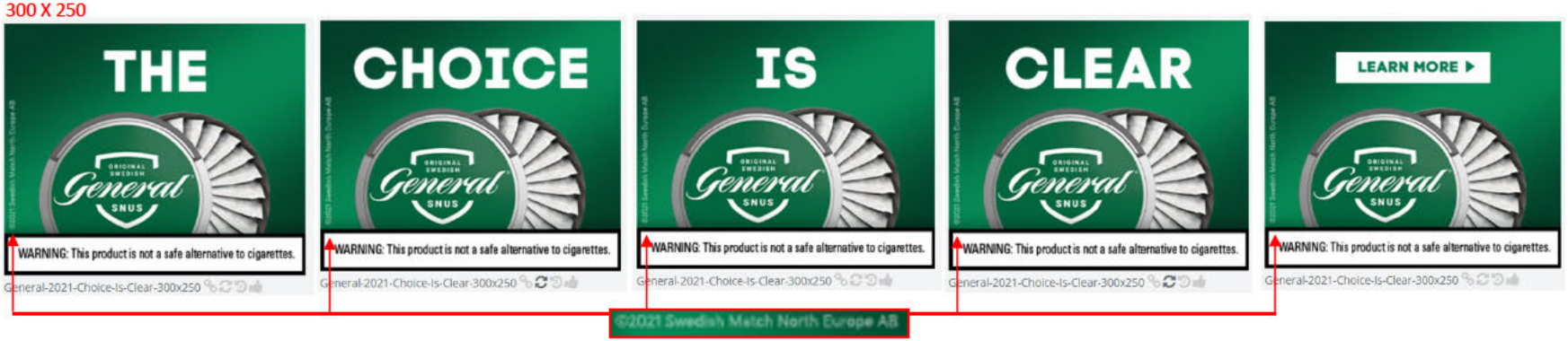


GEN_Media_The-Choice-Is-Clear-WTG 728x90.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame
'THE CHOICE IS CLEAR': 300 X 250

300 X 250



GEN_Media_The-Choice-Is-Clear WTG_300X250.mp4

Swedish Match

General Snus Digital Ads: Display – Animated, Multi-Frame
'FIRST EVER': 300 x 600

GEN_Media_First_Ever_300X600.mp4

300 X 600

Swedish Match

General Snus Jan. – June ‘21 Digital Ad .mp4 File Guide

One size ad shown for reference

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
	GEN_First Ever.Banner_Ads_160x600_2.mp4 00:00:08 GEN_First Ever.Banner_Ads_300x250_2.mp4 00:00:08 GEN_First Ever.Banner_Ads_300x600_2.mp4 00:00:08 GEN_First Ever.Banner_Ads_320x50_2.mp4 00:00:08 GEN_First Ever.Banner_Ads_728x90_2.mp4 00:00:08	Shows a partial graphic of trees and a can of mint General Snus. States “First Ever” and it was granted the first Modified Risk Tobacco Product order. Has a call-to-action that directs consumers to register/age-verification or log-in, then the MRTP page on the General Snus website.
	GEN_The Choice Is Clear.Banner_Ads_300x250_1.mp4 00:00:08 GEN_The Choice Is Clear.Banner_Ads_300x600_1.mp4 00:00:08 GEN_The Choice Is Clear.Banner_Ads_320x50_1.mp4 00:00:08 GEN_The Choice Is Clear.Banner_Ads_728x90_1.mp4 00:00:08 GEN_The Choice Is Clear_Banner_Ads_160x600_1.mp4 00:00:08	Show a partial graphic of snow-capped mountains and a can of mint General Snus. States “The Choice Is Clear’ and the approved MRTP claim. Has a call-to-action that directs consumers to register age-verification/log-in, then the MRTP page on the General Snus website.

[redacted]

Swedish Match

General Snus Jan. – June ‘21 Digital Ad .mp4 File Guide

One size ad shown for reference

.mp4 Image

.mp4 File Name and Length

GEN_Flavor Like No Other_Digital_Ads_160X600-StoreLocator.mp4	00:00:09
GEN_Flavor Like No Other_Digital_Ads_300X250-StoreLocator.mp4	00:00:10
GEN_Flavor Like No Other_Digital_Ads_300X600-StoreLocator.mp4	00:00:09
GEN_Flavor Like No Other_Digital_Ads_320x50-StoreLocator.mp4	00:00:09
GEN_Flavor Like No Other_Digital_Ads_728x90-StoreLocator.mp4	00:00:09

.mp4 Descripton

Shows the four flavor cans of General Snus and states “Flavor Like No Other” with a call-to-action that directs consumers to the store locator on the General Snus website.

GEN_Flavor Like No Other_Digital_Ads_300X250-Coupon.mp4	00:00:09
GEN_Flavor Like No Other_Digital_Ads_320x50-Coupon.mp4	00:00:09

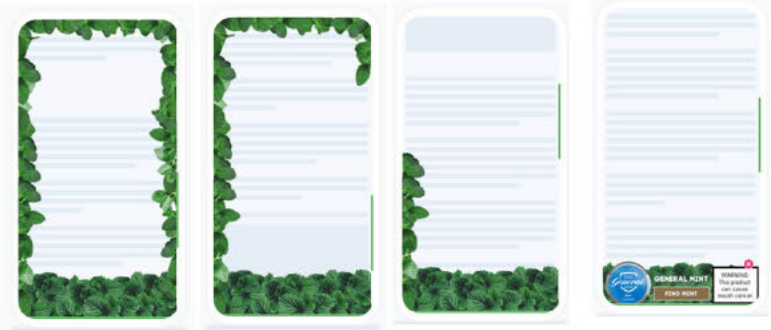
Only one size two size ads were done.

Shows the four flavor cans of General Snus and states “Flavor Like No Other” with a call-to-action that directs consumers to register/age-verification or log-in and then to the coupon page on the General Snus website.

[redacted]

Swedish Match

General Snus Jan. – June ‘21 Digital Ad .mp4 File Guide

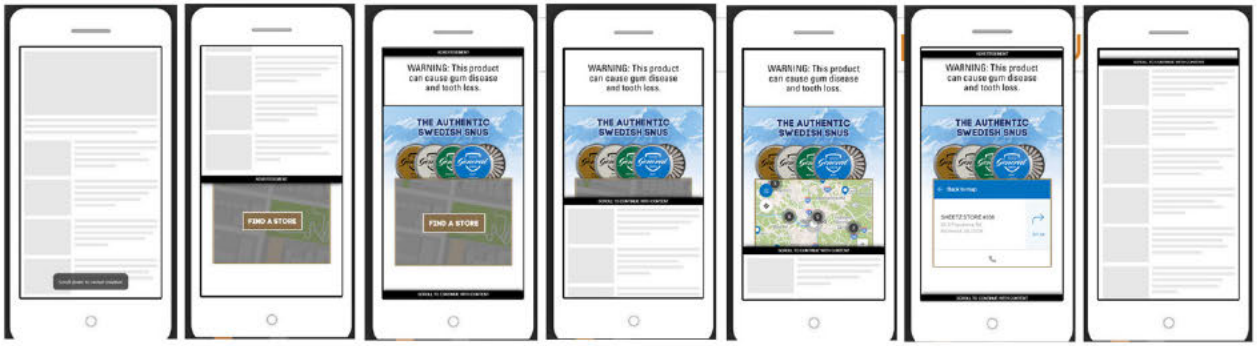
.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
	General Snus MINT Press&Hold Duo.mp4 00:00:09	(b) (4) (b)(4)
	General Snus MINT Superscape.mp4 00:00:08	(b) (4) (b)(4)

[redacted]

Swedish Match

General Snus Jan. – June ‘21 Digital Ad .mp4 File Guide

Appears when scrolling on the screen.



General Snus Tap to Map Scroller Q3 2021 Digital Ad.mp4

.mp4 File Name and Length: 00:00:15

.mp4 Descripton

(b) (4)

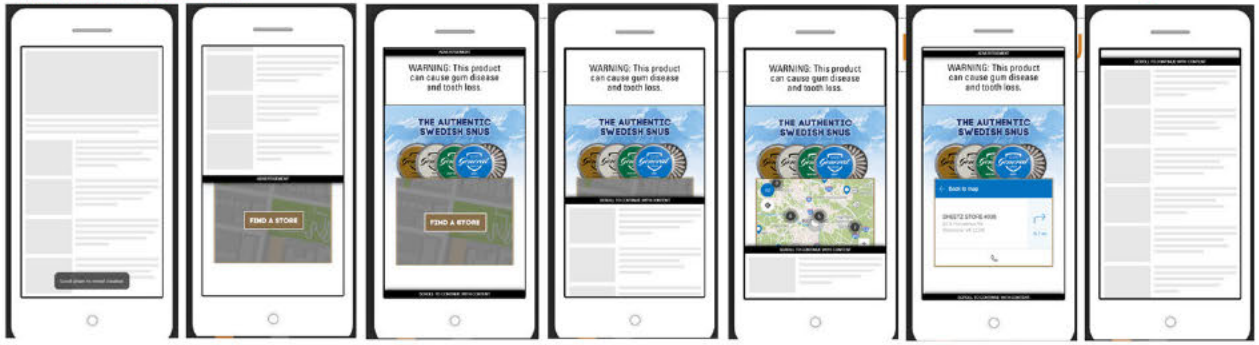
[redacted]

Swedish Match

General Snus Jan. – June ‘21 Digital Ad .mp4 File Guide

General Snus Tap to Map Scroller Q3 2021 Digita...

Appears when scrolling on the screen.



General Snus Tap to Map Scroller Q3 2021 Digital Ad.mp4

.mp4 File Name and Length: 00:00:15

.mp4 Description

(b) (4)

(b)(4)

[redacted]

Swedish Match

General Snus July – Dec. ‘21 Digital Ad .mp4 File Guide

One size ad shown for reference

.mp4 Image

GEN_Media_The-Choice-Is-Clear WTG_160X600.mp4	00:00:02
GEN_Media_The-Choice-Is-Clear WTG_300X250.mp4	00:00:04
GEN_Media_The-Choice-Is-Clear WTG_300X600.mp4	00:00:02
GEN_Media_The-Choice-Is-Clear WTG_320x50.mp4	00:00:06
GEN_Media_The-Choice-Is-Clear-WTG 728x90.mp4	00:00:05

.mp4 Description

Features all four flavors on the 160 x 600 and 728 x 90 and only the wintergreen flavor on the 300 x 600, 300 x 250 and 320 x 50 sizes. Animates “The Choice Is Clear” with a CTA to GeneralSnus.com and register/log-in, auto directs to the Products page.

General Snus July – Dec. ‘21 Digital Ad .mp4 File Guide

One size ad shown for reference

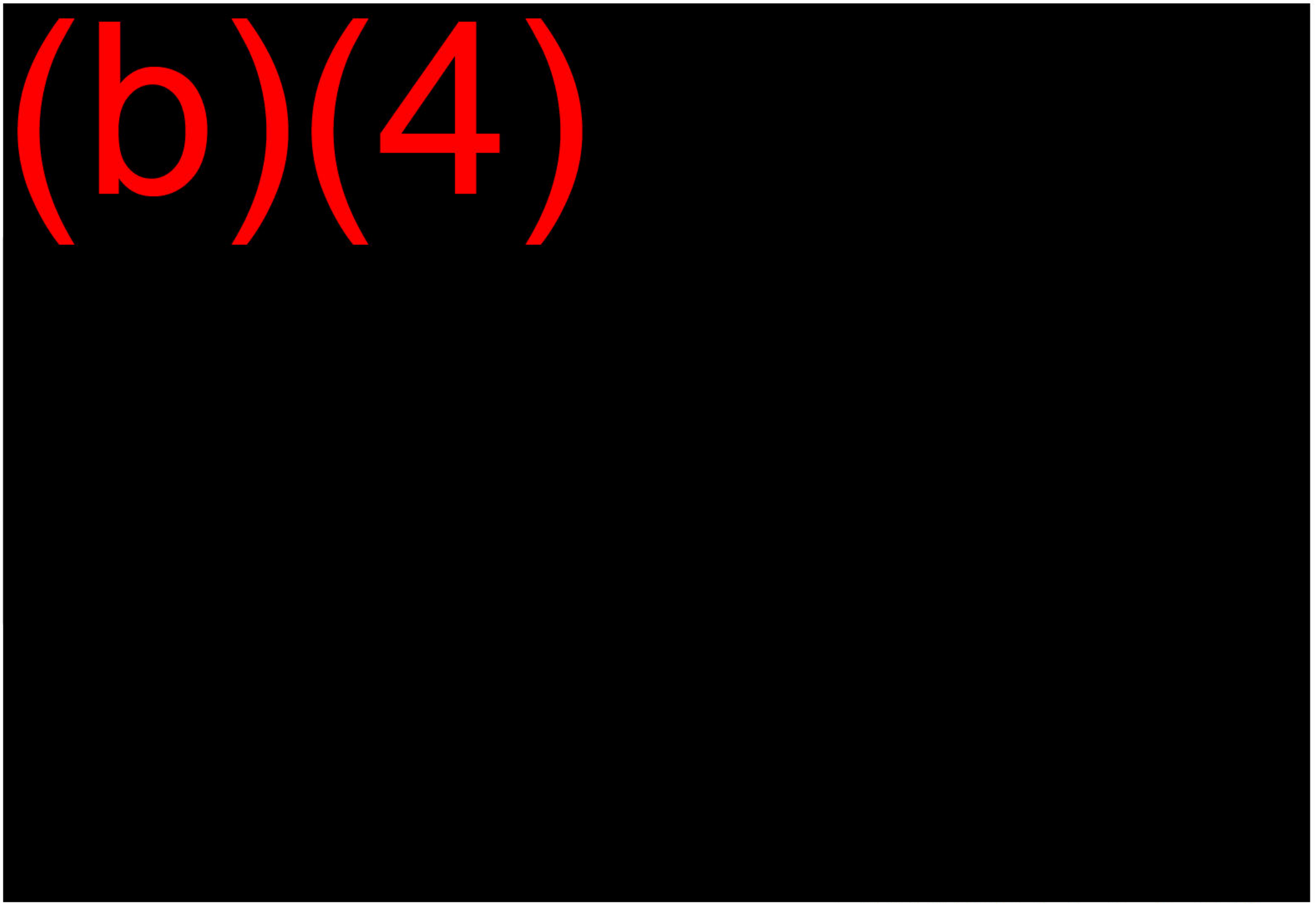
.mp4 Image

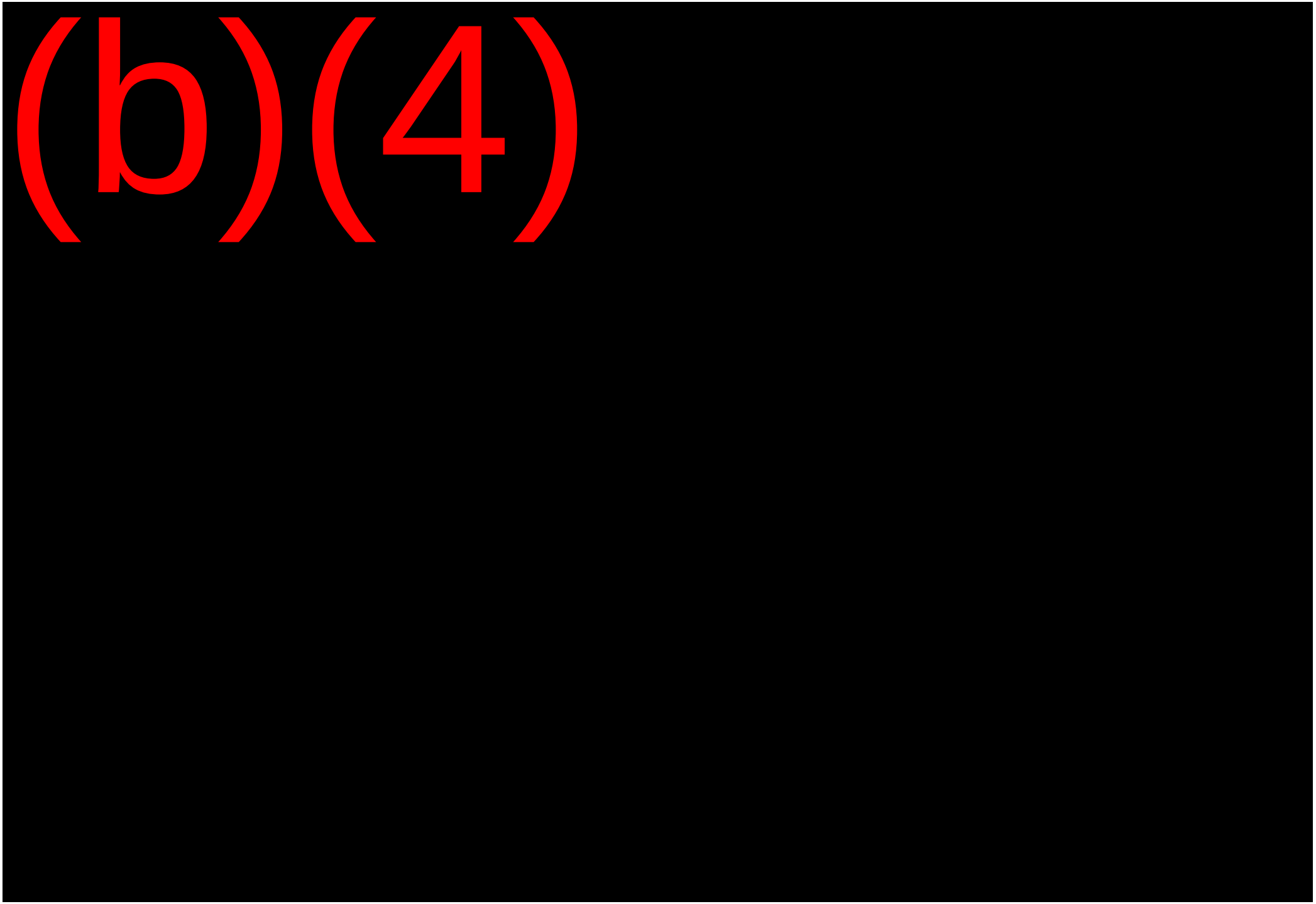
.mp4 File Name and Length

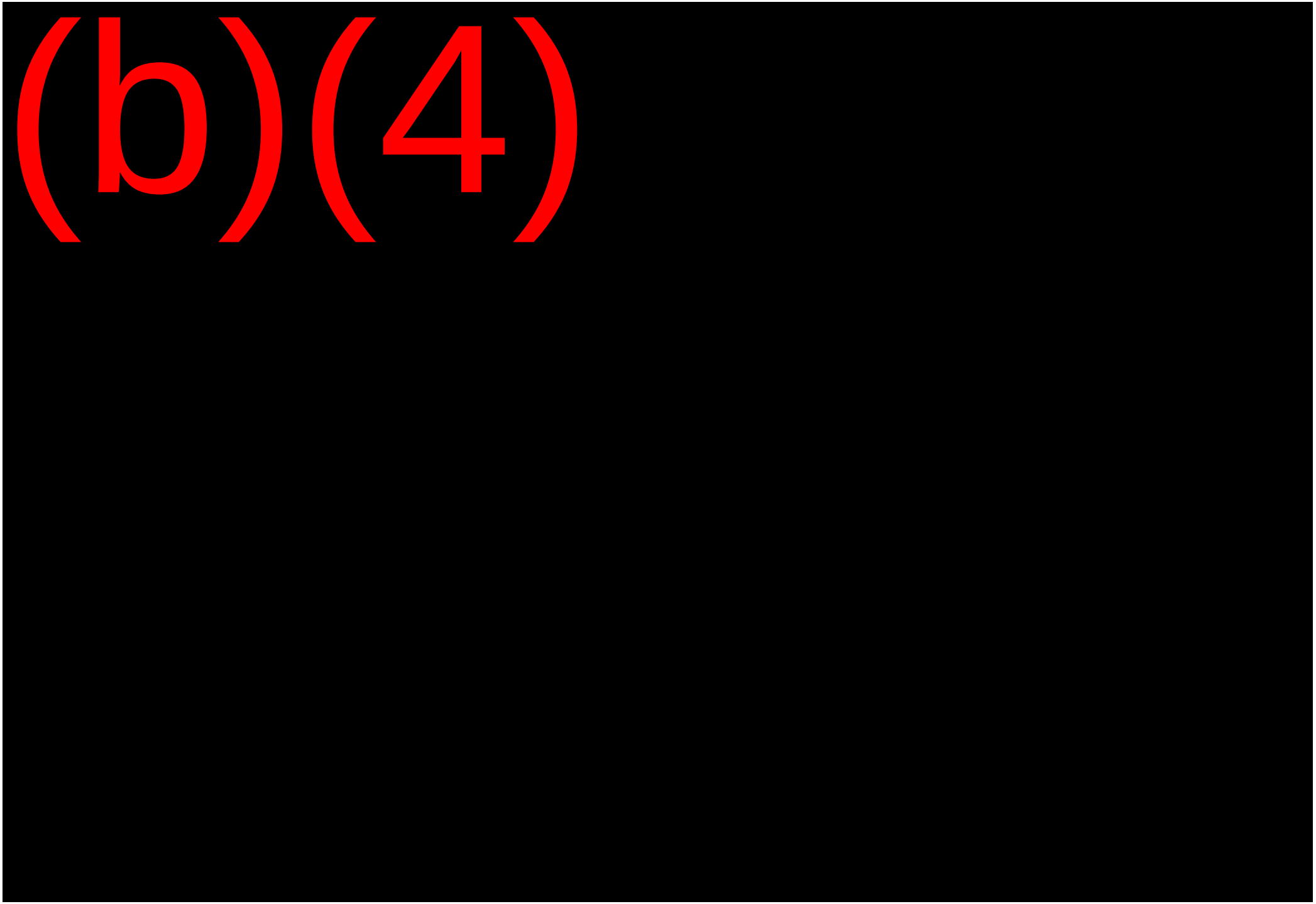
GEN_Media_First_Ever_300X600.mp4 00:00:01

.mp4 Description

Features mint can in front of landscape with animation “First Ever” with CTA directing to GeneralSnus.com and register/log-in, auto directs to FDA Info page.


(b)(4)


(b)(4)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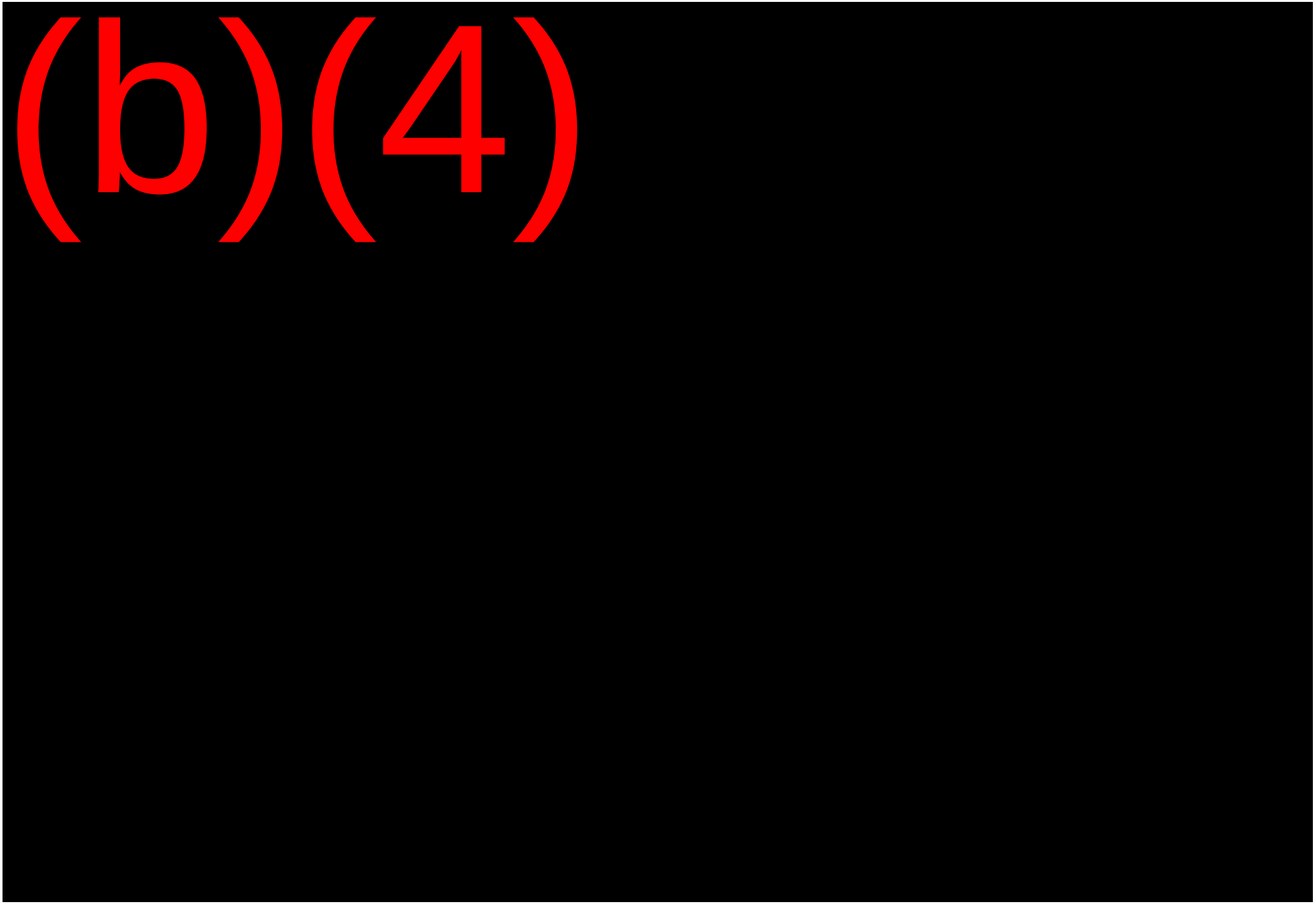
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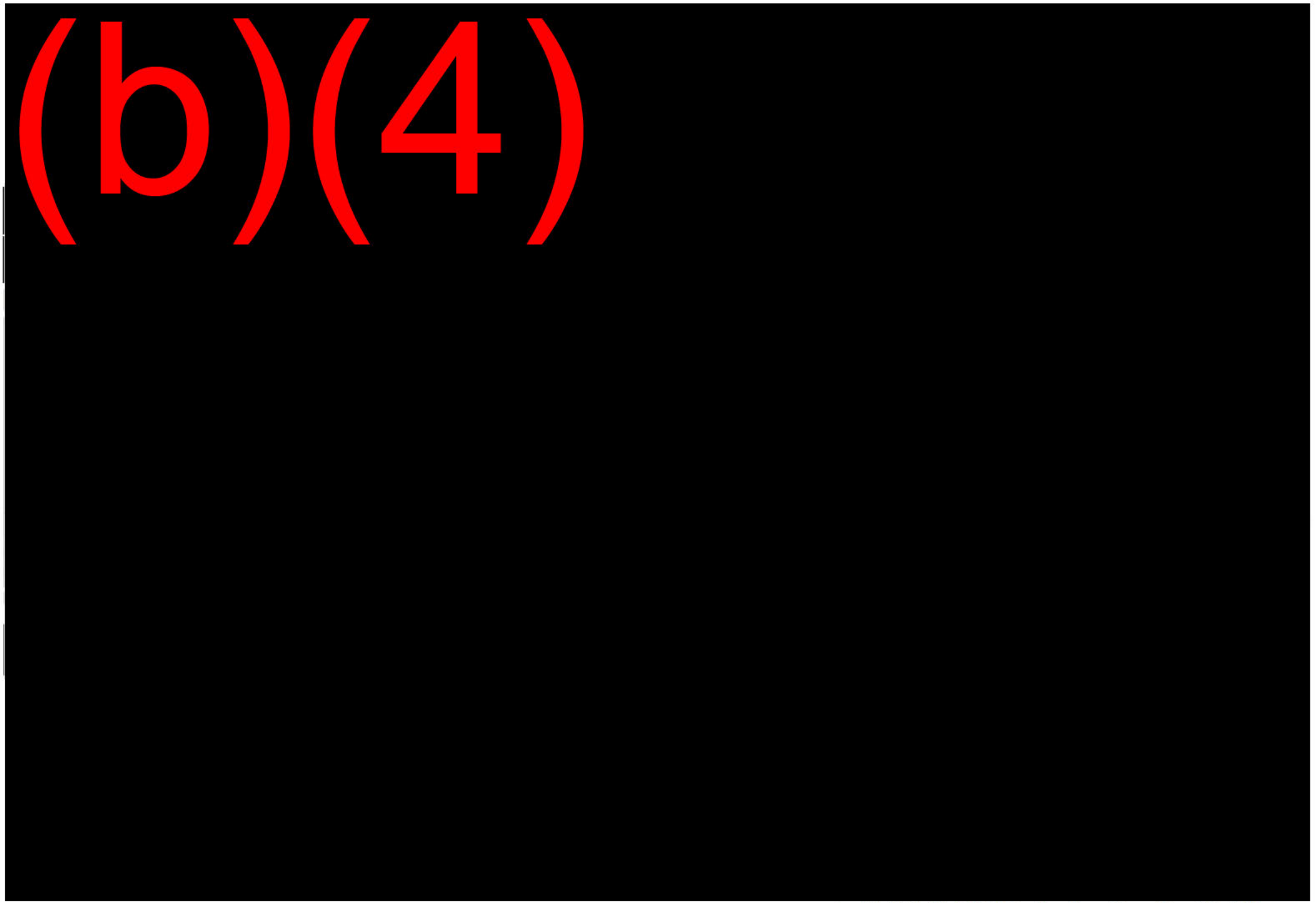
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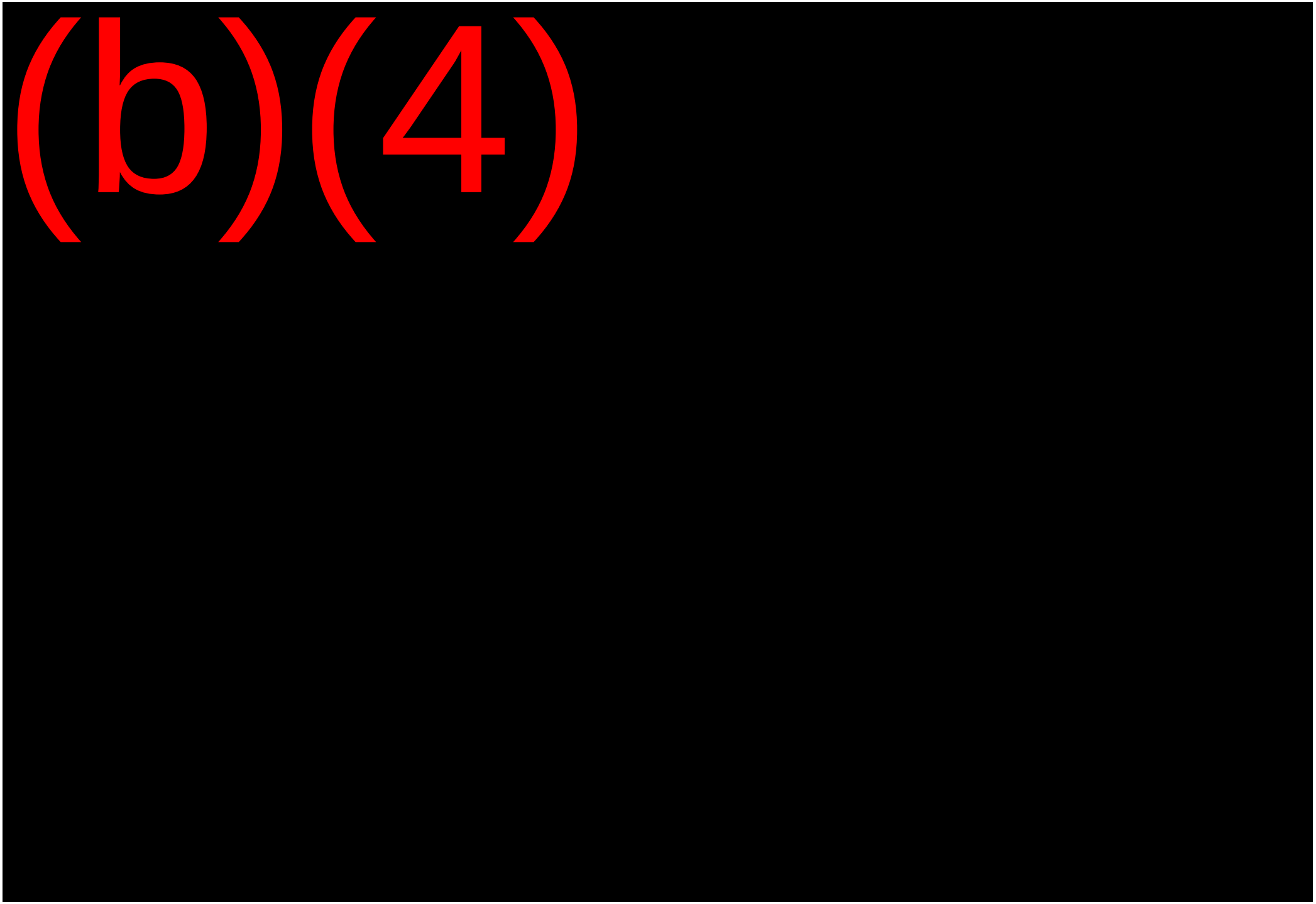
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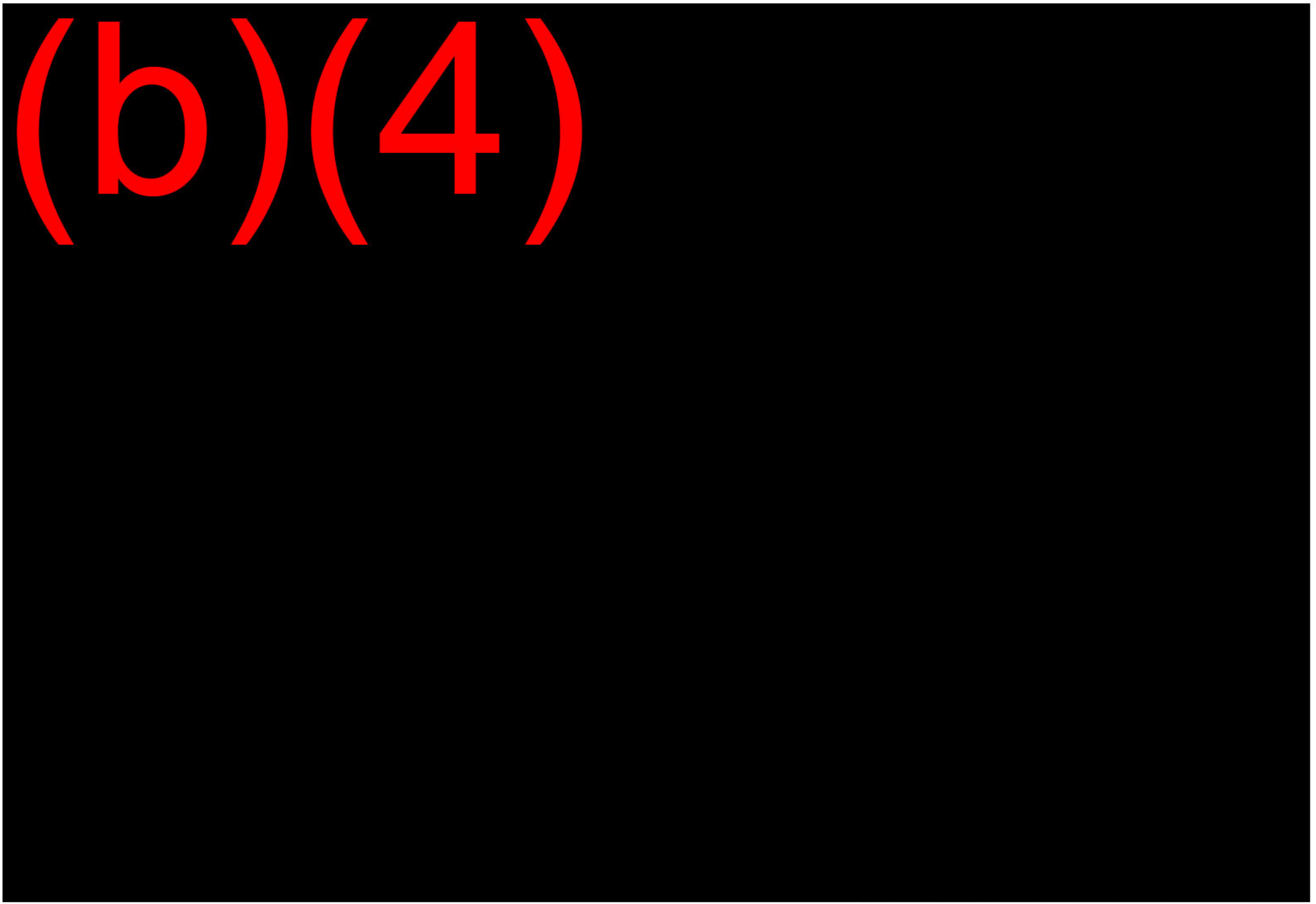
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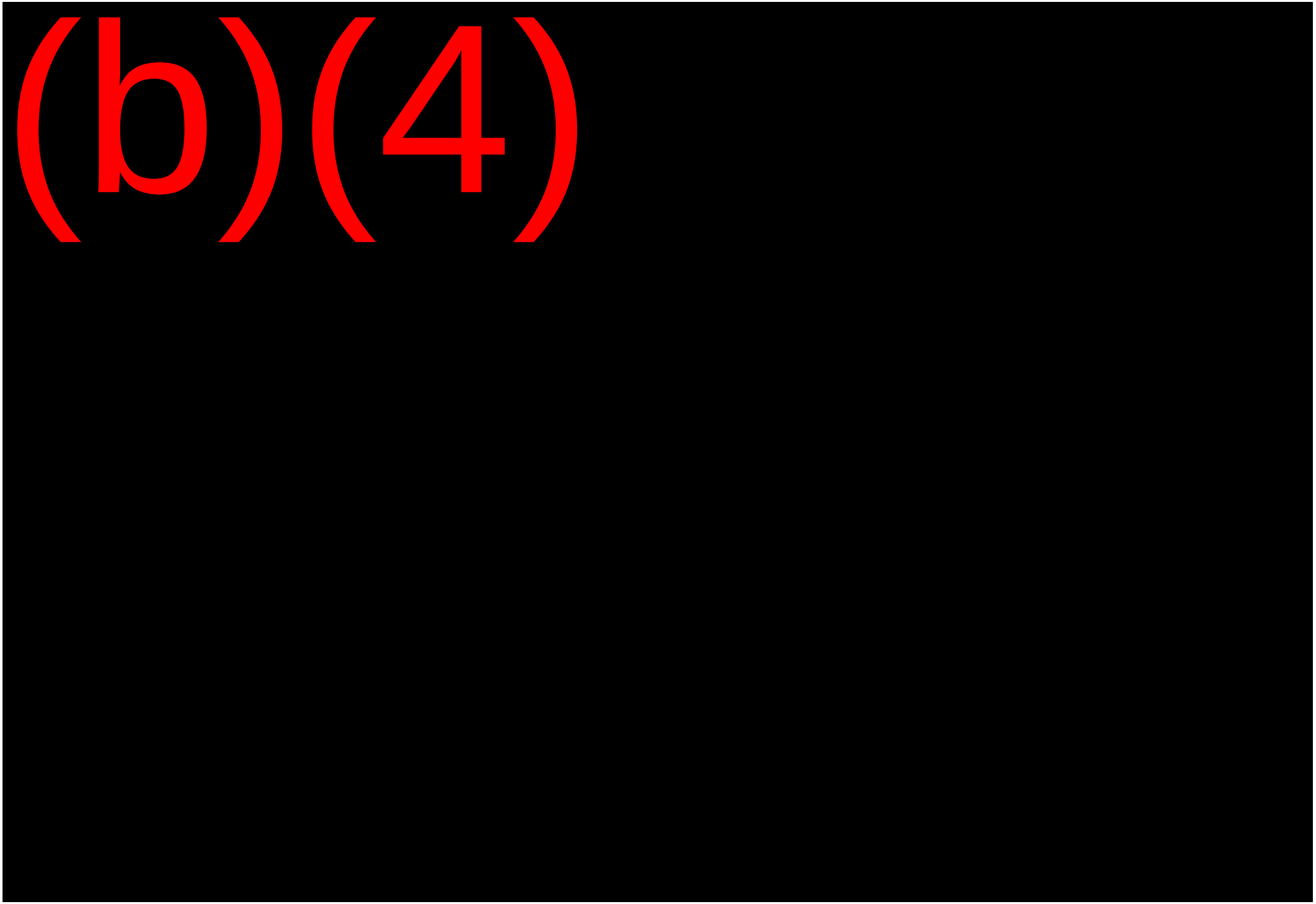
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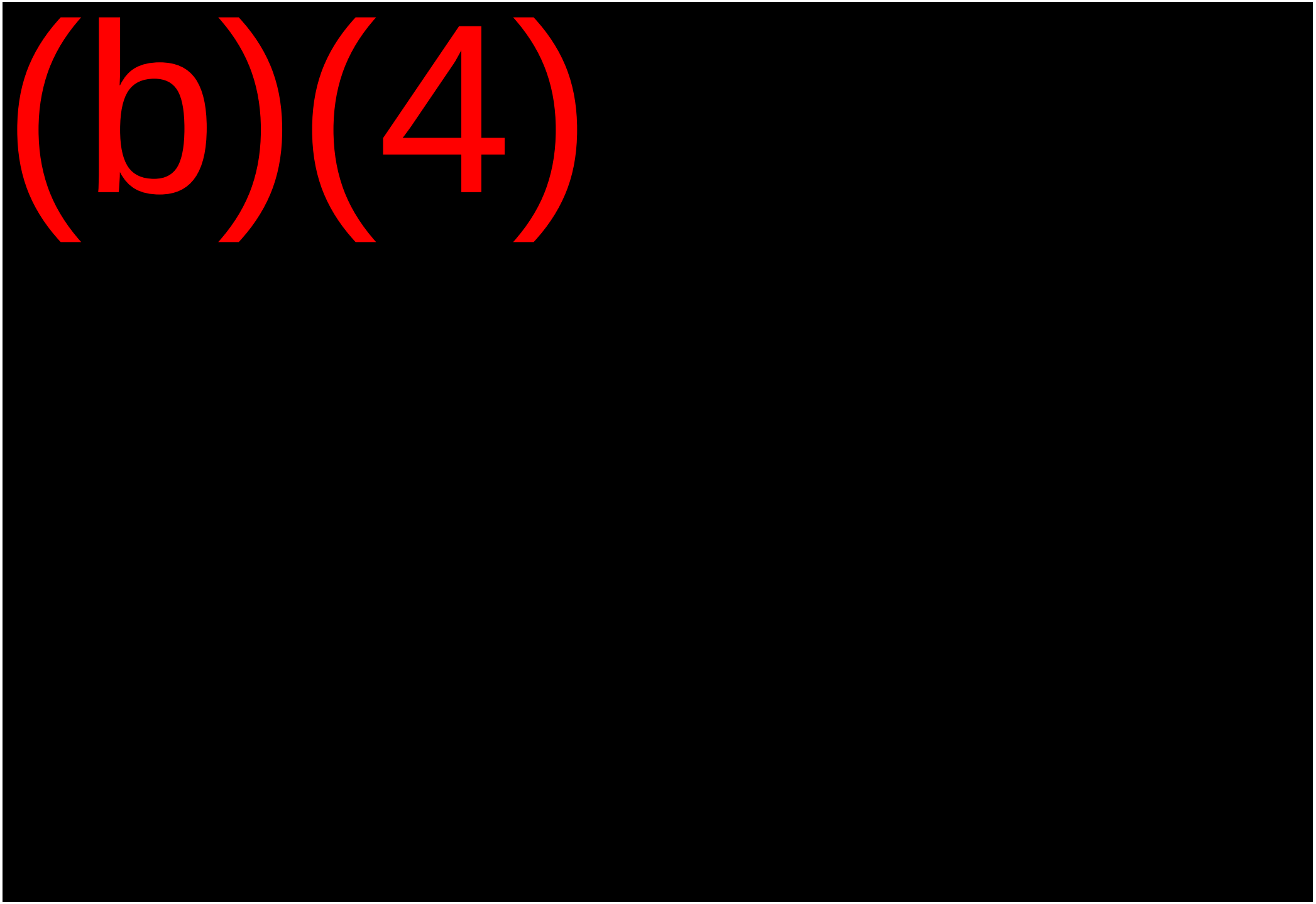
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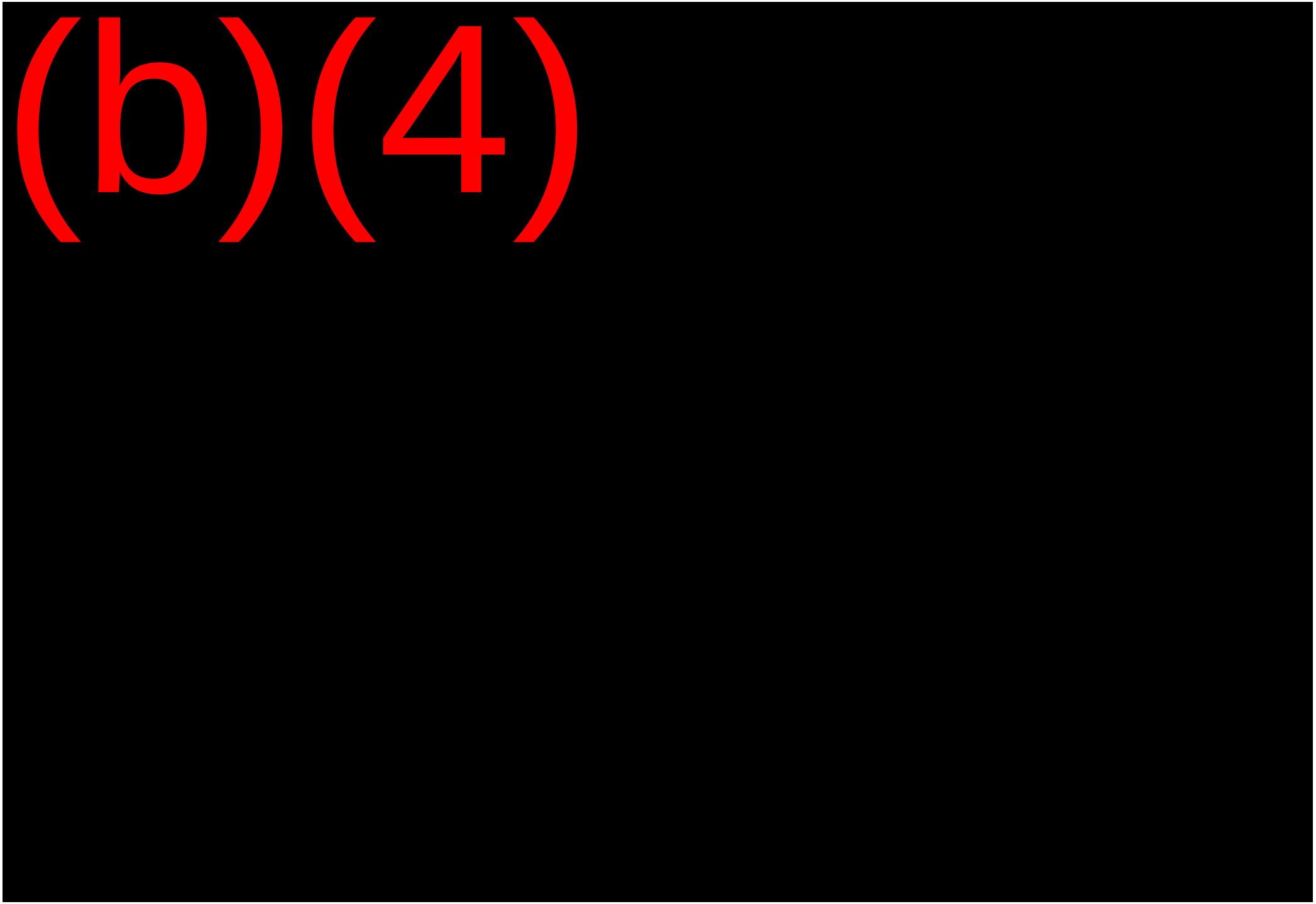
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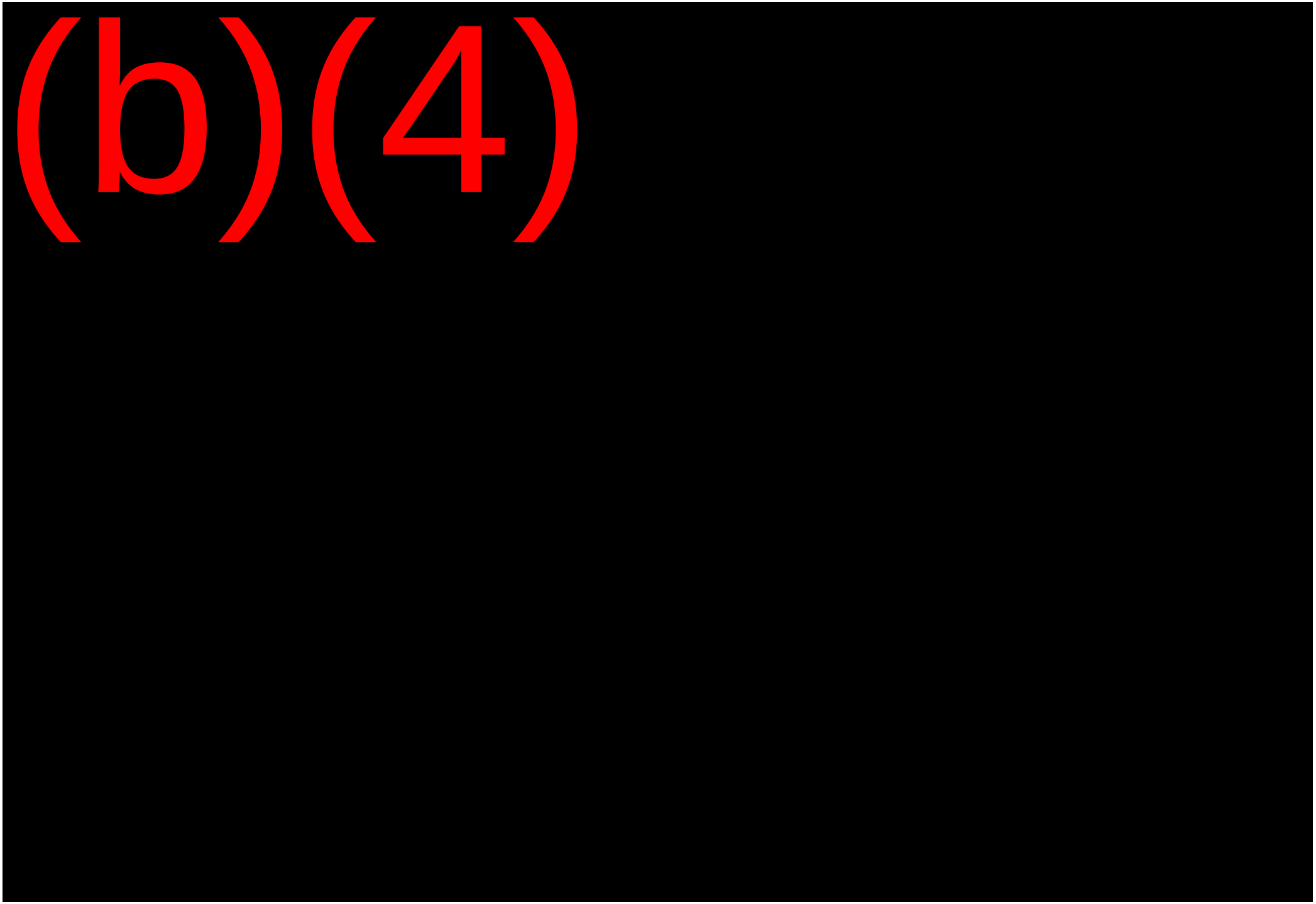
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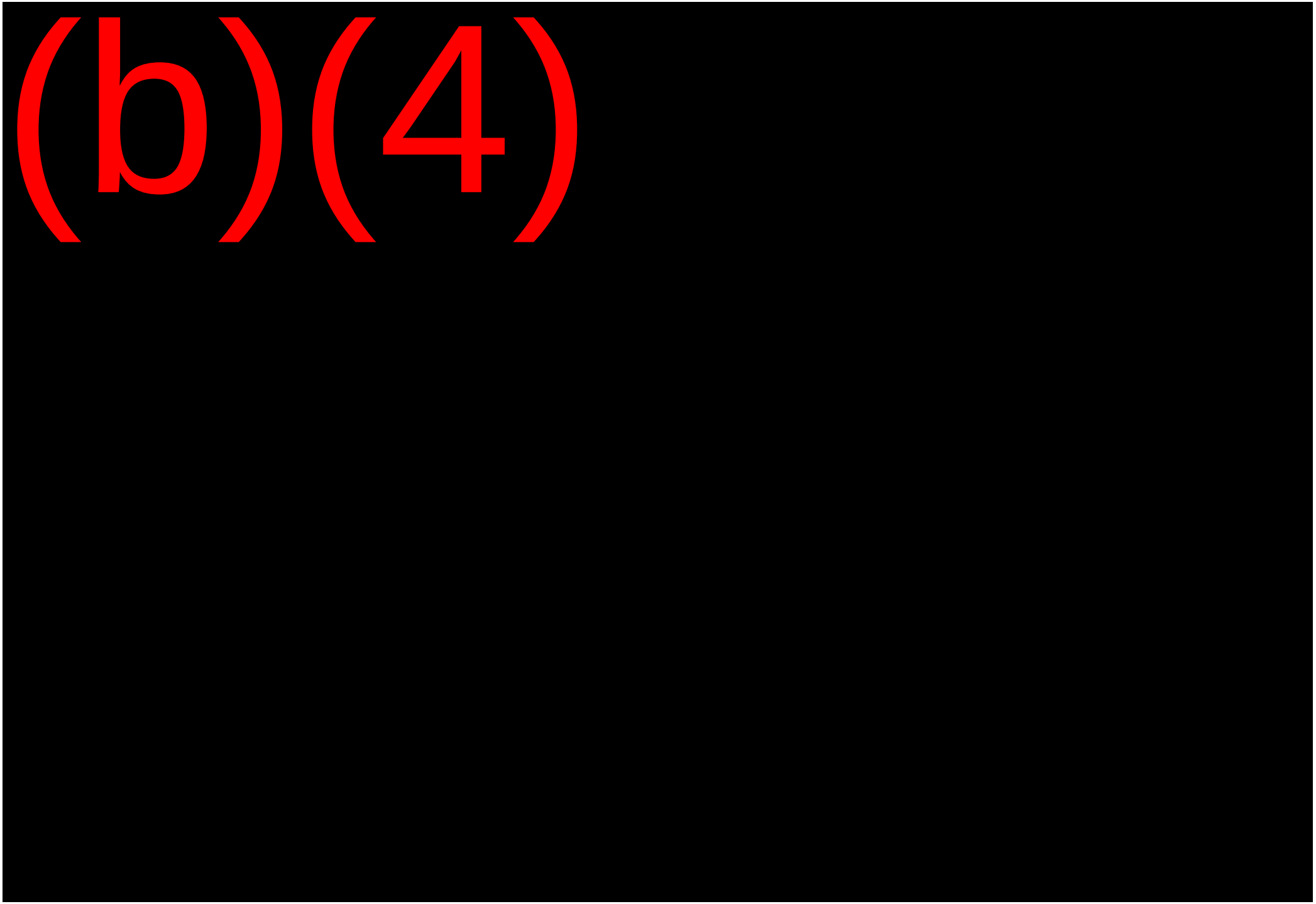

(b)(4)

GENERAL SNUS TRADE ADVERTISING

[redacted]

General Snus Trade Advertising

Swedish Match

Appendix 4: Facebook / Email / Direct Mail / POS / Packaging

CATEGORY: SNUS

BRAND: GENERAL

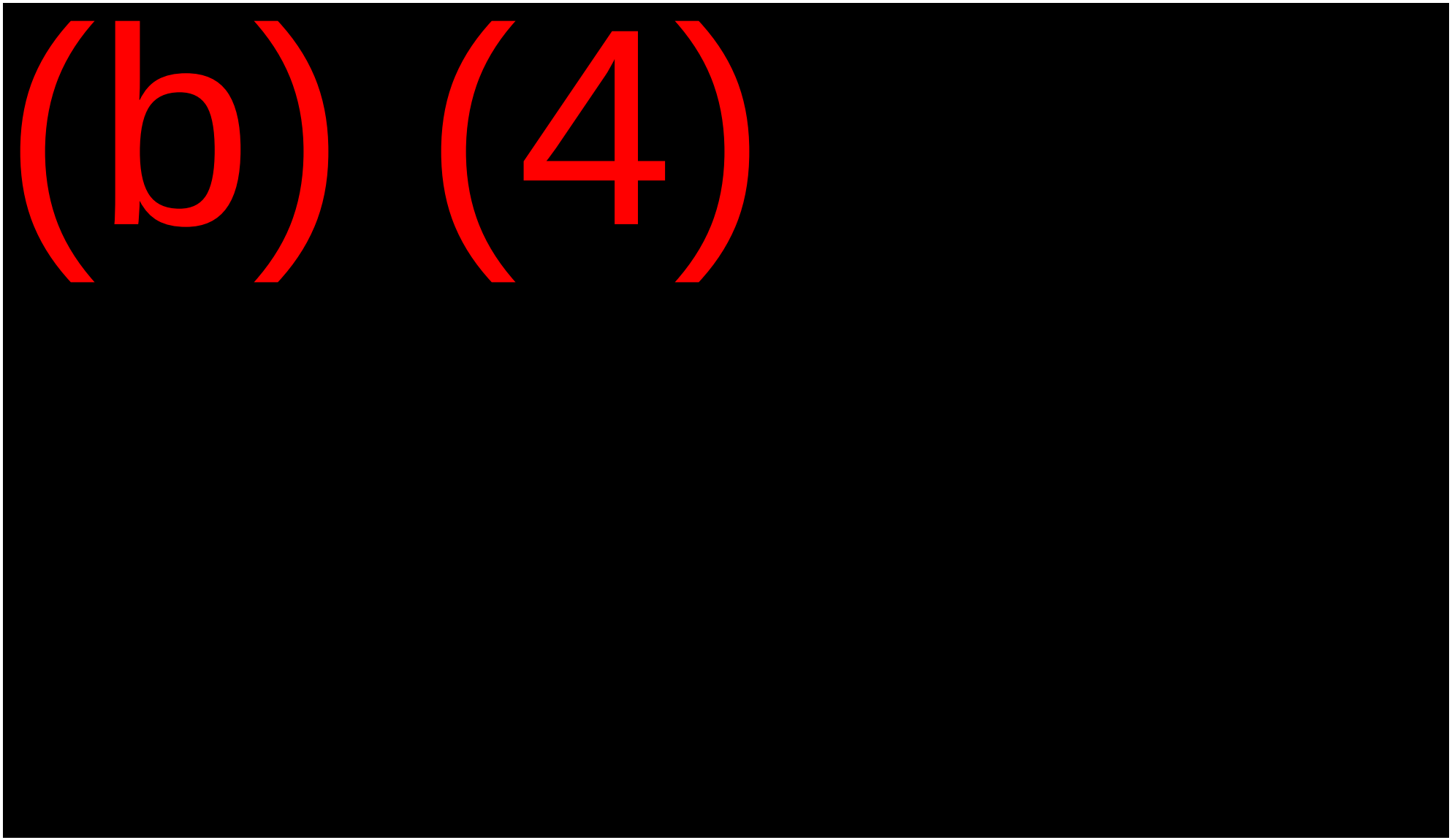
Annual Report

October 2020 – October 2021

GENERAL SNUS SOCIAL MEDIA
Oct. 2020 – Oct. 2021

[redacted]

General Snus Facebook Page Results: Oct. 2020 – Oct. 2021



Q4 2020 General Snus Facebook Cover Image & Profile Photos

Swedish Match

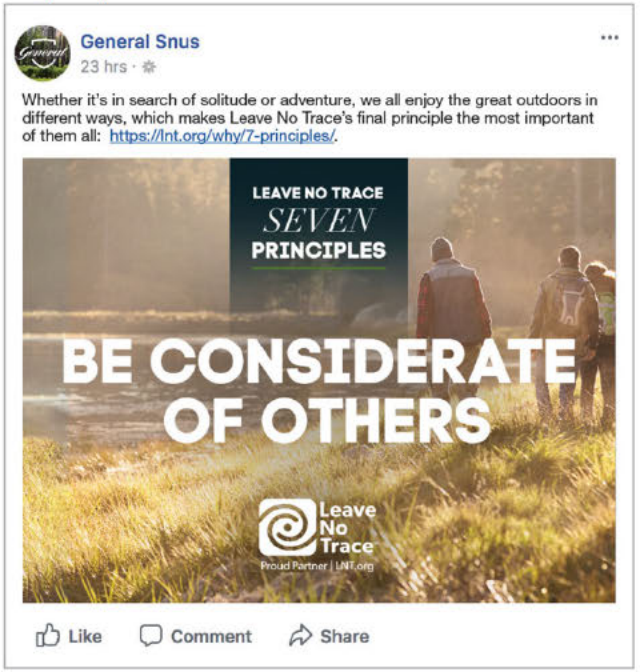
Oct. 2020 General Snus Facebook Posts

10/2/20

10/6/20

10-06-20 Gen LAGOM-FB.mp4

10/10/20



Swedish Match

Oct. 2020 General Snus Facebook Posts

10/15/20

See attached video.

10-15-20 Gen Snus was born-FB.mp4

10/19/20

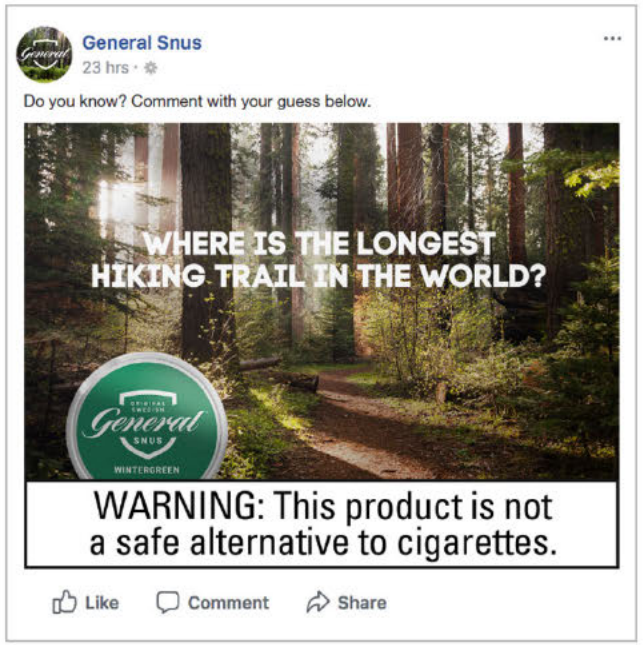
COMMENT COPY:
Thanks for guessing! The Appalachian Trail is the longest hiking-only path in the world. The total elevation gain/loss across the AT is equivalent to climbing Mt. Everest 16 times.

10/23/20

Swedish Match

Oct. 2020 General Snus Facebook Posts

10/19/20



COMMENT COPY:
Thanks for guessing! The Appalachian Trail is the longest hiking-only path in the world. The total elevation gain/loss across the AT is equivalent to climbing Mt. Everest 16 times.

10/28/20

10-28-20 LNT Thank you Gen-FB.mp4

10/31/20

COMMENT COPY:
None other than Harry Houdini himself died on Halloween in 1926, but many details surrounding his death remain mysteriously unknown. Records show he suffered from severely ruptured appendix, but some theories turn to Houdini's strong dose of skepticism for Spiritualism – a pseudo-religion where followers used seances and mediums to communicate with the dead, a group historically known for poisoning its adversaries.

Swedish Match

Nov. 2020 General Snus Facebook Posts

11/4/20

COMMENT COPY:
If you guessed the U.S., you're correct! The bridge crossing over Lake Pontchartrain in New Orleans is so long that for 8 of its 24 miles, you can't see land in any direction.

11/7/20

11/10/20

Swedish Match

Nov. 2020 General Snus Facebook Posts

11/12/20

General Snus
23 hrs ·

Did you know that our pouch containers are recyclable? When finished enjoying General Snus, dispose of used pouches and recycle the empty cans to ensure they don't end up in a landfill.

Like Comment Share

See al

11-12-20 Sustainability Gen-FB.mp4

11/15/20

General Snus
23 hrs ·

After more than 150 years, we're proud to still be making history. Learn more at GeneralSnus.com/mrtpLanding.

Like Comment Share

11/18/20

General Snus
23 hrs ·

Long before gentleman's pockets held boarding tickets for the first electric train, they carried premium General Snus. Learn more of our story at GeneralSnus.com/OurStory.

Like Comment Share

See attached video.

11-18-20 Ticket 1890 Gen-FB.mp4

Swedish Match

Nov. 2020 General Snus Facebook Posts

11/21/20

General Snus
23 hrs ·

History has deemed Hot Buttered Rum to be winter's most unique and refined drink. The rich and creamy flavors found in this recipe are best enjoyed with a fire going and your favorite flavor of General Snus. Learn how to make it in the comments below!

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

COMMENT COPY:

Buttered Rum Batter
4 tbsp. unsalted butter, softened
3 tbsp. packed brown sugar
½ cup vanilla ice cream, softened
½ tsp. ground cinnamon
½ tsp. ground nutmeg

Rum Drink
2 cups apple cider
1 cup rum

Buttered Rum Batter:
Mix together butter, brown sugar, nutmeg, and cinnamon until light and fluffy. Combine with ice cream and spoon into mason jar. Store in freezer until ready to serve.

Make the Drink:
Place 2 tbsp of buttered rum batter into a mug, then fill about 1/3 if the way with rum and top it off with hot apple cider. Stir and enjoy.

11/26/20

General Snus
23 hrs ·

Smörgåsbord isn't just a term to describe a table full of food, it's a Swedish celebration, centered around an abundant Swedish feast with bread, cheese, savory, and sweet dishes. Think of it as the Swedish cousin of today's American tradition – where are you spending Thanksgiving this year?

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

11/27/20

General Snus
23 hrs ·

Winter is officially on its way, which makes it the perfect time to find a new indoor pursuit and put your craftsman abilities to the test. Have you picked up any new projects lately?

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

Nov. 2020 General Snus Facebook Posts

11/30/20

11-30-20 Arctic Gen-FB.mp4

See attached video.

Swedish Match

Dec. 2020 General Snus Facebook Cover Image & Profile Photos

Swedish Match

Dec. 2020 General Snus Facebook Posts

12/3/20

12/6/20

12/9/20

See attached video.

12-09-20 Every Season Gen-FB.mp4

COMMENT COPY:
Thanks for guessing! General Snus is kept at a precise 46 degrees Fahrenheit to ensure maximum flavor and freshness in every portion.

Dec. 2020 General Snus Facebook Posts

12/5/20

General Snus
23 hrs ·

The approaching winter season sends most fisherman to pack their tackle boxes and head home until next spring, but a growing community of ice anglers will travel far and wide for the perfect hardwater to cast their lines. Have you ever gone ice fishing before?

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

12/15/20

General Snus
23 hrs ·

The same recipe that we've used for more than 150 years continues to set new standards for snus around the world. Learn more about our official Modified Risk Tobacco Product order at GeneralSnus.com/mrtpLanding.

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

12/18/20

General Snus
23 hrs ·

For adventure-seekers who crave the breathtaking views of a winter snowscape, here are the top U.S. hiking spots for the season. Wherever you're headed to next, make sure to pack General Snus.

WARNING: This product is not a safe alternative to cigarettes.

Like Comment Share

See attached video.

12-18-20 Fairyland Gen-FB.mp4

Swedish Match

Dec. 2020 General Snus Facebook Posts

12/21/20

12/23/20

COMMENT COPY:
Swedish Glogg:
2 bottles dry red wine
1 bottle sweet white wine
Juice from 1 orange
10 cloves
10 cardamom pods
3 cinnamon sticks
1 cup raisins
1 cup blanched almonds

Combine all ingredients in large saucepan. Bring to boil, then simmer over low heat for 15 minutes. Serve and enjoy!

Swedish Match

Dec. 2020 General Snus Facebook Posts

12/26/20

See attached video.

12-26-20 A star is born Gen-FB.mp4

12/29/20

Swedish Match

Q1 2021 General Snus Facebook Cover Image & Profile Photos

Swedish Match

General Snus January ‘21 Facebook Posts

1/1

1/5

1/7

General Snus January ‘21 Facebook Posts

1/9

1-9 Breathing Technique_GEN_FB.mp4

1/13

1/17

1-17 Lower Risk Table_GEN_FB.mp4

General Snus January ‘21 Facebook Posts

1/21

1/25

[redacted]

General Snus January ‘21 Facebook Posts

1/28

1/30

[redacted]

General Snus February ‘21 Facebook Posts

2/5

[redacted]

2/8

General Snus February ‘21 Facebook Posts

2/9

General Snus
Published by Tracy Vernon · February 9 at 4:09 PM ·

It seems like everyone is making their own bread these days. Put a Swedish twist on your winter breadmaking with this traditional Braided Cardamom Bread. (Recipe in comments.)

Author
General Snus
Ingredients:
1 cup whole milk
1/3 cup granulated sugar
1/4 cup unsalted butter
1 packet active dry yeast or instant yeast
3 cups all-purpose flour divided
1/4 teaspoon kosher salt
1 teaspoons ground cardamom
1 large egg
½ tablespoon whole milk
1 tablespoon Swedish pearl sugar

Directions:
Warm and combine the milk, sugar, butter, and yeast. Add 2 cups of flour, salt, ground cardamom, and egg, and mix in the bowl of a stand-up mixer with a hook attachment. Let rise for 1 hour in a well-oiled bowl, then knead for 3-4 minutes. Divide the dough into 3 equal pieces and braid. Let rise for 30 minutes on a parchment-lined baking sheet. Brush with a beaten egg and top with pearl sugar. Bake at 375 degrees for 20 minutes or until browned on top.

[redacted]

2/12

General Snus
23 hrs ·

For some people it's putting ketchup on pizza, and for others it's a peanut butter and pickle sandwich. What unexpected flavor have you discovered pairs perfectly with your choice of General?

General Snus February ‘21 Facebook Posts

2/15

[redacted]

2/18

2-18 Ingredients Perfection_GEN_FB.mp4

2/21

2-21 All Cans_GEN_FB.mp4

General Snus February ‘21 Facebook Posts

2/24

2/27

[redacted]

General Snus Q2 ‘21 Facebook Cover Image & Profile Photos

Swedish Match

General Snus March ‘21 Facebook Posts

3/3

General Snus
23 hrs ·

Wetlands: swamps, bogs, marshes, and other water-covered areas are the most biologically diverse of all ecosystems. They're also found in every state in the U.S. Do you know which state proportionally has the most wetlands? (No Googling!) #WorldWildlifeDay

COMMENTS COPY

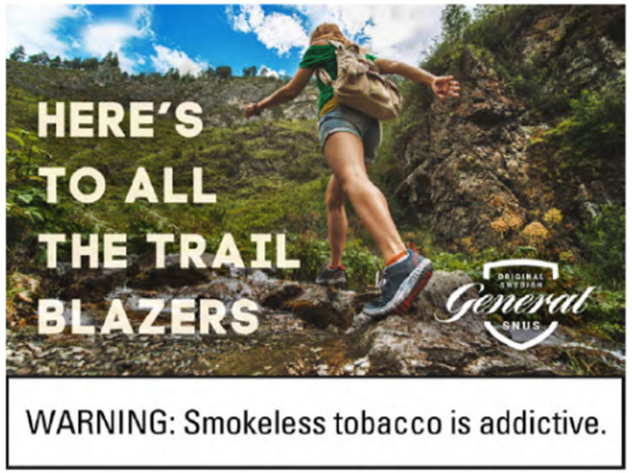
The correct answer is Alaska! With nearly half of the state covered in wetlands — about 170 million acres — it's home to more wetland habitat than the other 49 states combined.

[redacted]

3/6

General Snus
23 hrs ·

Pack a portion in honor of all of those who fearlessly push forward into uncharted territory. #WomensHistoryMonth



Like Comment Share

3/9

General Snus
23 hrs ·

Wherever you go, whatever adventure lies ahead — General can help you elevate every experience. What's one of your favorite past adventures?

3-9 Seasons_GEN_FB.mp4

General Snus March ‘21 Facebook Posts

3/12

[redacted]

3/15

3-15 How To Spot Fake Snus_GEN_FB.mp4

FRAME D

FRAME C

FRAME D

General Snus March ‘21 Facebook Posts

3/18

3-18 Adventure is in the Air_GEN_FB.mp4

[redacted]

3/22

General Snus March ‘21 Facebook Posts

3/25

3/30

3-30 Weekender_GEN_FB.mp4

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[redacted]

General Snus April ‘21 Facebook Posts

4/7

[redacted]

4/10

4-10_Dig Deeper_GEN_FB.mp4

General Snus April ‘21 Facebook Posts

4/13

4/16

4/19

[redacted]

General Snus April ‘21 Facebook Posts

4/22

4-22_Earth Day_GEN_FB.mp4

4/24

4-24_Record Player_GEN_FB.mp4

[redacted]

General Snus April ‘21 Facebook Posts

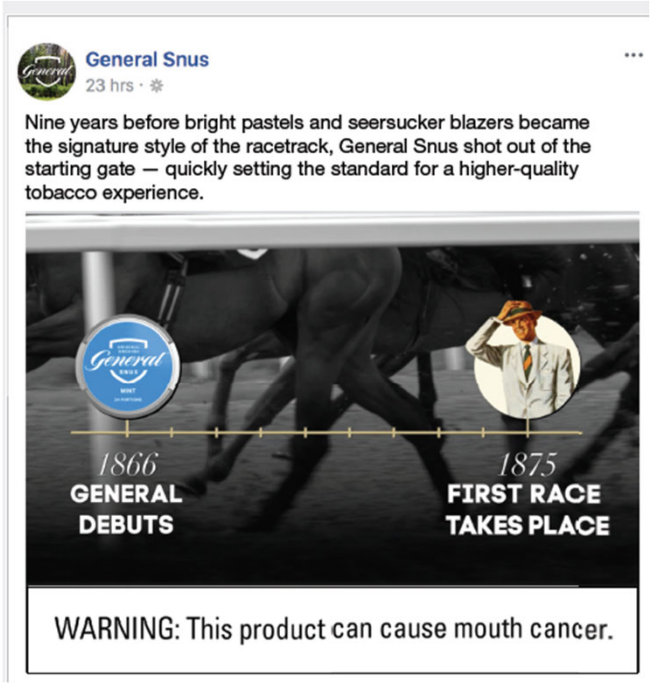
4/27

[redacted]

4/30

General Snus May ‘21 Facebook Posts

5/1



5-1_GEN_May_FB.First Race Takes Place.mp4

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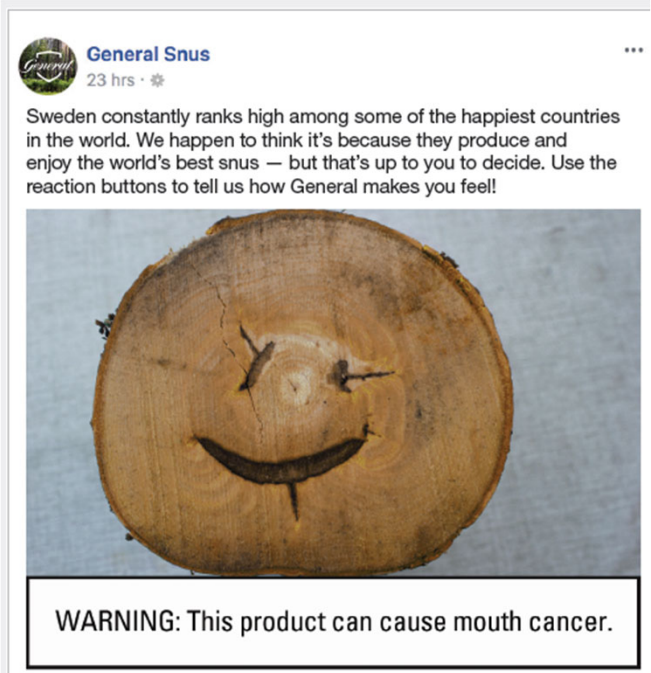
5/4



5-4_GEN_May_FB.be happy.mp4

5/7

5-7_GEN_May_FB.jetski the blend.mp4

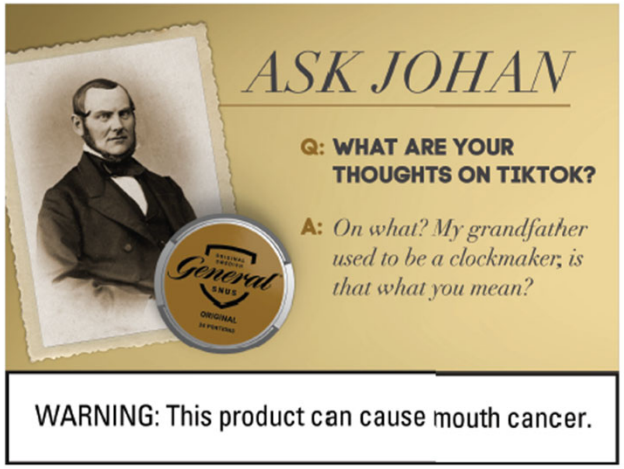
General Snus May ‘21 Facebook Posts

5/10

General Snus
23 hrs ·

We asked the man who started it all — General creator Johan A. Boman — what he thought about some modern-day topics.

Is there something you’d like to hear Johan’s opinion on? Leave a question for him in the comments and you might see it answered next month!



[redacted]

5/12

General Snus
23 hrs ·

Tobacco, water, salt, and natural flavors come together in perfect harmony to create the bold, balanced taste of General Snus.

Get to know the refined process that sets General apart from the rest at GeneralSnus.com/OurProcess.

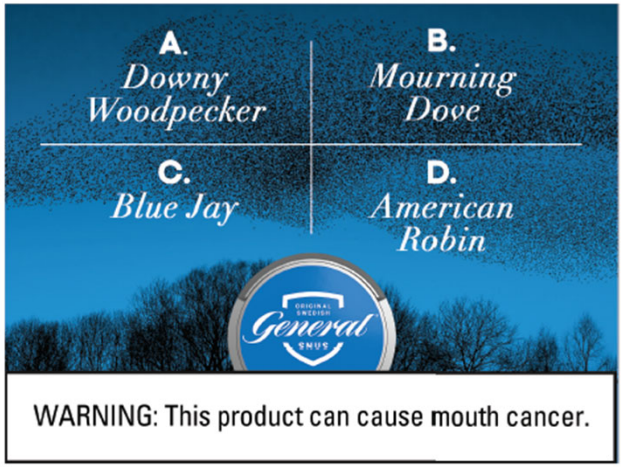
5-12_Post_Ingredient-Infographic.mp4

5/17

General Snus
23 hrs ·

May is known as the best month for bird watching — with warm temperatures, nesting activity, and budding trees full of returning migratory species.

Can you guess which of these backyard birds is the most commonly spotted species in North America? Leave a comment below with your answer!



ANSWER COMMENT:
Thanks for guessing! The answer: The Mourning Dove! These easily identified birds are spotted with 35% frequency among birders in North America.

General Snus May ‘21 Facebook Posts

5/20

General Snus
23 hrs ·

Kebnekaise — literally meaning “kettle top” — is Sweden’s tallest peak. Its glacial valleys are rumored to hold the freshest water in the whole of the country.

Located along the Kungsleden, the King’s Trail, these waters quenched the thirst of hikers on their long journeys. One of these adventurers was Johan A. Boman — who realized only the freshest ingredients could be used in his revolutionary new tobacco product.

To this day, pure, clean water like that found at Kebnekaise remains one of the most crucial ingredients in the production of General Snus.

WARNING: This product can cause mouth cancer.

5/24

General Snus
23 hrs ·

Taking a few minutes in the morning to relax with a portion of General is the best way to help you sail through the rest of the workday.

And because General goes wherever you go, any moment can easily become an #ElevatedMoment. What’s your favorite time of day to enjoy General?

WARNING: This product can cause mouth cancer.

5/28

General Snus
23 hrs ·

With a centuries-old story of our own, we know how easy it can be for things to get mixed up. That’s why we’re sharing a new series titled #TheOriginalStory where we help to uncover the authentic story behind some common misconceptions in history.

First up, Vikings didn’t actually wear horned helmets.

Though they did exist, archaeological evidence suggests horned headgear was reserved for ceremonial purposes — horns would have gotten in the way in battle or on board cramped warships.

WARNING: This product can cause mouth cancer.

[redacted]

General Snus June ‘21 Facebook Posts

6/2

General Snus
23 hrs ·

From humble roots to the world’s best-selling snus.

You deserve a snus with a story as extraordinary as your own.

WARNING: This product can cause mouth cancer.

[redacted]

6/5

General Snus
23 hrs ·

The mountainous region of Dalarna — with its glacier-formed lakes, campgrounds, and lush forests — is the top destination for Swedes from all over the country on their summer vacations.

It’s also where General Snus finally became more than an idea.

Everyone Johan A. Boman met while on vacation in Dalarna held a different opinion on where the best tobacco in the world came from — It’s India! No way, it’s Central America. Or maybe Brazil?

But only Boman saw an opportunity to combine each of these premium tobaccos from around the world into one superior tobacco product.

WARNING: This product can cause mouth cancer.

6/7

General Snus
23 hrs ·

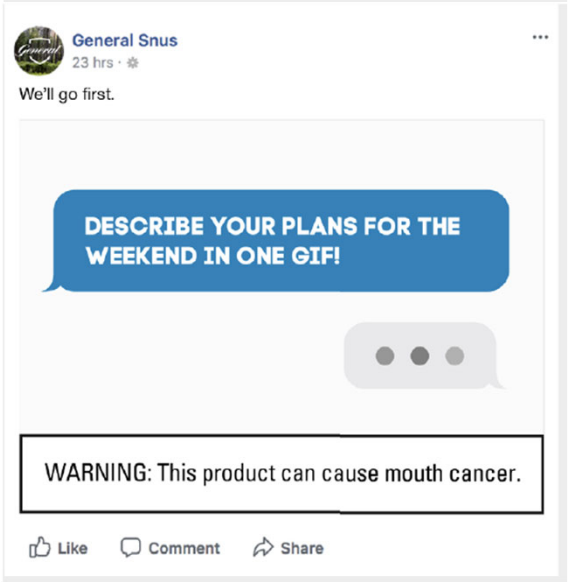
June is #NationalGetOutdoorsMonth — and luckily for us, General is best enjoyed outdoors.

Share a picture of where you’re enjoying the outdoors this month!

WARNING: This product can cause mouth cancer.

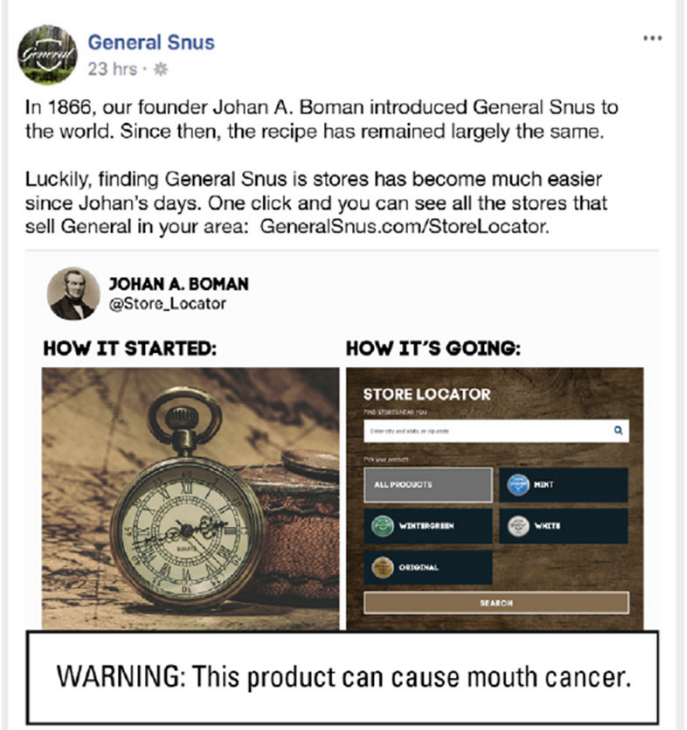
General Snus June ‘21 Facebook Posts

6/11



6-11 GEN_June_FB. Fishing.mp4

6/13



6/15

6-15_GEN_June_FB.Best Selling Snus.mp4

[redacted]

General Snus June ‘21 Facebook Posts

6/17

General Snus
23 hrs ·

Today is #BunkerHillDay, meaning it’s a perfect time to uncover the truth about a seemingly well-known Revolutionary War event, the Battle of Bunker Hill.

Turns out, the fighting actually occurred on nearby Breed’s Hill — it’s where the battle began, and where the battle was decided. American troops had originally been instructed to set up their fortifications on Bunker Hill, but instead chose Breed’s Hill because it was smaller and had a better location.

That’s #TheOriginalStory. Brought to you by the Original Swedish Snus.

WARNING: This product can cause mouth cancer.

6/20

General Snus
23 hrs ·

For this Father’s Day installment of #AskJohan, we asked the unofficial father of snus to share his best dad joke.

Do you have a favorite dad joke?

WARNING: This product can cause mouth cancer.

6/23

General Snus
23 hrs ·

Today’s forecast? Blue skies and a 100% chance of General Mint.

WARNING: This product can cause mouth cancer.

6-23_GEN_June_FB.silboat and can.mp4

[redacted]

General Snus June ‘21 Facebook Posts

6/25

General Snus
23 hrs ·

Our furry friends aren’t the only ones who deserve a treat today.
#BringYourDogToWorkDay

WARNING: This product can cause mouth cancer.

[redacted]

6/28

General Snus
23 hrs ·

Inside every portion of General, there’s a story.

An entire adventure jam-packed into a pouch that’s small enough to fit into your pocket. Whether your experience can fit into a single portion of snus, or into just six words like the story below, we think it’s one that’s worth sharing.

Create your own six-word story and share it with us in the comments! #SixWordLegends

WARNING: This product can cause mouth cancer.

6/30

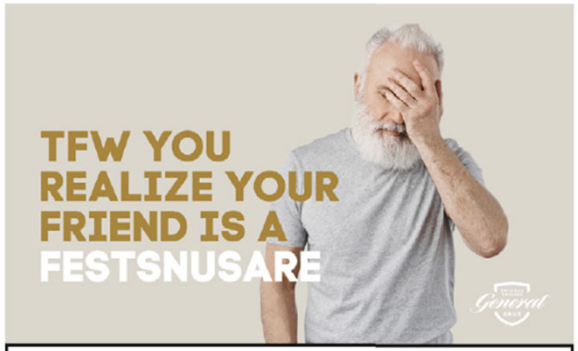
General Snus
23 hrs ·

That feeling when… you realize your friend is a festsnusare.

Festsnusare; noun.
[fest-snoos-aar-eh]

Someone who has their own snus but who will “borrow” a friend’s when they’re out socializing. The first person to approach you right after you open a fresh can.

“Hey, long time no see! Can I have one of your snus?”



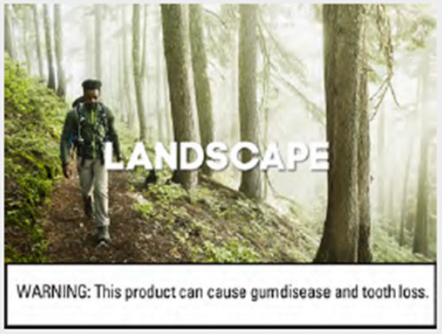
WARNING: This product can cause mouth cancer.

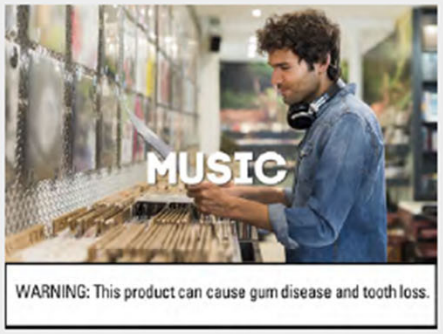
Q3 General Snus Facebook Cover Image & Profile Photos

Swedish Match

General Snus July ‘21 Facebook Posts

7/2





7-2-21 July4 What Swedes Love_Gen FB.mp4

General Snus July ‘21 Facebook Posts

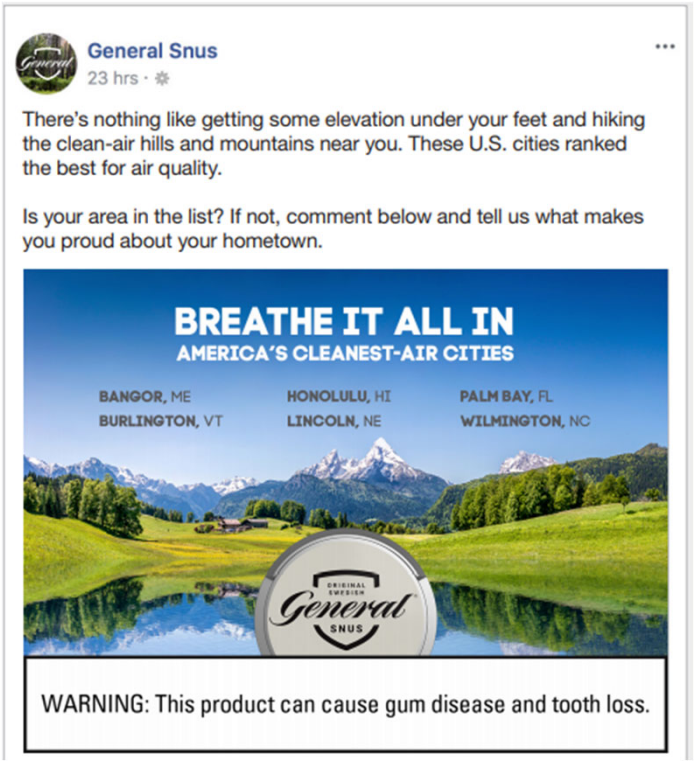
7/7

7/9

7/13

General Snus July ‘21 Facebook Posts

7/15



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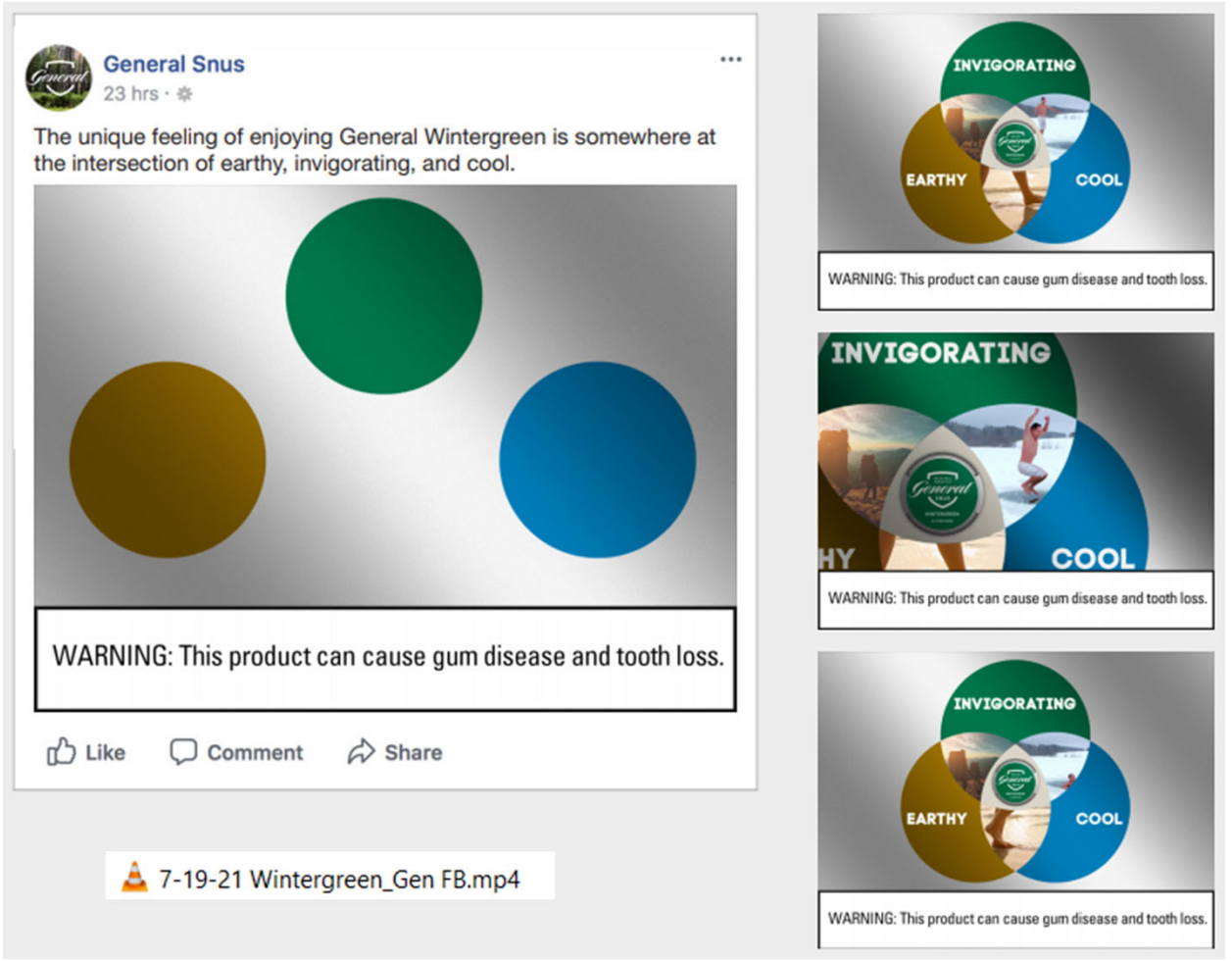
7/19



General Snus July ‘21 Facebook Posts

7/21

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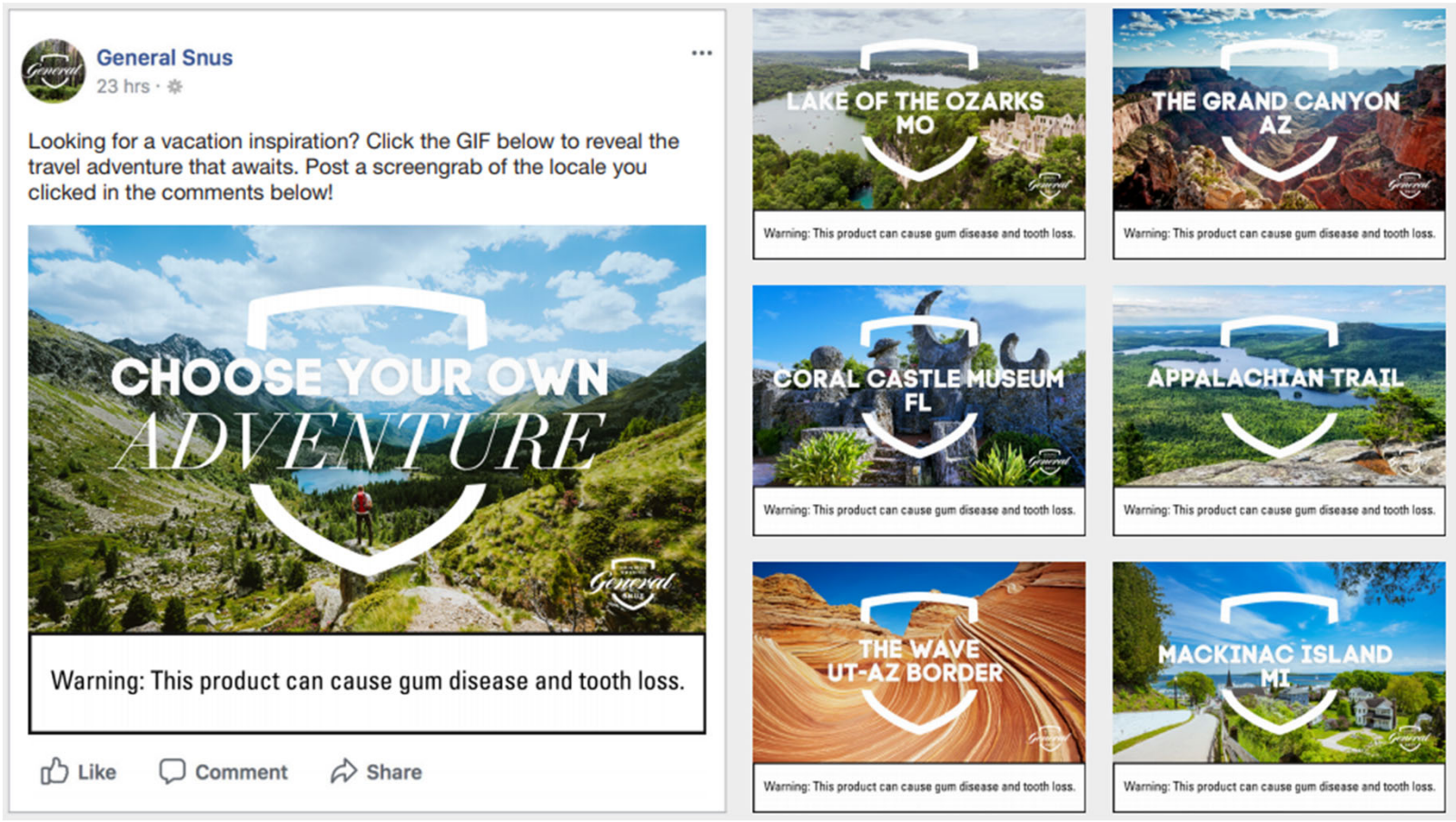
General Snus July ‘21 Facebook Posts

7/23



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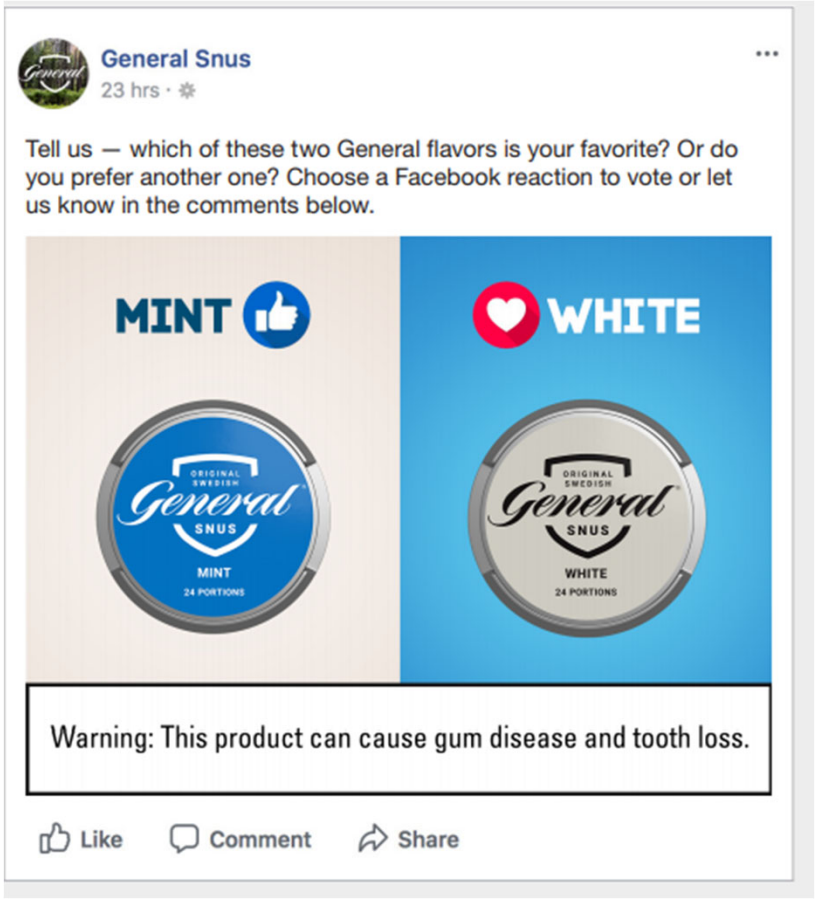
7-23-21 Social_Adventure_Gen FB.mp4

General Snus July ‘21 Facebook Posts

7/28



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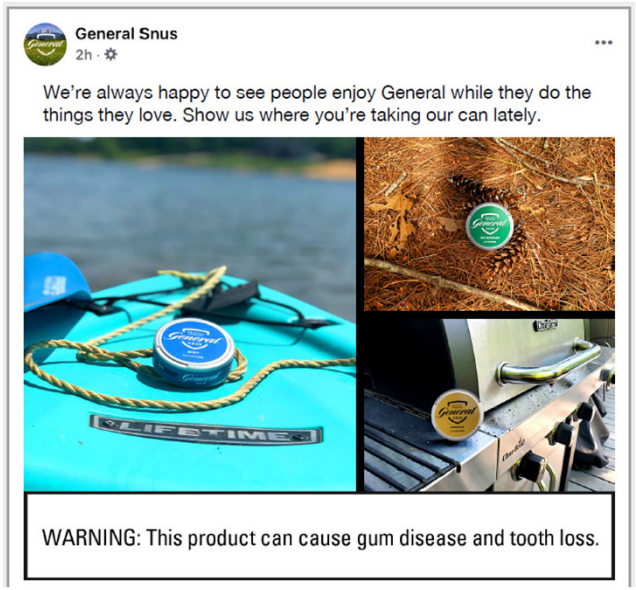
General Snus August ‘21 Facebook Posts

8/3



8/5

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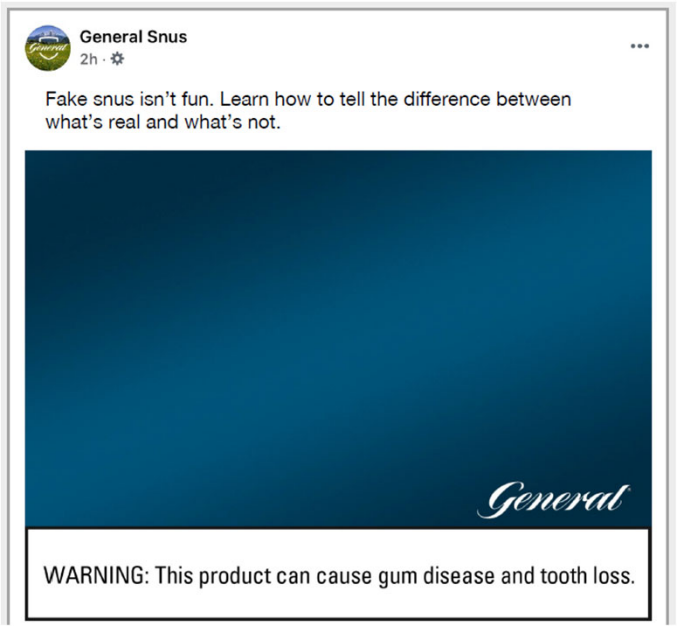
General Snus August ‘21 Facebook Posts

8/6

8-6-21 Real Story Electricity_Gen FB.mp4

8/9



8-9-21 How To Spot Fake Snus Pt 2_Gen FB.mp4

8/12

8-12-21 Map For Living_Gen FB.mp4

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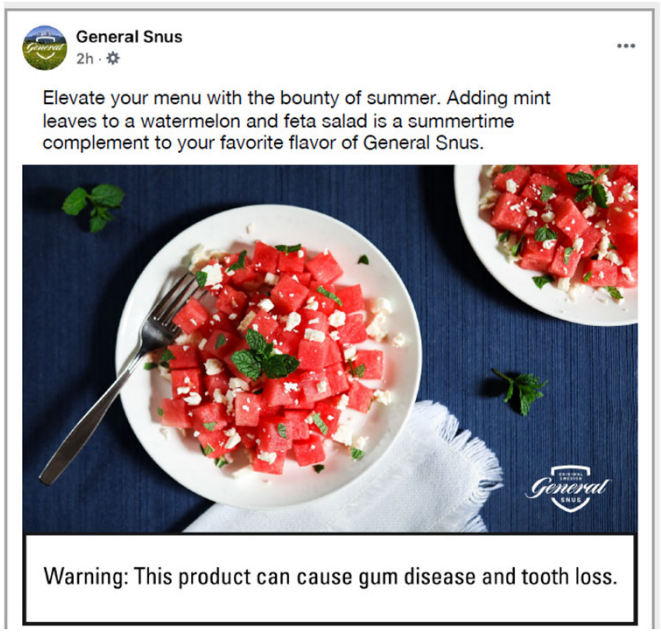
General Snus August ‘21 Facebook Posts

8/13



8/17

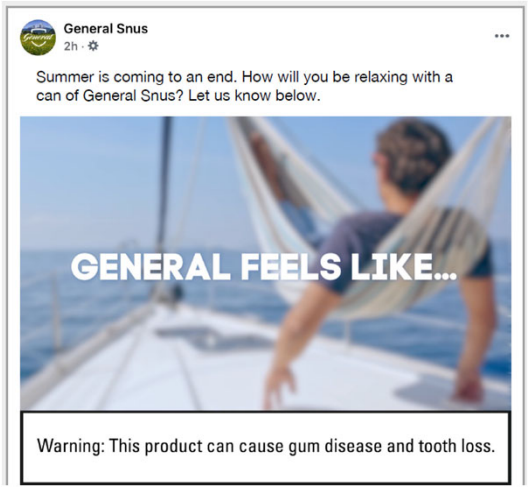
8-17-21 _Social_Can Reveal Gen.mp4

8/19

[redacted]

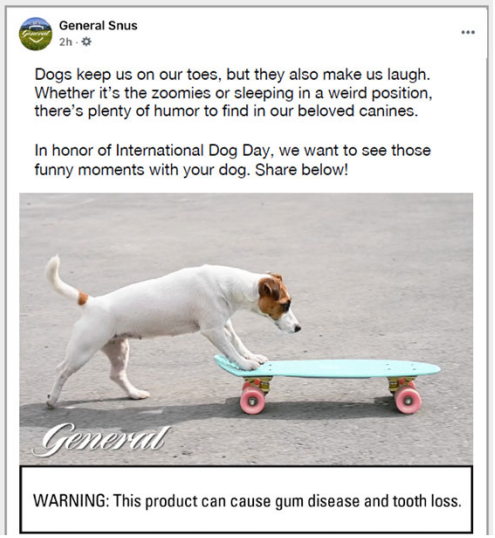
General Snus August ‘21 Facebook Posts

8/24



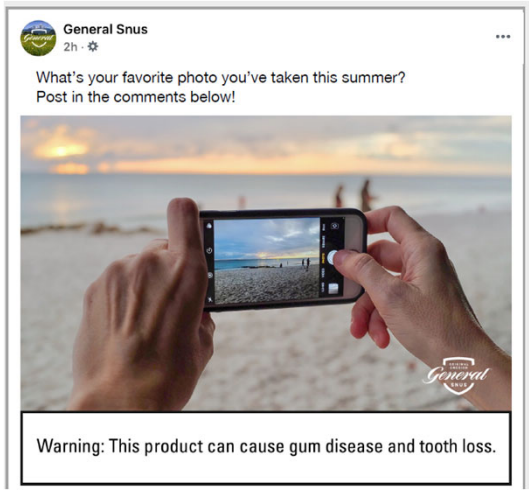
8-24-21 General Is Gen_FB_8-24.mp4

8/26



8-26-21 Intnrl Dog Day_Gen FB.mp4

8/27



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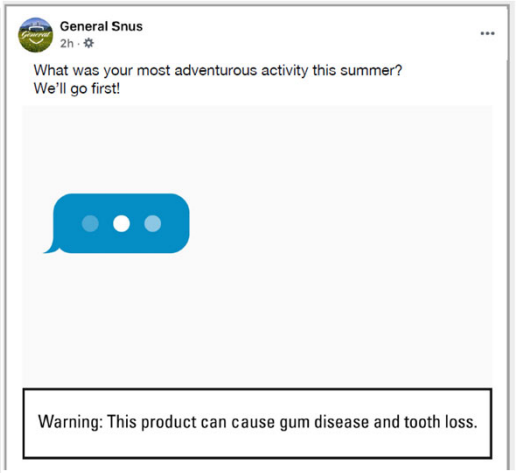

8-31-21 Greatest Summer Adventure_Gen FB.mp4

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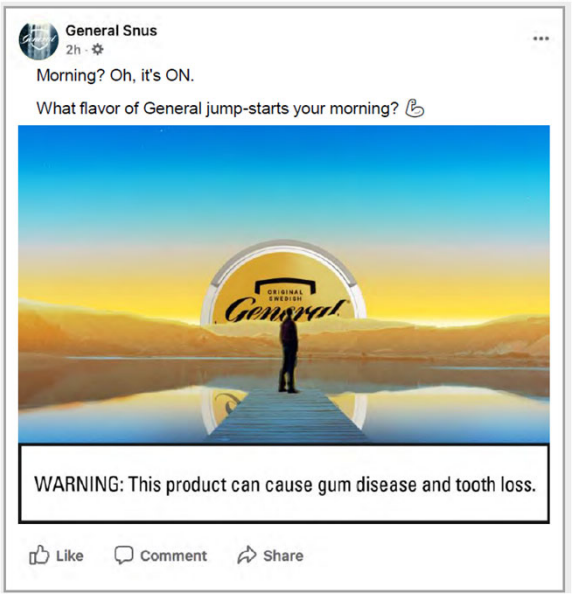
General Snus September ‘21 Facebook Posts

9/1



9-1_GEN_September-Social_Morning.mp4

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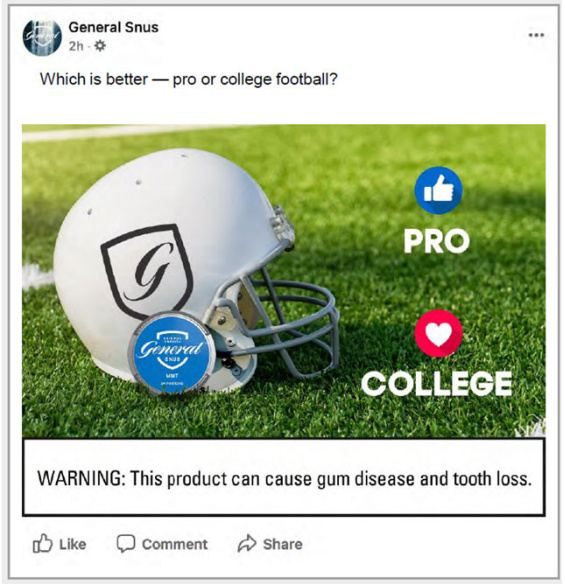
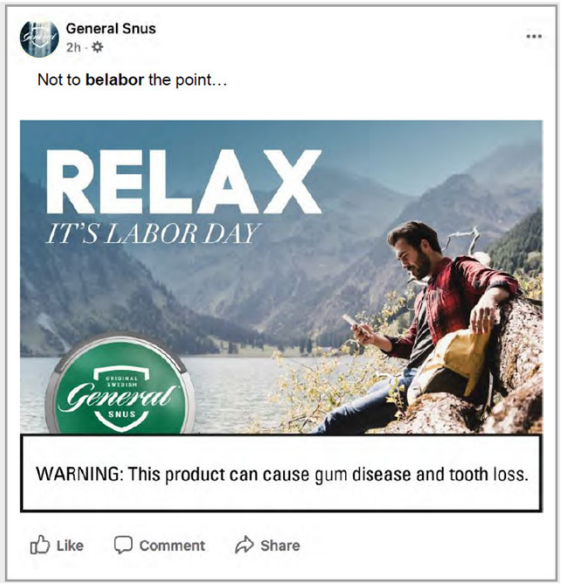
9/3

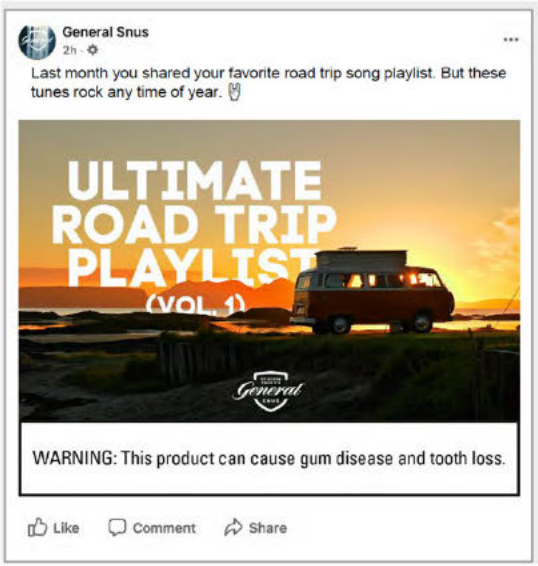


9/6



General Snus September ‘21 Facebook Posts

9/7



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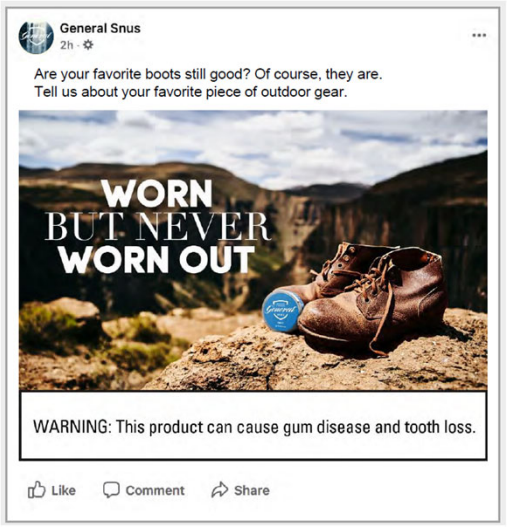
9-10_GEN_September-Snus_Facts.mp4

9/13

Swedish Match

General Snus September ‘21 Facebook Posts

9/15



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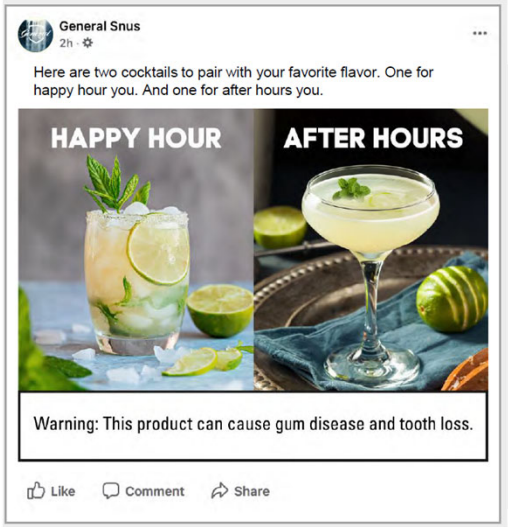


Additional PC:

MINT SPLIT
*****
Classic Mojito
6 mint leaves, plus additional for garnish
1oz (2 tablespoons) lime juice
1oz (2 tablespoons) simple syrup
2oz (4 tablespoons) white rum
2–4oz soda water
In cocktail shaker, muddle mint leaves. Add lime juice, simple syrup, and rum. Fill shaker with ice and shake until cold. Strain into glass with fresh ice and top off with soda water. Garnish with additional mint leaves.
*****
Southside Cocktail
2oz gin
1oz fresh lime juice
½ pour (.75oz) simple syrup
8–10 fresh mint leaves
2 dashes bitters
Mint leaf to garnish
Combine all ingredients in a cocktail shaker filled with ice and shake vigorously for 15–20 seconds. Double strain and garnish with a mint leaf.

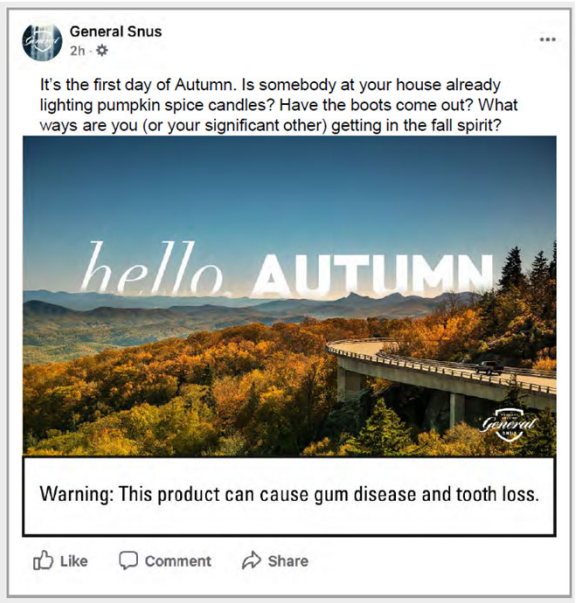
9/21

9-21_GEN_September-Social_Ask-Johan.mp4

[redacted]

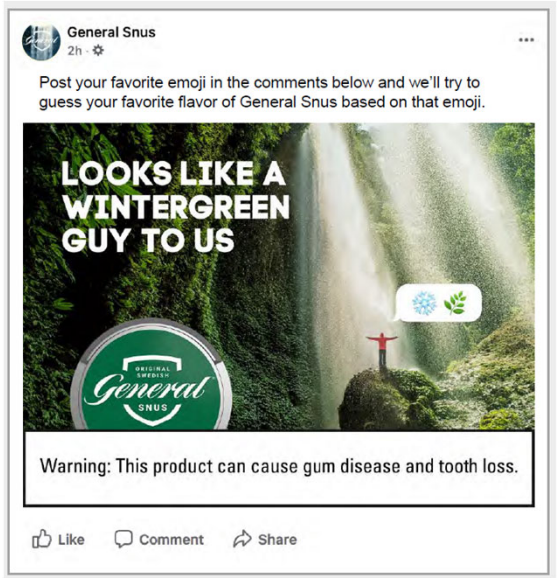
General Snus September ‘21 Facebook Posts

9/22



9/24

9/29



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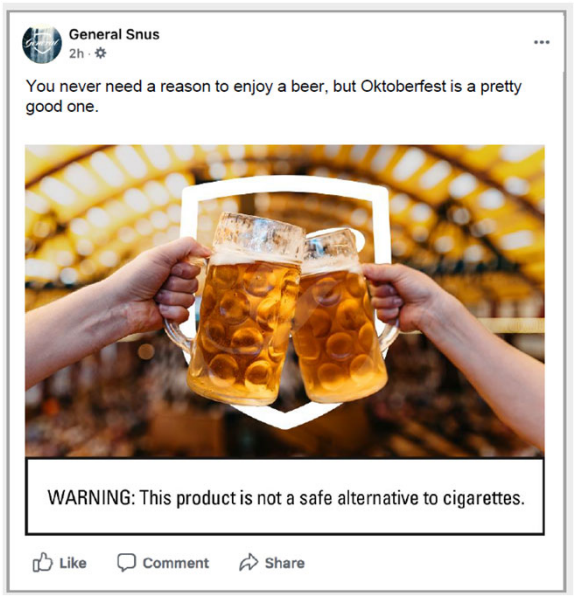
General Snus October ‘21 Facebook Posts

10/1



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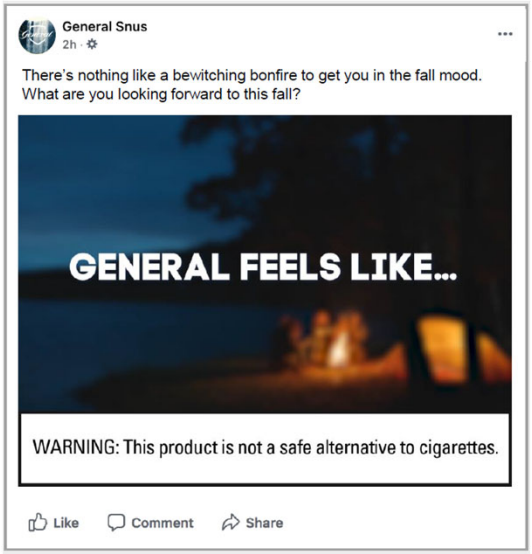
General Snus October ‘21 Facebook Posts

10/6



10-6-21. FeelsLike Fall Campfire Gen FB.mp4

10/8

10-8-21 AskJohan Pumpkin Spice Gen FB.mp4

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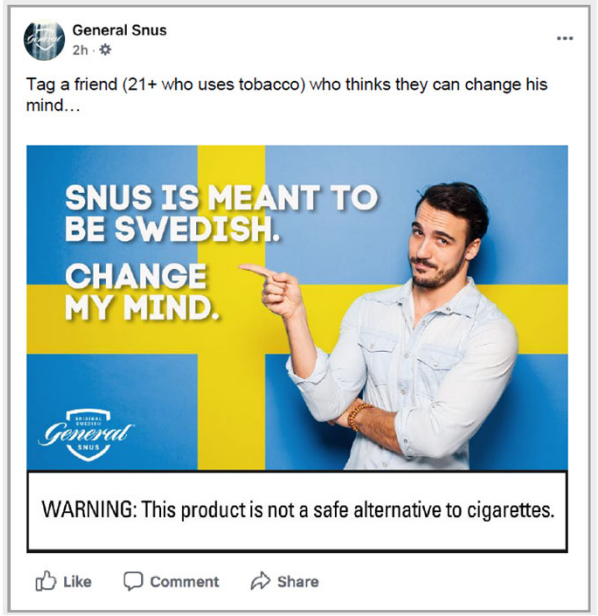
General Snus October ‘21 Facebook Posts

10/12

10/15

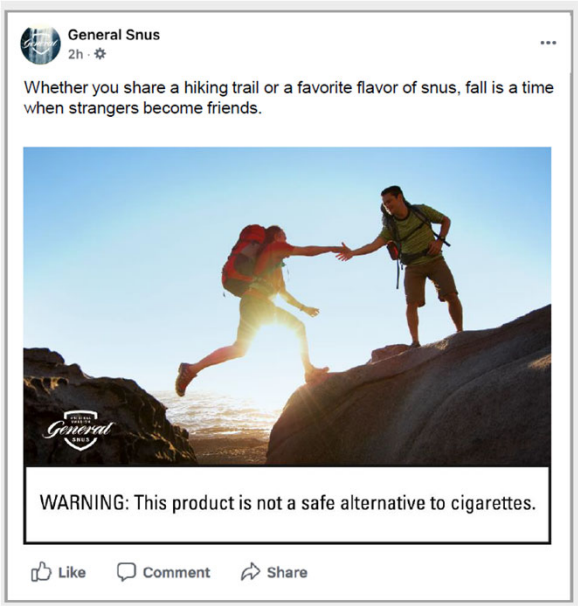


10/18

[redacted]

General Snus October ‘21 Facebook Posts

10/20



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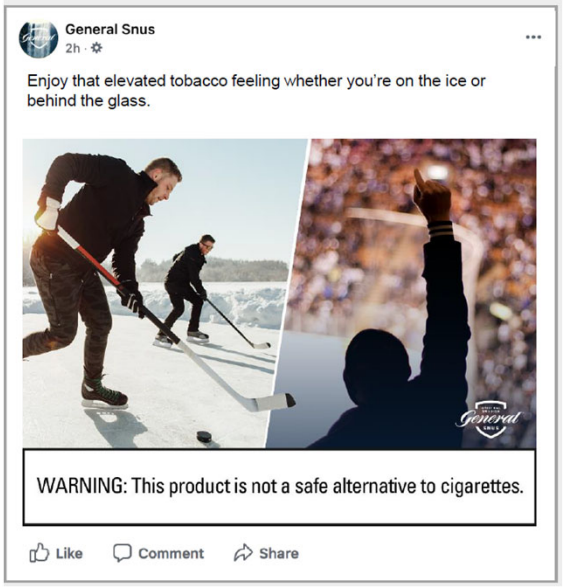

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General Snus October ‘21 Facebook Posts

10/26

10-26-21 TheOriginalStory Frankenstein Gen FB.mp4

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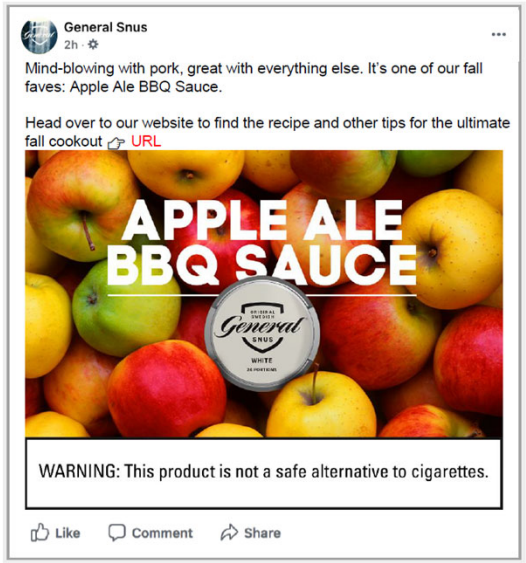
10/28



RECIPE COPY:

4 teaspoon butter
1 clove garlic, minced
1 small onion, diced
2 cups ketchup
1 cup apple ale
4 teaspoons sugar
4 teaspoons barbeque sauce
1/3 cup cider vinegar
2 teaspoons Dijon mustard
Freshly ground black pepper

In a large pot, melt butter and cook onions and garlic until soft. Add remaining ingredients and stir until blended. Blend further in a food processor until smooth. Taste test and adjust ingredients if needed. Makes about 4 cups of sauce.

General Snus October ‘21 Facebook Posts

10/29

COMMENTS COPY/ADDITIONAL PC:

Classic Bloody Mary
1 tsp sea salt
1 cup ice
1 ½ oz. vodka
¾ cup spicy tomato juice
2 dashes Worcestershire sauce
1 dash hot sauce
Salt and pepper to taste
1 stalk celery
2 stuffed green olives

Salt the rim of a tall glass and fill it with ice cubes. In a cocktail mixer full of ice, combine the vodka, tomato juice, Worcestershire sauce, hot sauce, salt and pepper. Shake vigorously and strain into the glass. Garnish with celery and olives stuck onto a toothpick.

[redacted]

Oct. ‘20 General Snus Facebook .mp4 File Guide

.mp4 Image

.mp4 File Name and Length & description

10-06-20 Gen LAGOM-FB.mp4

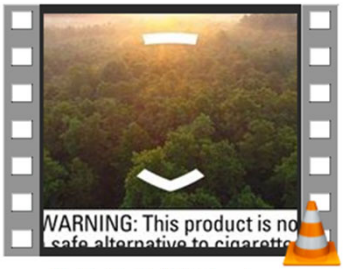
10-06-20 Gen LAGOM-FB.mp4 00:00:07

Defines the Swedish term LAGOM, perfect balance.

10-15-20 Gen Snus was born-FB.mp4

10-15-20 Gen Snus was born-FB.mp4 00:00:20

General Snus was born 1866, 1st movie played 1877, #1 selling snus 2000



10-28-20 LNT Thank you Gen-FB.mp4

10-28-20 LNT Thank you Gen-FB.mp4 00:00:04

Thanking consumers for participating in the Leave No Trace program.

Swedish Match 63

Nov. ‘20 General Snus Facebook .mp4 File Guide

.mp4 Image | **.mp4 File Name and Length & description**

11-12-20 Sustainability Gen-FB.mp4

11-12-20 Sustainability Gen-FB.mp4 00:00:06

Each can makes a difference.

11-18-20 Ticket 1890 Gen-FB.mp4

11-18-20 Ticket 1890 Gen-FB.mp4 00:00:12

1866 first can of General Snus. 1890 first electric train.

11-30-20 Arctic Gen-FB.mp4

11-30-20 Arctic Gen-FB.mp4 00:00:10

Shows dogs pulling a dog sled

Swedish Match 64

Dec. ‘20 General Snus Facebook .mp4 File Guide

.mp4 Image **.mp4 File Name and Length & description**

12-09-20 Every Season Gen-FB.mp4

12-09-20 Every Season Gen-FB.mp4 00:00:12

Features each of the four flavors of General for each of the four season.

12-18-20 Fairyland Gen-FB.mp4

12-18-20 Fairyland Gen-FB.mp4 00:00:14

Mt. Eleanor Trail WA, Fairyland Loop UT, Harding Icefield Trail AK

12-26-20 A star is born Gen-FB.mp4

12-26-20 A star is born Gen-FB.mp4 00:00:06

Shows can spinning, featuring star formation of pouches, ending with image of White can.

Swedish Match 65

Jan. – Feb. ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
1-7 Growing Herbs_GEN_FB.mp4	1-7 Growing Herbs_GEN_FB.mp4 00:00:25	Illlustrates the five-Step process for growing herbs: source seedlings, pot them in soil, get full four days of sun/day, harvest a little at a time, wrap trimmings in a damp towel & put in a plastic bag.
1-9 Breathing Technique_GEN_FB.mp4	1-9 Breathing Technique_GEN_FB.mp4 00:00:34	Illustrates the 3-2-1 Breathing technique: Inhale, Hold, Exhale.
1-17 Lower Risk Table_GEN_FB.mp4	1-17 Lower Risk Table_GEN_FB.mp4 00:00:12	Shows a table that compares Swedish Snus and Cigarettes. Shows checks and Xs for mouth cancer, lung cancer, heart disease, stroke and which ones Swedish Snus and Cigarettes causes.
2-18 Ingredients Perfection_GEN_FB.mp4	2-18 Ingredients Perfection_GEN_FB.mp4 00:00:07	Lists ingredients of General Snus: water, salt, flavor. Don’t mess with perfection.

Swedish Match 66

Feb.-March ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
2-21 All Cans_GEN_FB. mp4	2-21 All Cans_GEN_FB.mp4 00:00:12	Shows each of the four General Snus flavors and the flavor profile for each. Tobacco, spicy bergamot, mint/leather, peppermint.
3-9 Seasons_GEN_ FB.mp4	3-9 Seasons_GEN_FB.mp4 00:00:08	Shows each of the four flavors of General Snus with imagery behind the cans that feature nature: Mint = water, wintergreen = grass, white = ski boat making peaks, original = sunflower.
3-15 How To Spot Fake Snus_GEN_FB.	3-15 How To Spot Fake Snus_GEN_FB.mp4 00:00:20	Describes how to spot fake snus: Undersize portion, overly sweet, made outside of Sweden.
3-18 Adventure is in the Air_GEN_FB....	3-18 Adventure is in the Air_GEN_FB.mp4 00:00:11	Shows imagery of running water through rapids.

Swedish Match

March-April ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
3-30 Weekender_GEN_FB.mp4	3-30 Weekender_GEN_FB.mp4 00:00:22	Shows images of how a man might spend his time on a weekend in different settings. No cell service Fri. 5pm-Mon. 9am, second home is a cave, only trails he uses are game trails, whitewater & elevation.
4-10_Dig Deeper_GEN_FB.mp4	4-10_Dig Deeper_GEN_FB.mp4 00:00:08	Shows a person kayaking on whitewater rapids, digging oar deeper.
4-22_Earth Day_GEN_FB.mp4	4-22_Earth Day_GEN_FB.mp4 00:00:08	Celebrates Earth Day and states what it means for General Snus: Disposable compartment, recyclable cans, spitless, smokeless.
4-24_Record Player_GEN_FB.mp4	4-24_Record Player_GEN_FB.mp4 00:00:07	Shows an image of record spinning on record player. The middle part of the record, the label is can of General original.

Swedish Match

May ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
5-1_GEN_May_FB.the original.mp4	5-1_GEN_May_FB.the original.mp4 00:00:08	Shows a timeline, the first date being 1866 when General debuted and the second time being 1875, the date when the 1st horse race took place.
5-4_GEN_May_FB.be happy.mp4	5-4_GEN_May_FB.be happy.mp4 00:00:17	Shows different images of nature that look like smiling faces.
5-7_GEN_May_FB.jetski the blend.mp4	5-7_GEN_May_FB.jetski the blend.mp4 00:00:03	Shows a jetski going around in circles in green water with the General logo in the middle.
5-12_Post_Ingredient-Infographic.mp4	5-12_Post_Ingredient-Infographic.mp4 00:00:24	Describes where the General Snus process meets perfection: Lists & shows icon of each, Prem tobacco + pure water + salt + natural flavors = General Snus.

Swedish Match

June ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image	.mp4 File Name and Length	.mp4 Descripton
6-11 GEN_June_FB. Fishing.mp4	6-11 GEN_June_FB. Fishing.mp4 00:00:02	Shows a man fishing with a fish on his hook, trying to pull it into the boat.
6-15_GEN_June_FB.Best Selling Snus.mp4	6-15_GEN_June_FB.Best Selling Snus.mp4 00:00:08	Features each of the four flavors: Elevate (white), Worlds best- selling (wintergreen), Gothiatek (mint) and The Original (original).
6-23_GEN_June_FB.silboat and can.mp4	6-23_GEN_June_FB.silboat and can.mp4 00:00:08	Shows a sailboat on blue waters and the mint General Snus can coming in, framing the image.

Swedish Match

July ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image **.mp4 File Name and Length & description**

7-2-21 July4 What Swedes Love_Gen FB.mp4

7-2-21 July4 What Swedes Love_Gen FB.mp4 00:00:15

Shows four things Swedes love about America: Cars, Landscape, Music & Friendliness

7-19-21 Wintergreen_Gen FB.mp4

7-19-21 Wintergreen_Gen FB.mp4 00:00:16

Illustrates the three elements that describe wintergreen General Snus

7-23-21 Social_Adventure_Gen FB.mp4

7-23-21 Social_Adventure_Gen FB.mp4 00:00:09

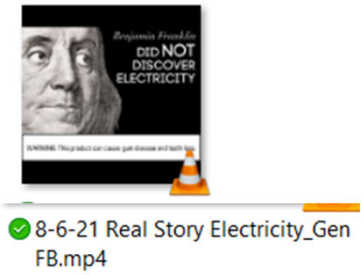
Shows places to explore an adventure: Grand Canyon, The Wave, Appalachian Trail, Georgia Aquarium

Swedish Match 71

August‘21 General Snus Facebook .mp4 File Guide

.mp4 Image

.mp4 File Name and Length & description



8-6-21 Real Story Electricity_Gen FB.mp4

8-6-21 Real Story Electricity_Gen FB.mp4 00:00:22

Tells the story that Benjamin Franklin did not discover electricity – and who did.

8-9-21 How To Spot Fake Snus Pt 2_Gen FB.mp4

8-9-21 How To Spot Fake Snus Pt 2_Gen FB.mp4 00:00:13

Tells Part 2 of the story, “How to Spot Fake Snus”

8-12-21 Map For Living_Gen FB.mp4

8-12-21 Map For Living_Gen FB.mp4 00:00:08

Shows map with can of General along the journey.

Swedish Match

August‘21 General Snus Facebook .mp4 File Guide

.mp4 Image

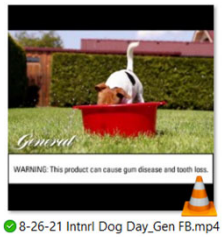
.mp4 File Name and Length & description

8-17-21 _Social_Can Reveal Gen.mp4 00:00:13

Cans of General reveal landscape image behind.

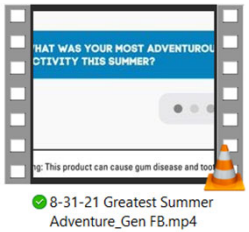
8-24-21 General Is Gen_FB_8-24.mp4 00:00:14

Shows man in hammock on a boat relaxing.



8-26-21 Intnrl Dog Day_Gen FB.mp4 00:00:15

Shows different images of dogs doing funny things.



8-31-21 Greatest Summer Adventure_Gen FB.mp4 00:00:14

Shows a mock post and response of a summer activity.

Swedish Match

September ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image **.mp4 File Name and Length & description**

9-1_GEN_September-Social_Morning.mp4

9-1_GEN_September-Social_Morning.mp4 00:00:12

Shows what appears to be the sun rising, represented by a can of General Original.

9-10_GEN_September-Snus_Facts.mp4

9-10_GEN_September-Snus_Facts.mp4 00:00:28

Shares several facts about Swedish Snus

9-21_GEN_September-Social_Ask-Johan.mp4

9-21_GEN_September-Social_Ask-Johan.mp4 00:00:14

Part of the “ask Johan” series. Asks what Johan’s Uber rating is.

Swedish Match

October ‘21 General Snus Facebook .mp4 File Guide

.mp4 Image | **.mp4 File Name and Length & description**

Gen_10-6.October_FeelsLike Fall Campfire.mp4 00:00:10

Shows group of people around a campfire.

GEN_10-8.October-Social_AskJohan Pumpkin Spice.mp4 00:00:13

Part of the “ask Johan” series. Asks what Johan Boman’s favorite pumpkin spice is.

GEN_10-26.October-Social_TheOriginalStory Frankenstein.mp4 00:00:23

Part of the “The Original Story” series. Explains the true story of the name ‘Frankenstein’.

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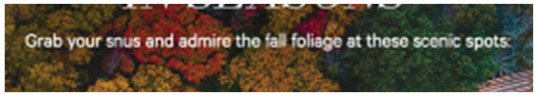
GENERAL SNUS EMAILS
Oct. 2020 – Oct. 2021

[redacted]

General Snus E-Mail Metrics

General Snus Oct. ‘20
EM 1 & 2



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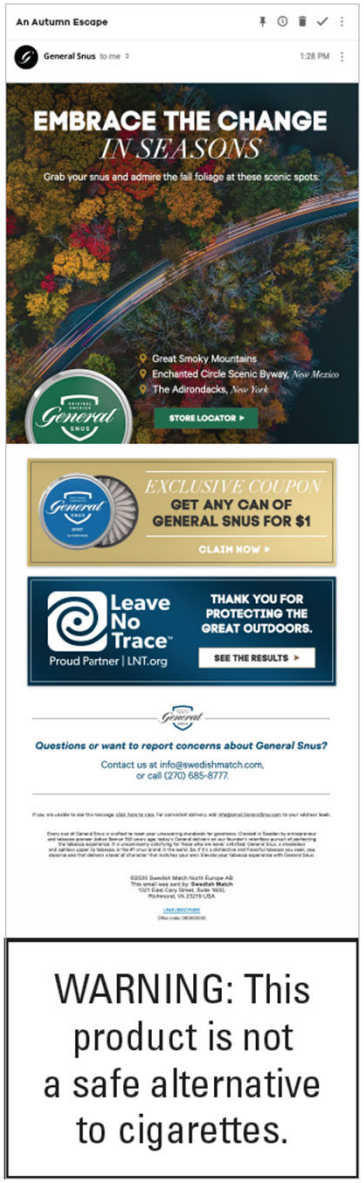

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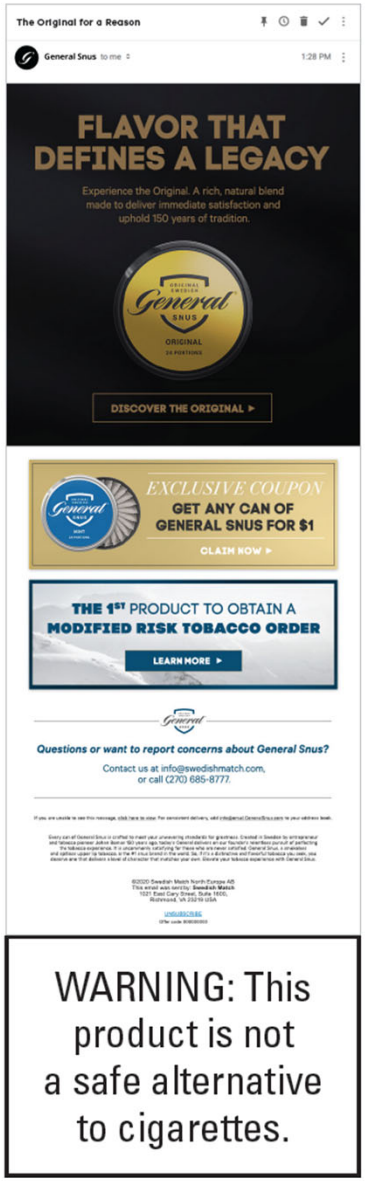

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General Snus Nov. ‘20
EM 1 & 2

This year give thanks for the great outdoors. Swap the dinner table for a tent and spend the day creating new Thanksgiving traditions together with friends and your favorite snus.

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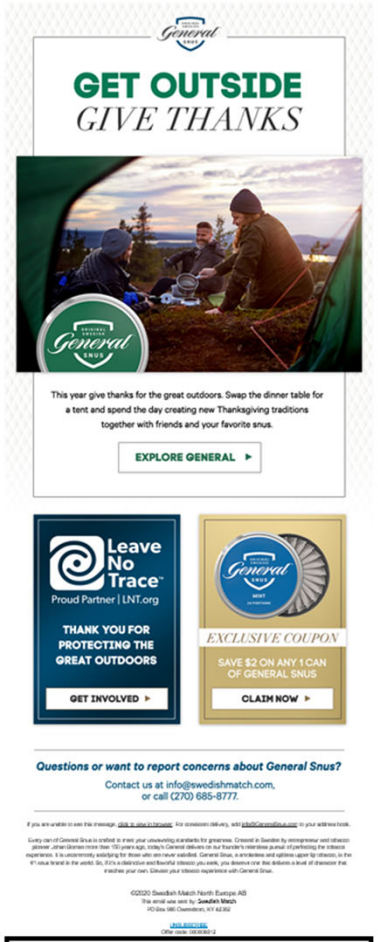

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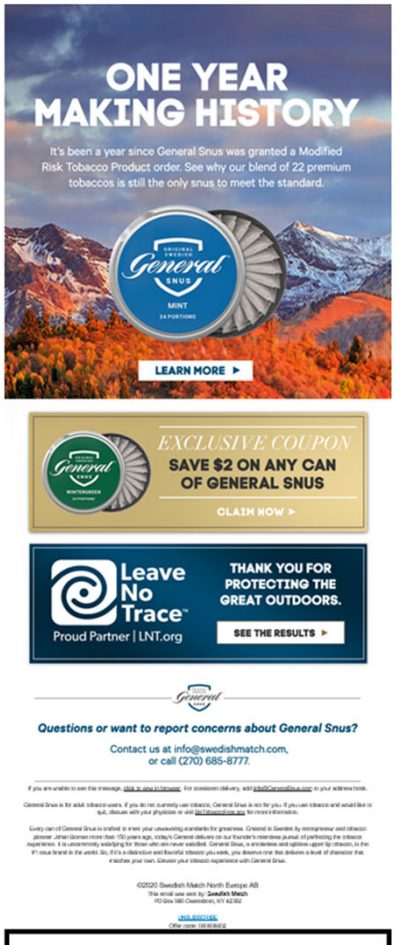

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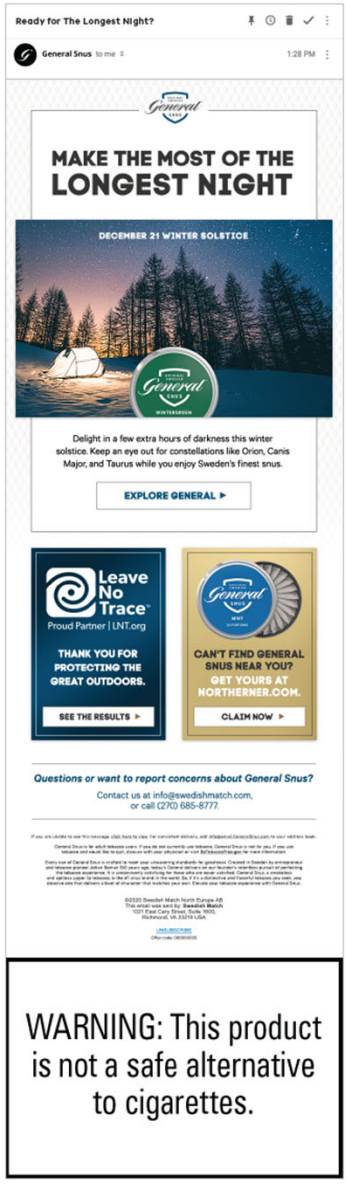
General Snus Dec. ‘20
EM 1 & 2



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Delight in a few extra hours of darkness this winter solstice. Keep an eye out for constellations like Orion, Canis Major, and Taurus while you enjoy Sweden's finest snus.

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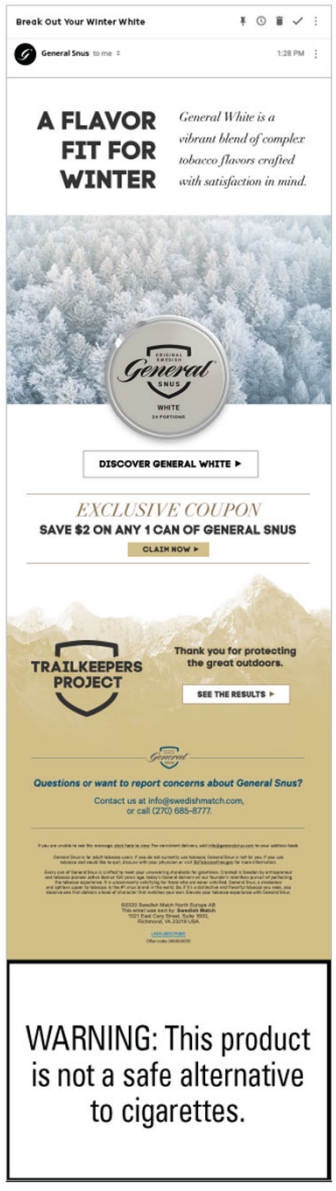

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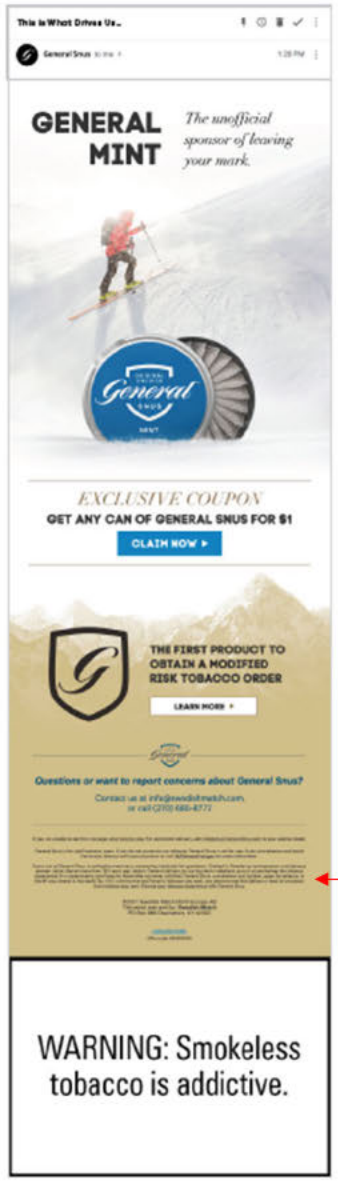
General Snus January EM1



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General Snus January EM2

The FDA has stated there is a continuum of risk. Combustible cigarettes sit at the highest risk end of the continuum, while Swedish Snus inhabits the lower risk end.

The perfect combination of cutting-edge science and old-world craft.

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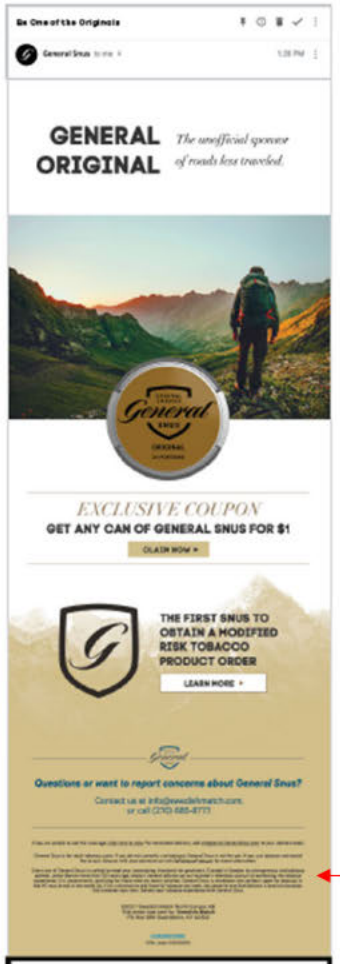
General Snus February EM 1



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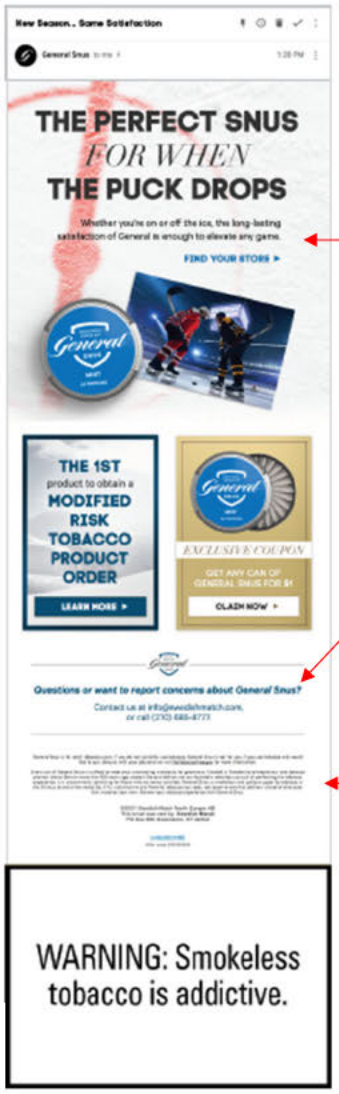
General Snus February EM 2



WARNING: Smokeless tobacco is addictive.

Whether you're on or off the ice, the long-lasting satisfaction of General is enough to elevate any game.

Questions or want to report concerns about General Snus?

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or call (270) 685-8777.

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General Snus March EM 1 – Non-Mobile Coupon Version

Non-Mobile Coupon Version

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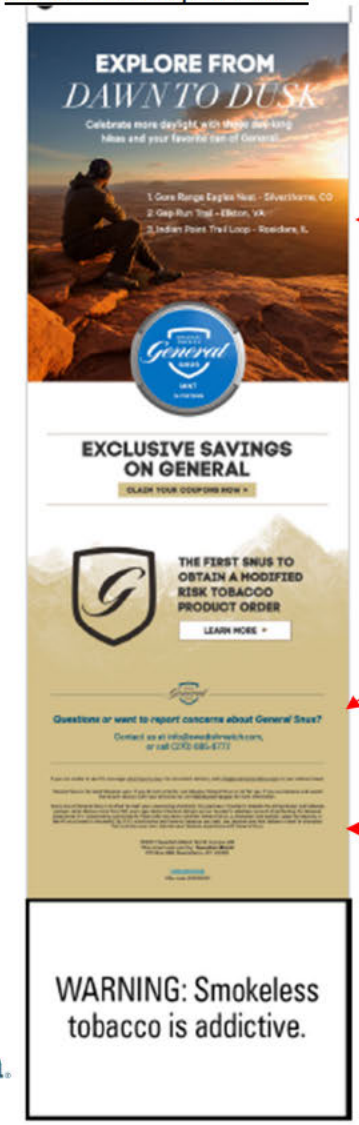
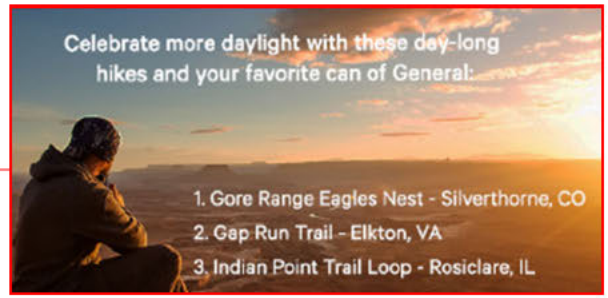
Non-Mobile Coupon Version

General Snus March EM 2 – Non-Mobile Coupon Version





Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com,
or call (270) 685-8777.

If you are unable to see this message, click here to view. For consistent delivery, add info@email.GeneralSnus.com to your address book.

General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

Every can of General Snus is crafted to meet your unwavering standards for greatness. Created in Sweden by entrepreneur and tobacco pioneer Johan Boman more than 150 years ago, today's General delivers on our founder's relentless pursuit of perfecting the tobacco experience. It is uncommonly satisfying for those who are never satisfied. General Snus, a smokeless and spitless upper lip tobacco, is the #1 snus brand in the world. So, if it's a distinctive and flavorful tobacco you seek, you deserve one that delivers a level of character that matches your own. Elevate your tobacco experience with General Snus.

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Mobile Coupon Version

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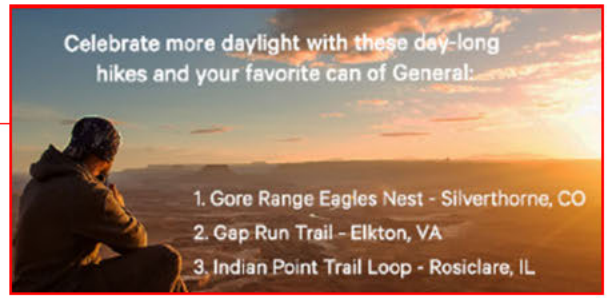

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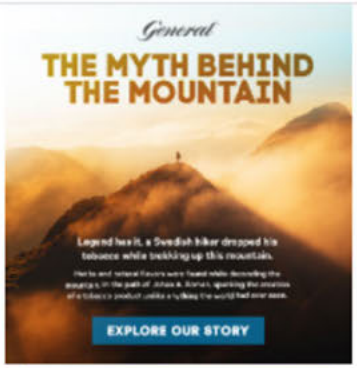
General Snus April EM 1 (no mobile coupon version)



WARNING: This product can cause mouth cancer.

Legend has it, a Swedish hiker dropped his tobacco while trekking up this mountain.

Herbs and natural flavors were found while decending the mountain, in the path of Johan A. Boman, sparking the creation of a tobacco product unlike anything the world had ever seen.

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When the winter frost melts into spring, one thing is sure to be true — waterfalls will be flowing. In Sweden, it's pure water found in waterfalls like Njupeskärsfallet that allows us to craft a tobacco experience like no other.

DISCOVER OUR PROCESS ▶

The perfect combination of cutting-edge science and old-world craft.

LEARN MORE ▶

EXCLUSIVE COUPON

GET ANY CAN OF GENERAL SNUS FOR $1

CLAIM NOW ▶

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General Snus April EM 2 – Mobile Coupon Version

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Mobile coupons are here.
Enjoy quick and easy savings on your favorite flavors of General.

GET YOURS NOW ▶

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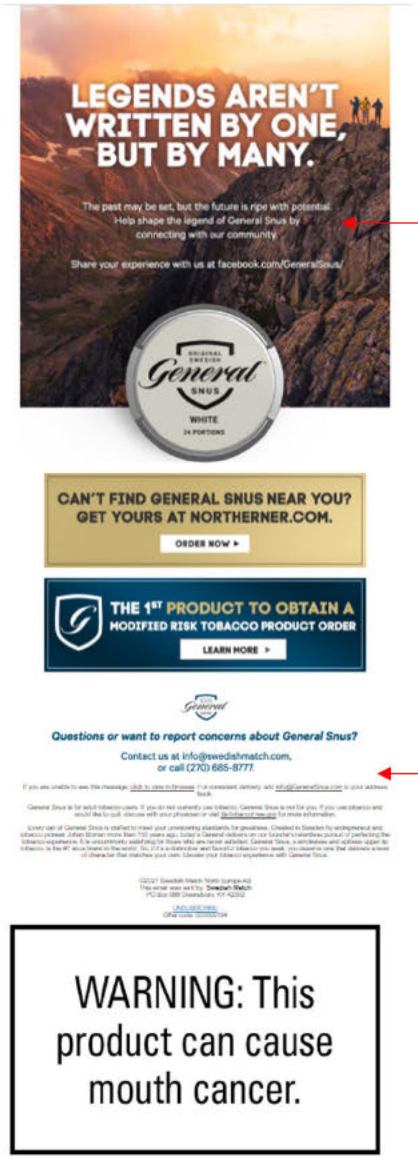
General Snus May EM 1



The past may be set, but the future is ripe with potential. Help shape the legend of General Snus by connecting with our community.

Share your experience with us at facebook.com/GeneralSnus/

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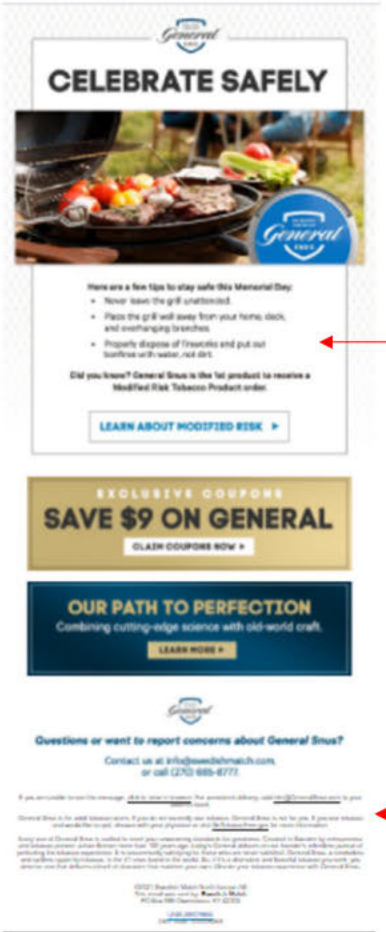
General Snus May EM 2



Here are a few tips to stay safe this Memorial Day:

- Never leave the grill unattended.
- Place the grill well away from your home, deck, and overhanging branches.
- Properly dispose of fireworks and put out bonfires with water, not dirt.

Did you know? General Snus is the 1st product to receive a Modified Risk Tobacco Product order.

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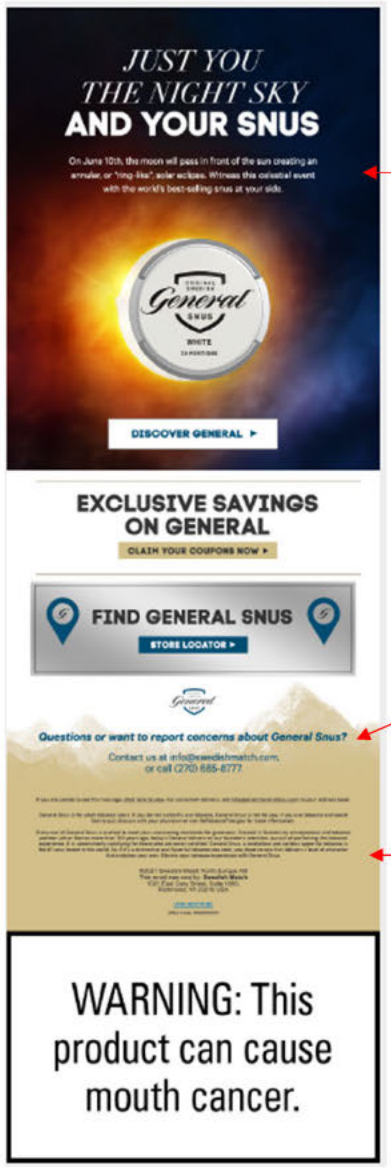
General Snus June EM 1



On June 10th, the moon will pass in front of the sun creating an annular, or "ring-like", solar eclipse. Witness this celestial event with the world's best-selling snus at your side.

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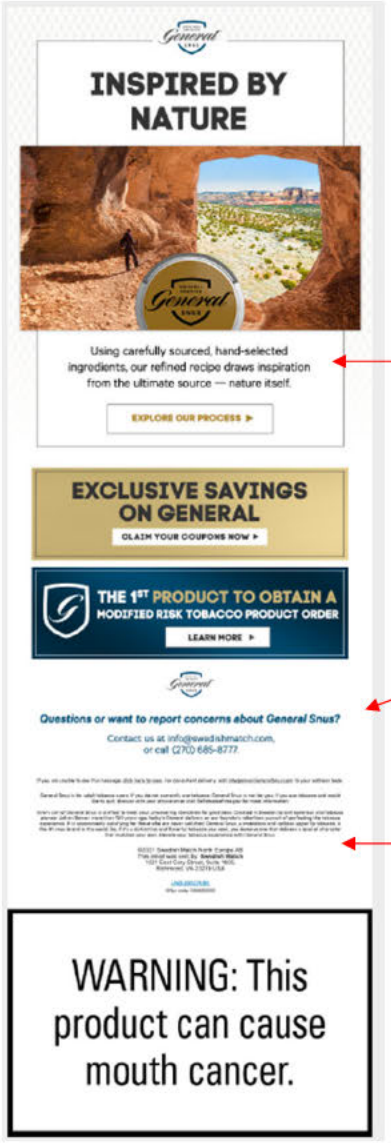
General Snus June EM 2



Using carefully sourced, hand-selected ingredients, our refined recipe draws inspiration from the ultimate source — nature itself.

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General Snus July EM1

The 4th of July holiday gives us a chance to reflect on our freedoms. But it's a celebration, too. The perfect time to kick back and pursue some happiness. In that spirit, we just wanted to say thanks for bringing us along for the ride.

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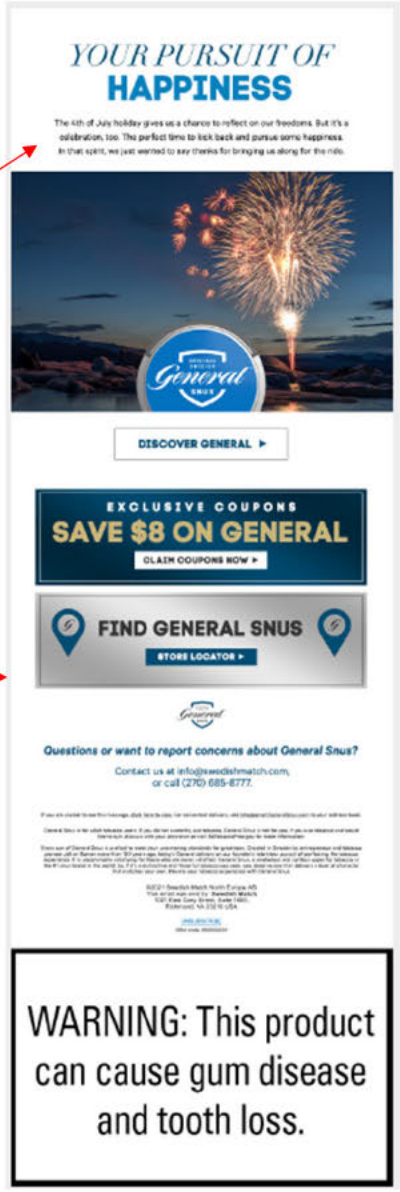

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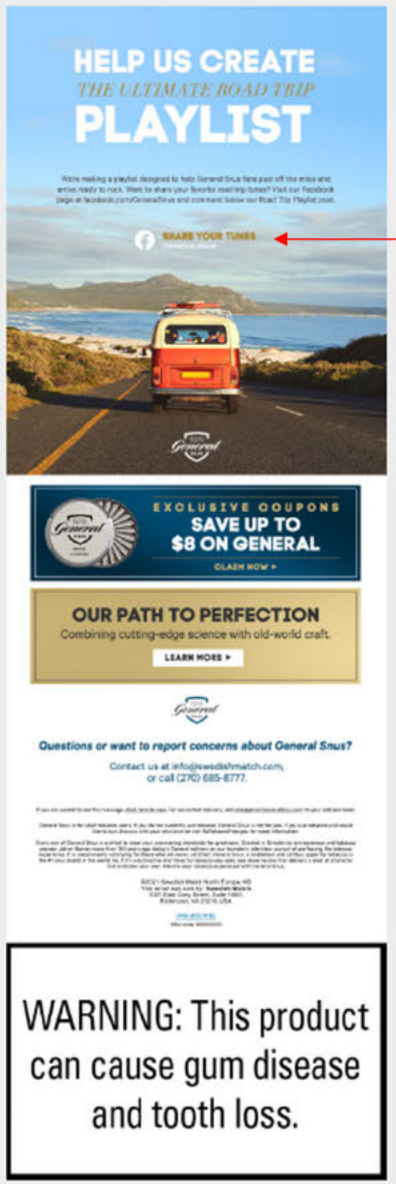
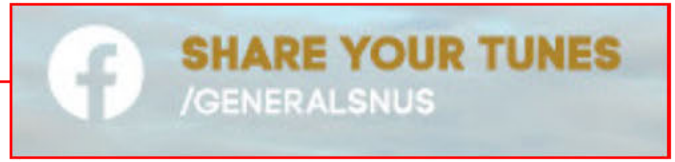
General Snus July EM2



We're making a playlist designed to help General Snus fans peel off the miles and arrive ready to rock. Want to share your favorite road trip tunes? Visit our Facebook page at facebook.com/GeneralSnus and comment below our Road Trip Playlist post.



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General Snus July EM3

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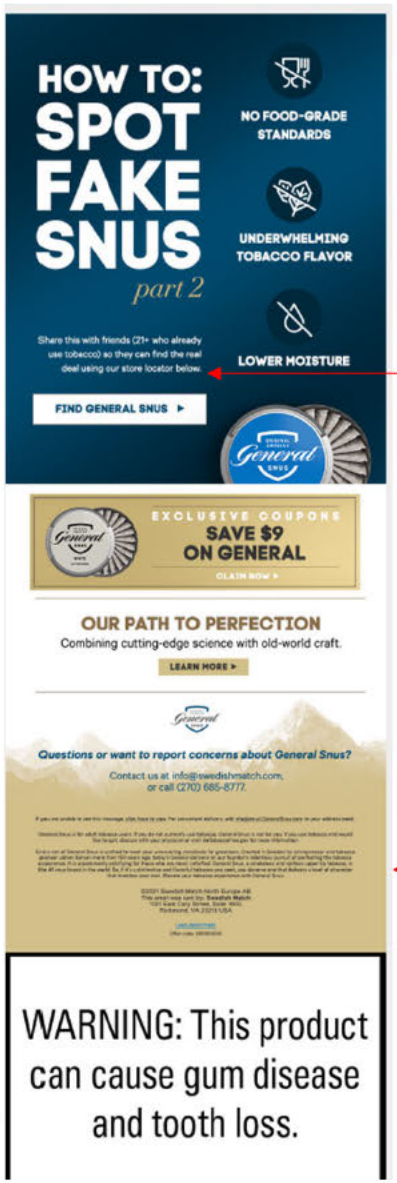
General Snus August EM 1



Share this with friends (21+ who already use tobacco) so they can find the real deal using our store locator below.

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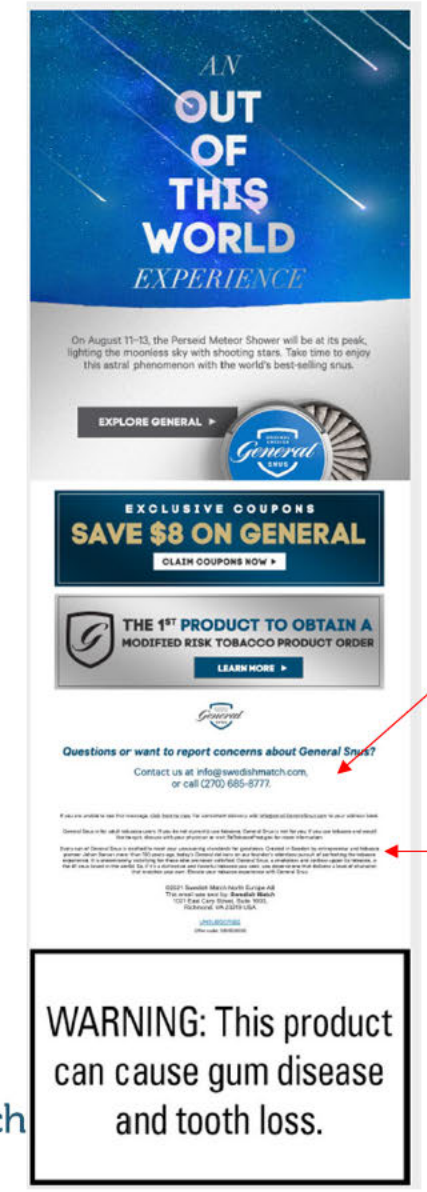
General Snus August EM 2



On August 11–13, the Perseid Meteor Shower will be at its peak, lighting the moonless sky with shooting stars. Take time to enjoy this astral phenomenon with the world's best-selling snus.

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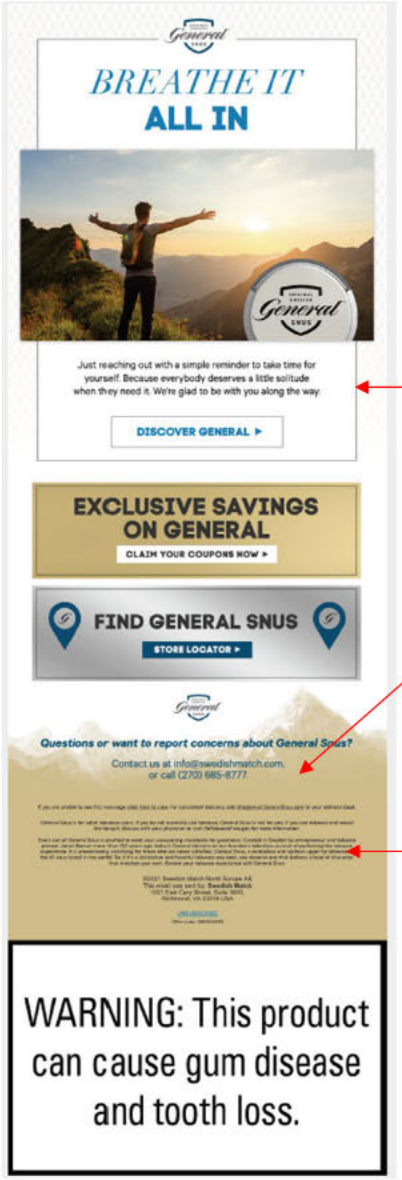

Just reaching out with a simple reminder to take time for yourself. Because everybody deserves a little solitude when they need it. We're glad to be with you along the way.

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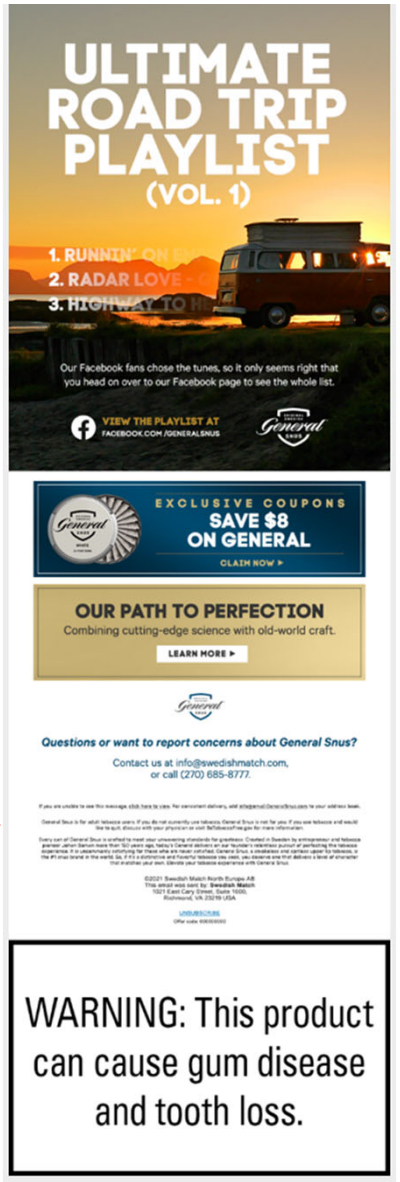

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General Snus September EM 2

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General Snus October EM 1

Fall is a season of fresh starts.
In Sweden, they say NY BÖRJAN, or "new beginning."
Enjoy this and more in our series of Swedish language lessons on Facebook.

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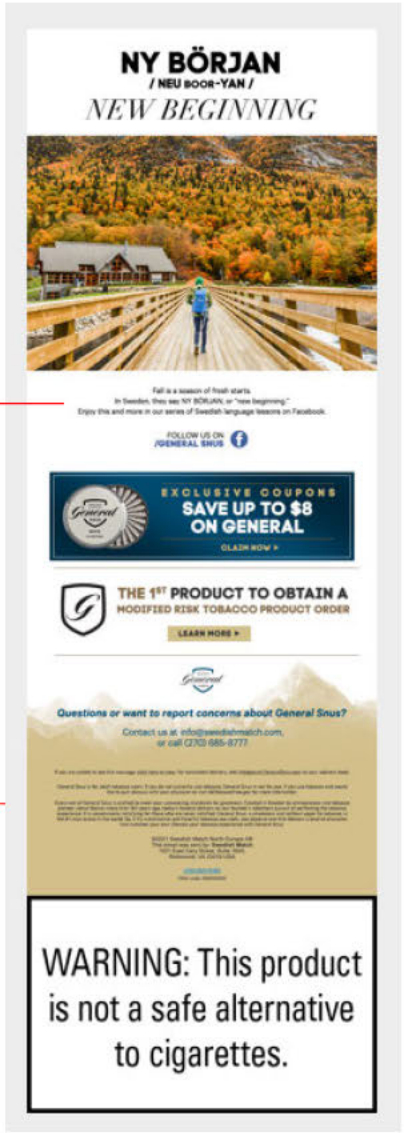
©2021 Swedish Match North Europe AB
This email was sent by: **Swedish Match**
1021 East Cary Street, Suite 1600,
Richmond, VA 23219 USA

UNSUBSCRIBE
Offer code: 000000000



Swedish Match

General Snus October EM 2

We may be the world's most storied tobacco brand, but we're always exploring new innovations. Which is why we've given our website a new look, so check it out.

Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com,
or call (270) 685-8777.

If you are unable to see this message, click to view in browser. For consistent delivery, add info@GeneralSnus.com to your address book.

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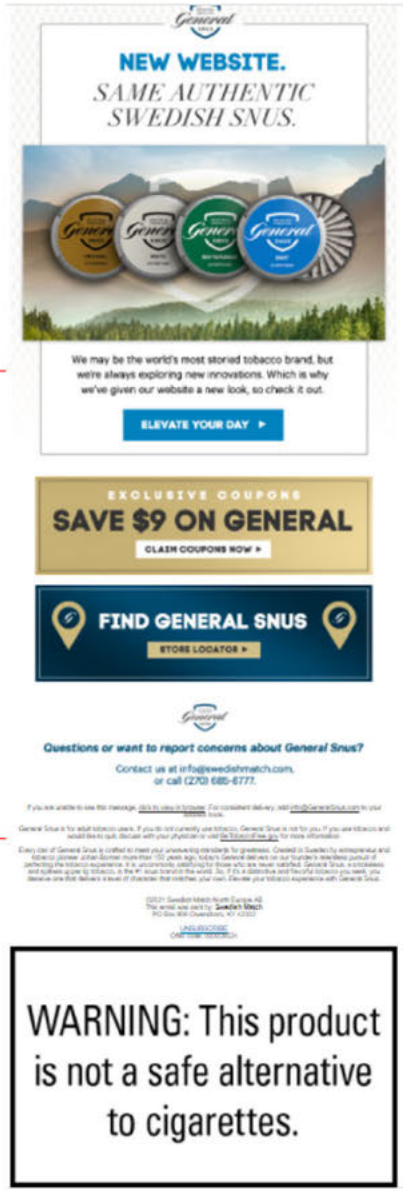
PO Box 986 Owensboro, KY 42302

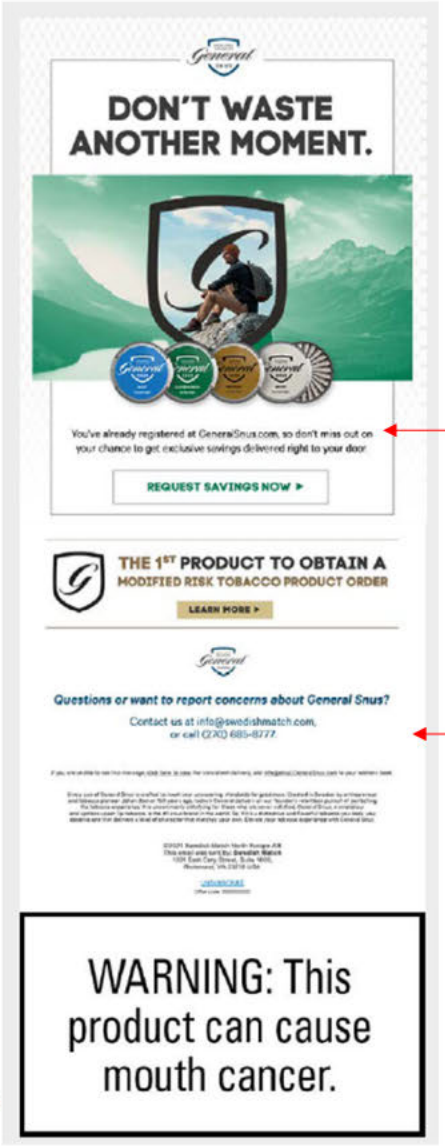
UNSUBSCRIBE
Offer code: 000009530



WARNING: This product is not a safe alternative to cigarettes.

Swedish Match

General Snus Ongoing E-mails: Site visitor, didn't request a coupon



You've already registered at GeneralSnus.com, so don't miss out on your chance to get exclusive savings delivered right to your door.

Questions or want to report concerns about General Snus?

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or call (270) 685-8777.

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UNSUBSCRIBE
Offer code: 000006936

Swedish Match

General Snus Ongoing E-mails:
Requested a coupon but have not redeemed a coupon

Claim your exclusive coupons today — and be sure to come back each month to receive your savings on the original Swedish snus.

Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com,
or call (270) 685-8777.

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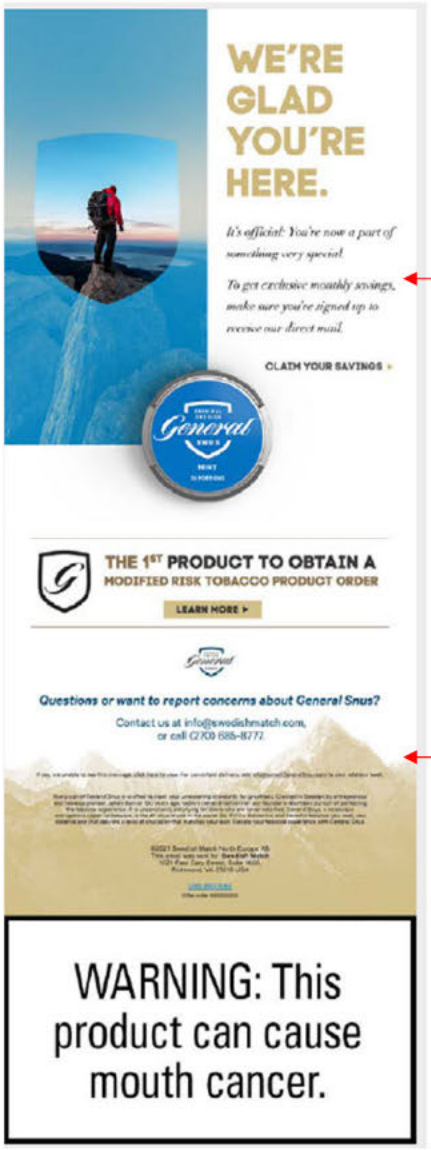
UNSUBSCRIBE
Offer code: 000006934

Swedish Match

General Snus Ongoing E-mails: Welcome E-mail, not opted-in for DM



It's official: You're now a part of something very special.

To get exclusive monthly savings, make sure you're signed up to receive our direct mail.

Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com,
or call (270) 685-8777.

If you are unable to see this message, click to view in browser. For consistent delivery, add info@GeneralSnus.com to your address book.

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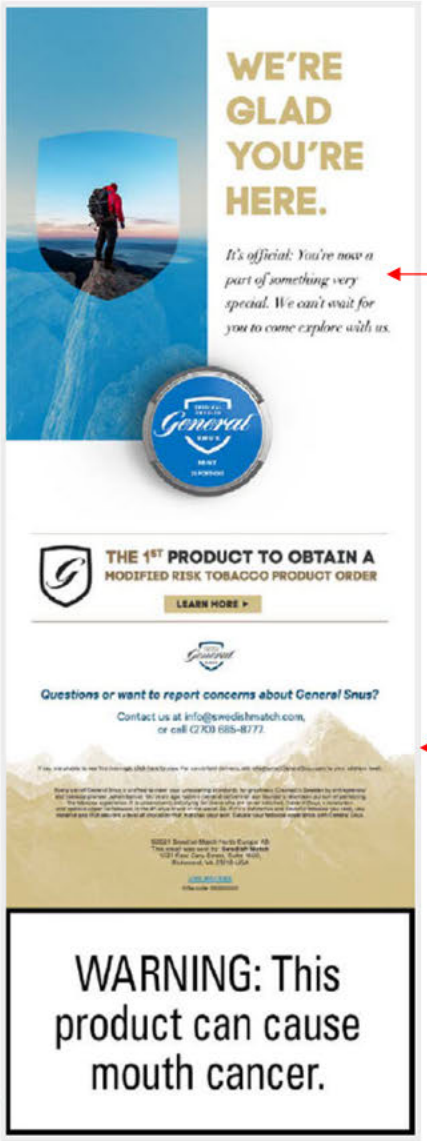
UNSUBSCRIBE
Offer code: 000006944

Swedish Match

General Snus Ongoing E-mails:
Welcome E-mail, geographies coupons not allowed



It's official: You're now a part of something very special. We can't wait for you to come explore with us.

Questions or want to report concerns about General Snus?

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or call (270) 685-8777.

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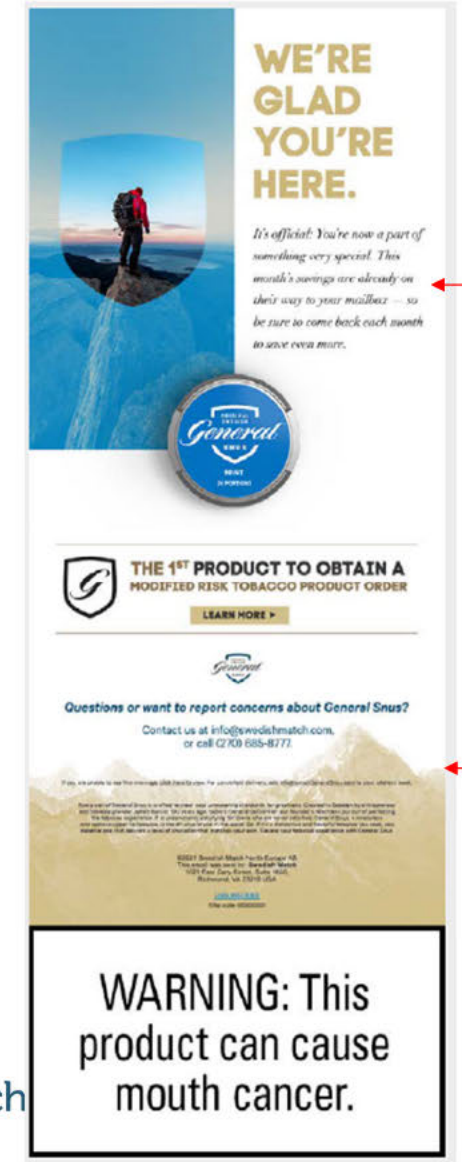
UNSUBSCRIBE
Offer code: 000009270

Swedish Match

General Snus Ongoing E-mails:
Welcome E-mail, new registrants opted-in for DM



It's official: You're now a part of something very special. This month's savings are already on their way to your mailbox — so be sure to come back each month to save even more.

Questions or want to report concerns about General Snus?

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UNSUBSCRIBE
Offer code: 000009272

Swedish Match

General Snus Ongoing E-mails: Birthday E-Mail, not opted-in for DM

Here's to everything you did, made, and accomplished in the past year. We're so glad we could be on this journey with you.

Questions or want to report concerns about General Snus?

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or call (270) 685-8777.

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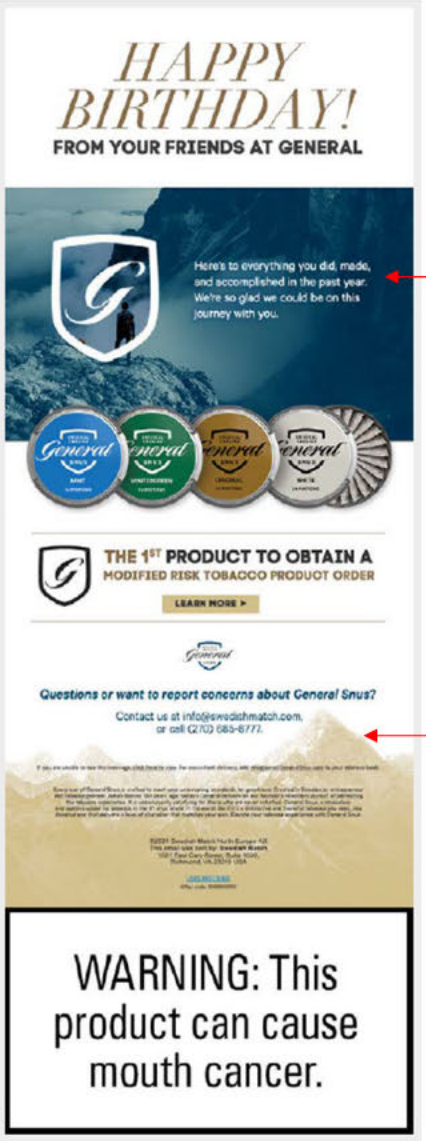
UNSUBSCRIBE
Offer code: 000006904

Swedish Match

General Snus Ongoing E-mails:
Birthday E-Mail, opted-in for DM & areas coupons not allowed



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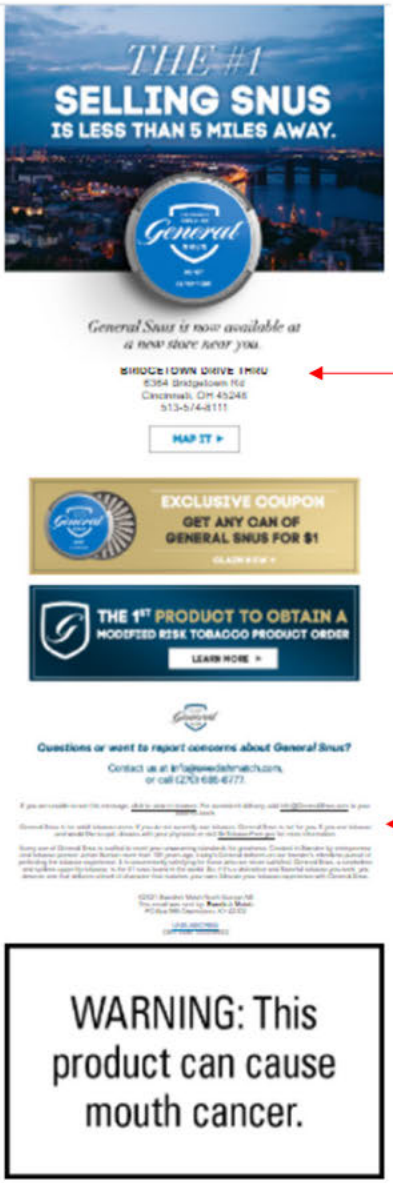
UNSUBSCRIBE
Offer code: 000009274

Swedish Match

General Snus Ongoing E-mails: New Store



General Snus is now available at a new store near you.

BRIDGETOWN DRIVE THRU
6364 Bridgetown Rd
Cincinnati, OH 45248
513-574-8111

Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com,
or call (270) 685-8777.

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UNSUBSCRIBE
Offer code: 000006932

WARNING: This product can cause mouth cancer.

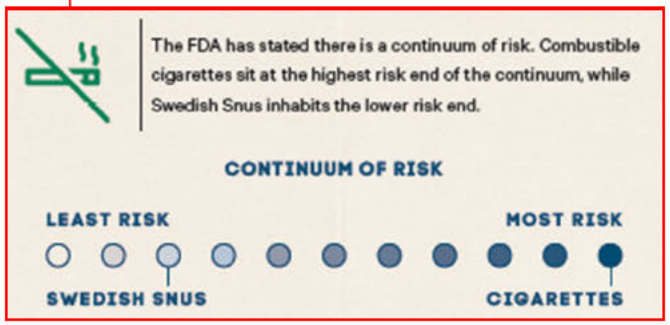
Swedish Match

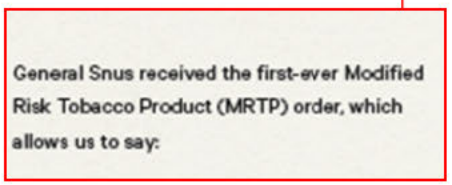
GENERAL SNUS DIRECT MAIL
Oct. 2020 – Oct. 2021

[redacted]

General Snus Direct Mail Metrics

General Snus January Specialty Direct Mailer



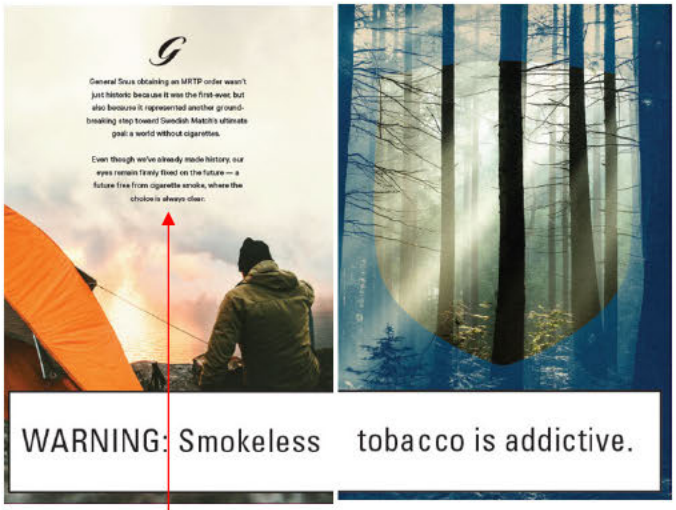


Swedish Match

General Snus January Specialty Direct Mailer con't

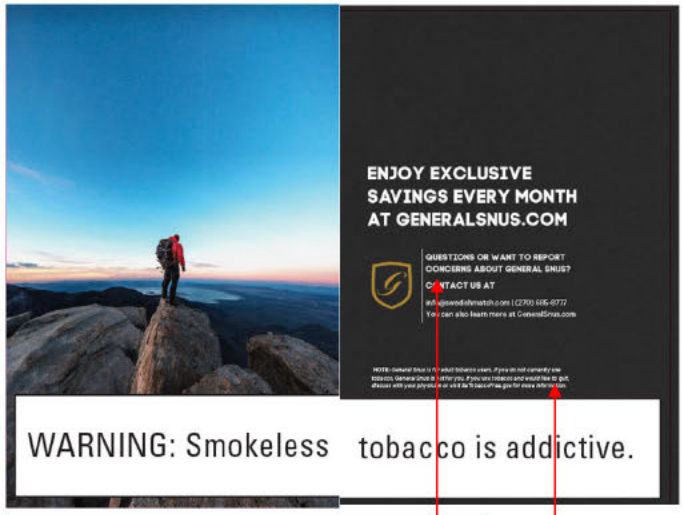
Twenty years ago, General Snus unveiled one of the strictest quality standards ever created: the GOTHIATEK® Standard.

Created in collaboration with the Swedish Standards Institute (SIS), the GOTHIATEK® Standard requires all tobacco being used in General Snus to exceed even the toughest Swedish food-grade requirements. It also promises to ensure every can meets the standards through a quality-controlled process.



General Snus obtaining an MRTP order wasn't just historic because it was the first-ever, but also because it represented another ground-breaking step toward Swedish Match's ultimate goal: a world without cigarettes.

Even though we've already made history, our eyes remain firmly fixed on the future — a future free from cigarette smoke, where the choice is always clear.



QUESTIONS OR WANT TO REPORT CONCERNS ABOUT GENERAL SNUS?

CONTACT US AT

Info@swedishmatch.com | (270) 685-8777
You can also learn more at GeneralSnus.com

NOTE: *General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.*

Swedish Match

General Snus January Specialty Direct Mailer con't

MANUFACTURER'S COUPON EXPIRES 12/31/21

RETAILER: Subtract $1.00 from your normal retail price including applicable sales tax. Write that amount (your price minus $1.00) in the space provided.

RETAILER: Swedish Match North America LLC, will pay you the face value of this coupon plus $.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of $.01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. Ship coupons to: Swedish Match North America LLC, CMS Department 70195, 1 Fawcett Dr., Del Rio, TX 78840. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 12/31/21. CONSUMER: By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS.

To opt out of future promotional mailings and be removed from our mailing list, please contact the Consumer Call Center at (270) 685-8777. ©2021 Swedish Match North Europe AB

Swedish Match

General Snus Monthly Coupon Mailer (via Email or Organic Request)

Front

Postcard [9" x 6"]

Back

©2021 Swedish Match North Europe AB

QUESTIONS OR WANT TO REPORT
CONCERNS ABOUT GENERAL SNUS?
CONTACT US AT

info@swedishmatch.com | (270) 685-8777
You can also learn more at GeneralSnus.com

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MANUFACTURER'S COUPON EXPIRES 03/15/22

RETAILER: Subtract $1.00 from your normal retail price including applicable sales tax. Write that amount (your price minus $1.00) in the space provided.

RETAILER: Swedish Match LLC, will pay you the face value of this coupon plus $.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of $.01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. Ship coupons to: Swedish Match LLC, CMS Department 70195, 1 Fawcett Dr., Del Rio, TX 78840. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 3/15/22. CONSUMER: By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS.

MANUFACTURER'S COUPON EXPIRES 03/15/22

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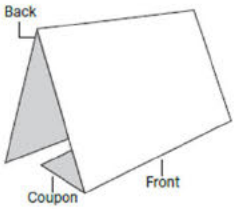
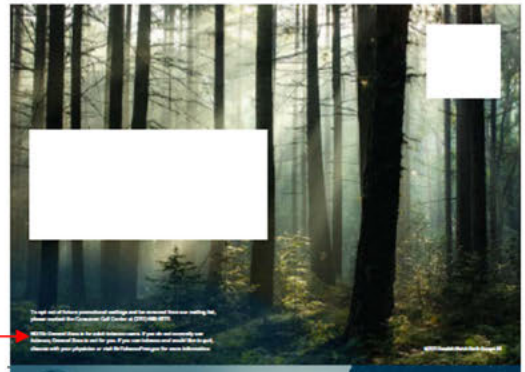
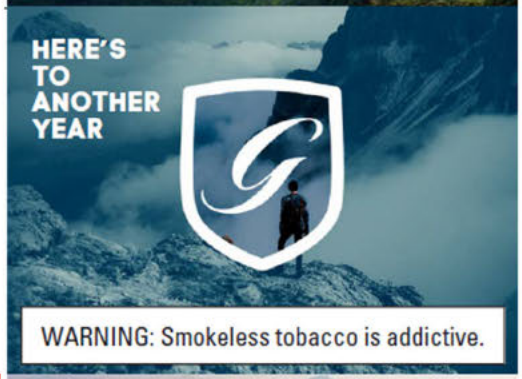
RETAILER: Swedish Match LLC, will pay you the face value of this coupon plus $.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of $.01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. Ship coupons to: Swedish Match LLC, CMS Department 70195, 1 Fawcett Dr., Del Rio, TX 78840. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 3/15/22. CONSUMER: By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS.

General Snus
Birthday Direct Mailer

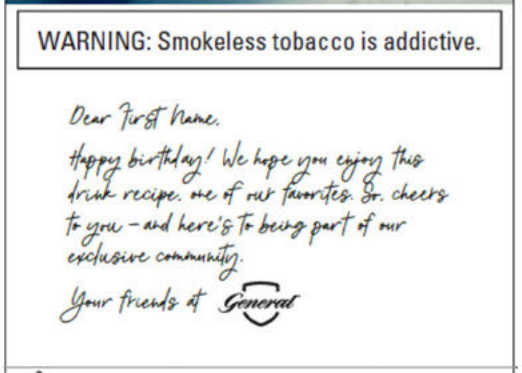
Flat [7" x 12.75"]
Folded [7" x 5"]







Exterior



Interior

To opt out of future promotional mailings and be removed from our mailing list, please contact the Consumer Call Center at (270) 685-8777.

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MANUFACTURER'S COUPON EXPIRES 03/15/22
RETAILER: Subtract $1.00 from your normal retail price including applicable sales tax. Write that amount (your price minus $1) in the space provided.

General Snus Welcome Mailer

Revised from Jan. submission

Flat [5.5" x 8.5"]
Folded [5.5" x 4.25"]

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JOIN US ON FACEBOOK AT FACEBOOK.COM/GENERALSNUS

You've joined a select community that knows that the pinnacle of tobacco satisfaction can only be reached by combining precise Swedish craft with an impeccable technique over 150 years in the making. **WE'RE GLAD YOU'RE HERE.**

General Snus is the 1st product to receive a Modified Risk Tobacco Product order by the FDA. Combustible cigarettes sit at the highest risk end of the continuum, while Swedish Snus inhabits the lower risk end.

CONTINUUM OF RISK — LEAST RISK: SWEDISH SNUS — MOST RISK: CIGARETTES

Exterior

Interior

RETAILER: Swedish Match LLC, will pay you the face value of this coupon plus $.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of $.01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. Ship coupons to: Swedish Match LLC, CMS Department 70195, 1 Fawcett Dr., Del Rio, TX 78840. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 3/15/22. CONSUMER: By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS.

QUESTIONS OR WANT TO REPORT CONCERNS ABOUT GENERAL SNUS?
Contact us at: info@swedishmatch.com
(270) 685-8777 | GeneralSnus.com

MANUFACTURER'S COUPON EXPIRES 03/15/22
RETAILER: Subtract $1.00 from your normal retail price including applicable sales tax. Write that amount (your price minus $1) in the space provided.

General Snus Welcome Mailer – Revised

Omitted continuum of risk

In-market September 2021

Flat [5.5" x 8.5"]
Folded [5.5" x 4.25"]

To opt out of future promotional mailings and be removed from our mailing list, please contact the Consumer Call Center at (270) 685-8777. ©2021 Swedish Match North Europe AB

NOTE: *General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.*

JOIN US ON FACEBOOK AT FACEBOOK.COM/GENERALSNUS

You've joined a select community that knows that the pinnacle of tobacco satisfaction can only be reached by combining precise Swedish craft with an impeccable technique over 150 years in the making. **WE'RE GLAD YOU'RE HERE.**

FIRST EVER

October 2019: General Snus received the first Modified Risk Tobacco Pro (MRTP) order.

OTHER BENEFITS OF GENERAL SNUS

- Over 155 years of unequaled Quality
- Simple, high-grade ingredients
- Smokeless and spitless
- Adheres to strict food-grade manufacturing progress

RETAILER: Swedish Match LLC, will pay you the face value of this coupon plus $.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of $.01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. Ship coupons to: Swedish Match LLC, CMS Department 70195, 1 Fawcett Dr., Del Rio, TX 78840. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 3/15/22. CONSUMER: By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS.

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QUESTIONS OR WANT TO REPORT CONCERNS ABOUT GENERAL SNUS?

Contact us at: info@swedishmatch.com
(270) 685-8777 | GeneralSnus.com

GENERAL SNUS PACKAGING

[redacted]

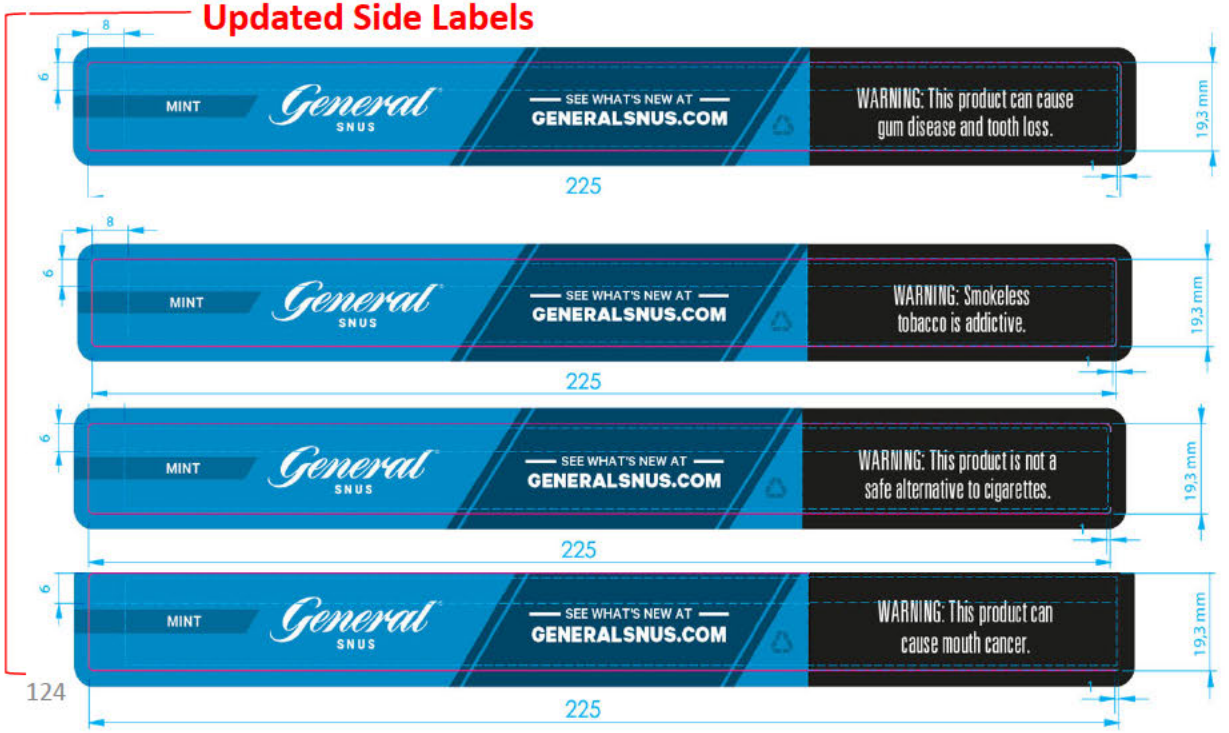
General Packaging – Mint – In stores January 2021

(Removed Leave No Trace Program from side label)

NO CHANGES MADE TO TOP OR BOTTOM LABEL

Original Side Label

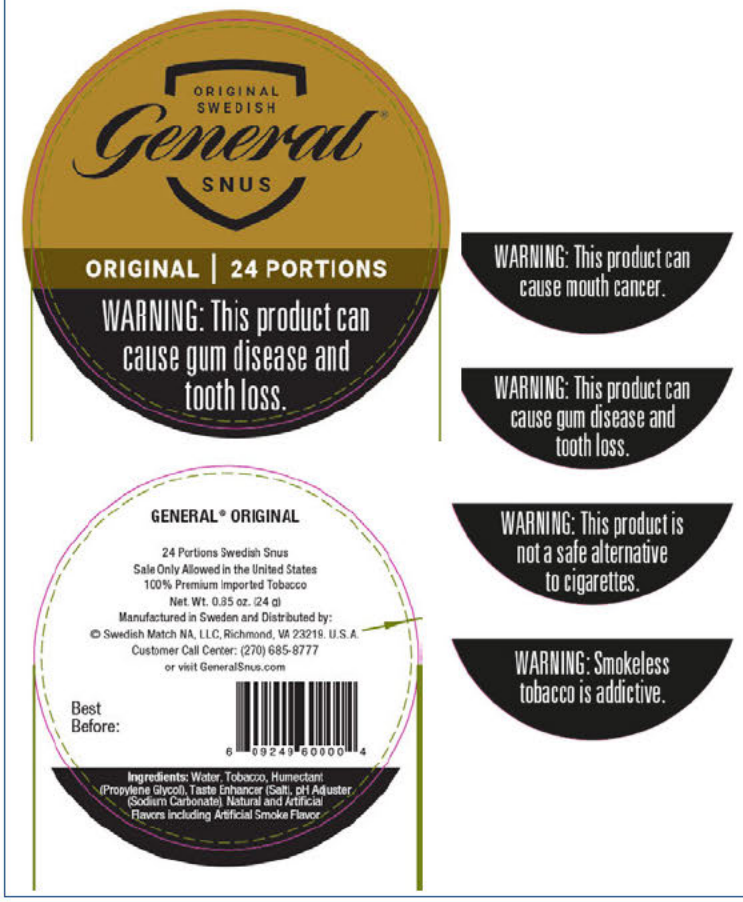
Updated Side Labels



General Packaging Update – Original – In stores January 2021

(removed Leave No Trace program from side label)

NO CHANGES MADE TO TOP OR BOTTOM LABEL



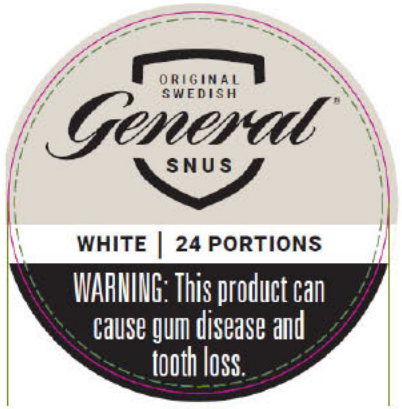
Original Side Label

Updated Side Labels

General Packaging Update – White – In stores January 2021

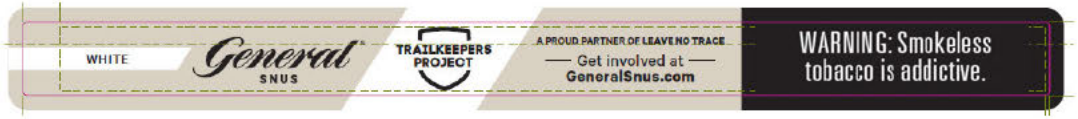
(removed Leave No Trace program from side label)

NO CHANGES MADE TO TOP OR BOTTOM LABEL



126

Original Side Label



Updated Side Labels

General Packaging Update – Wintergreen – In stores January 2021

(removed Leave No Trace program from side label)

NO CHANGES MADE TO TOP OR BOTTOM LABELS

127

Original Side Label

Updated Side Labels

GENERAL SNUS POS
Oct. 2020 – Oct. 2021

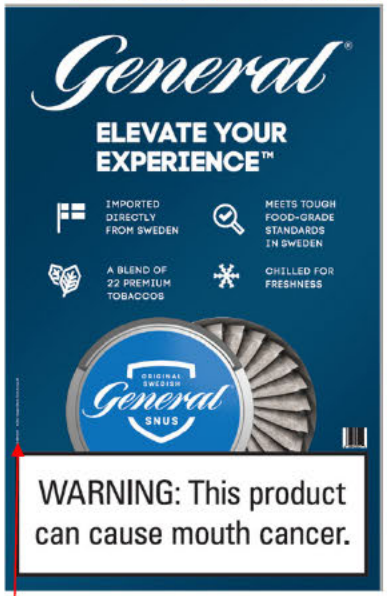
[redacted]

General Point-of-Sale Refresh In stores Sept. 2021

V4 Chiller Pedestal Front Graphics

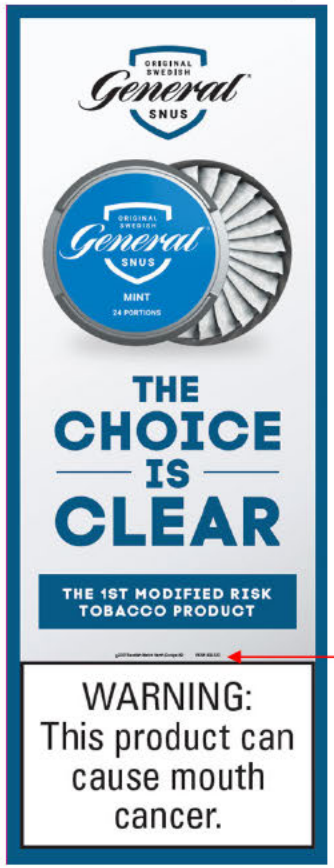
POS #894393
©2021 Swedish Match North Europe AB

V4 Chiller Pedestal Side Graphics



POS #894393 ©2021 Swedish Match North Europe AB

Vertical Door Spanner



©2021 Swedish Match North Europe AB POS# 894530

Yard Sign

©2021 Swedish Match North Europe AB POS# 894528

Chiller Header

©2021 Swedish Match North Europe AB POS# 894532

Window Decal

©2021 Swedish Match North Europe AB POS# 894527

General Snus Chiller MRTP 'Contact Us' POS

Oct. 2020 – Aug. 2021

Sept. 2021 - current

[redacted]

General Snus Point-of-Sale: Oct. 2020 – Aug. 2021

Created in 2019 when the MRTP order was approved.

POS #894510 ©2019 Swedish Match North Europe AB

Door Spanner

Door Decal

Poster

General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit *BeTobaccoFree.gov* for more information.

©2019 Swedish Match North Europe AB POS # 894519

Shelf Talker

General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit *BeTobaccoFree.gov* for more information.

General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit *BeTobaccoFree.gov* for more information.

©2019 Swedish Match North Europe AB POS # XXXXXX

Shelf Talker: July 2020 – December 2020

Appendix 7: Trade Advertising

CATEGORY: SNUS

BRAND: GENERAL SNUS

Annual Report

October 2020 – September 2021

GENERAL SNUS TRADE ADVERTISING

[redacted]

General Snus Q1 – Q2 Trade Print Ad

[redacted]

For trade purposes only.
©2021 Swedish Match North Europe AB

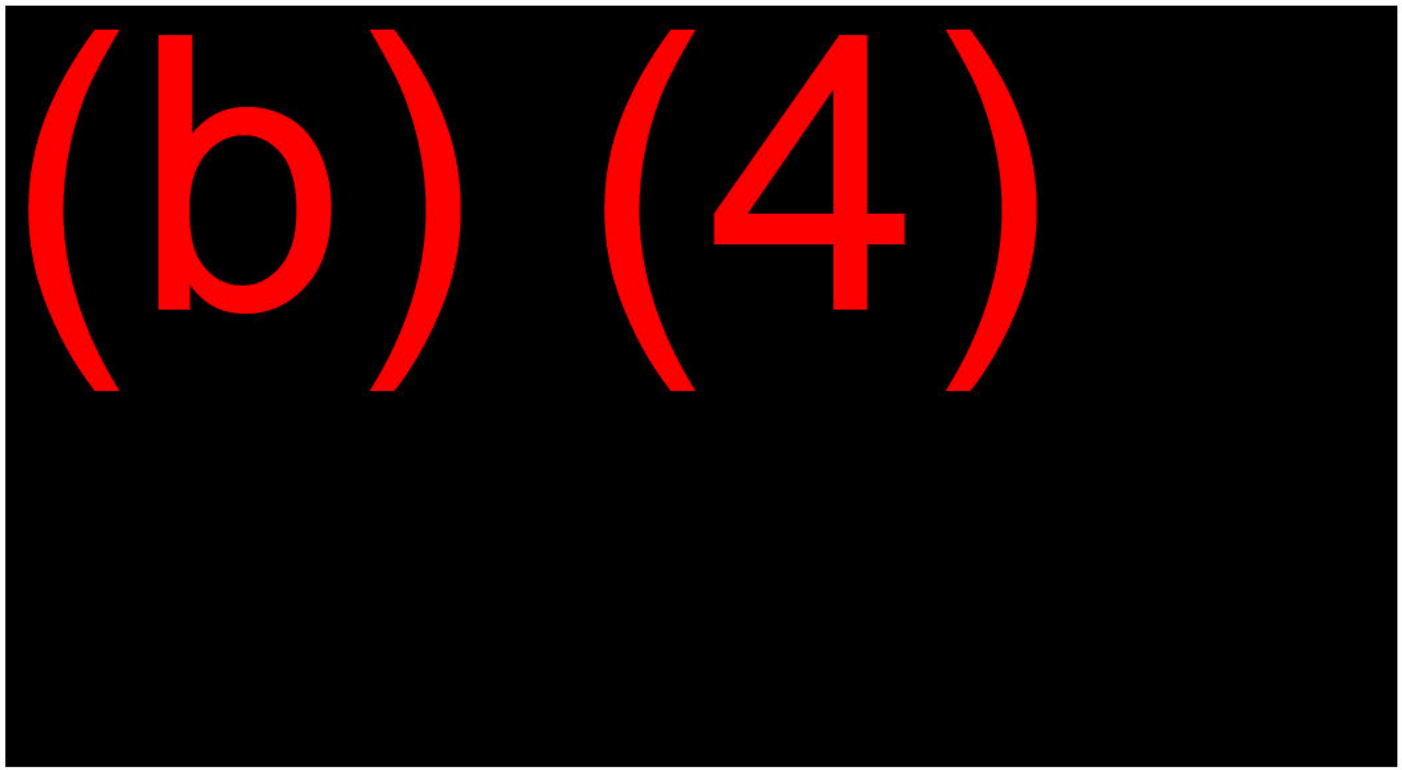
General Snus Q3 – Q4 Trade Print Ad

Version for NACS Show

[redacted]

All Other Issues non-NACS Show

General Snus Trade Print Ad Schedule Jan. – June ‘21



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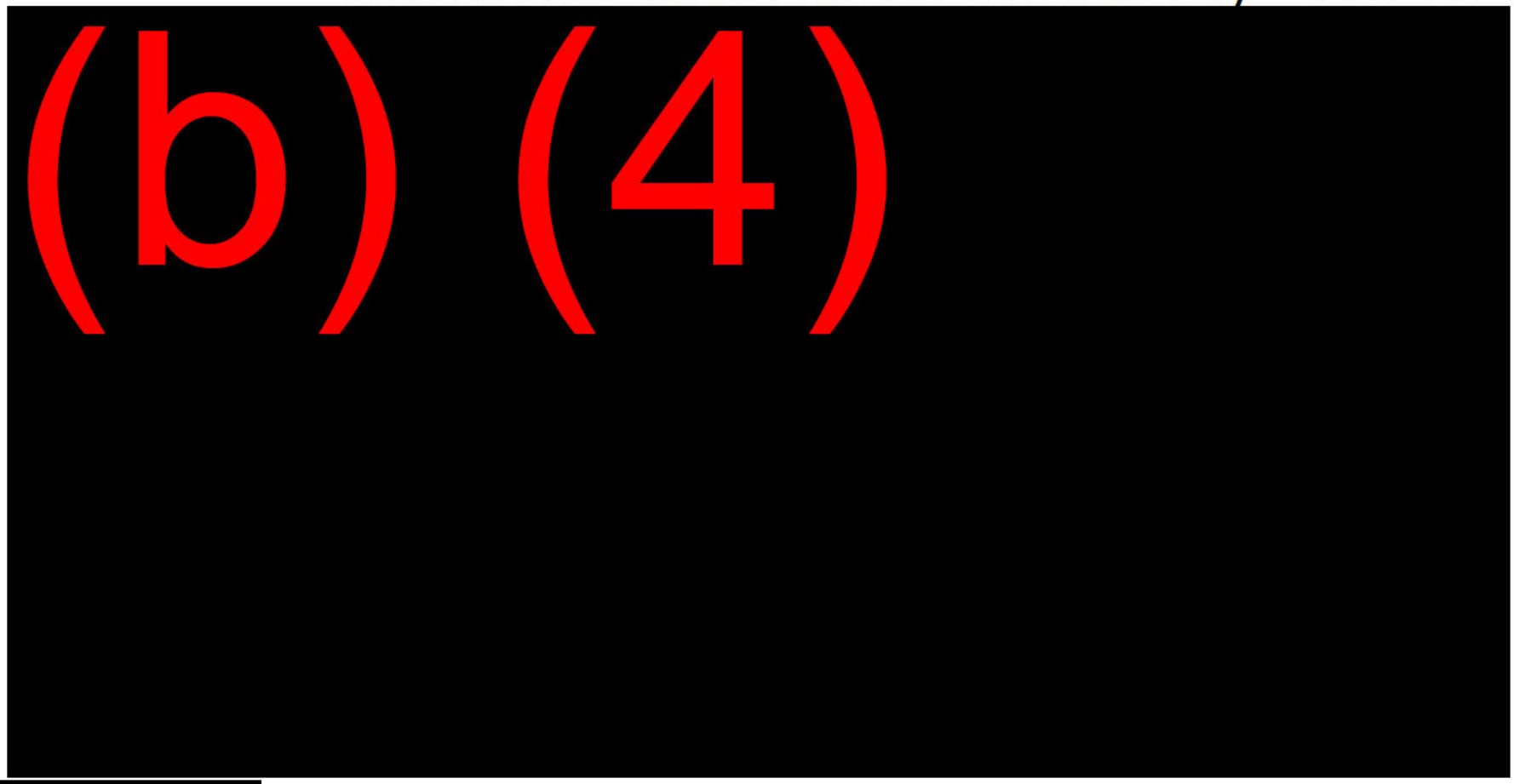
General Snus Trade Print Ad Schedule July – Dec. ‘21



U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

JUN - 4 2018
RECEIVED
LEGAL UPS

June 01, 2018

GENERAL CORRESPONDENCE

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STN(s)): MULTIPLE STNs, See Below

Dear Mr. Roerty:

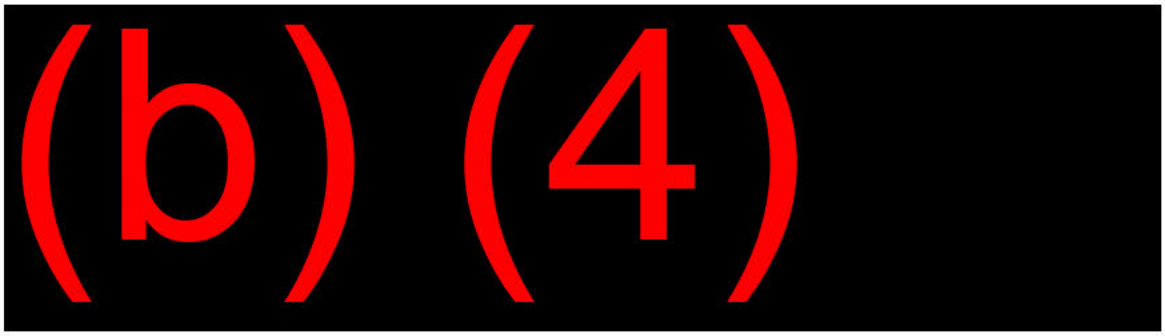
Please refer to your Postmarket Periodic reports for the Premarket Tobacco Applications (PMTAs) received on October 27, 2017 and November 22, 2017, submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco products:

Periodic Report STN	STN	TOBACCO PRODUCT NAME
TC0003310	PM0000010	General Loose
TC0003024	PM0000017	General Wintergreen Portion White Large
TC0003025	PM0000011	General Dry Mint Portion Original Mini
TC0003026	PM0000012	General Portion Original Large
TC0003028	PM0000014	General Mint Portion White Large
TC0003030	PM0000016	General Portion White Large

Based on our review of your 2017 Periodic reports, we have identified the following issues for which we believe additional information or clarification will be helpful to FDA in performing a complete substantive review of **subsequent** Periodic Reports.

1. (b)(4)

2. (b) (4)



3. For all of the products you provide a table of publications identified through a literature search. In this post-market report 23 publications were identified. However, 2 of 23 publications in the table did not include complete information (citations #13 and 16). In subsequent reports, include a complete citation for the publications identified including full title, author names, publications date, and publisher so that FDA can easily identify the referenced publication.

4.

5.

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter or mailed to :

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Shireen Ahmad, MS, Regulatory Health Project Manager, at (240) 402 – 0435 or at Shireen.Ahmad@fda.hhs.gov.

Sincerely,

Iilun C. Murphy -S
2018.06.01 13:12:30 -04'00'

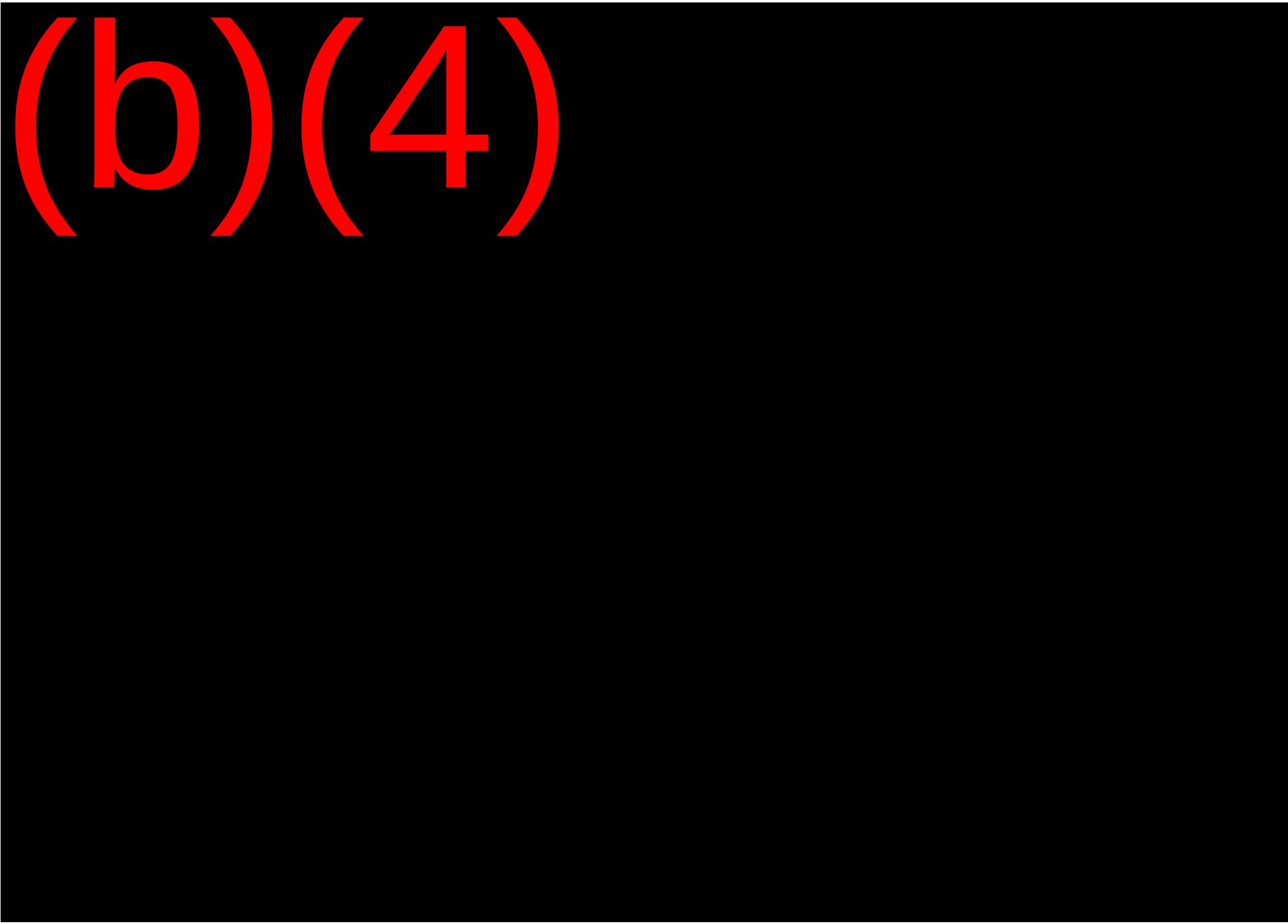
Iilun Murphy, M.D.
Director, Division of Individual Health Science
Office of Science
Center for Tobacco Products

Appendix 5: Consumer Insights

CATEGORY: SNUS
BRAND: GENERAL SNUS
Annual Report
October 2020 – September 2021

Swedish Match

CONSUMER INSIGHTS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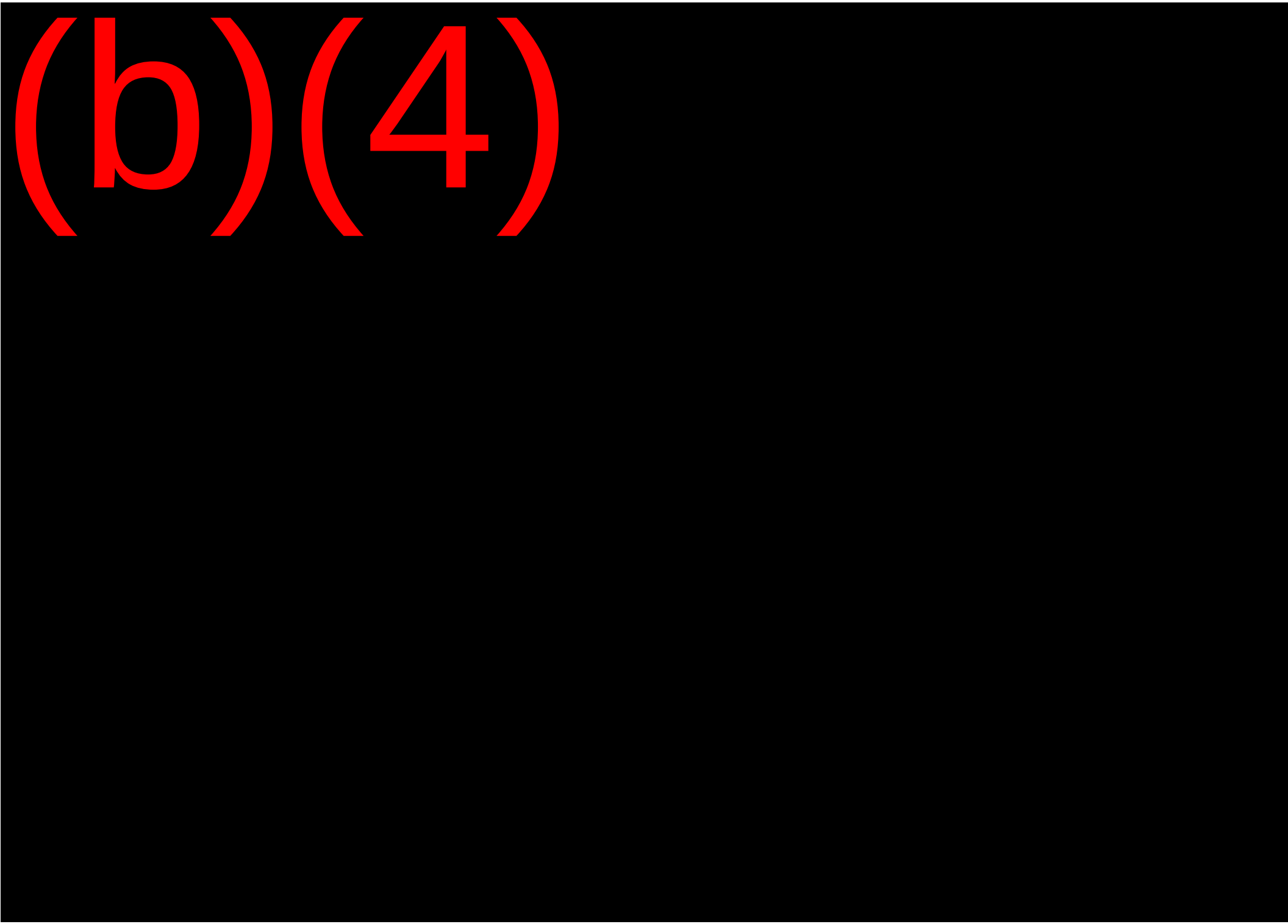
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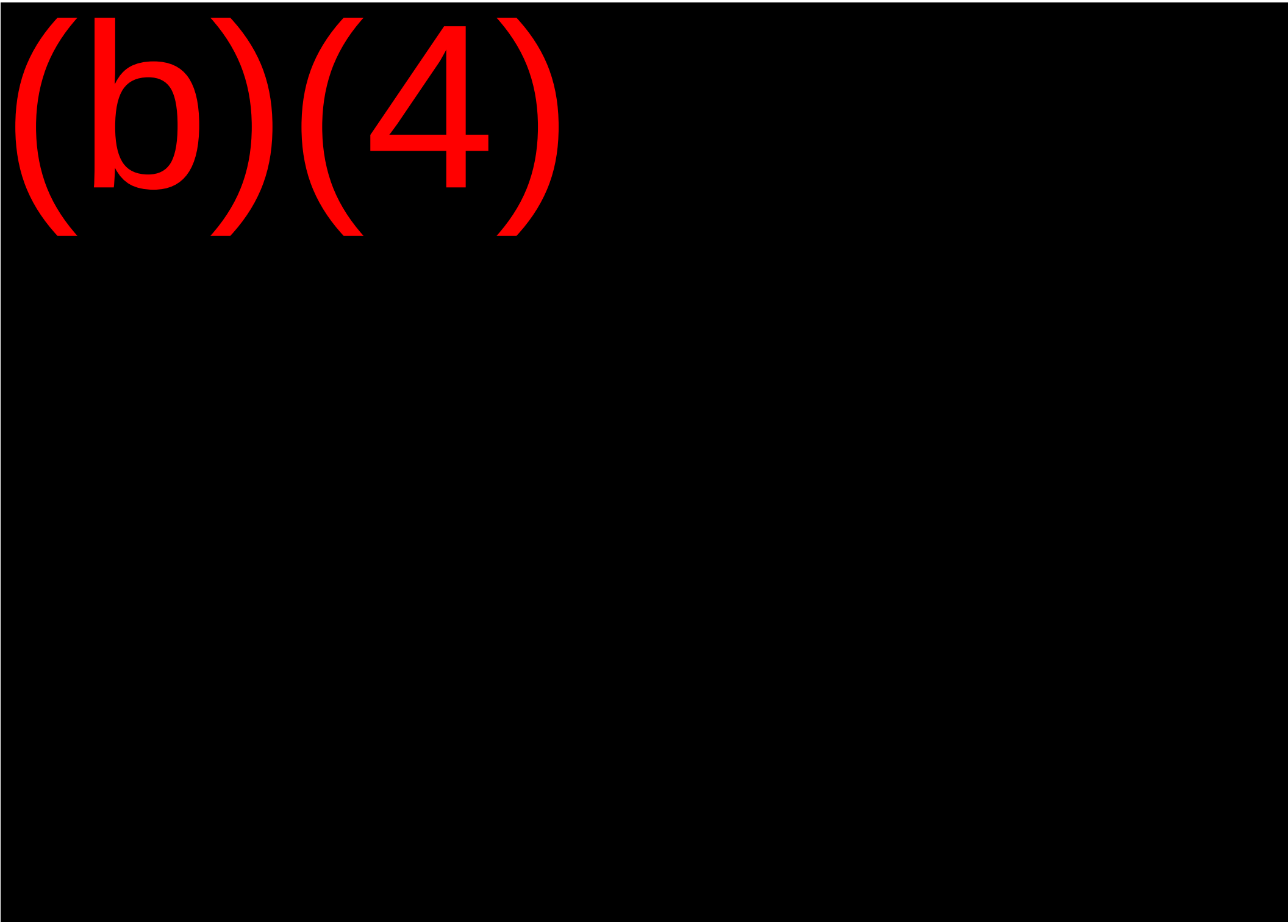
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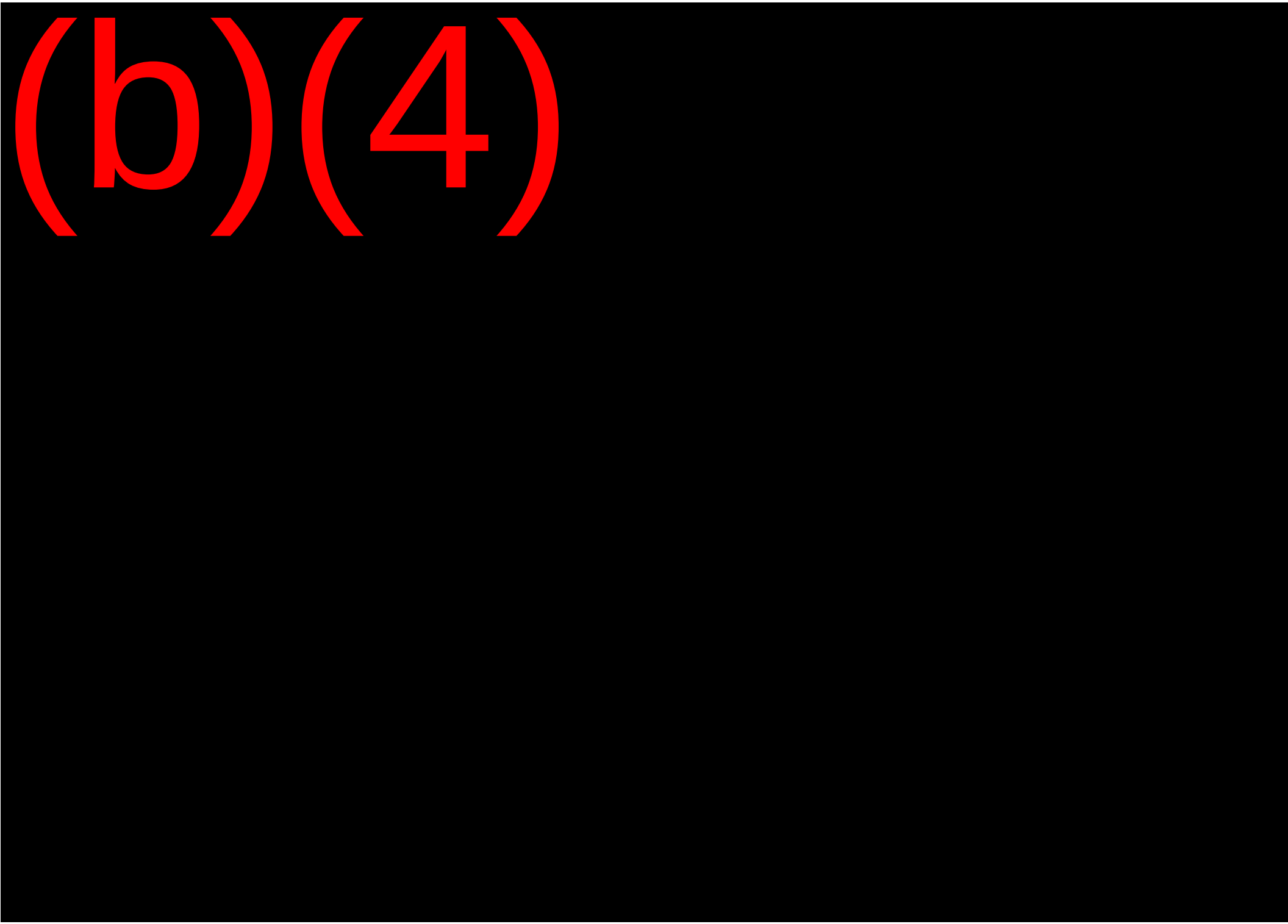
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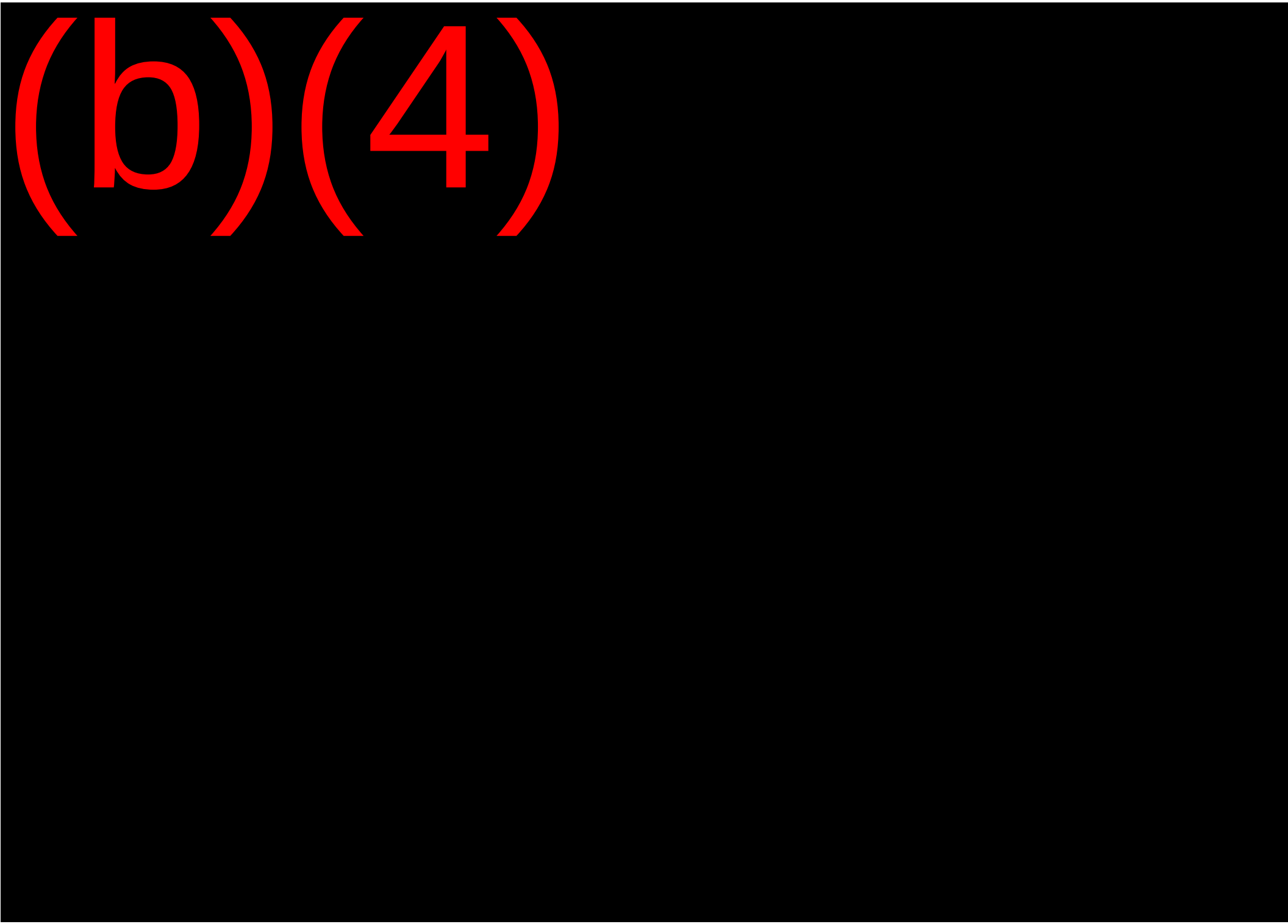
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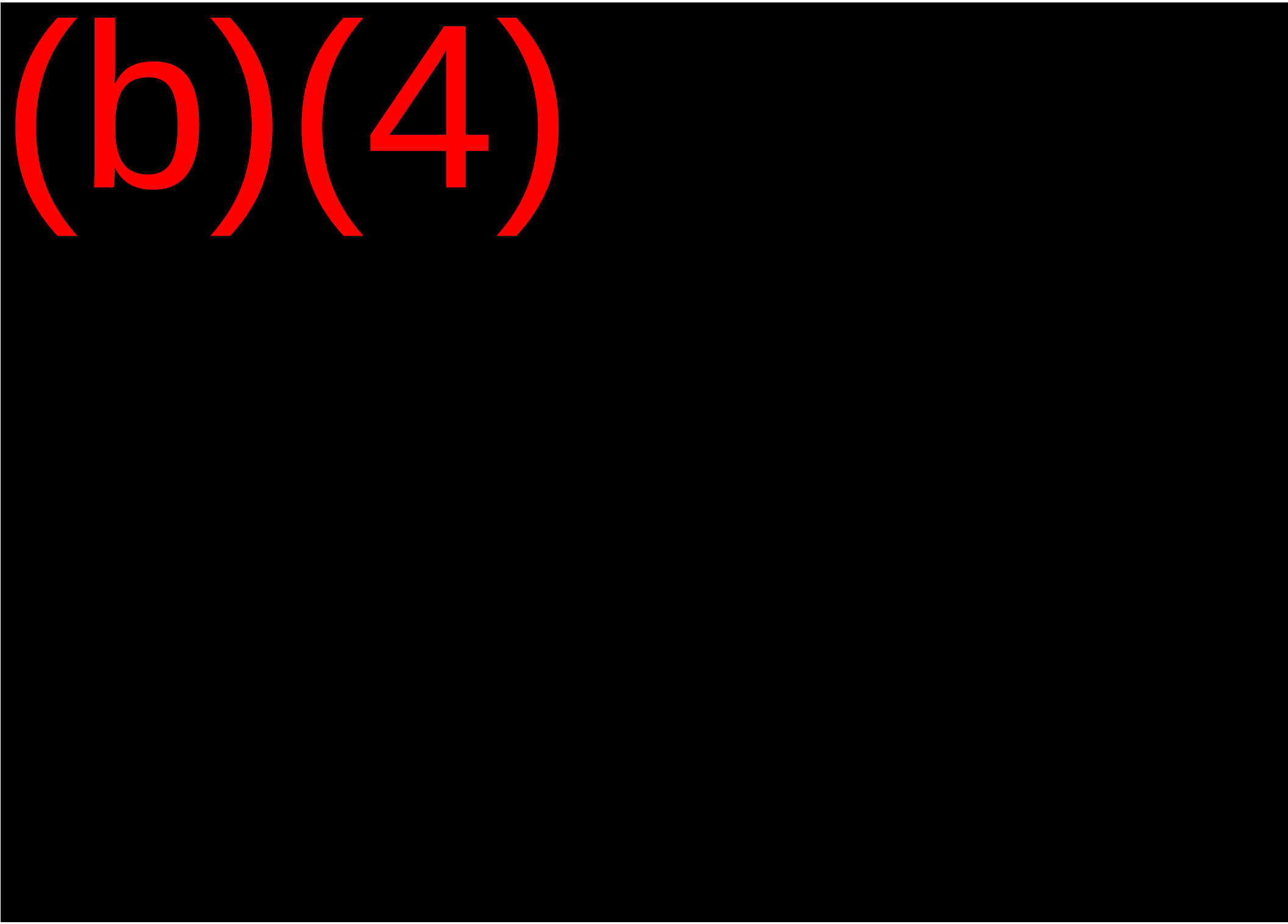
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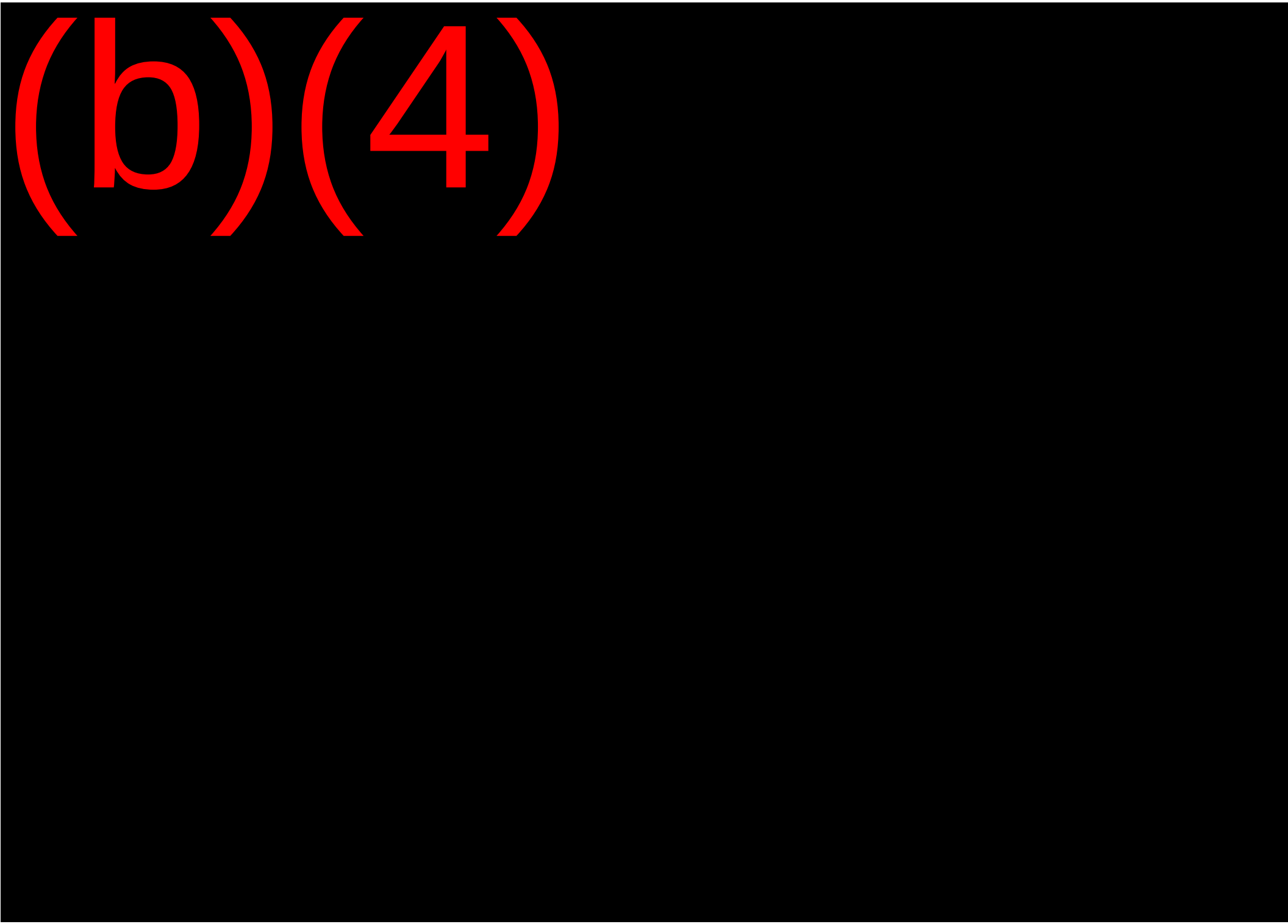
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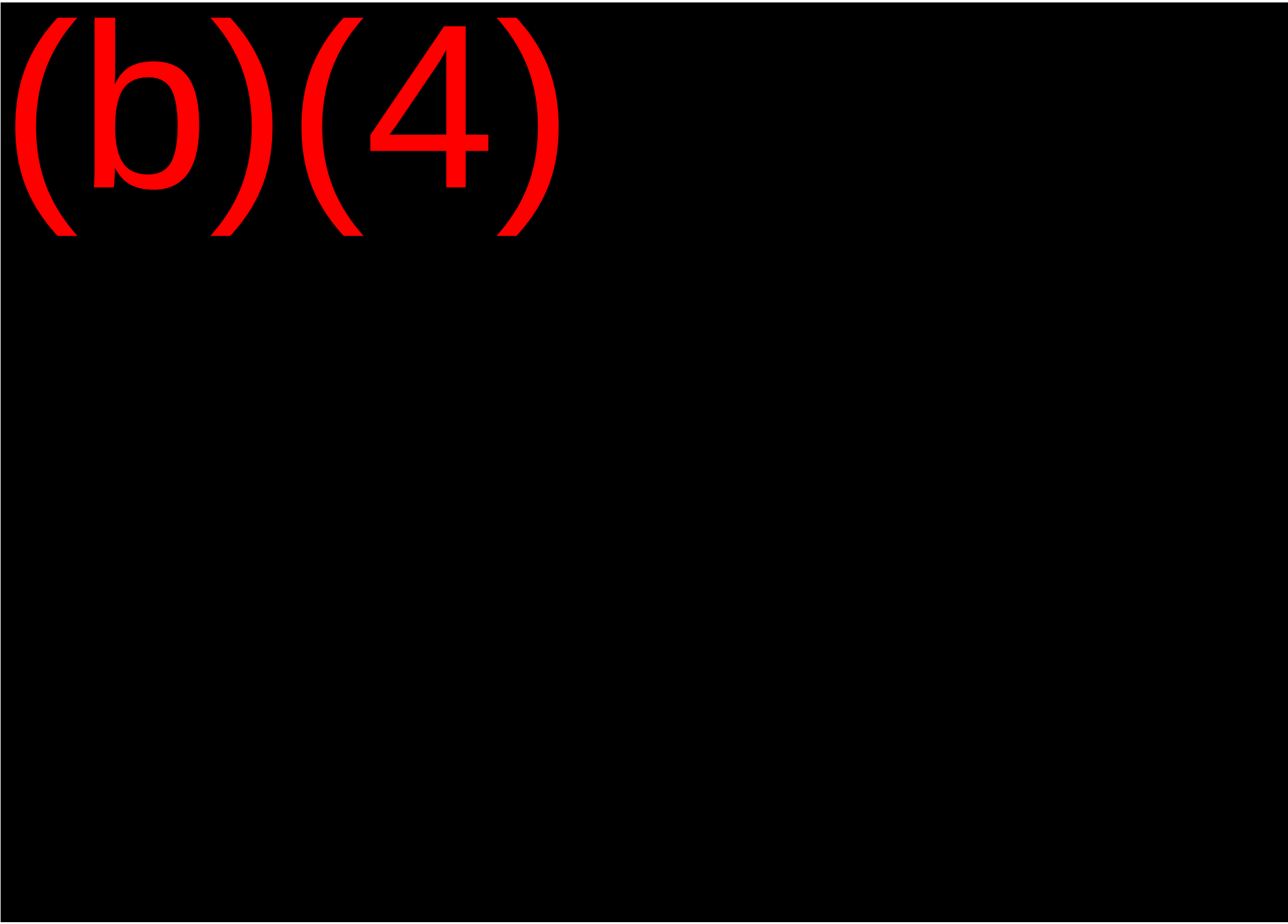
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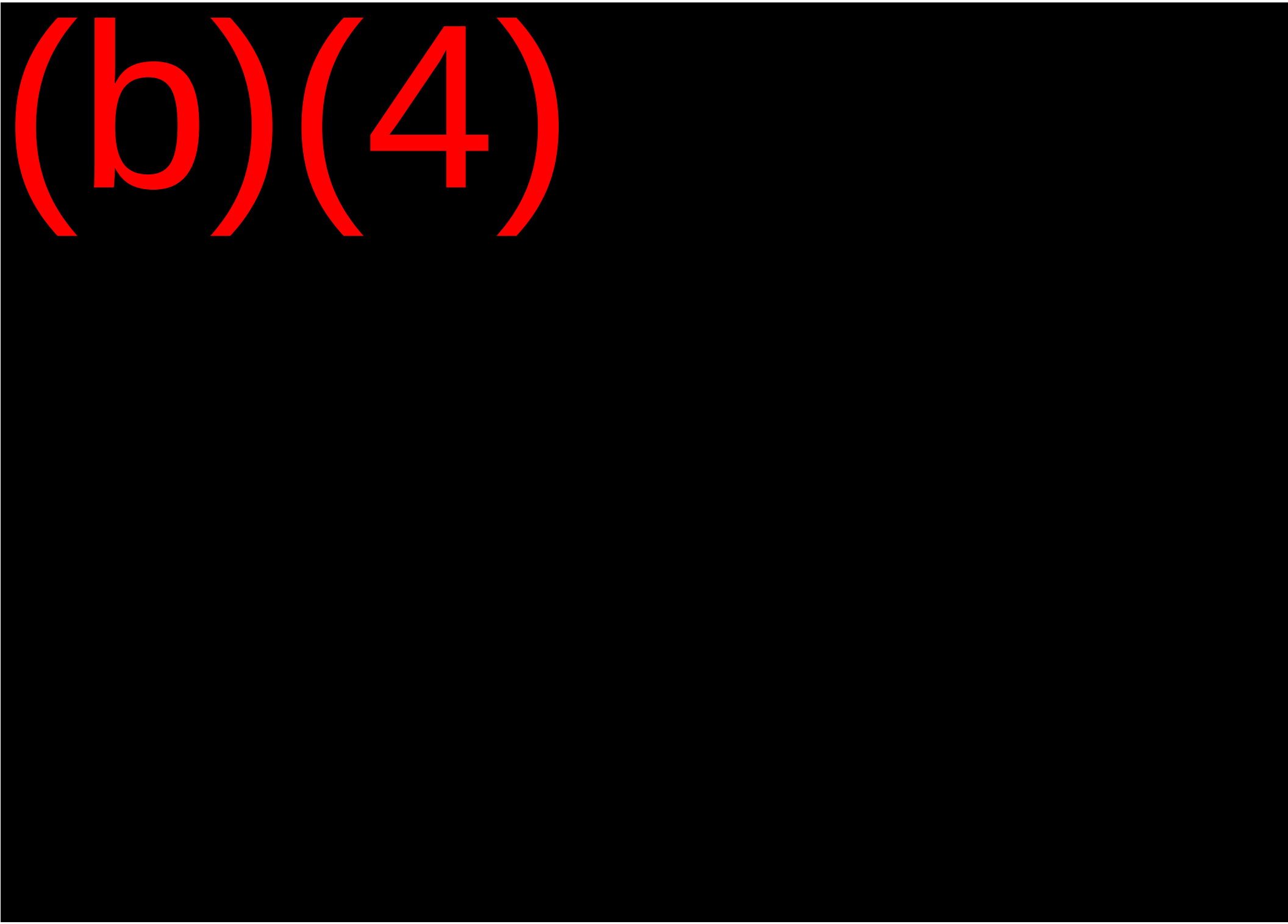
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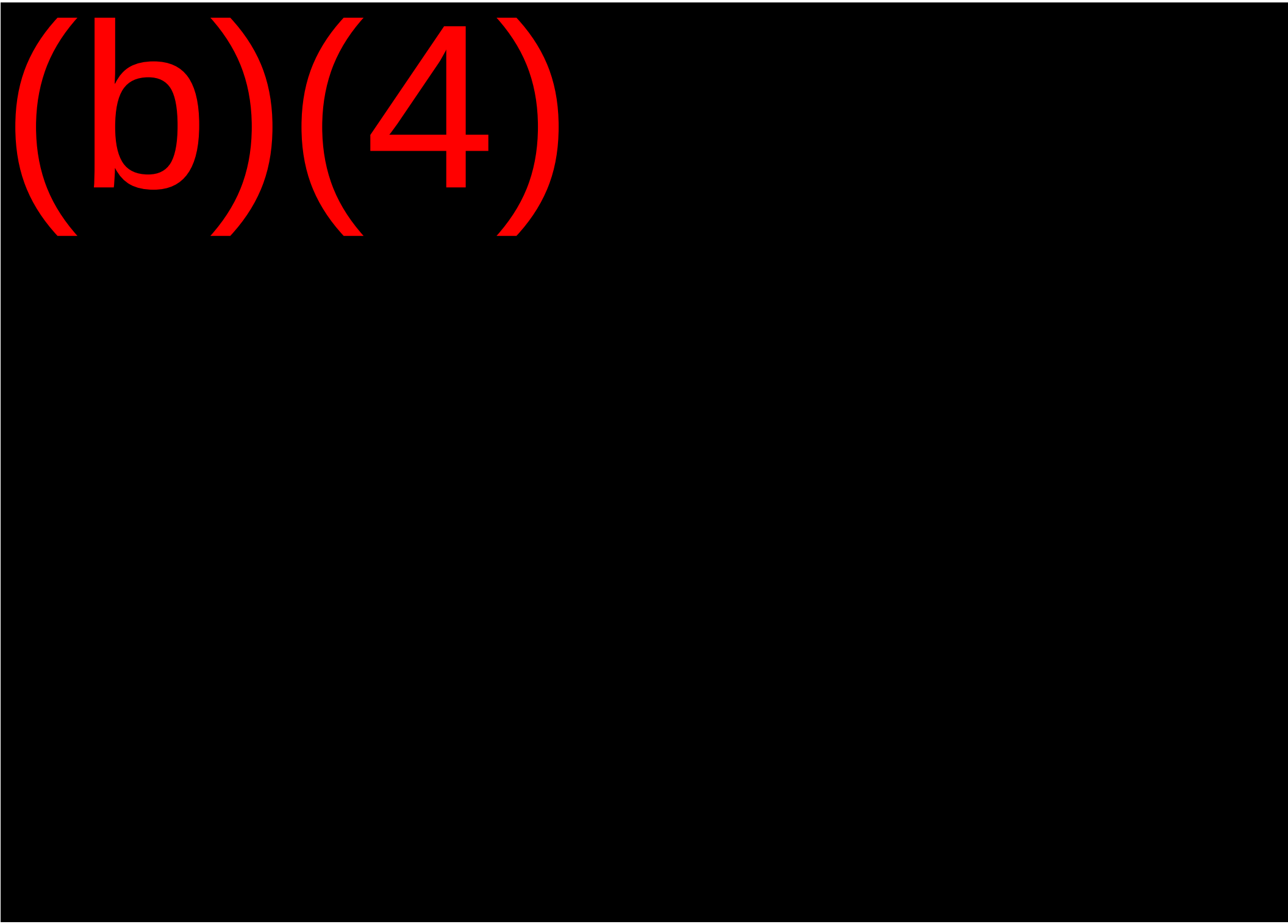
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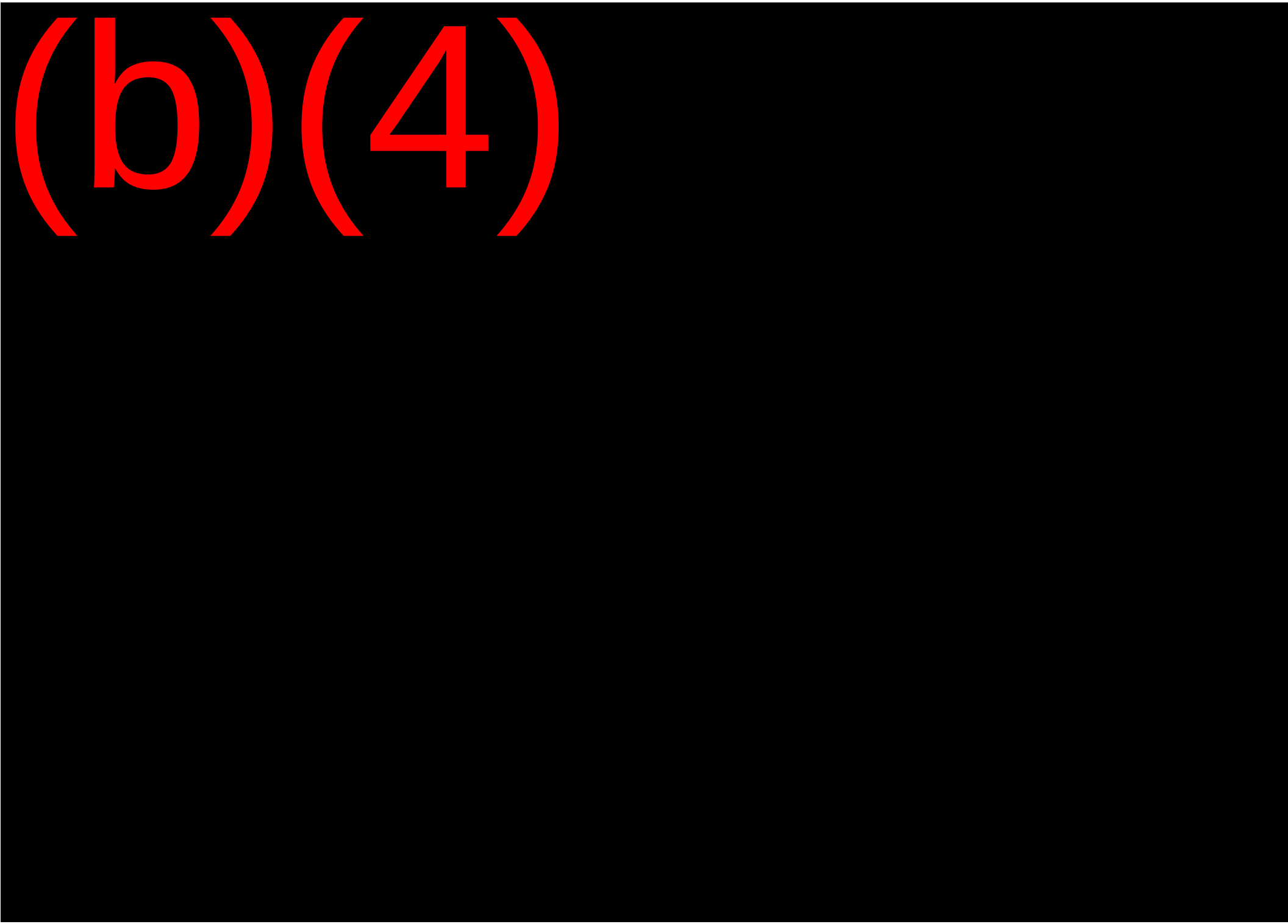
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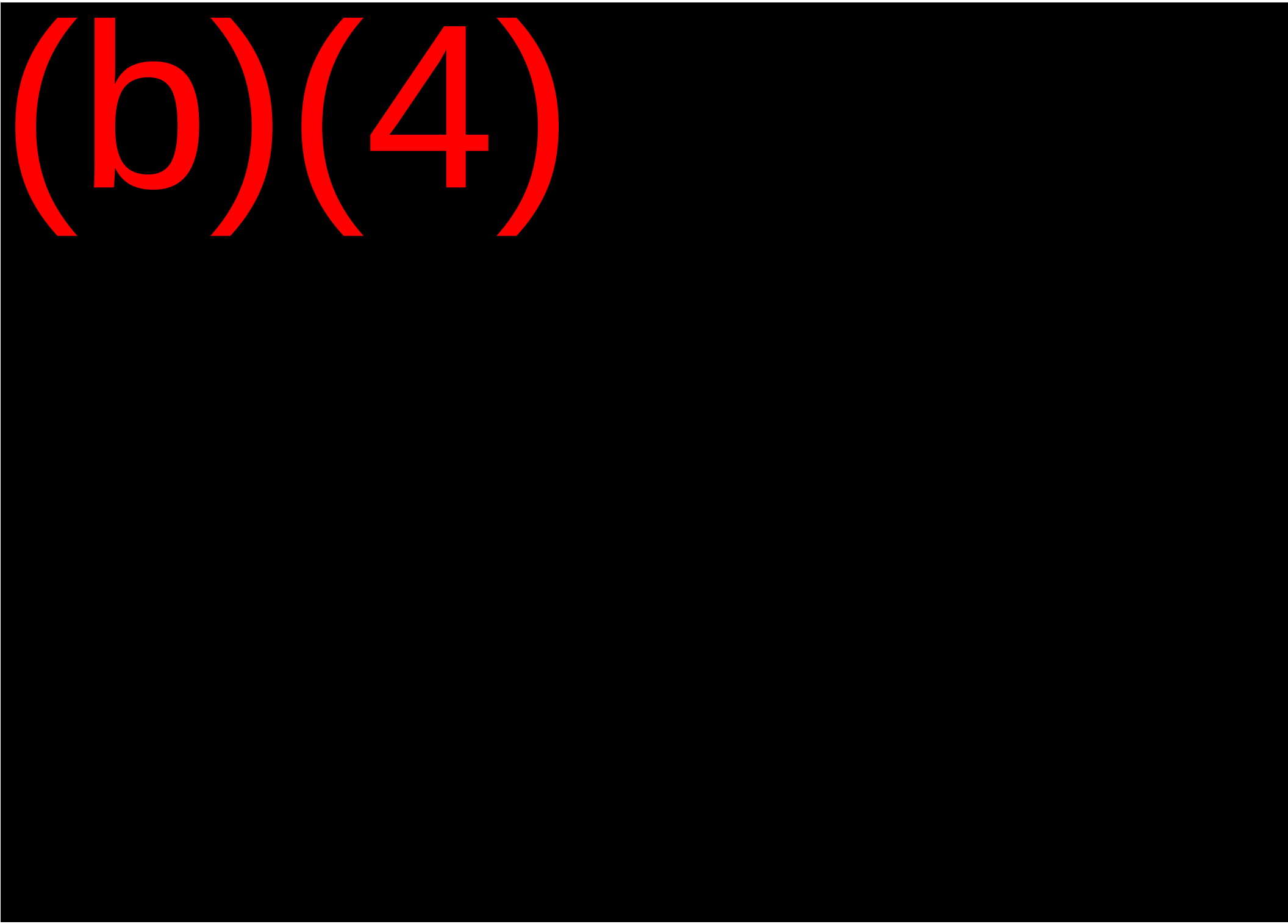
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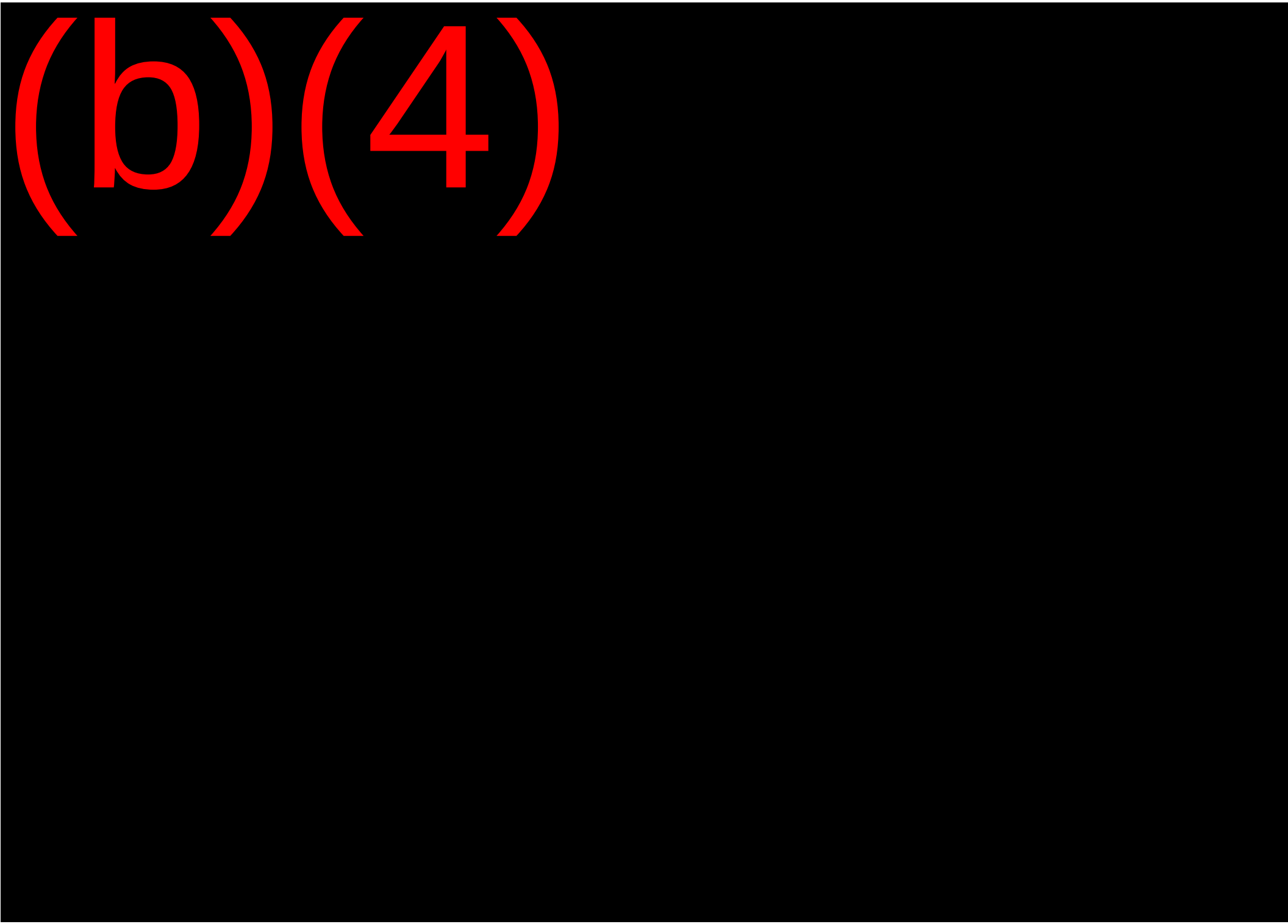
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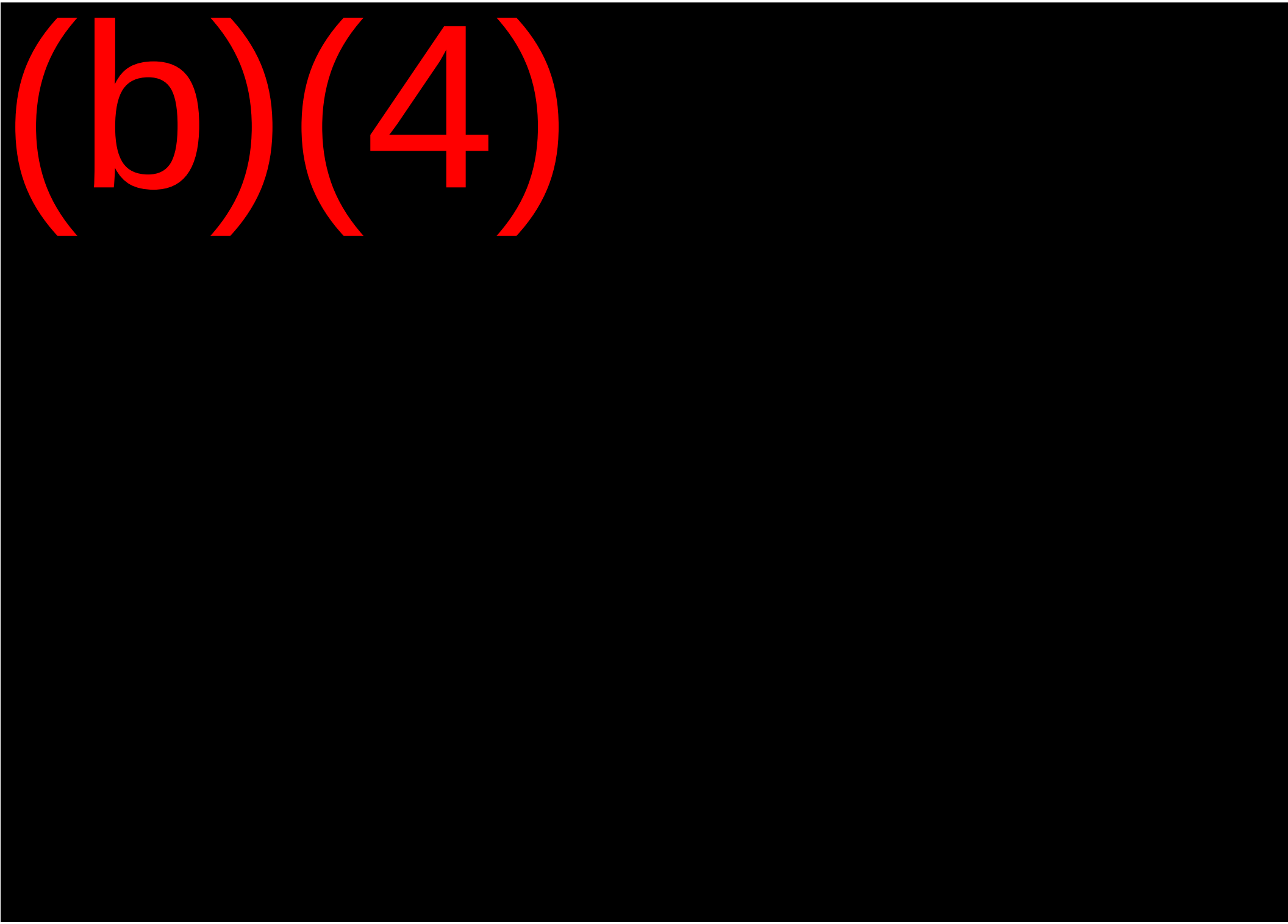
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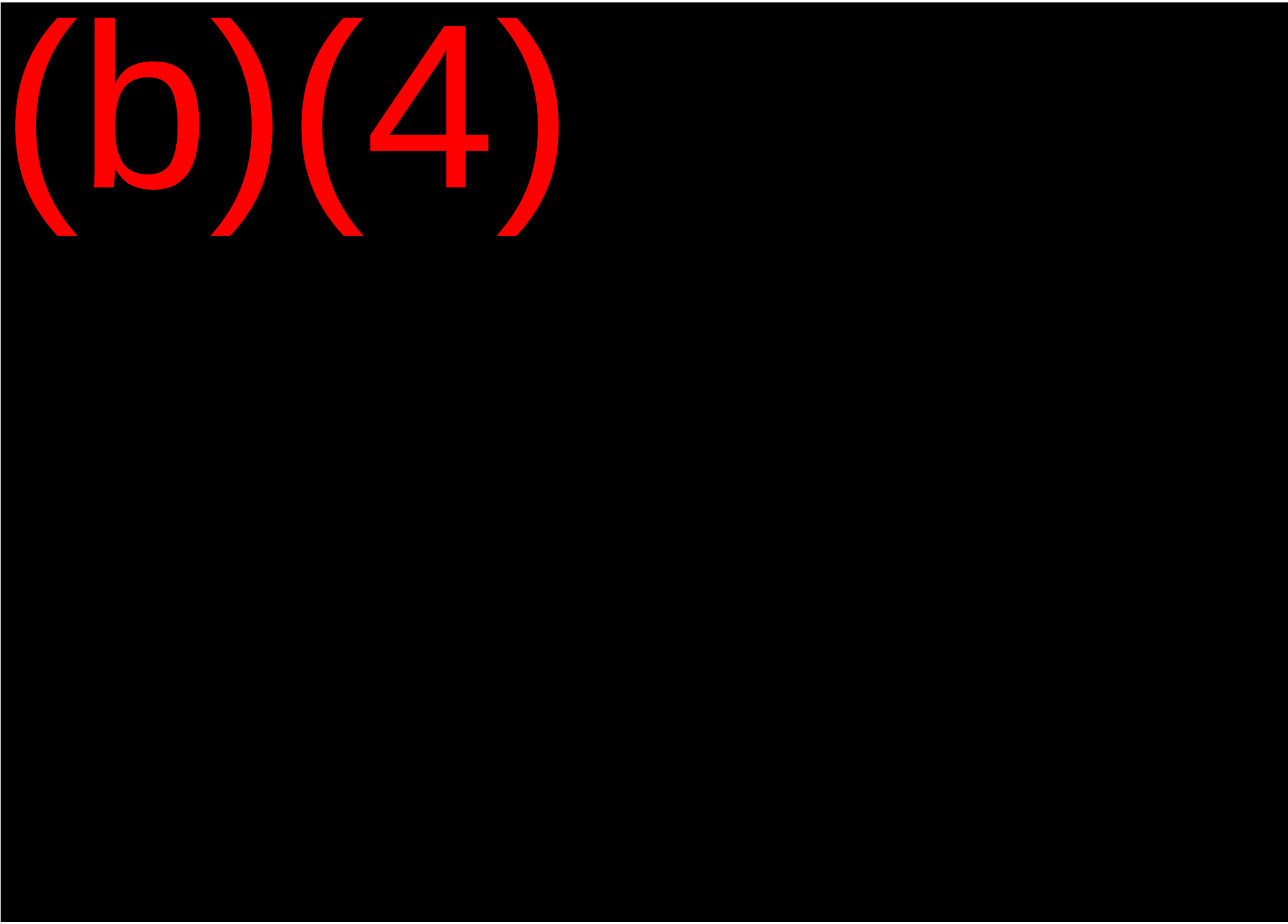
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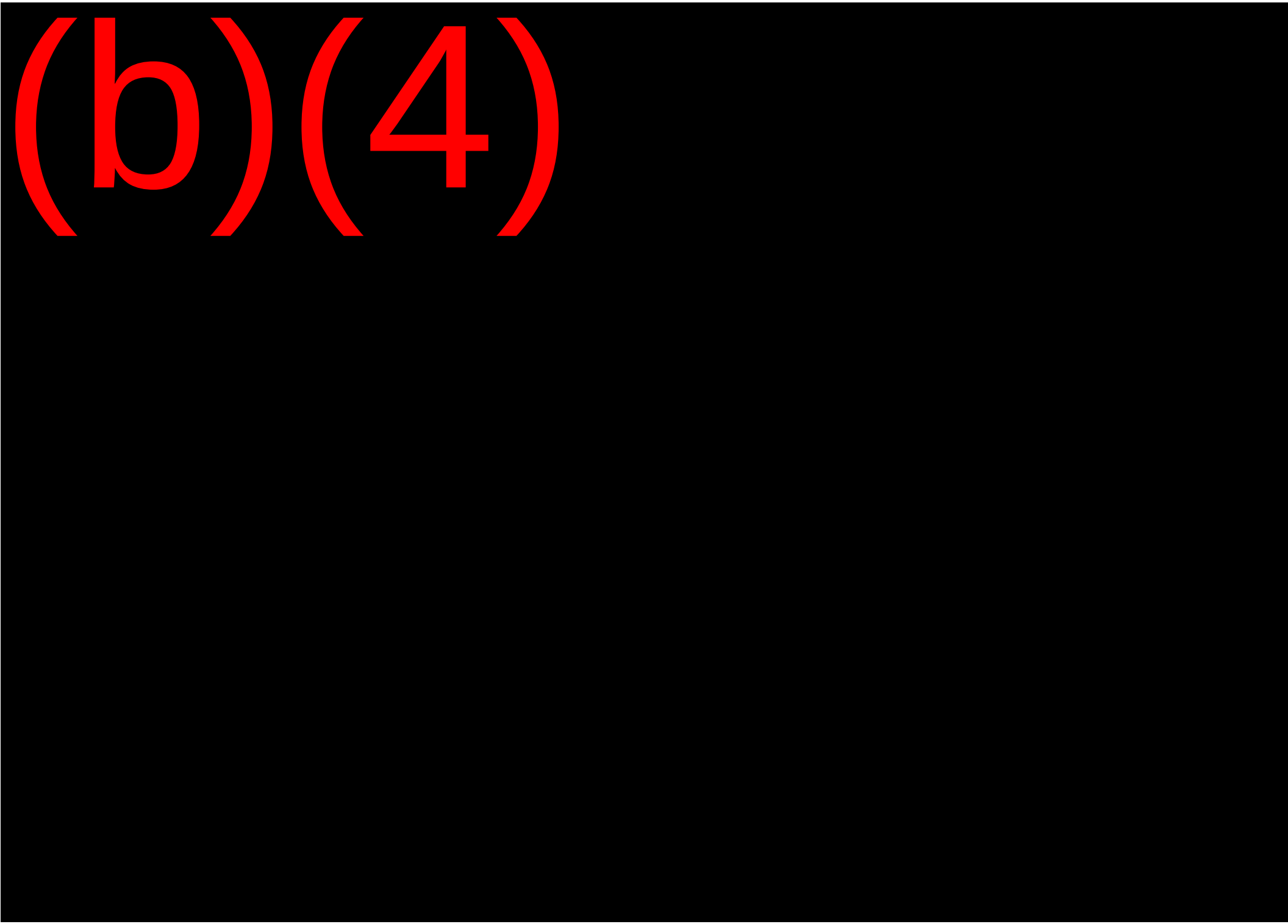
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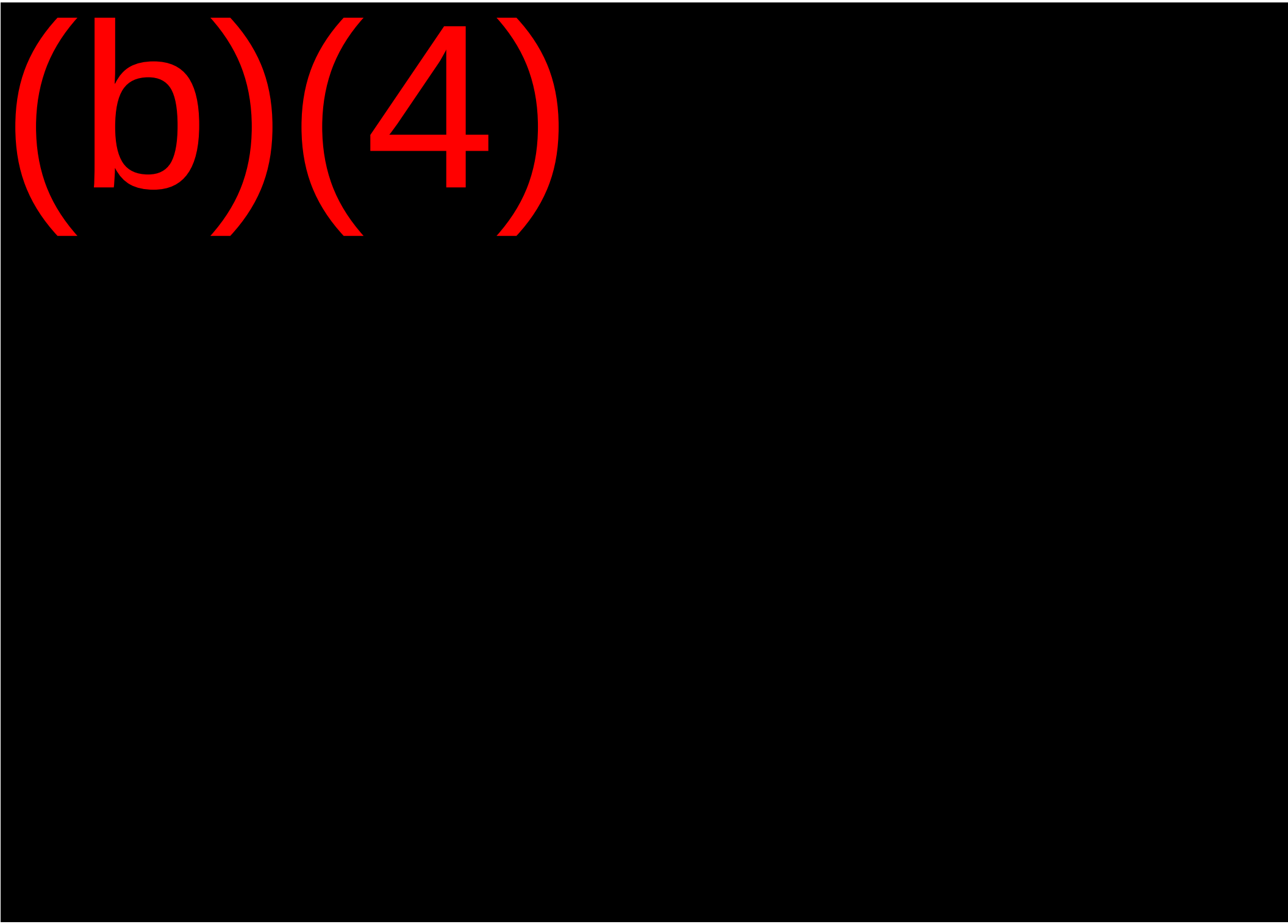
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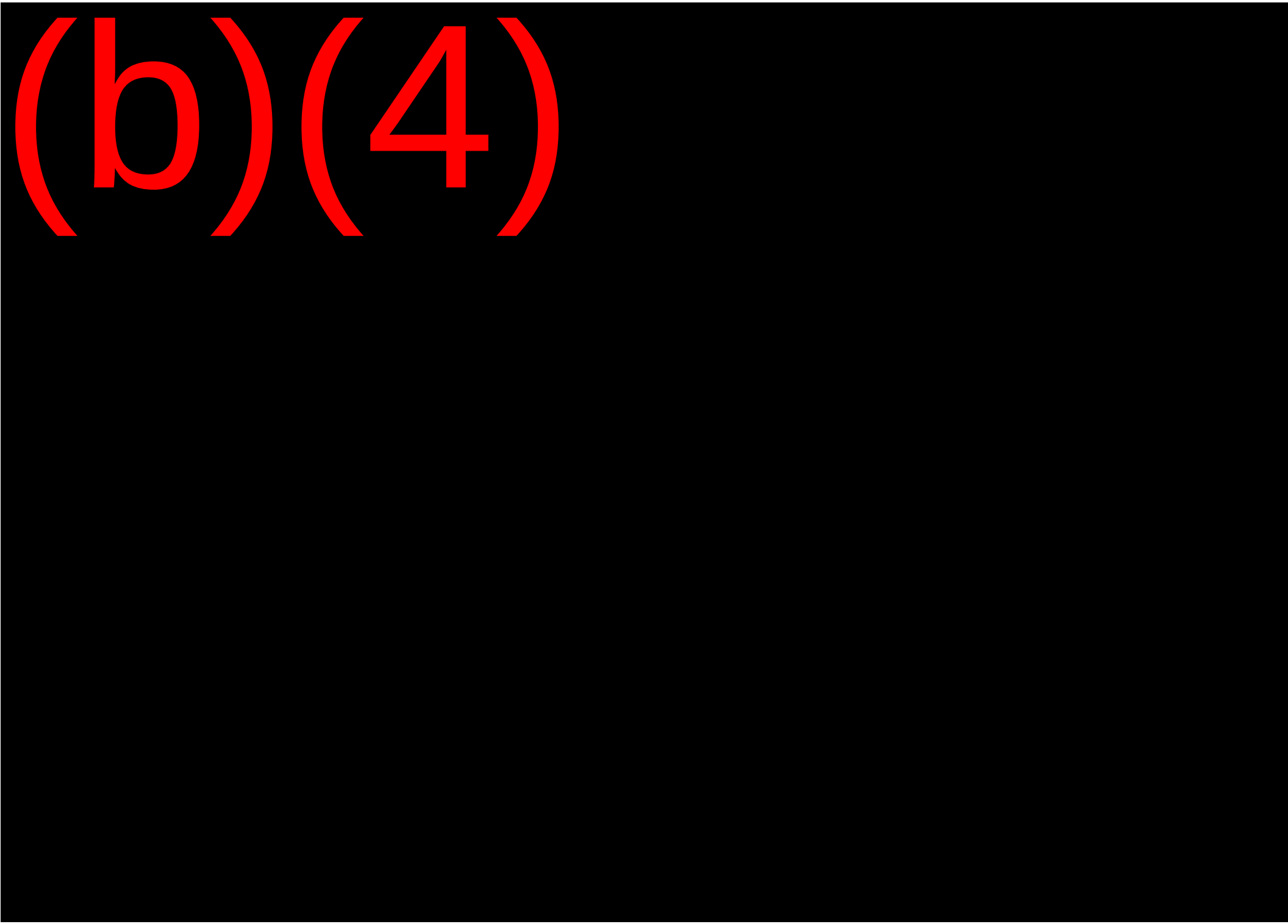
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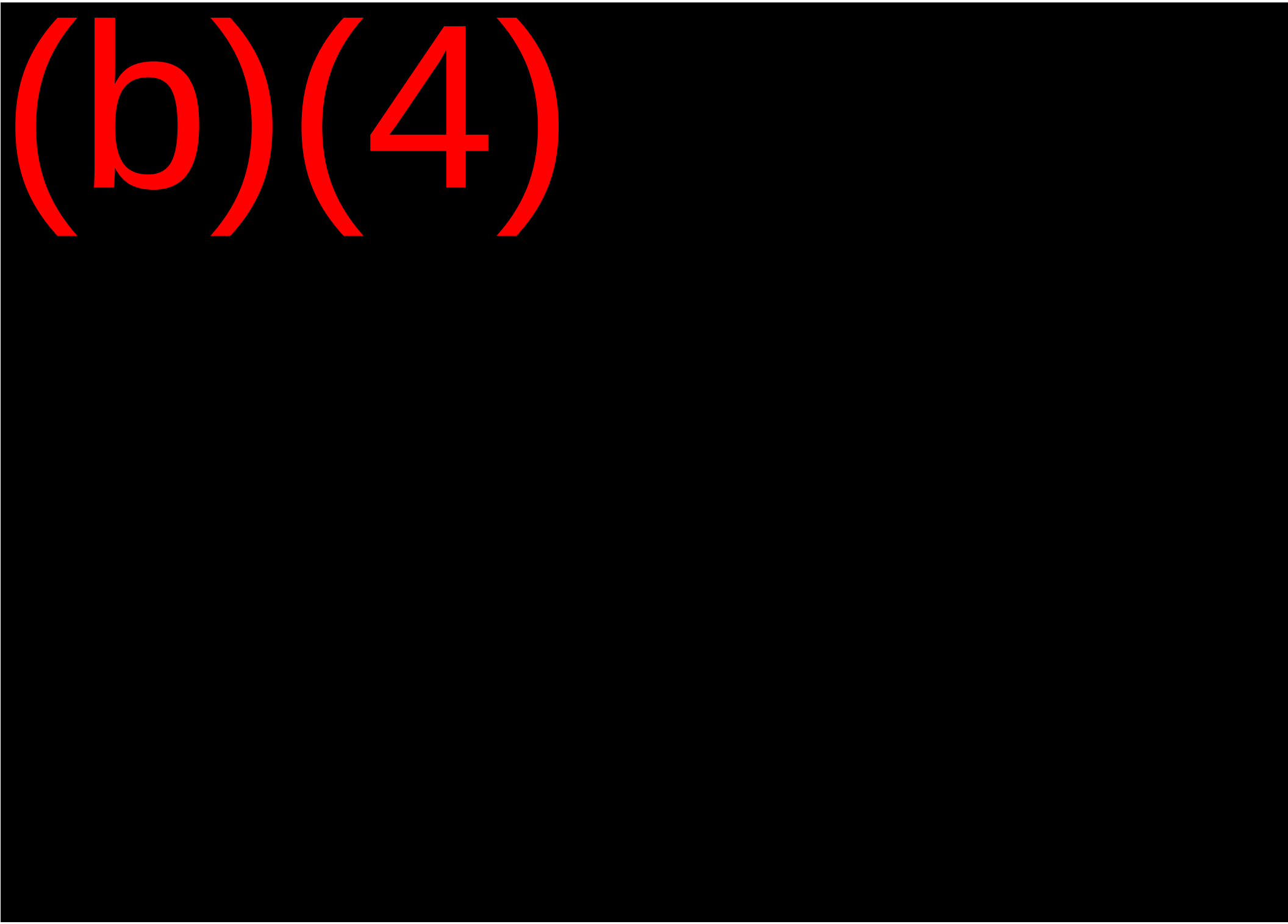
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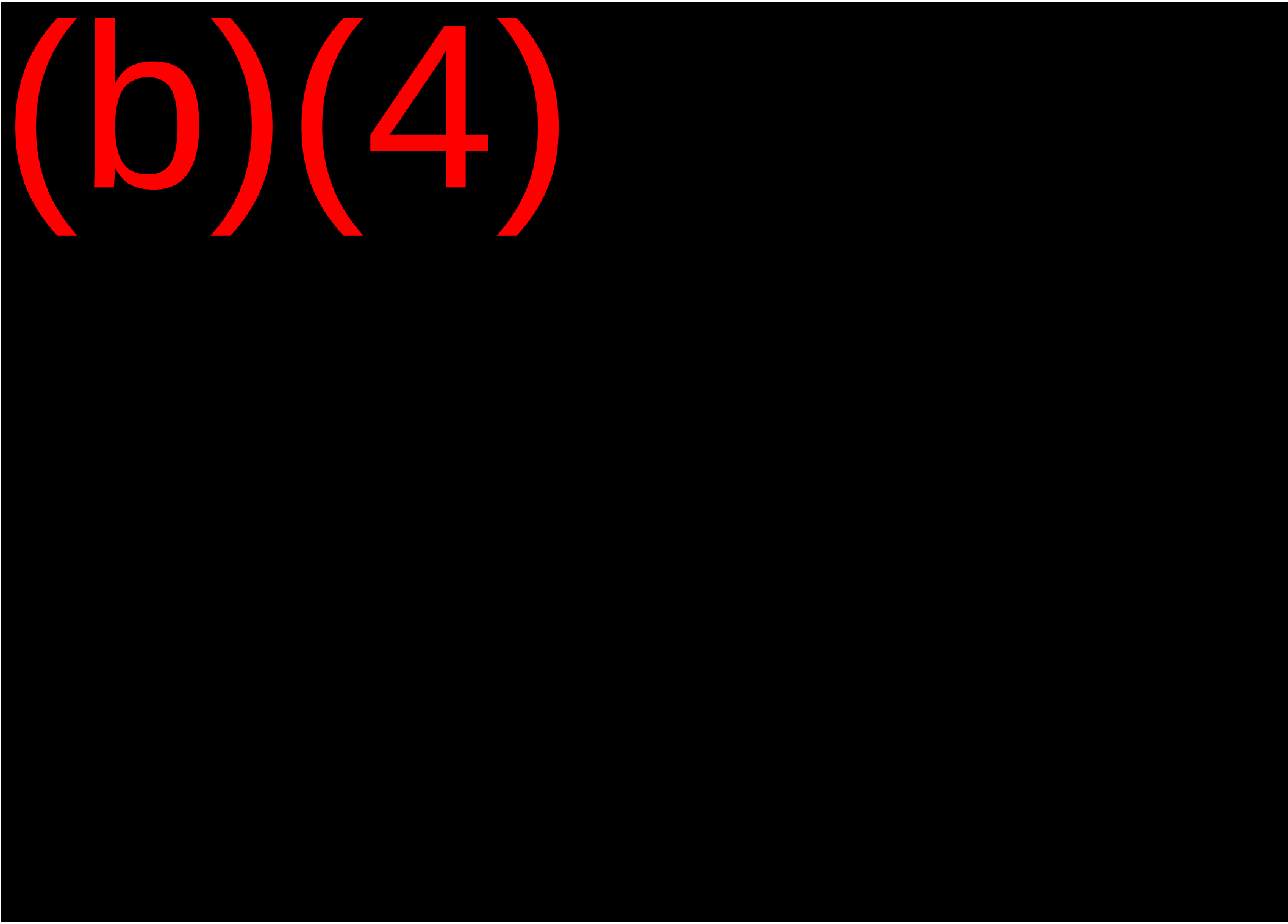
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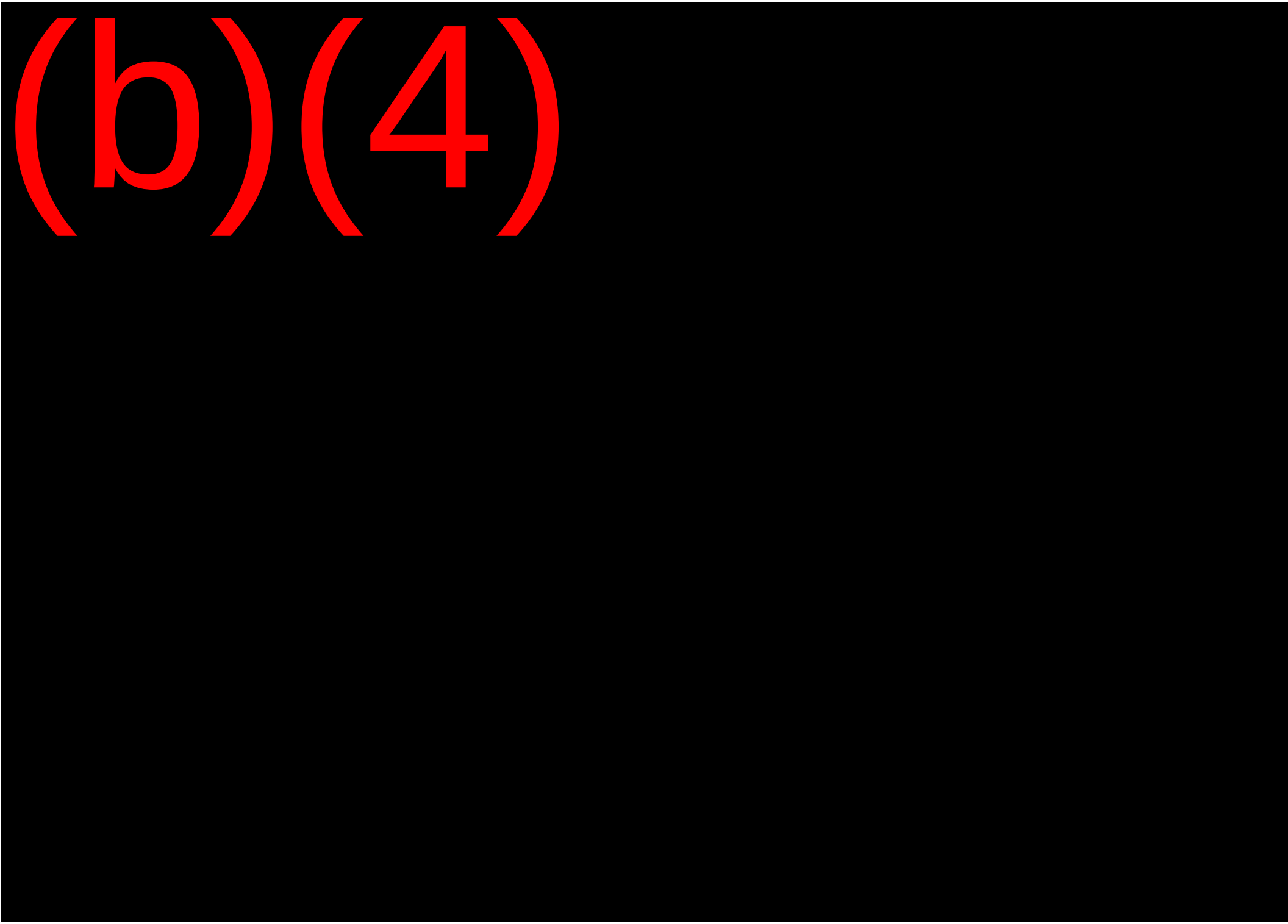
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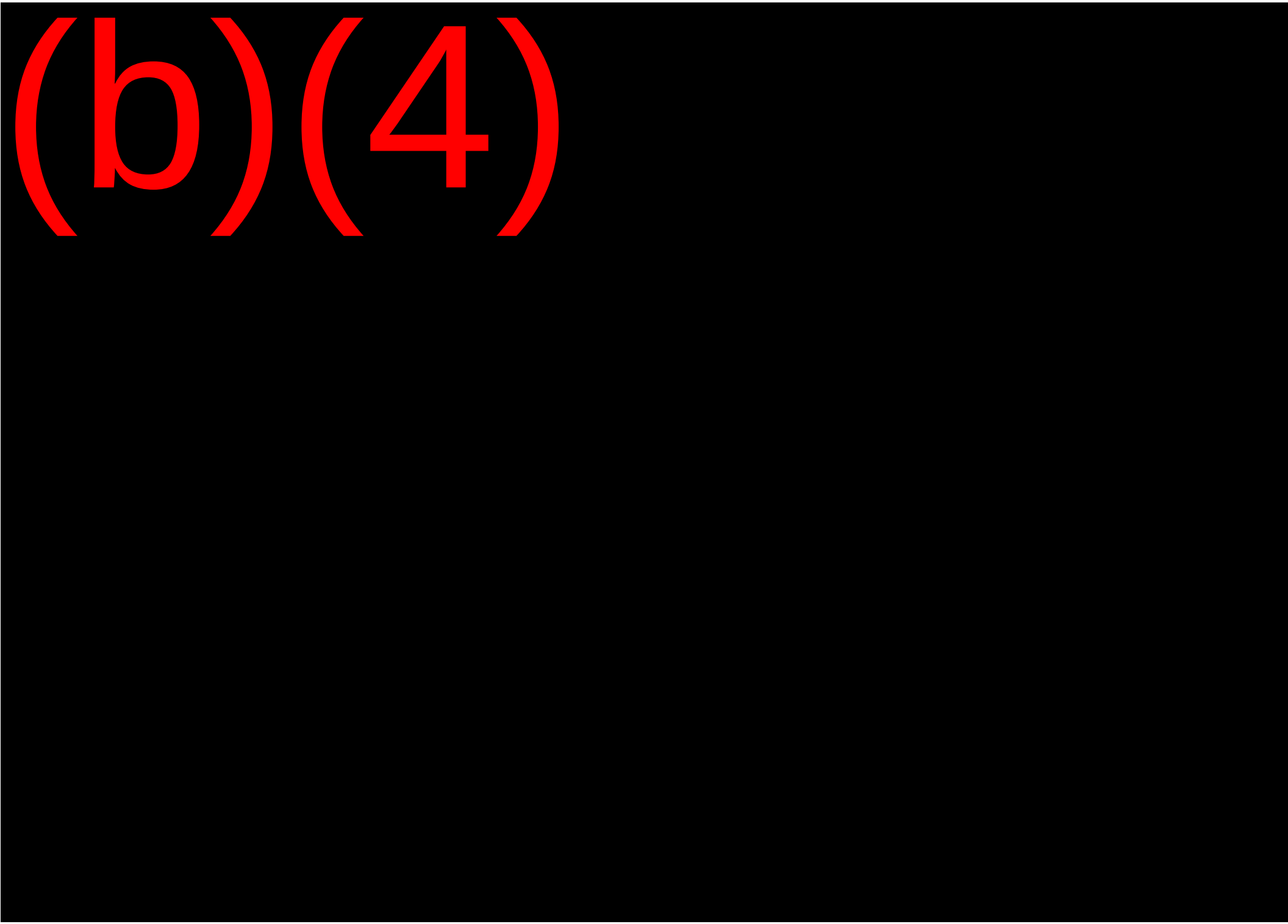
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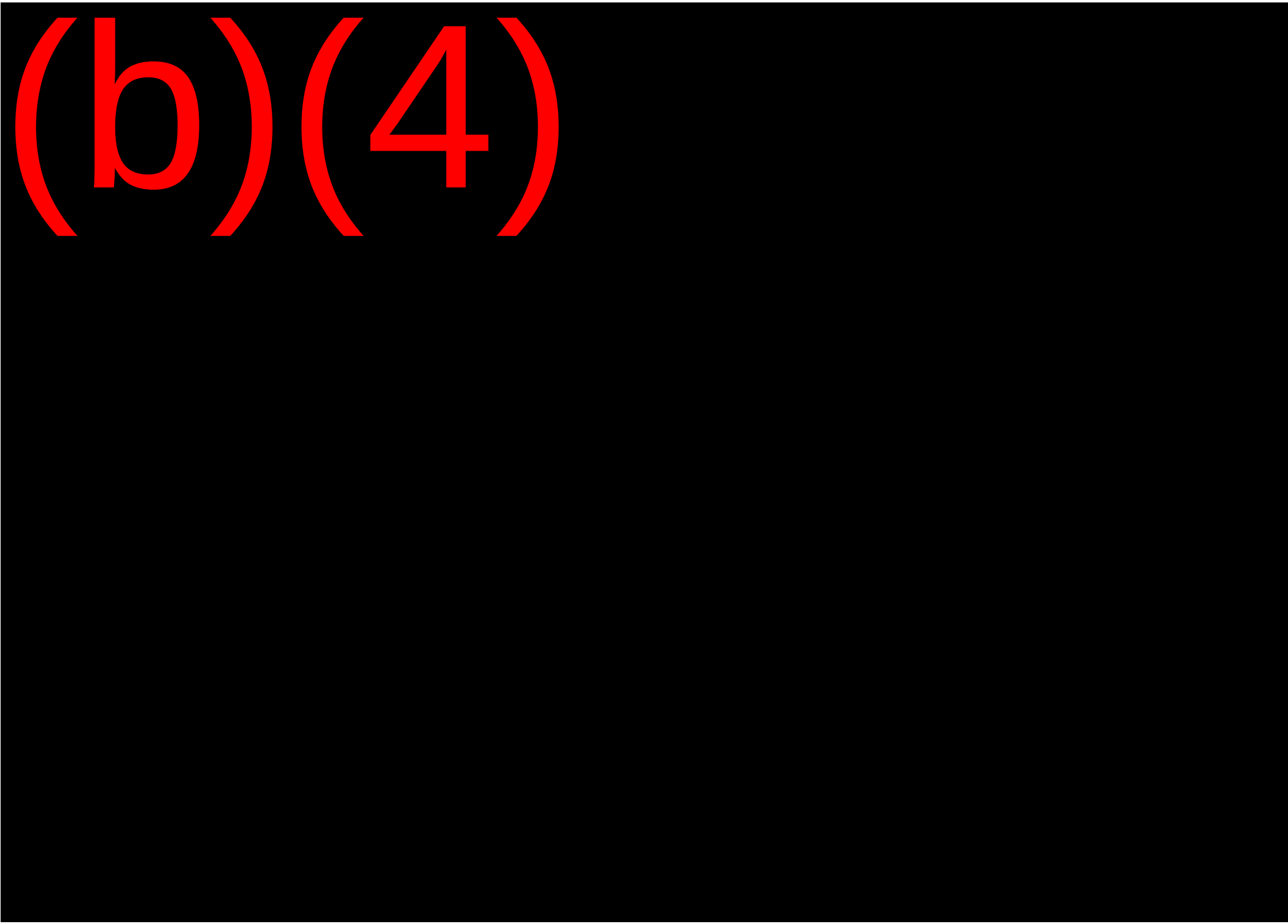
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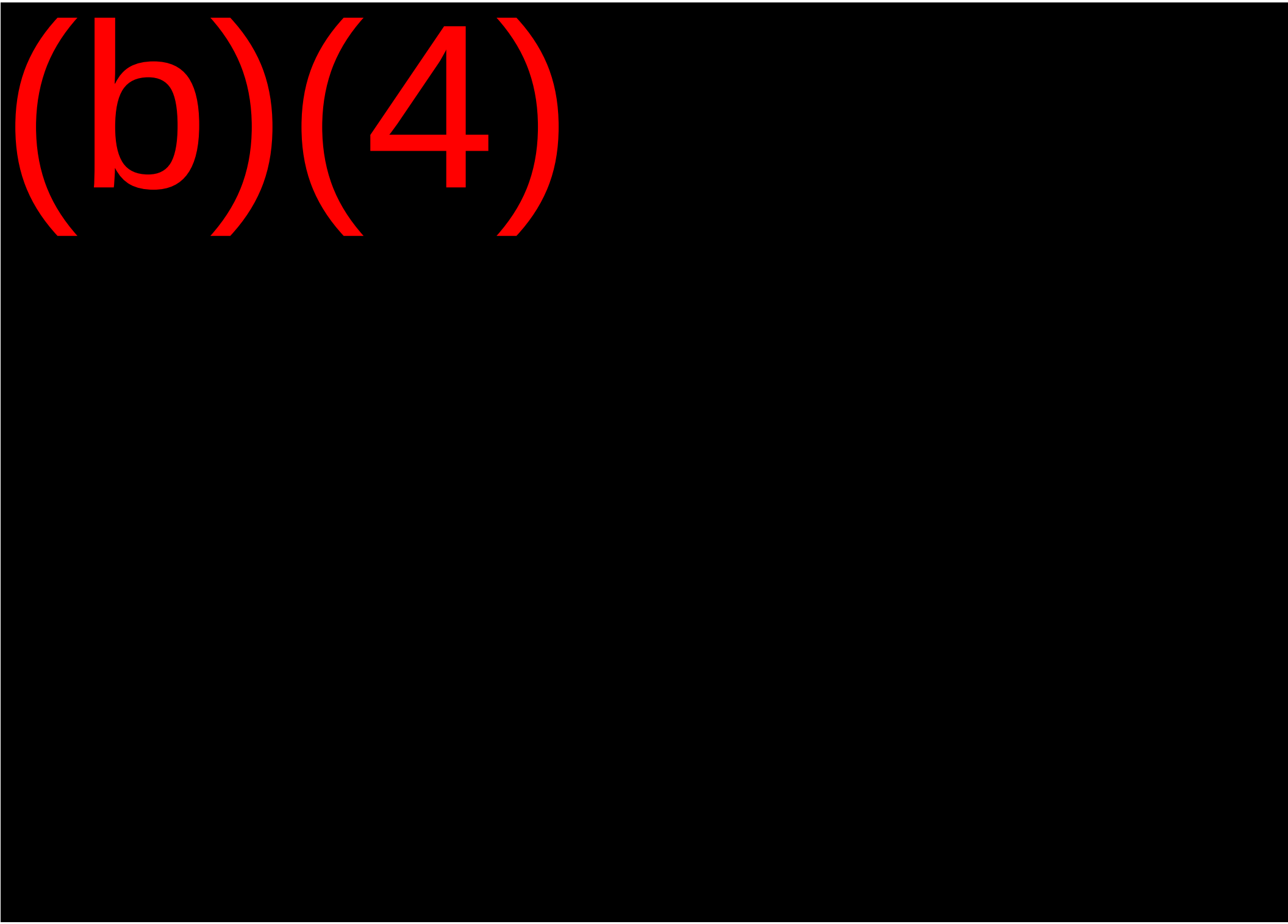
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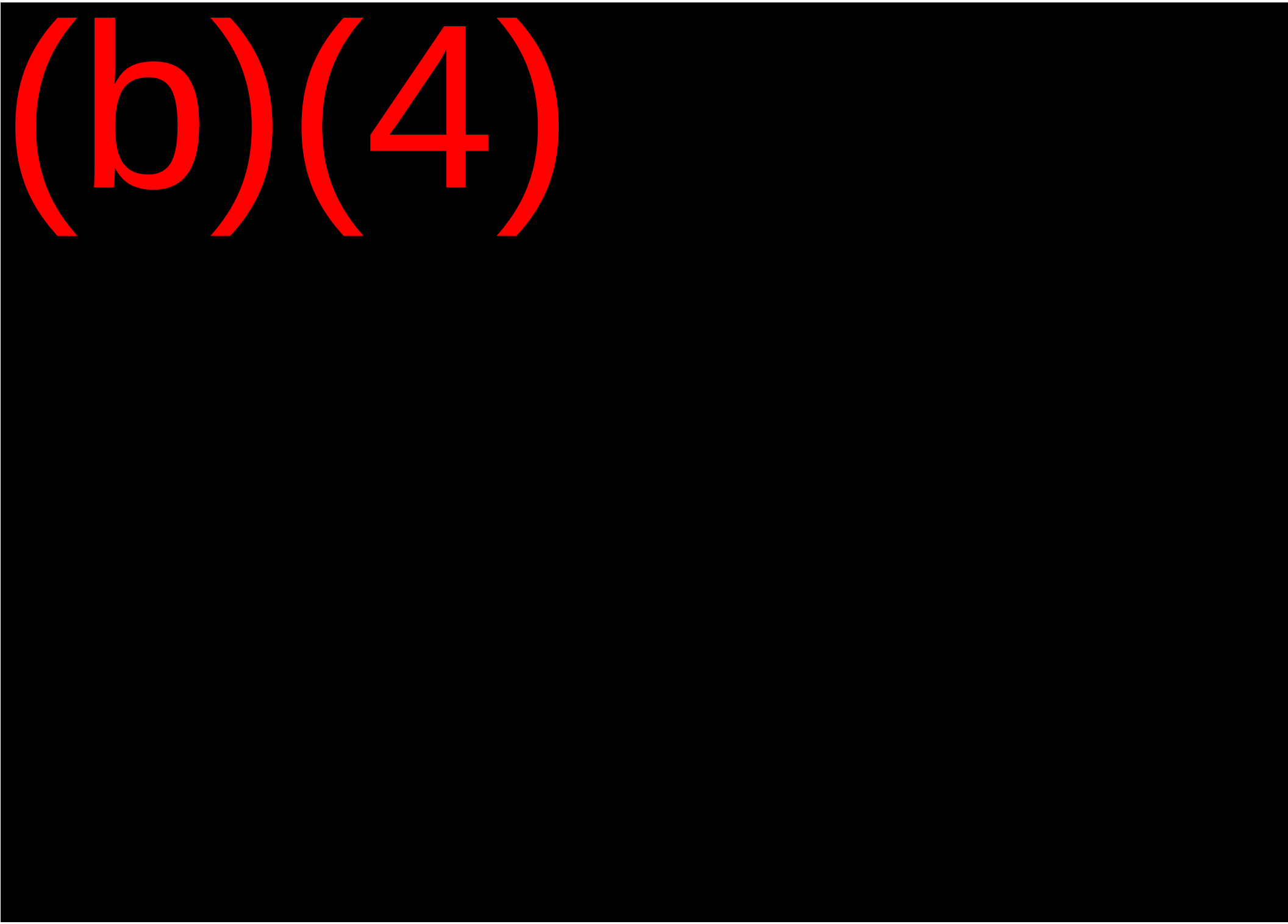
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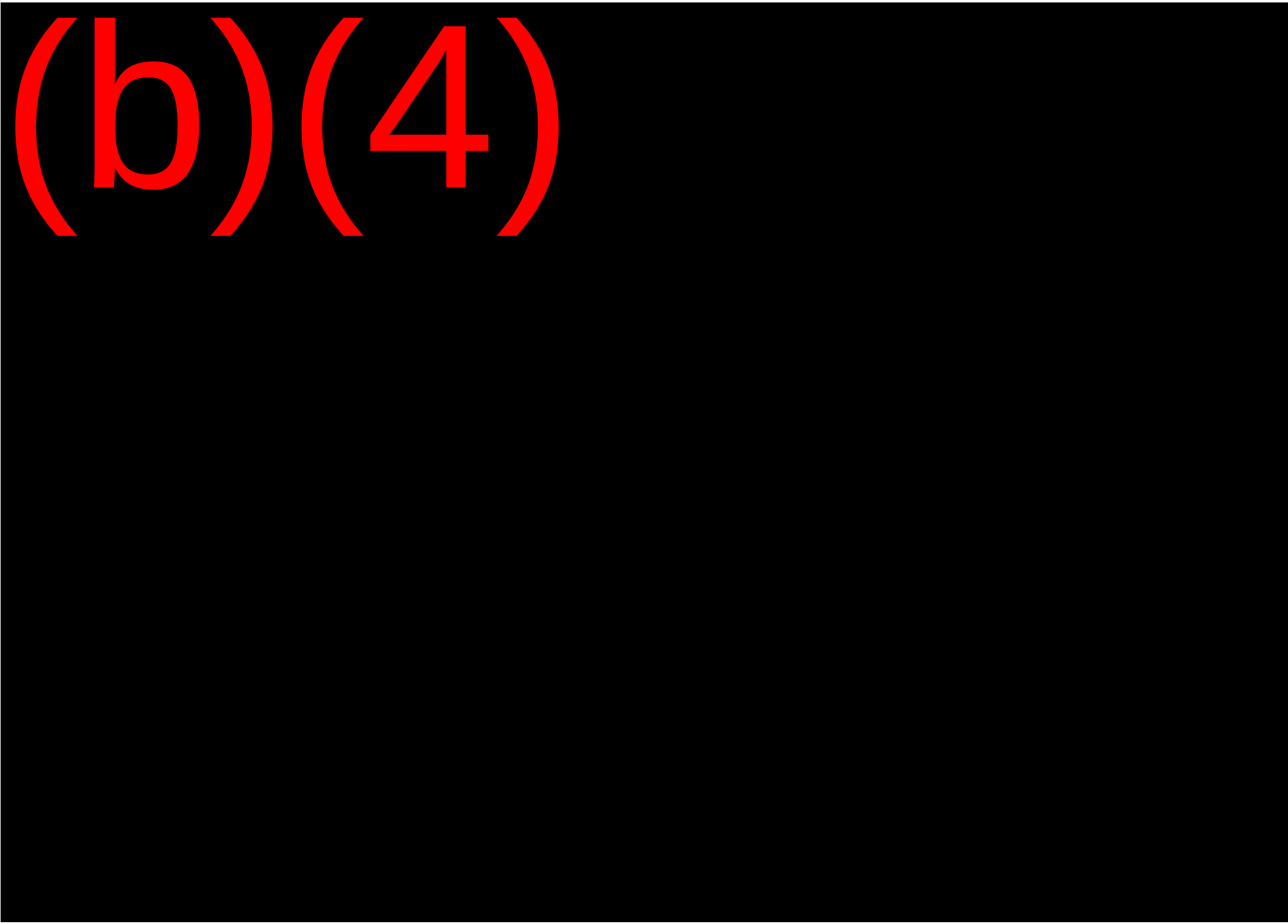
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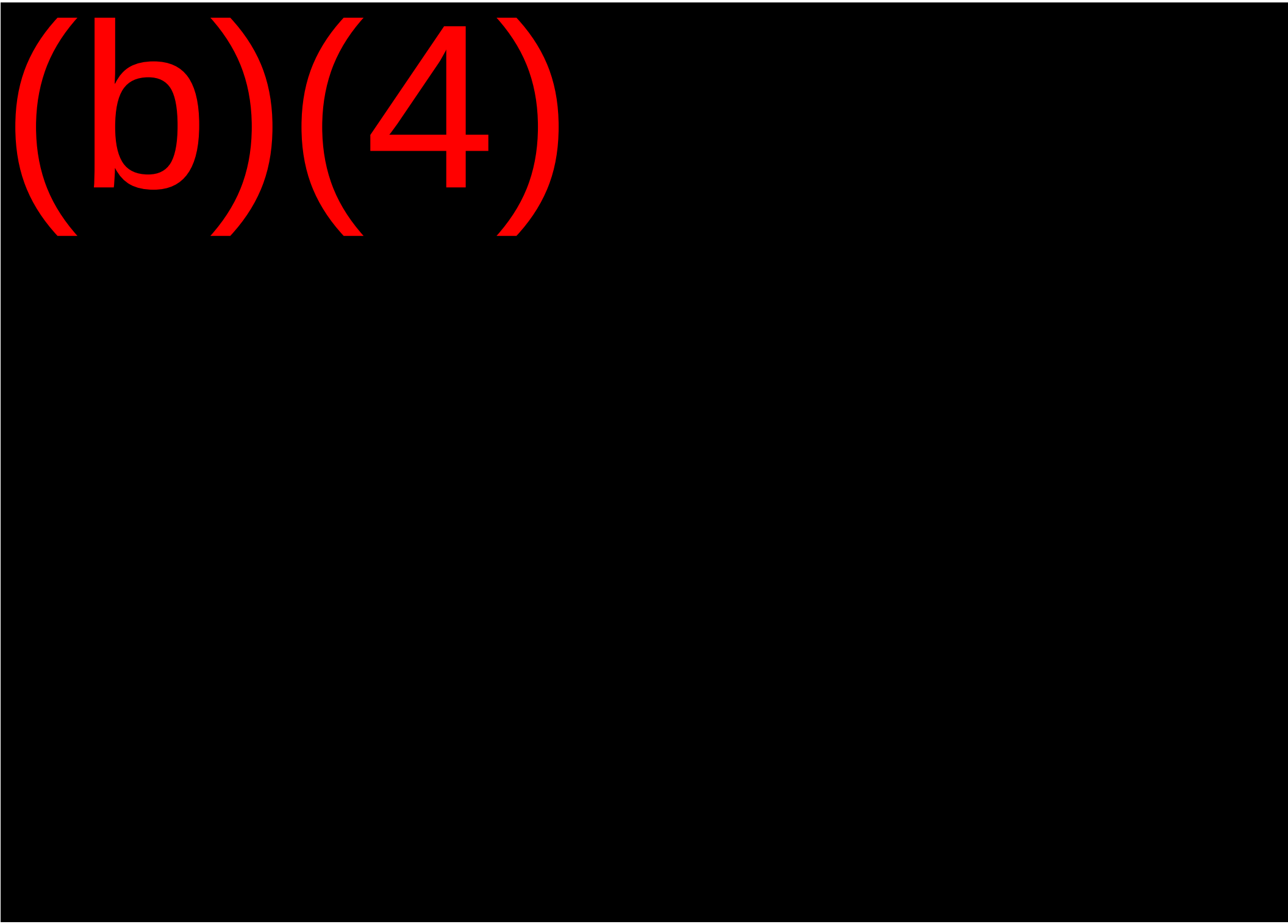
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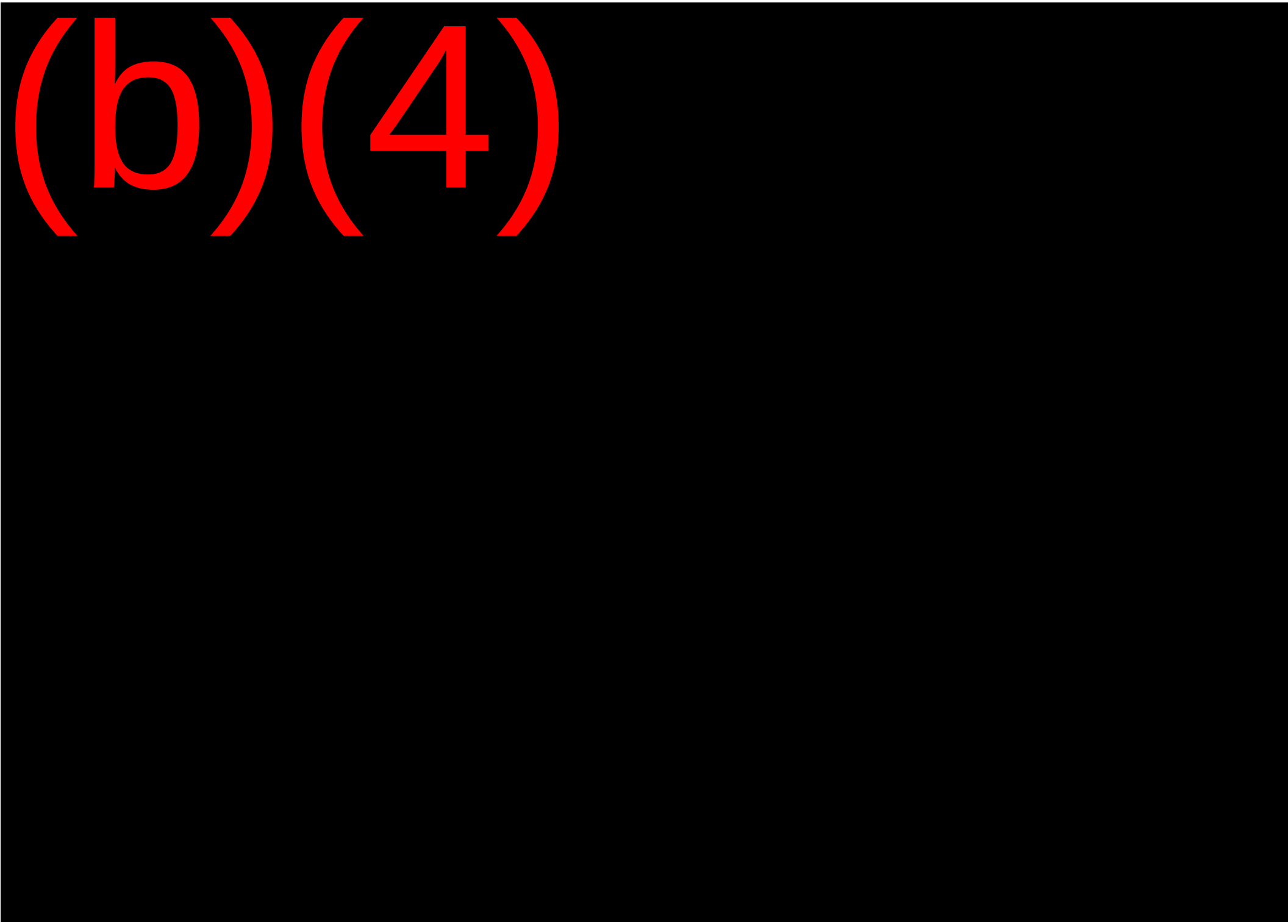
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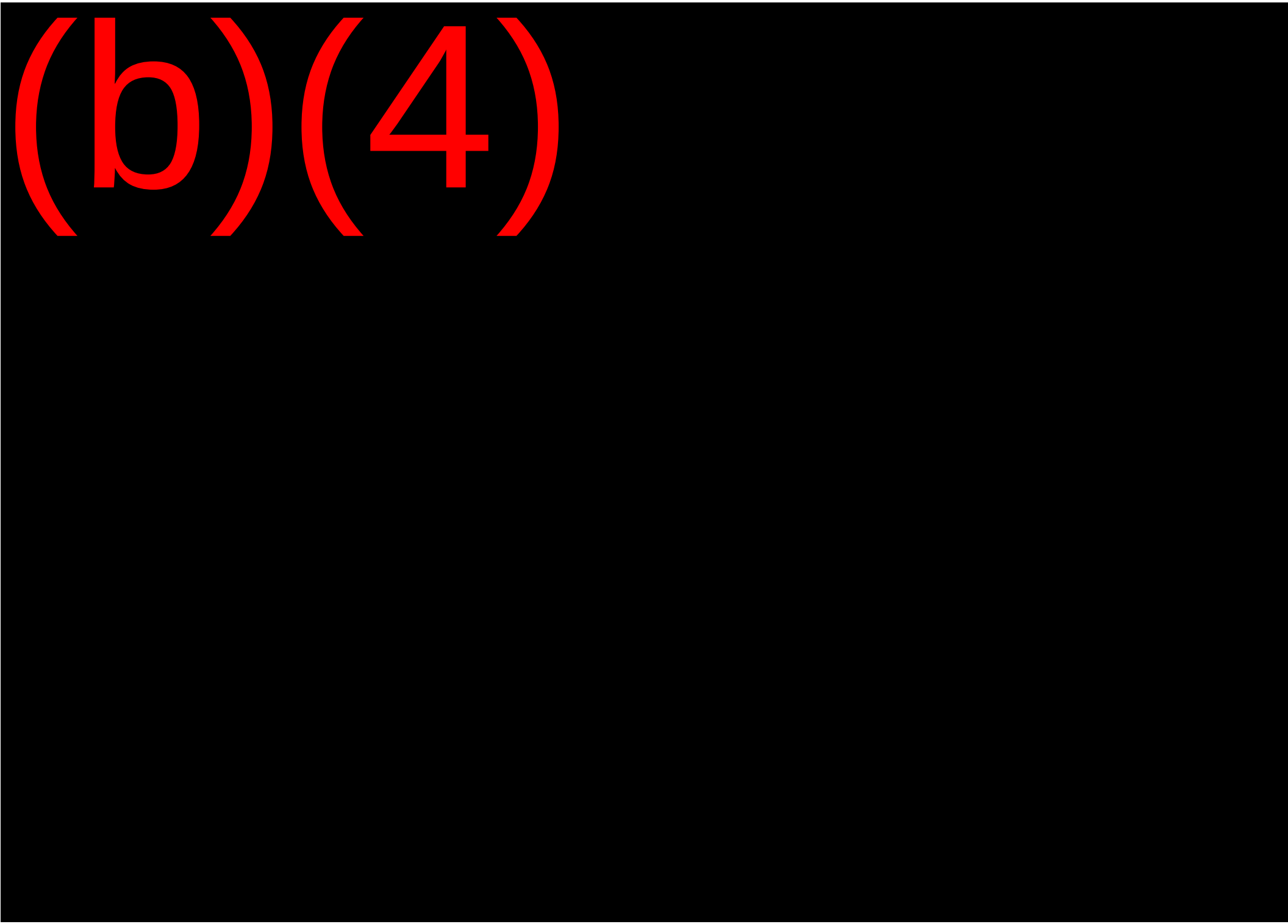
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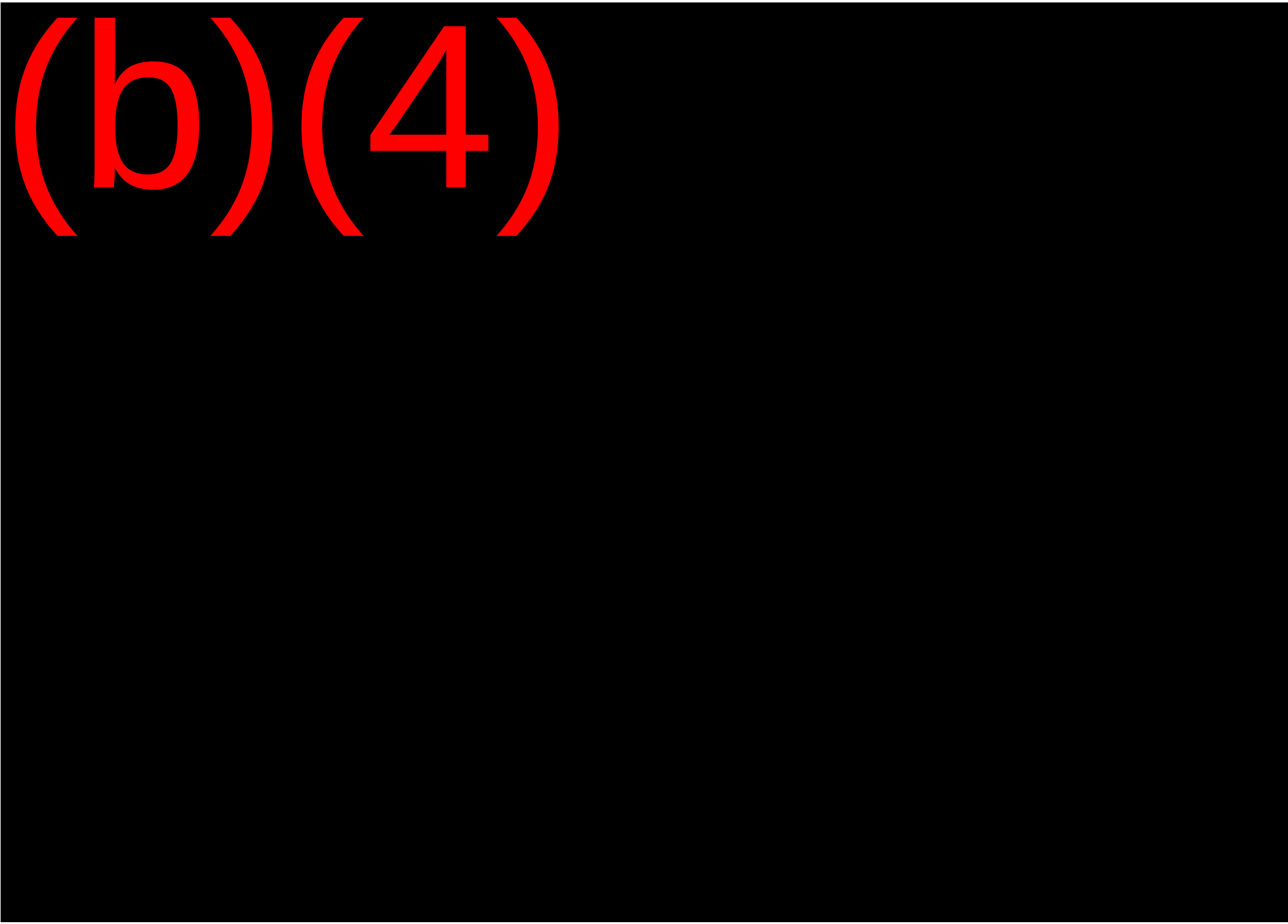
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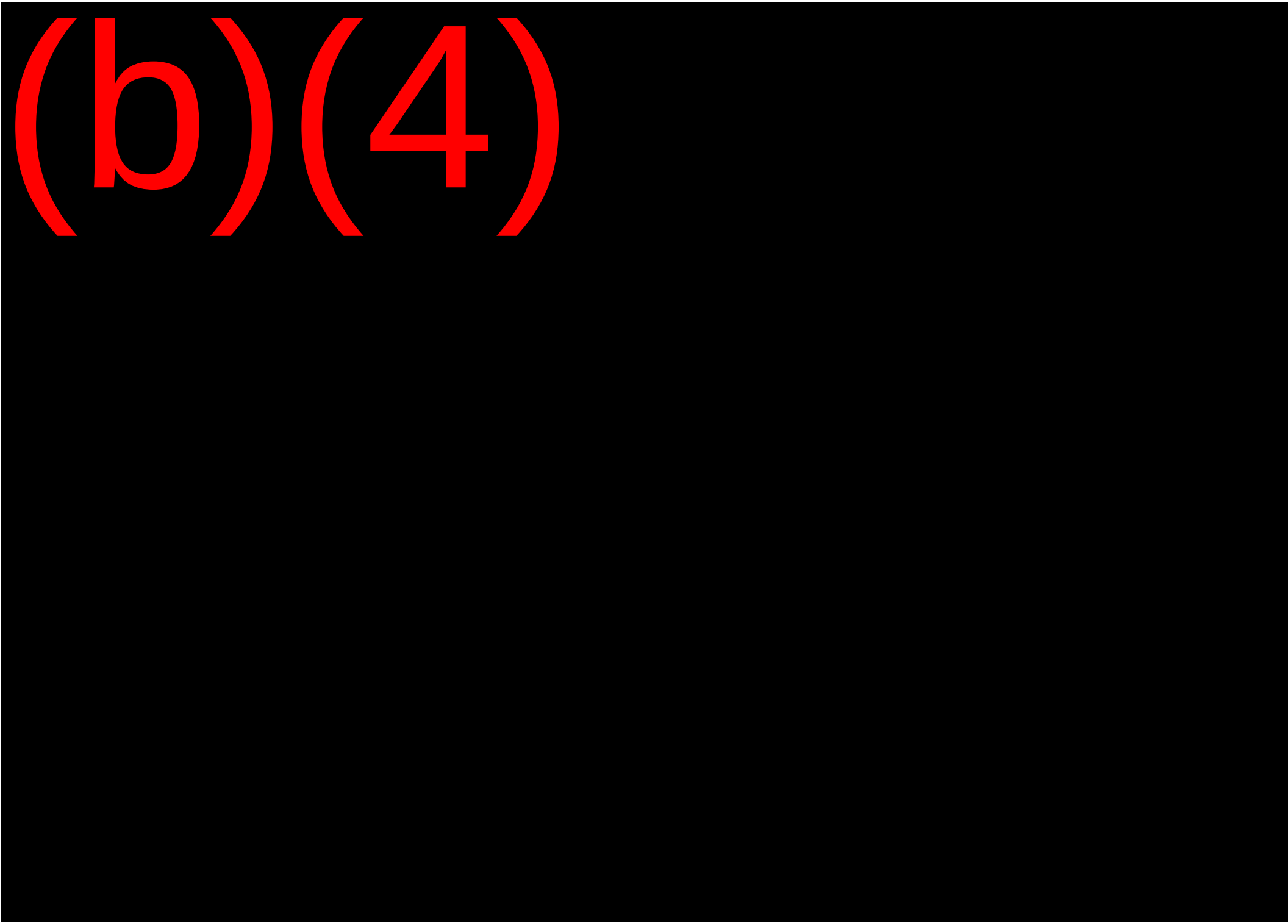
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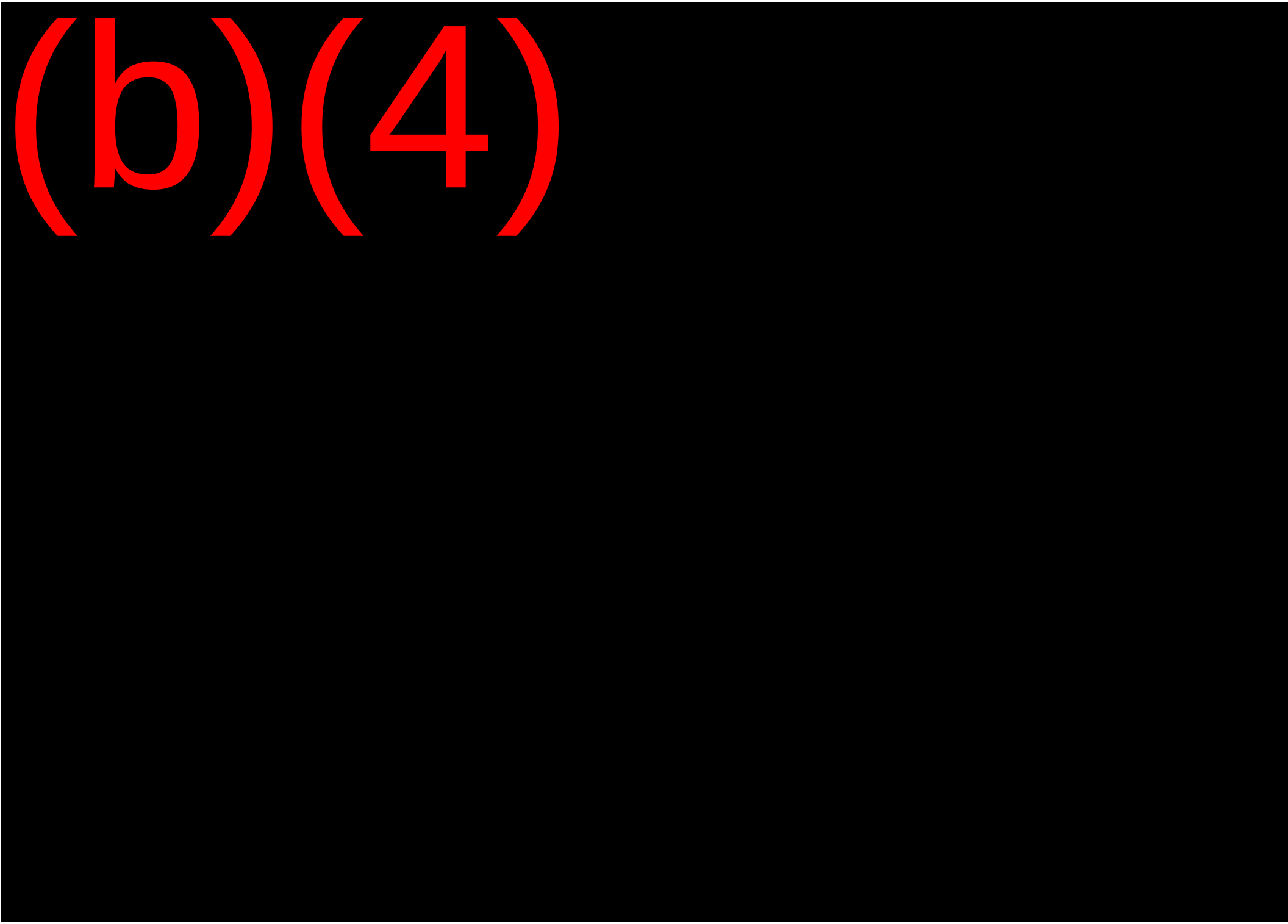
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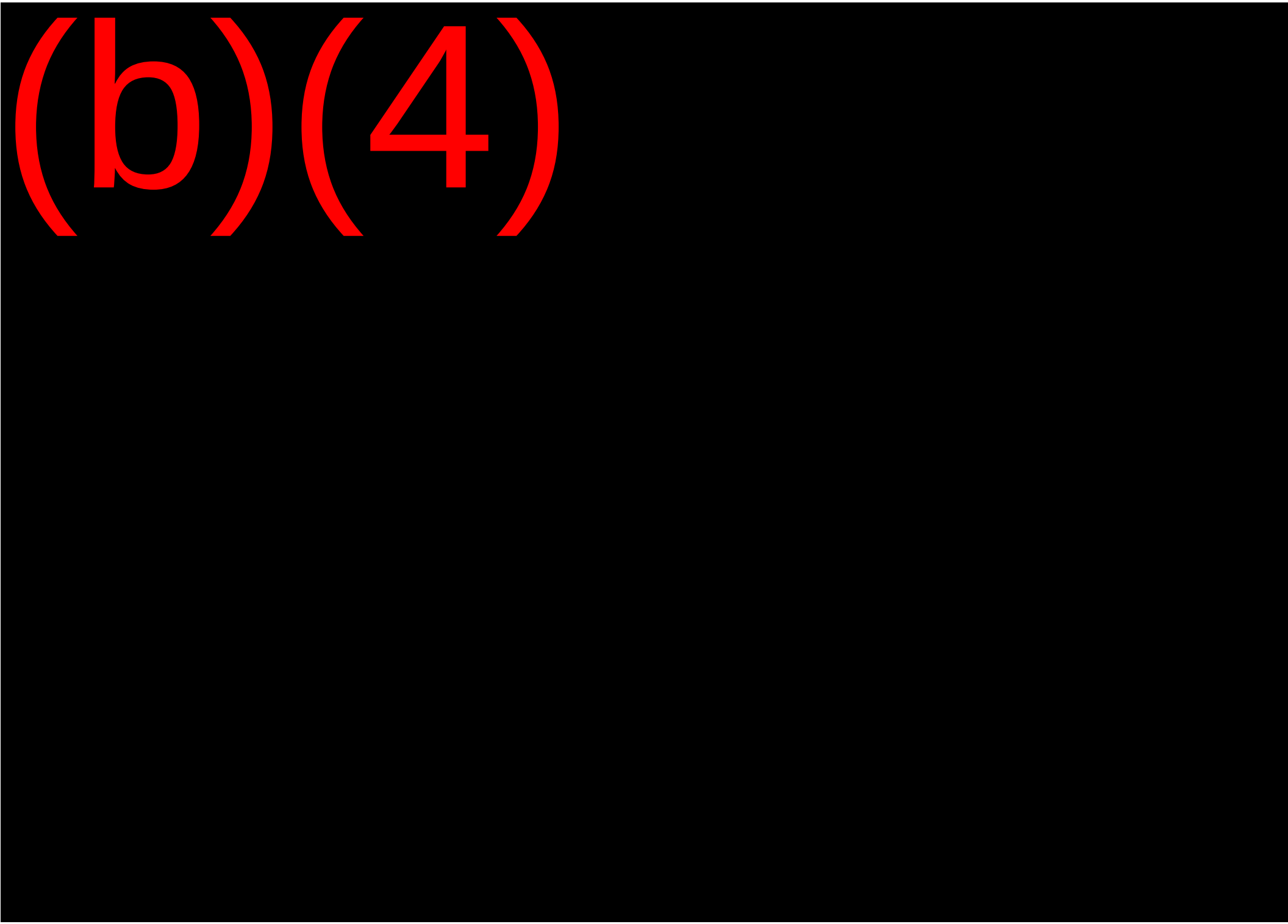
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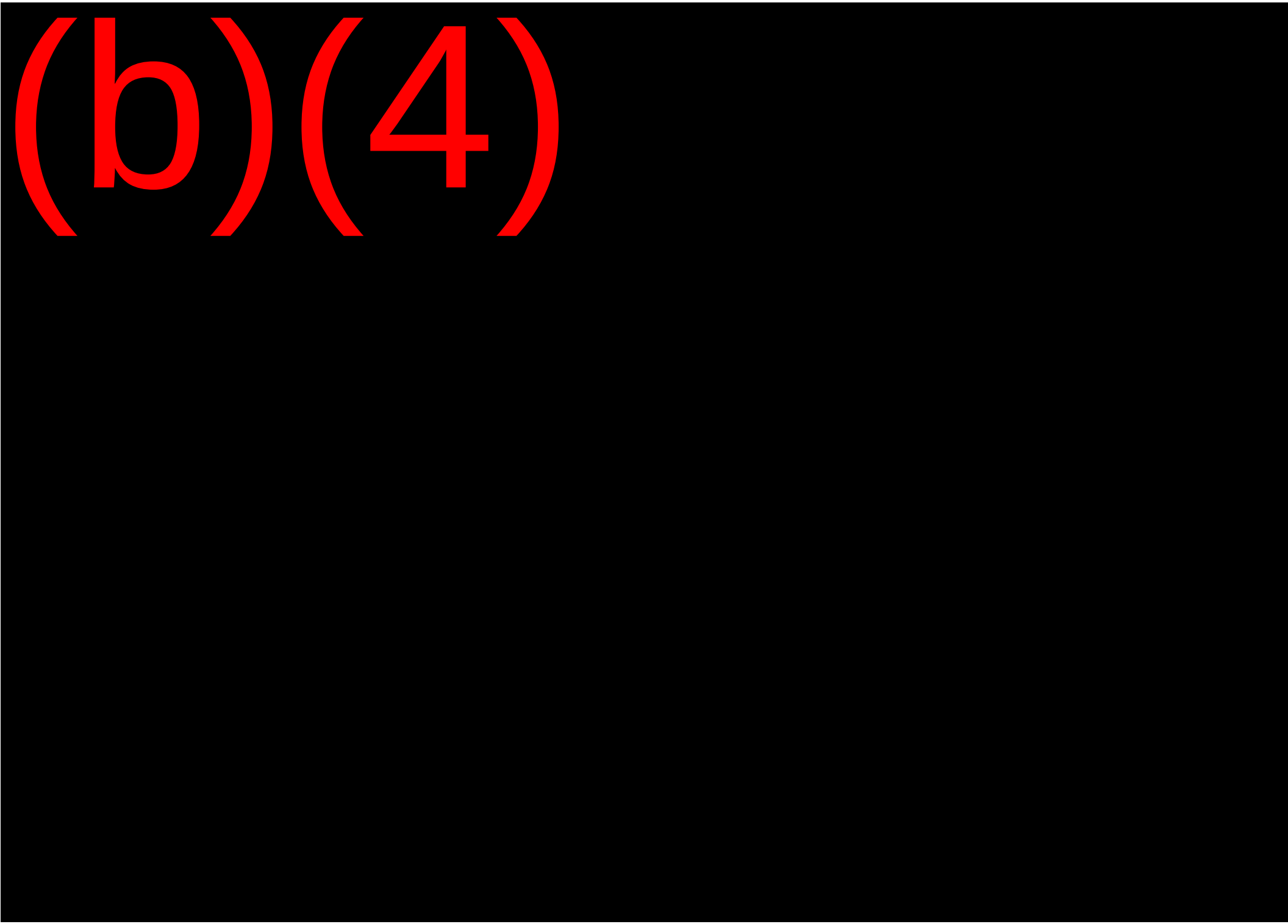
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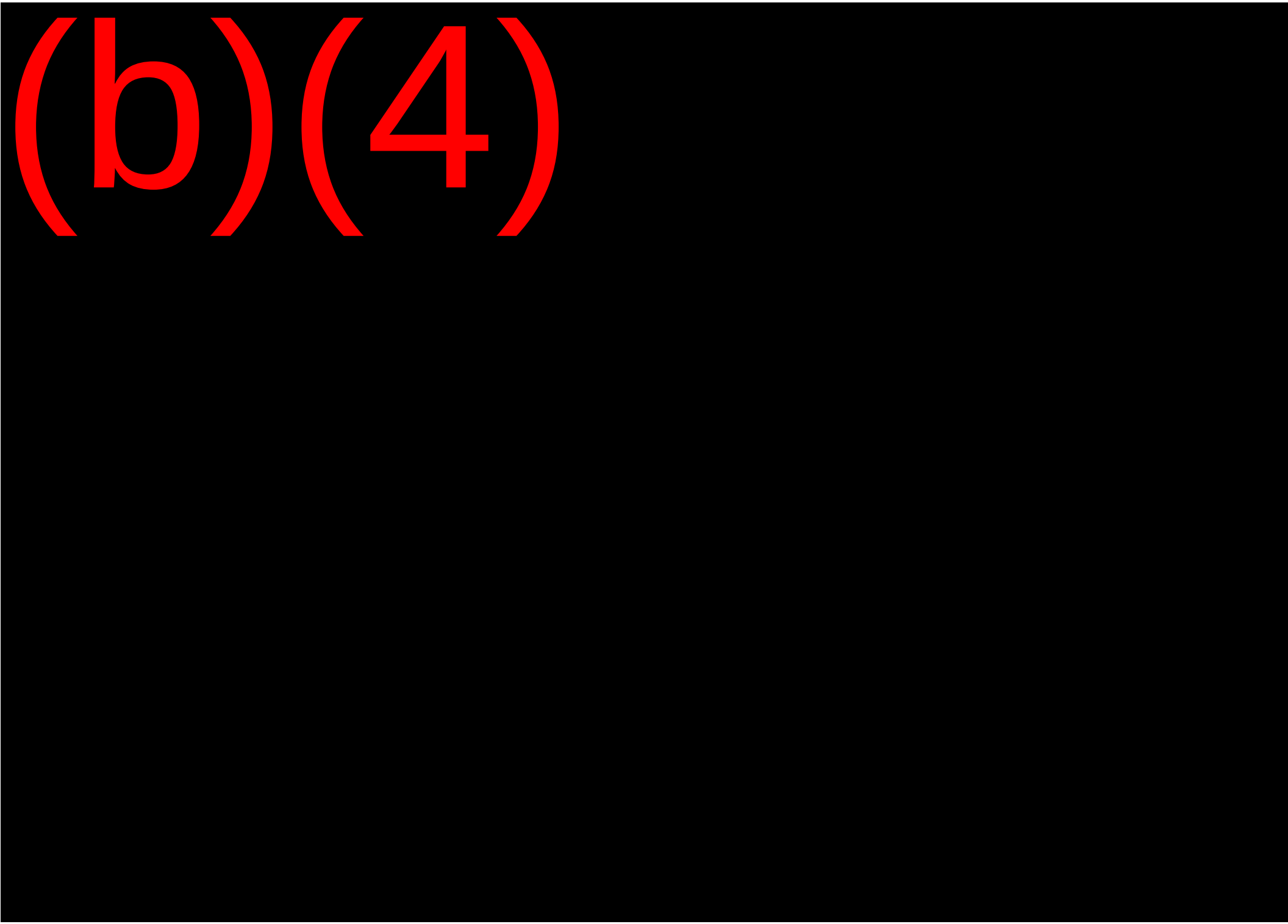
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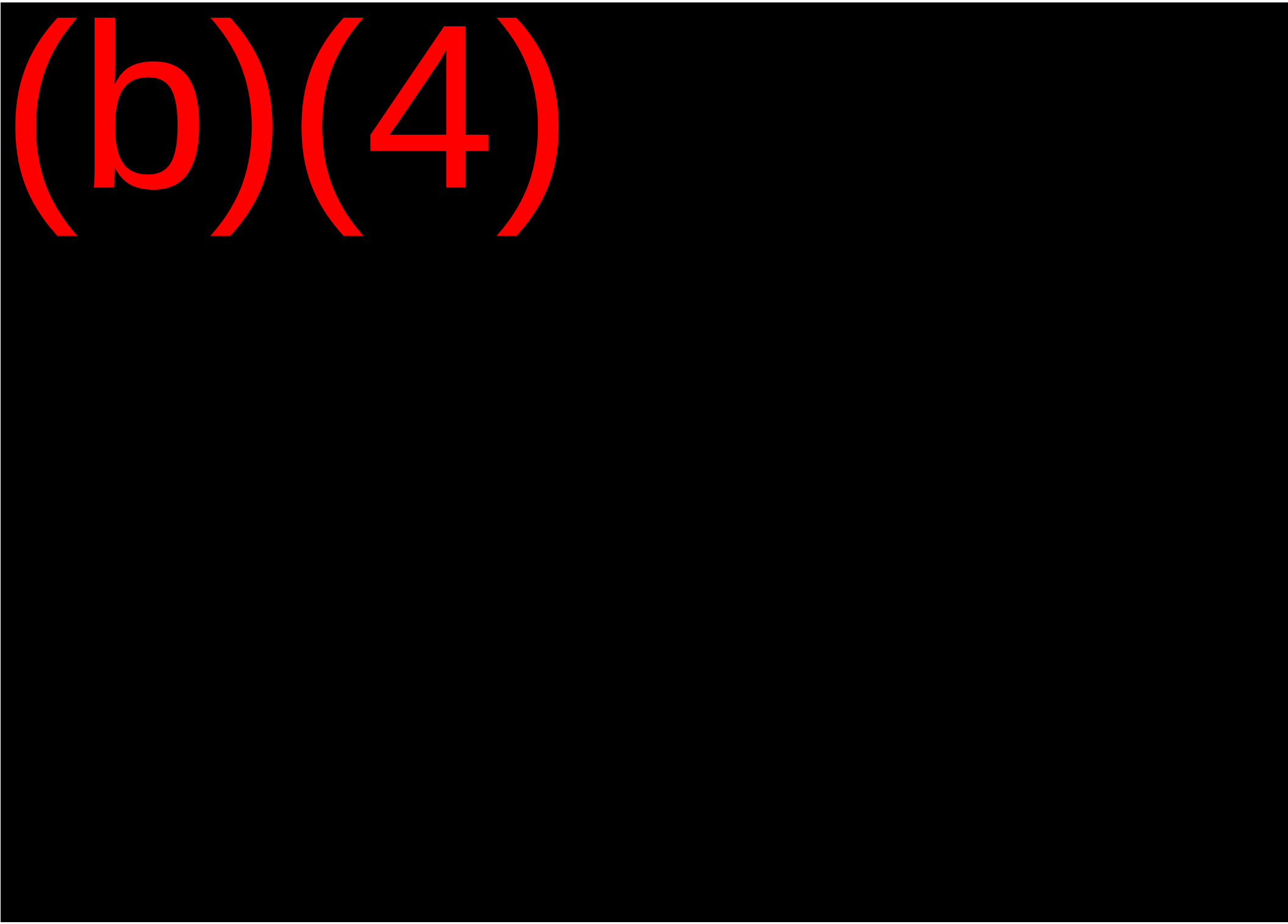
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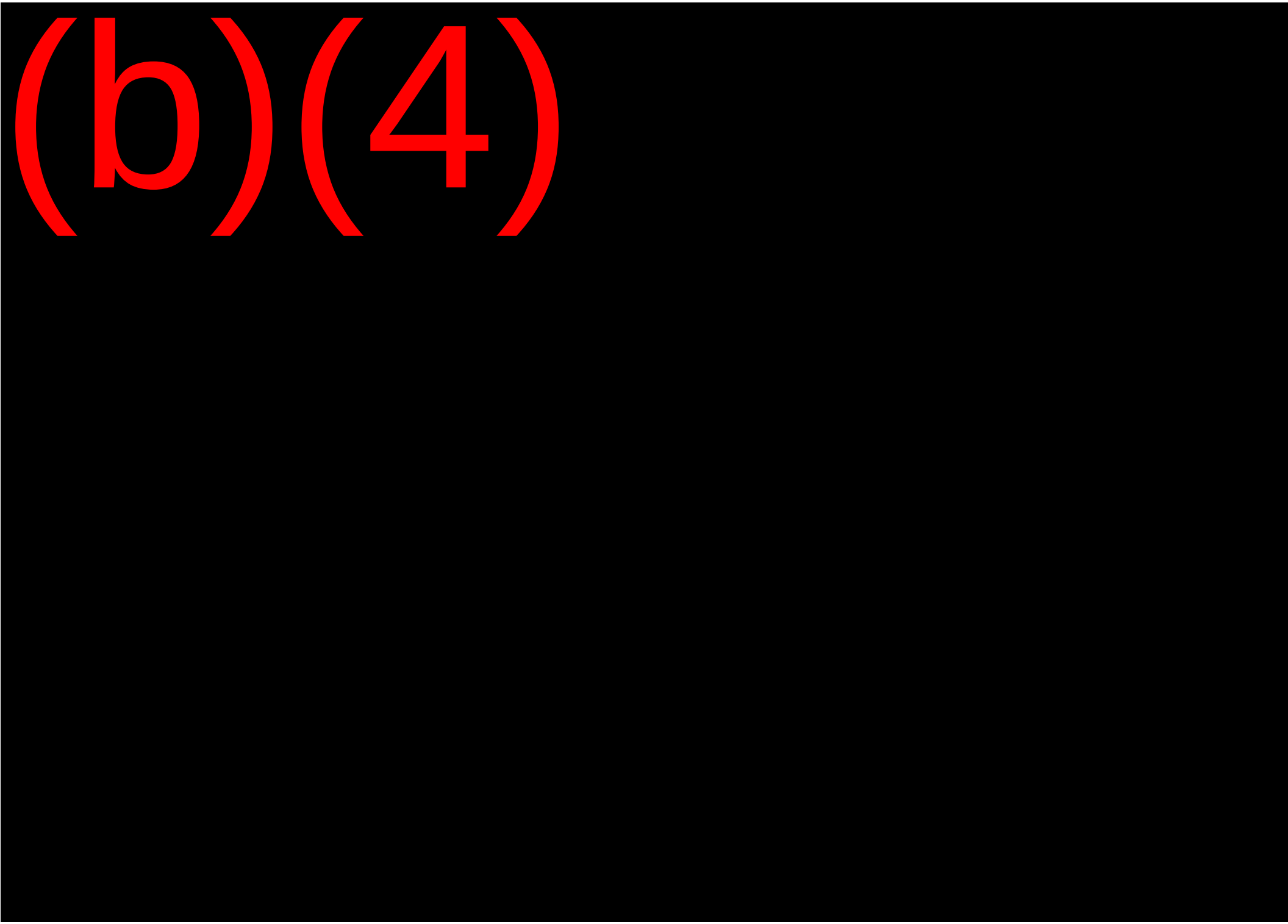
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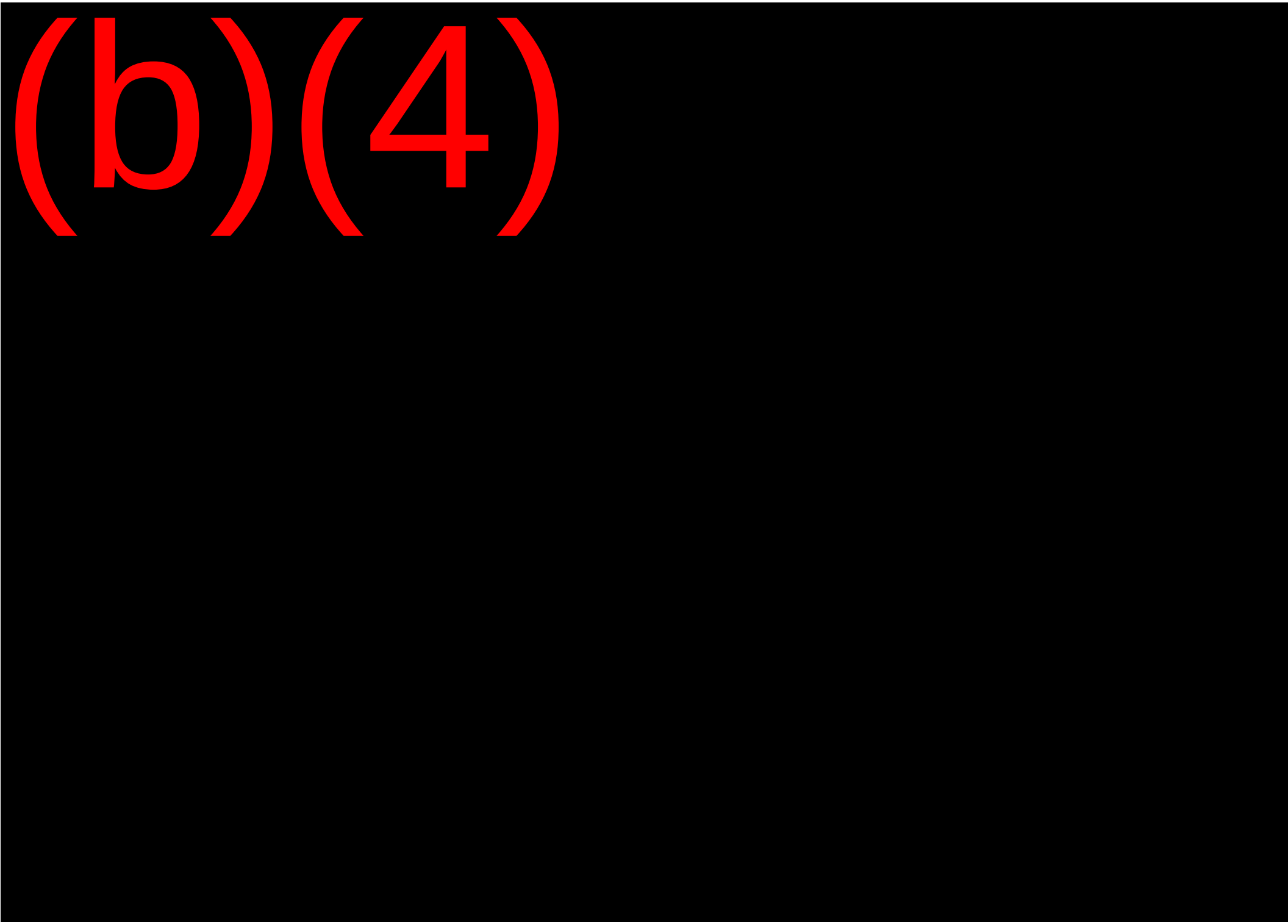
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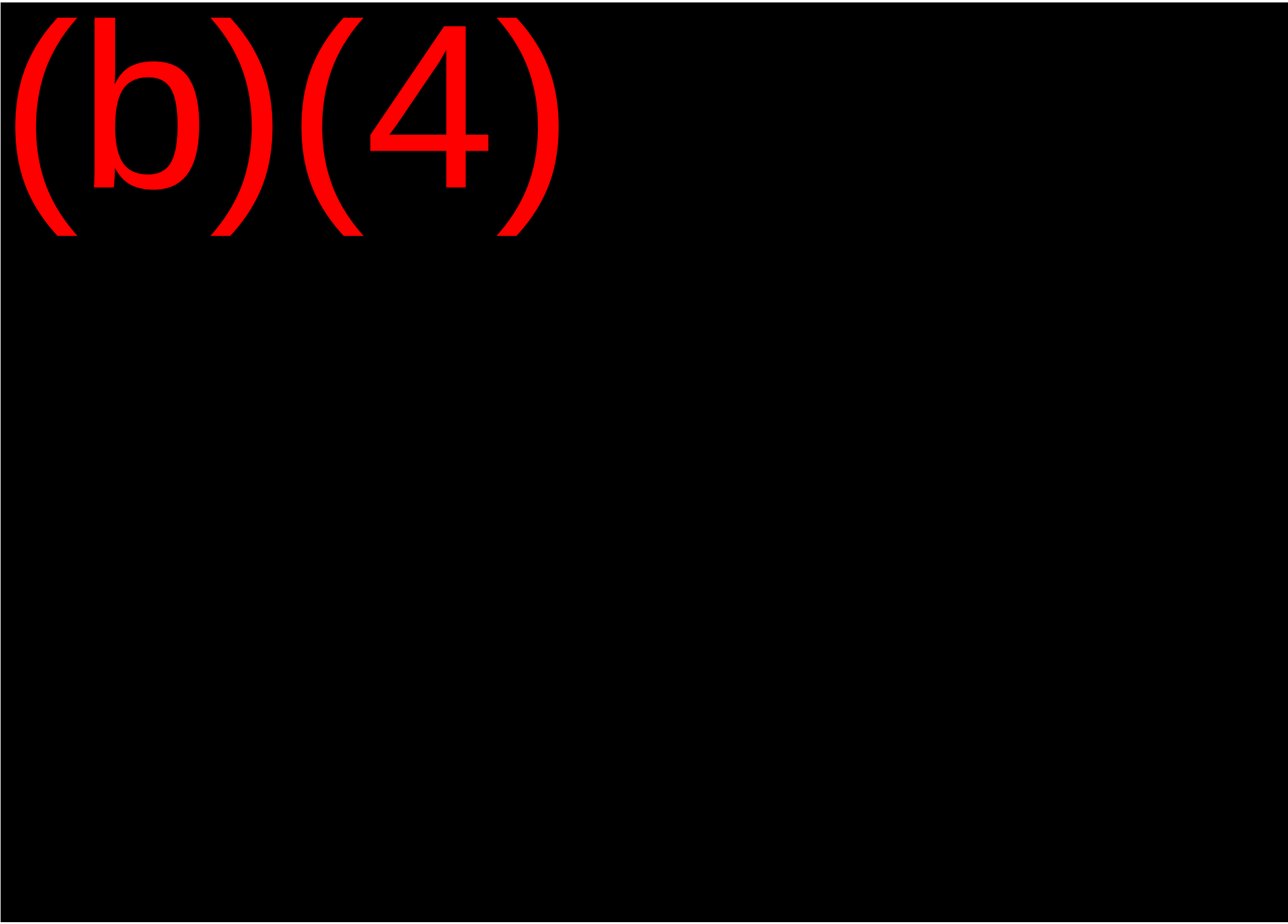
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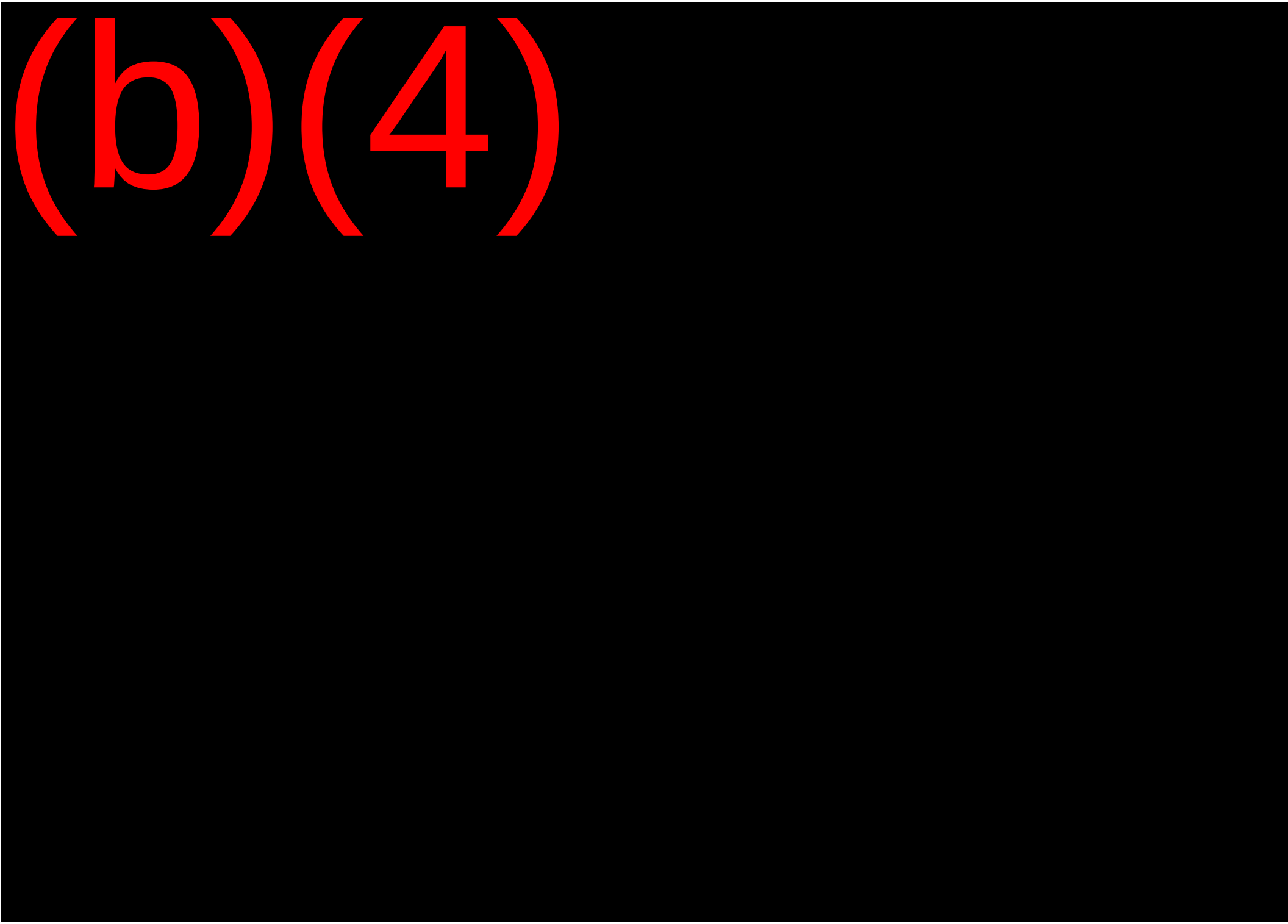
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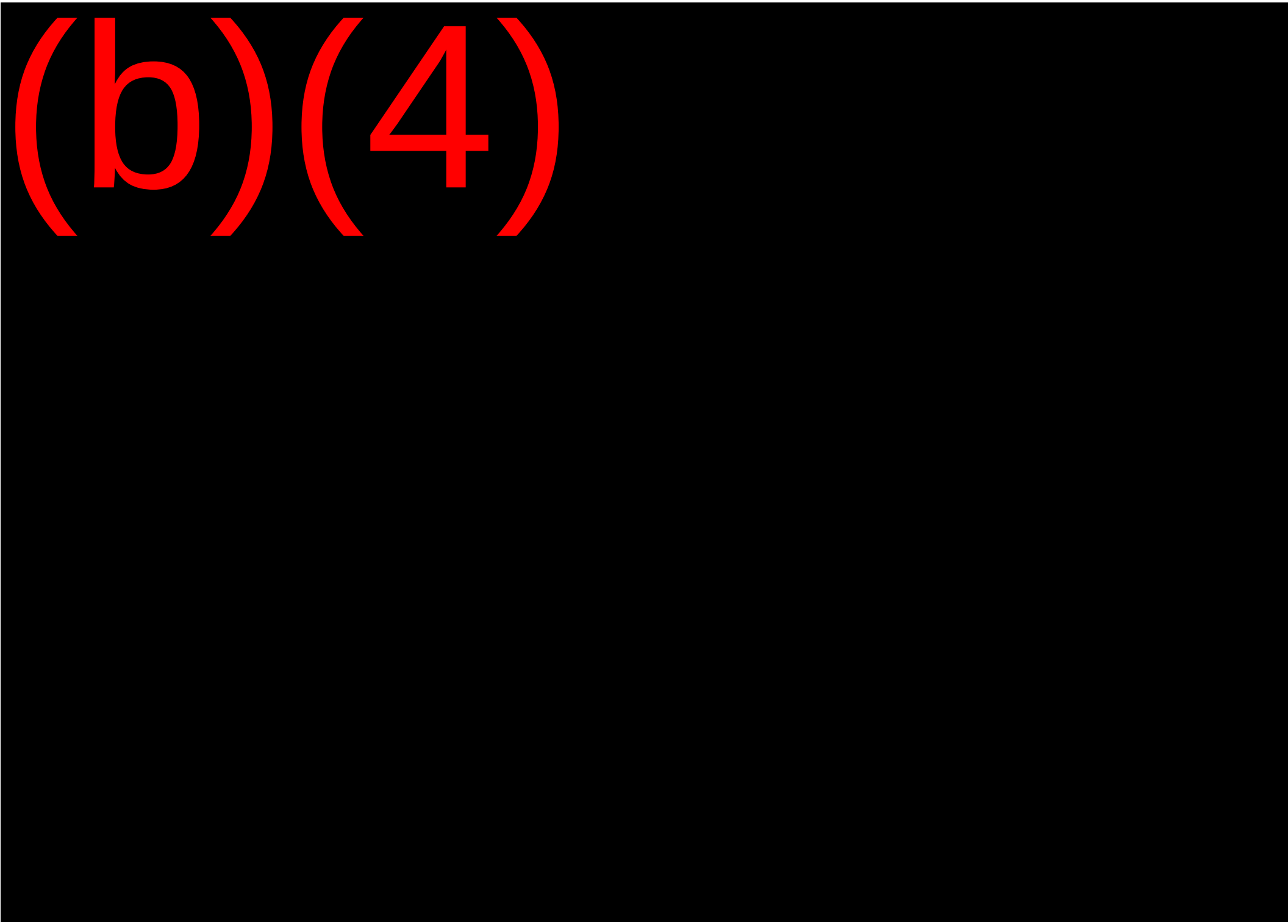
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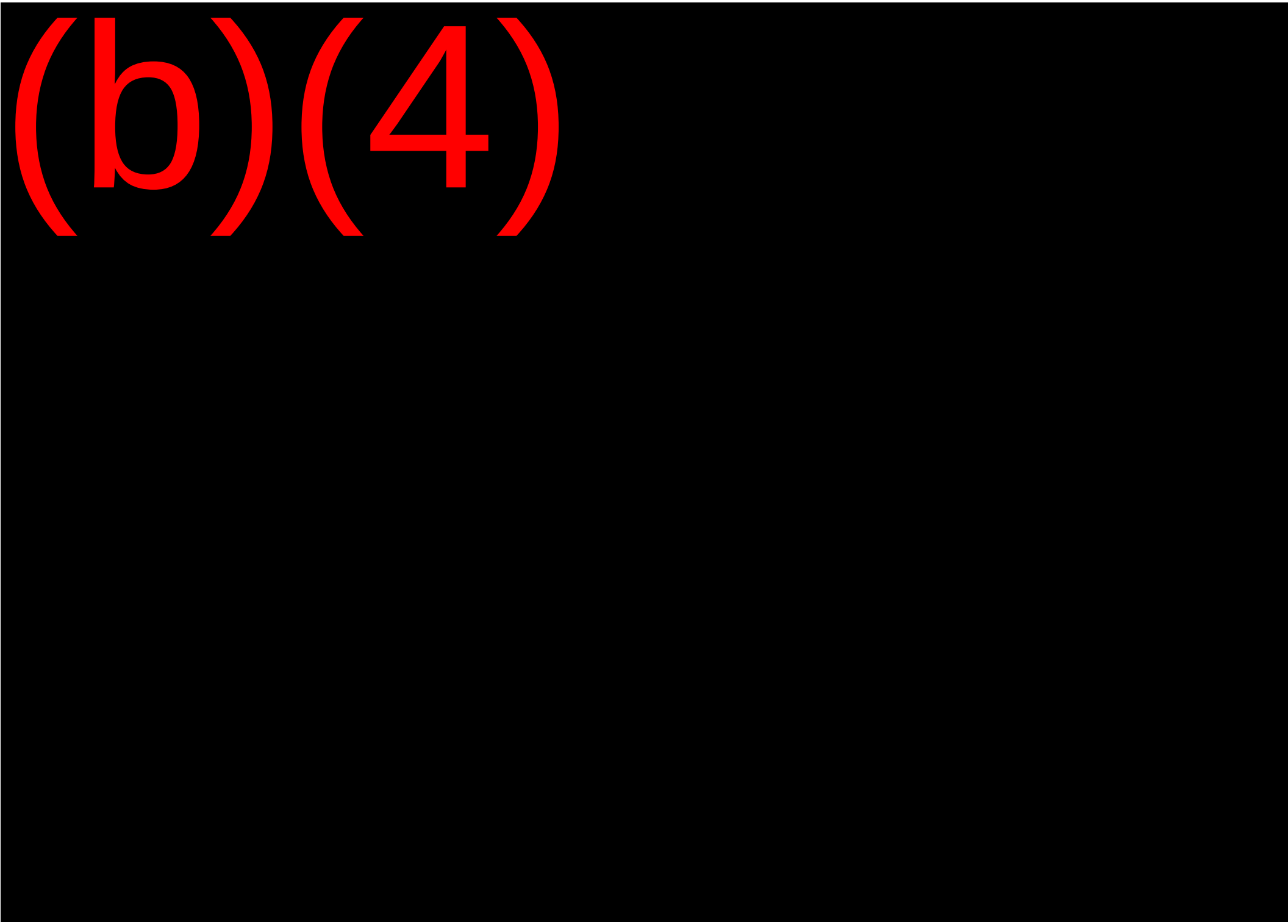
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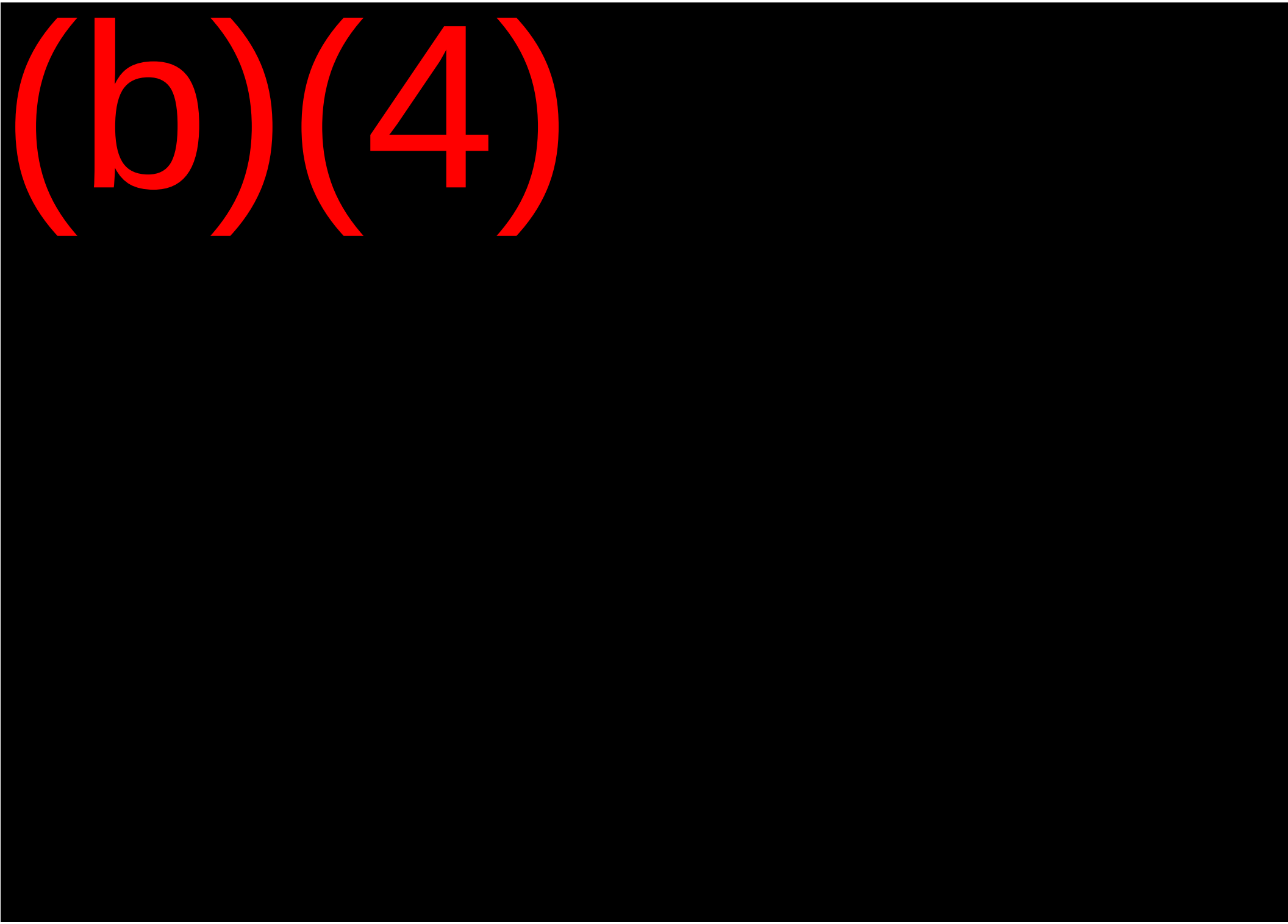
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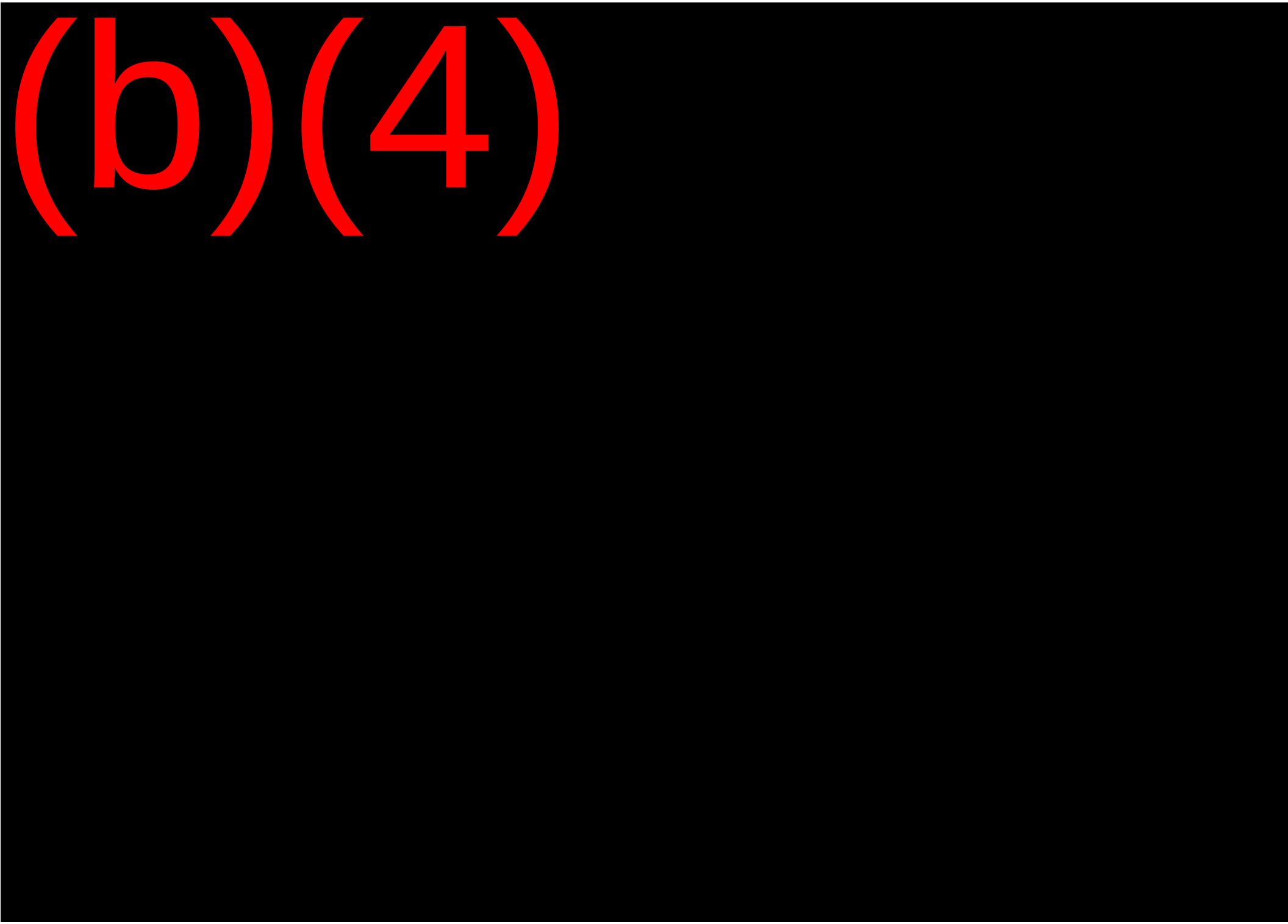
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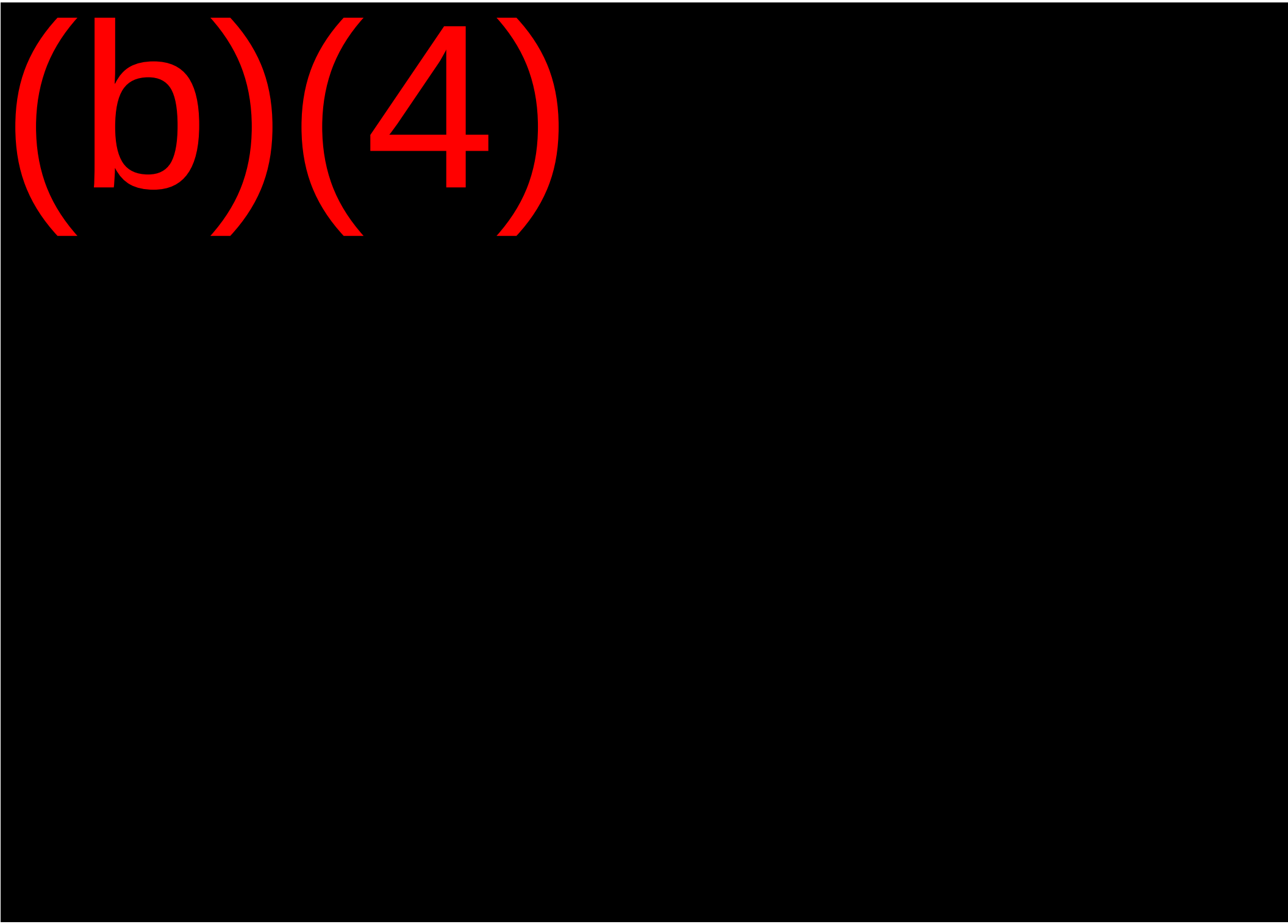
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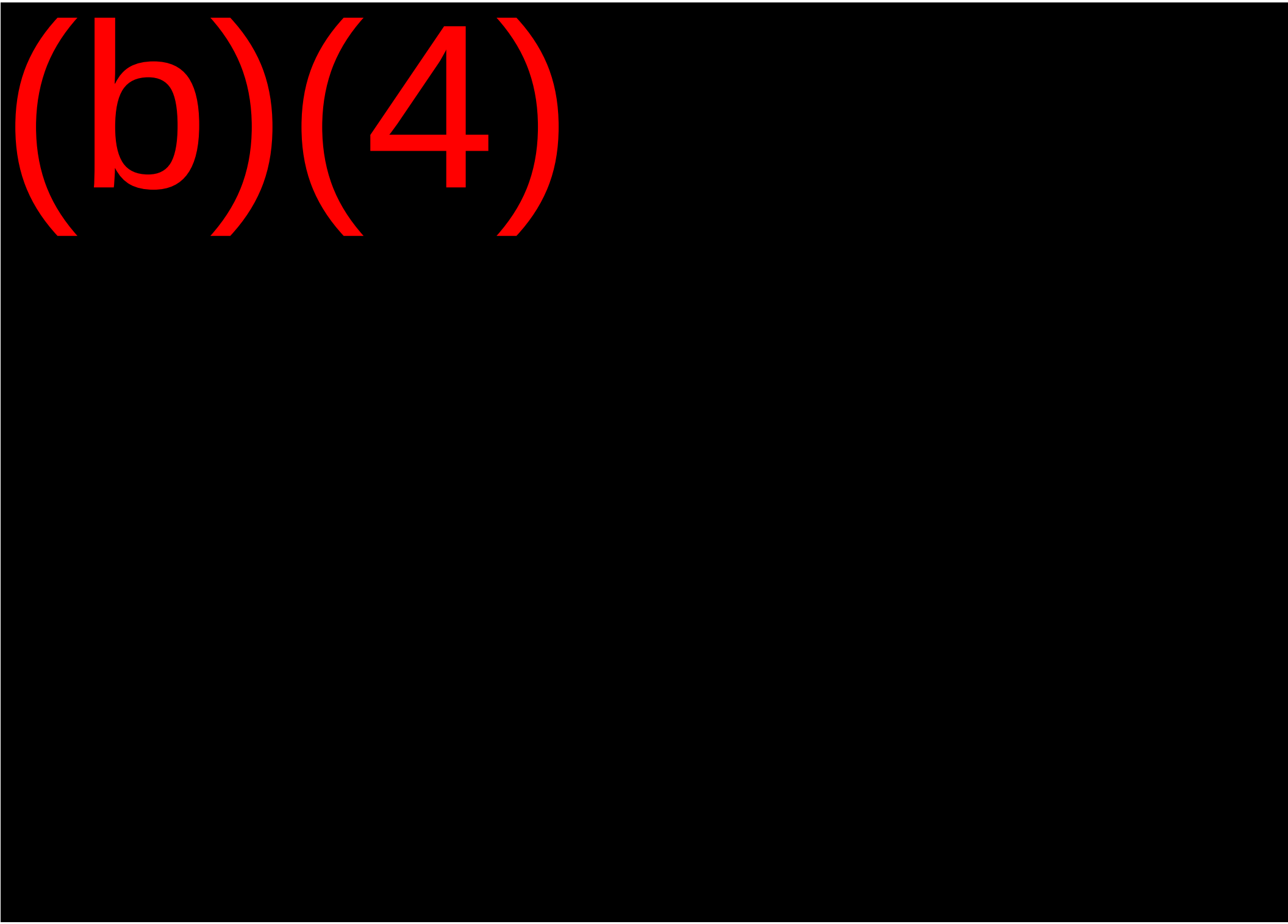
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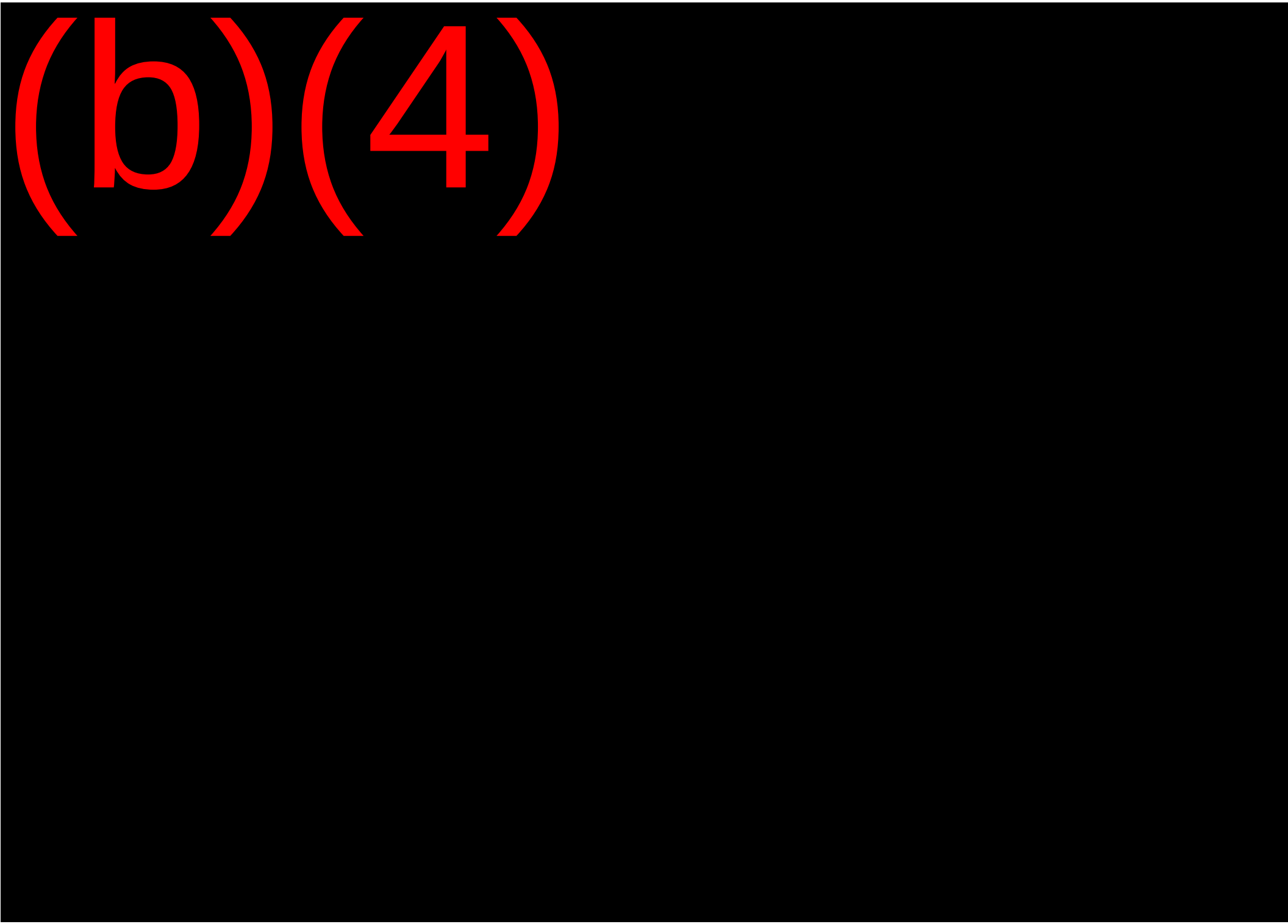
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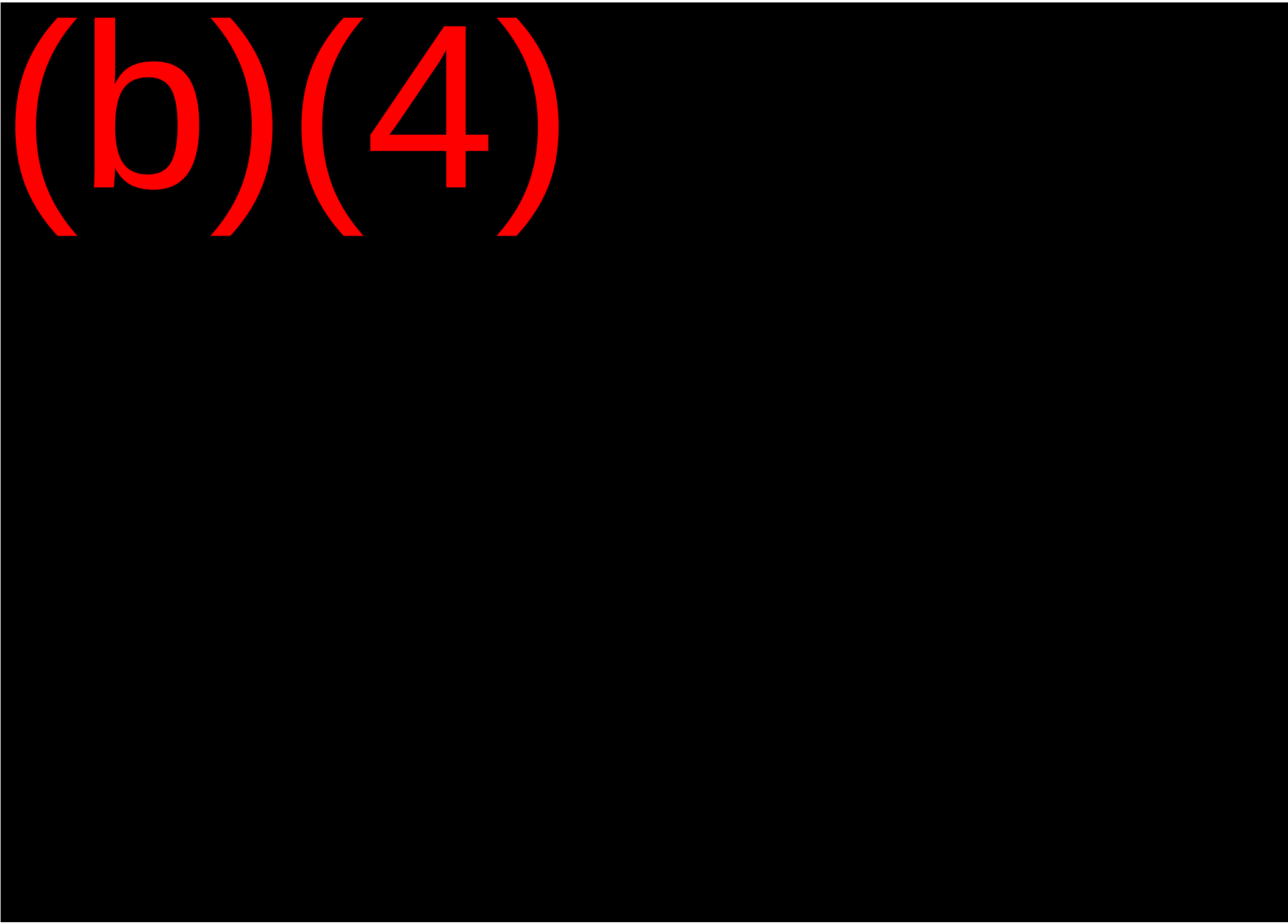
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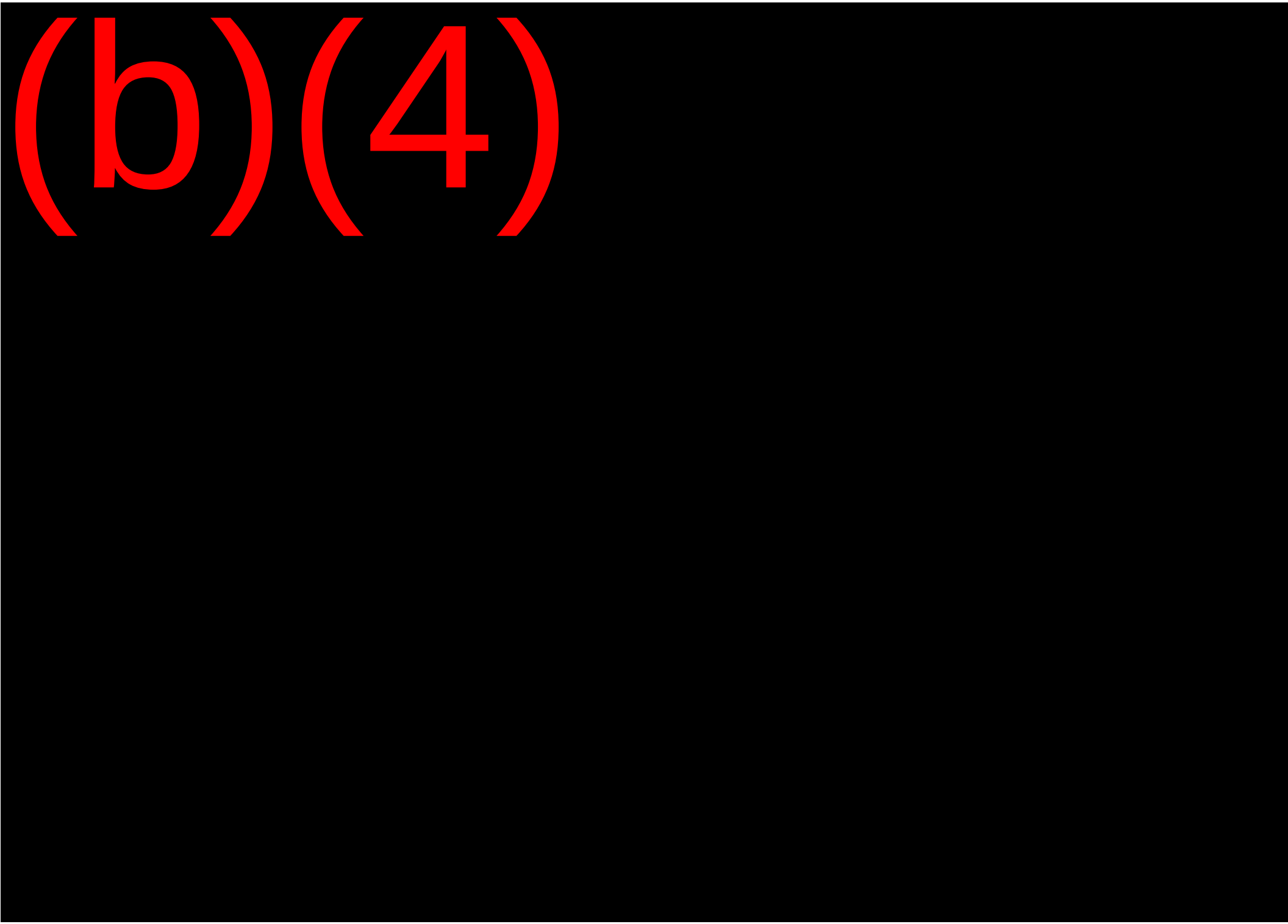
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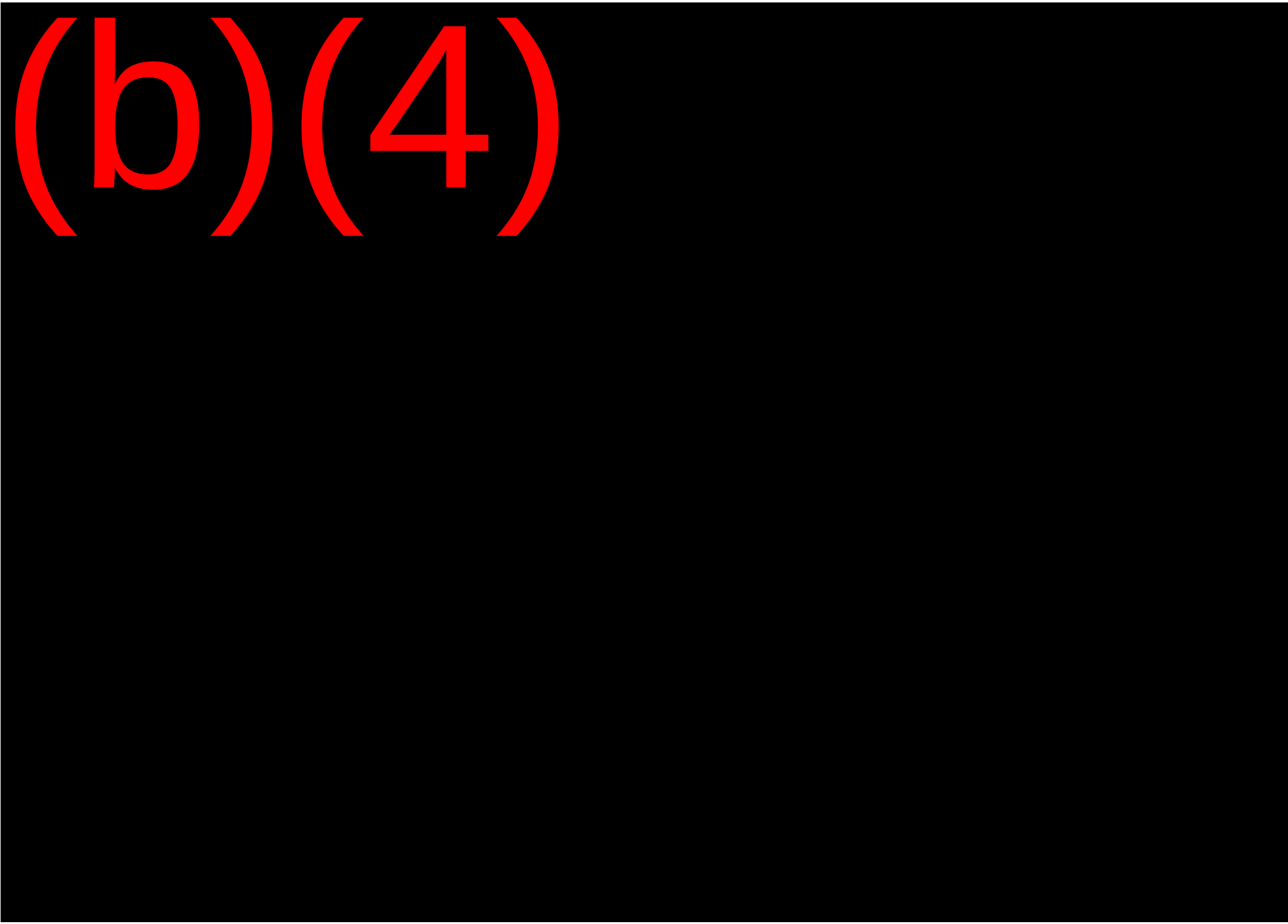
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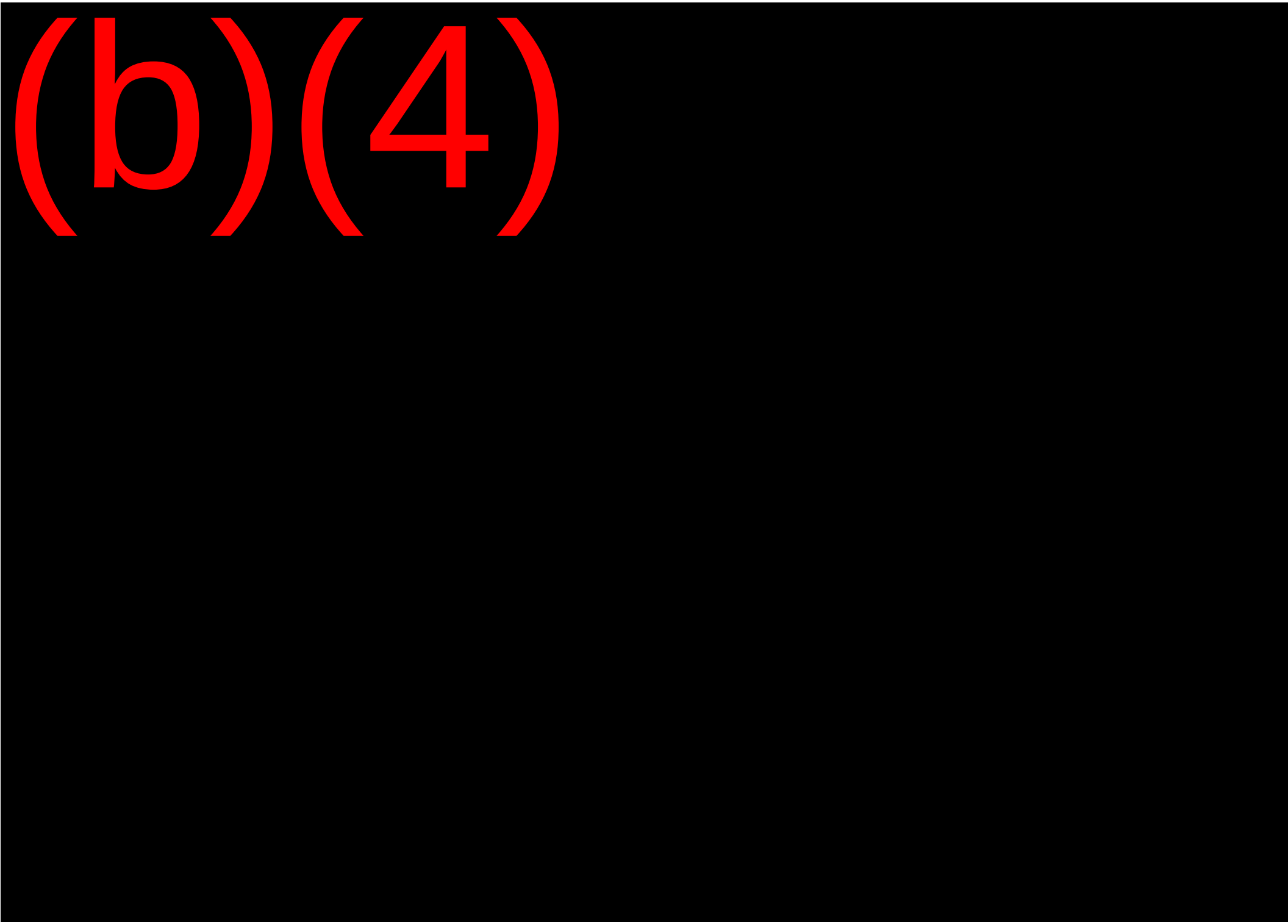
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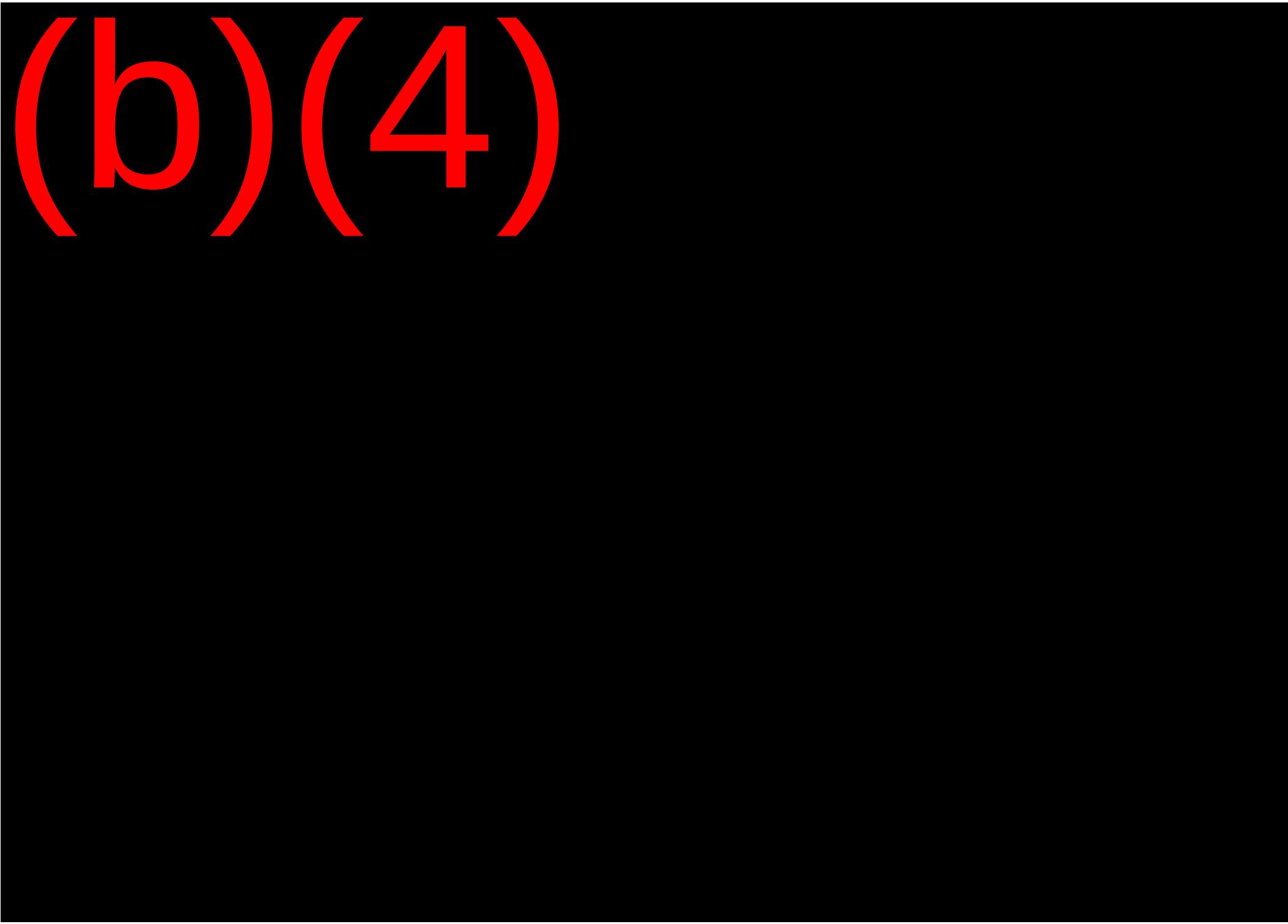
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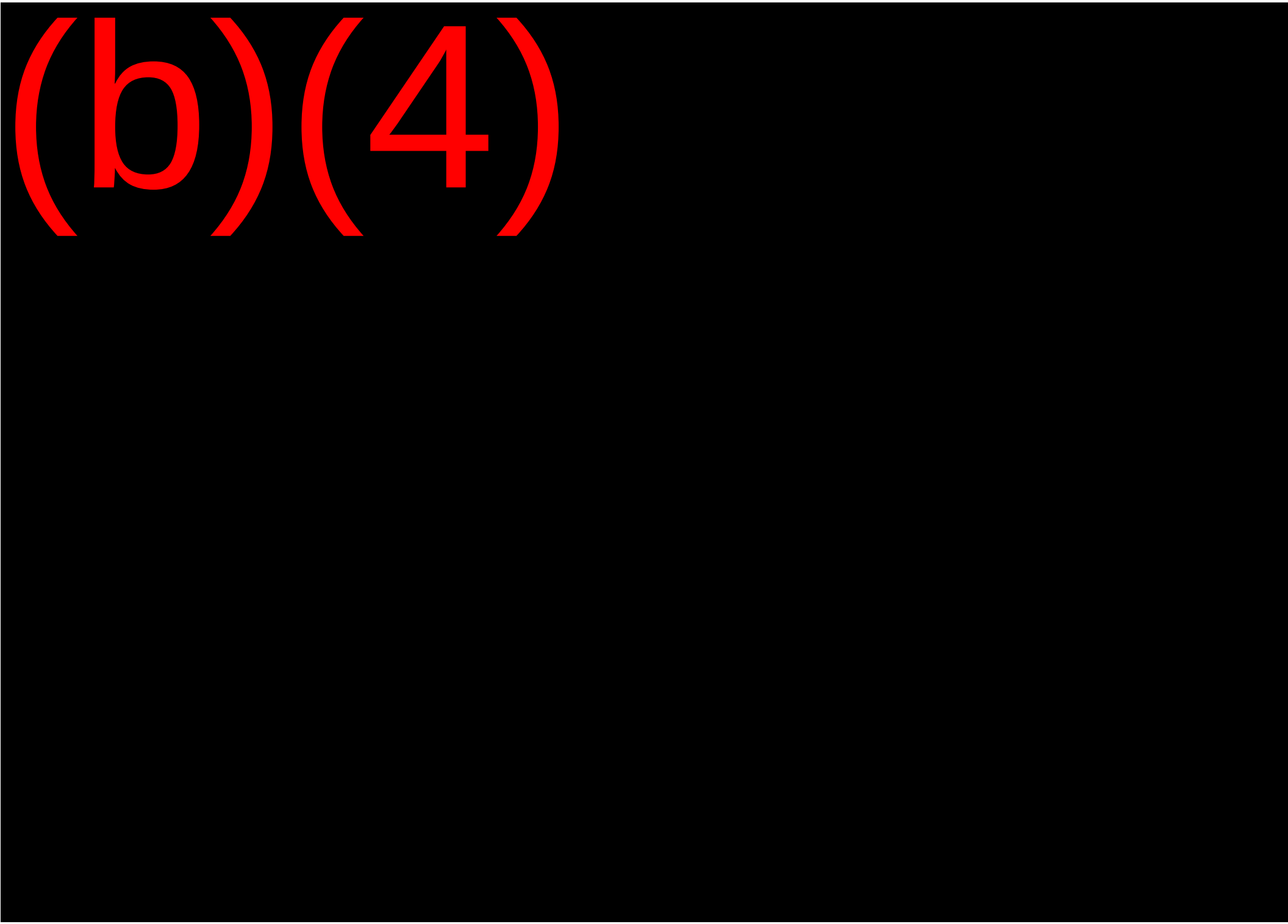
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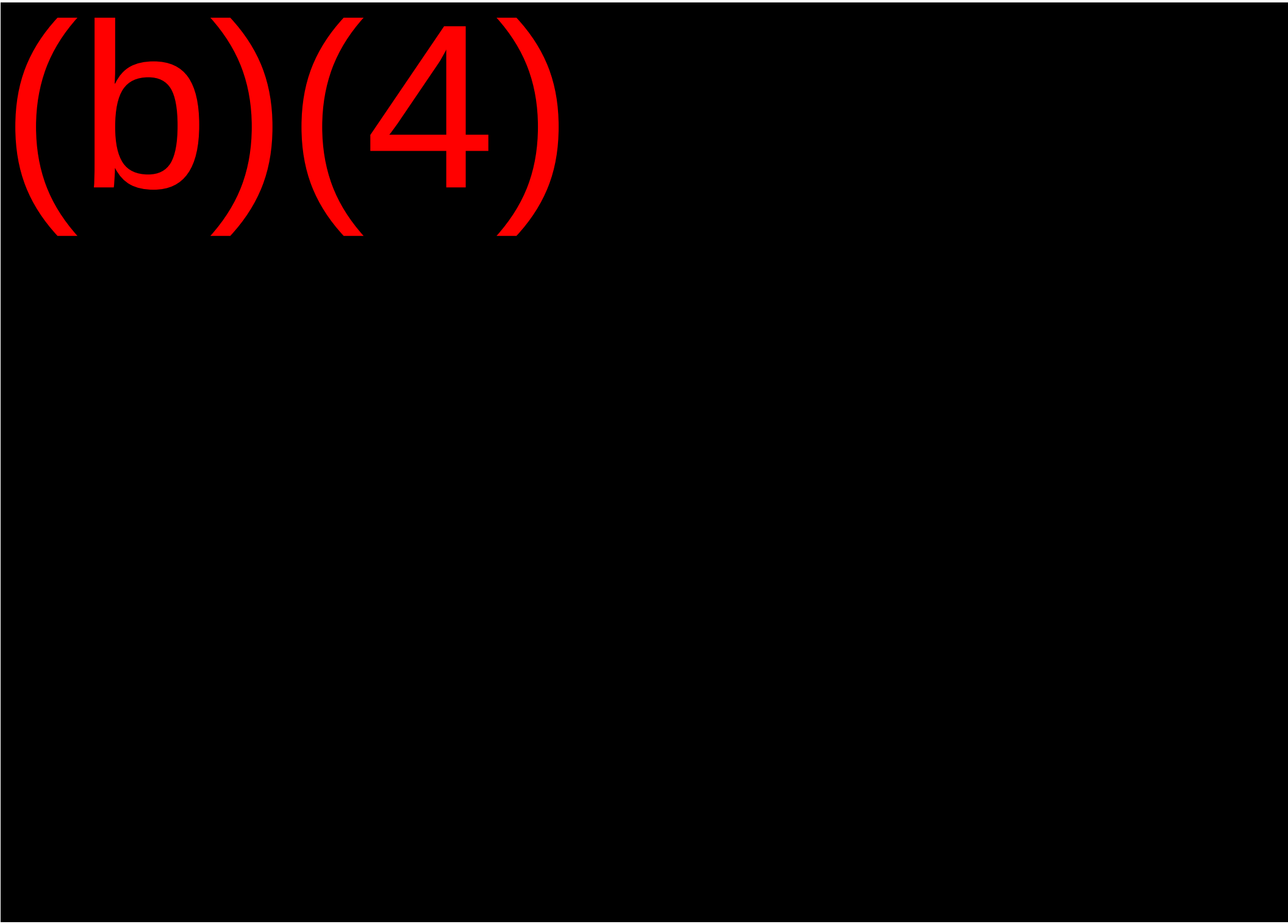
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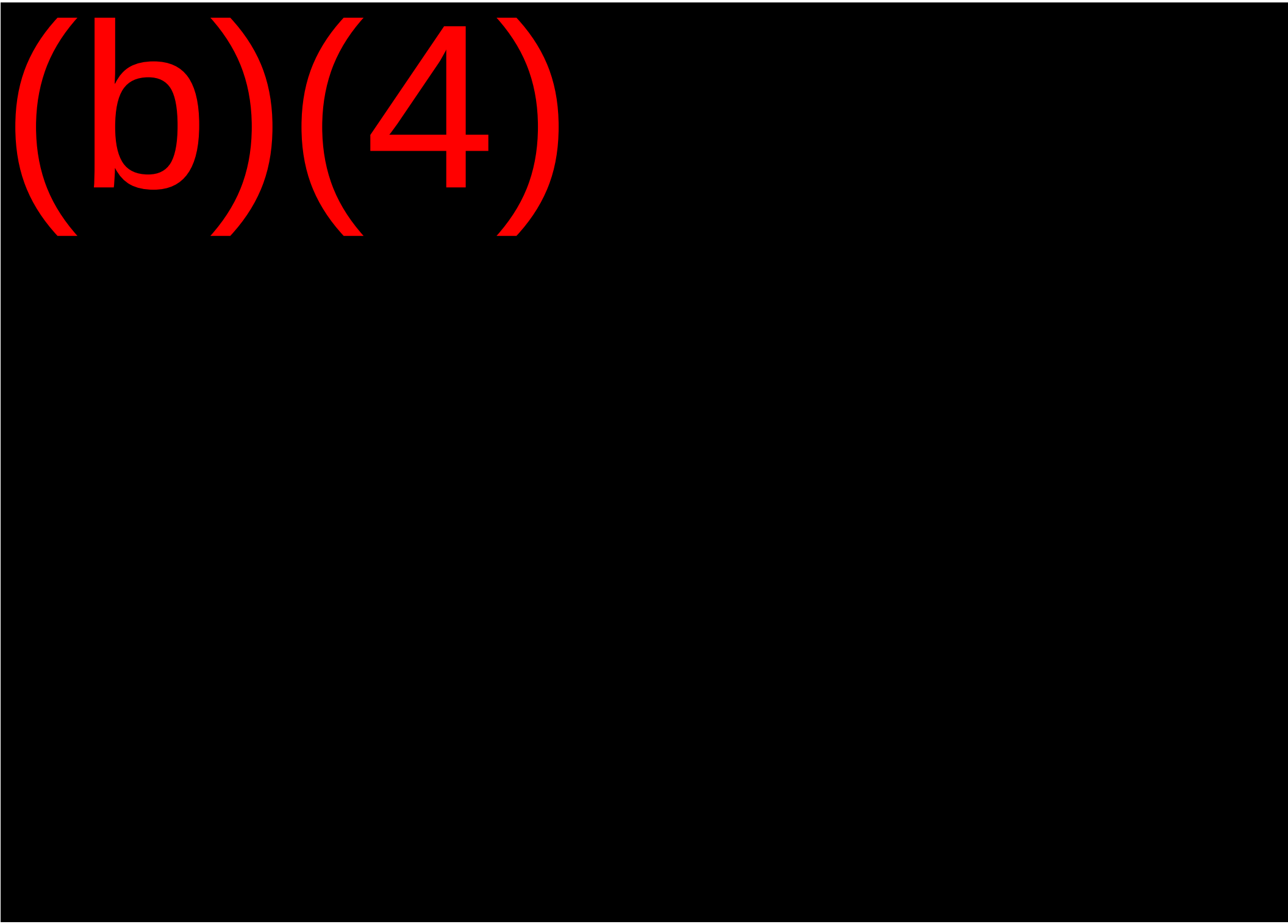
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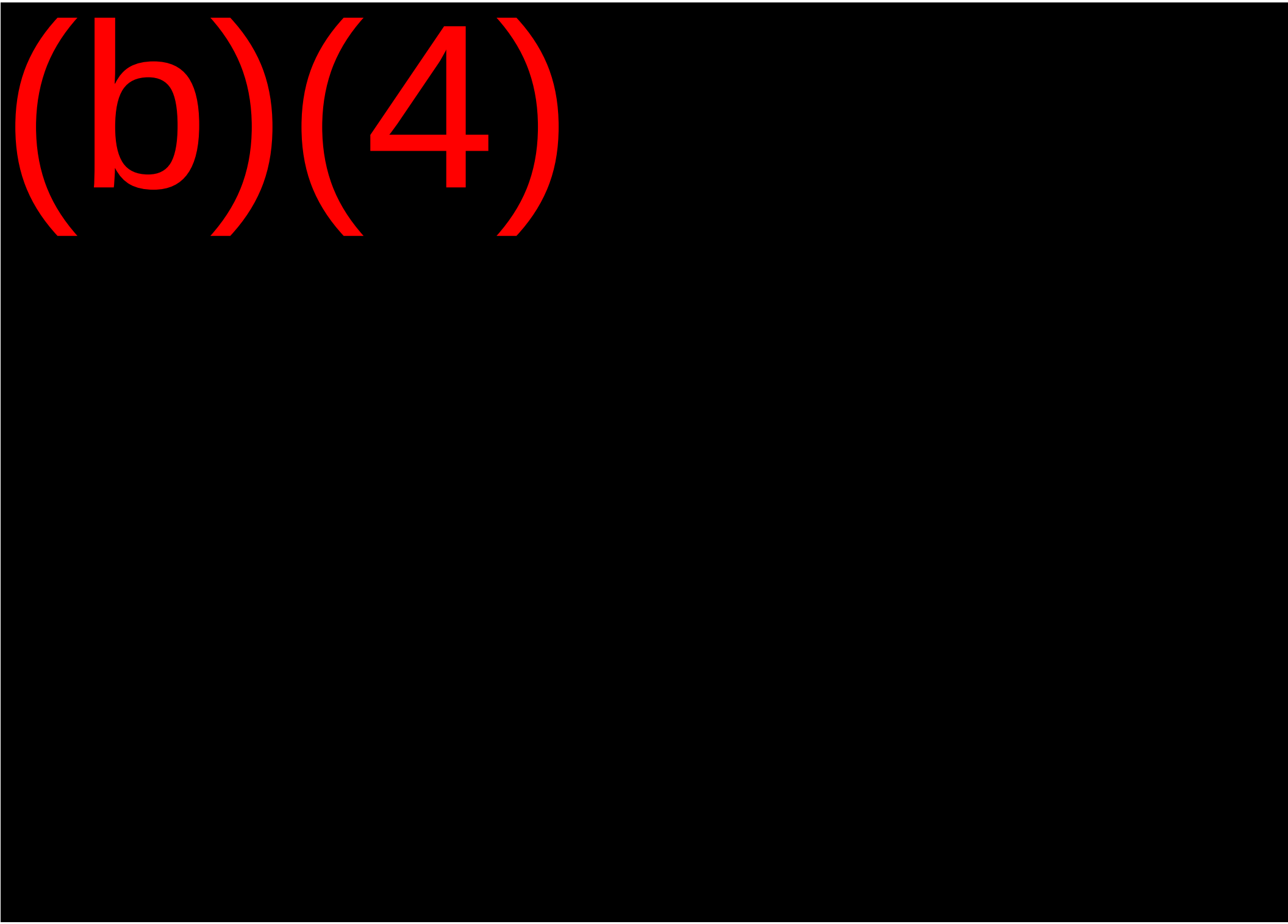
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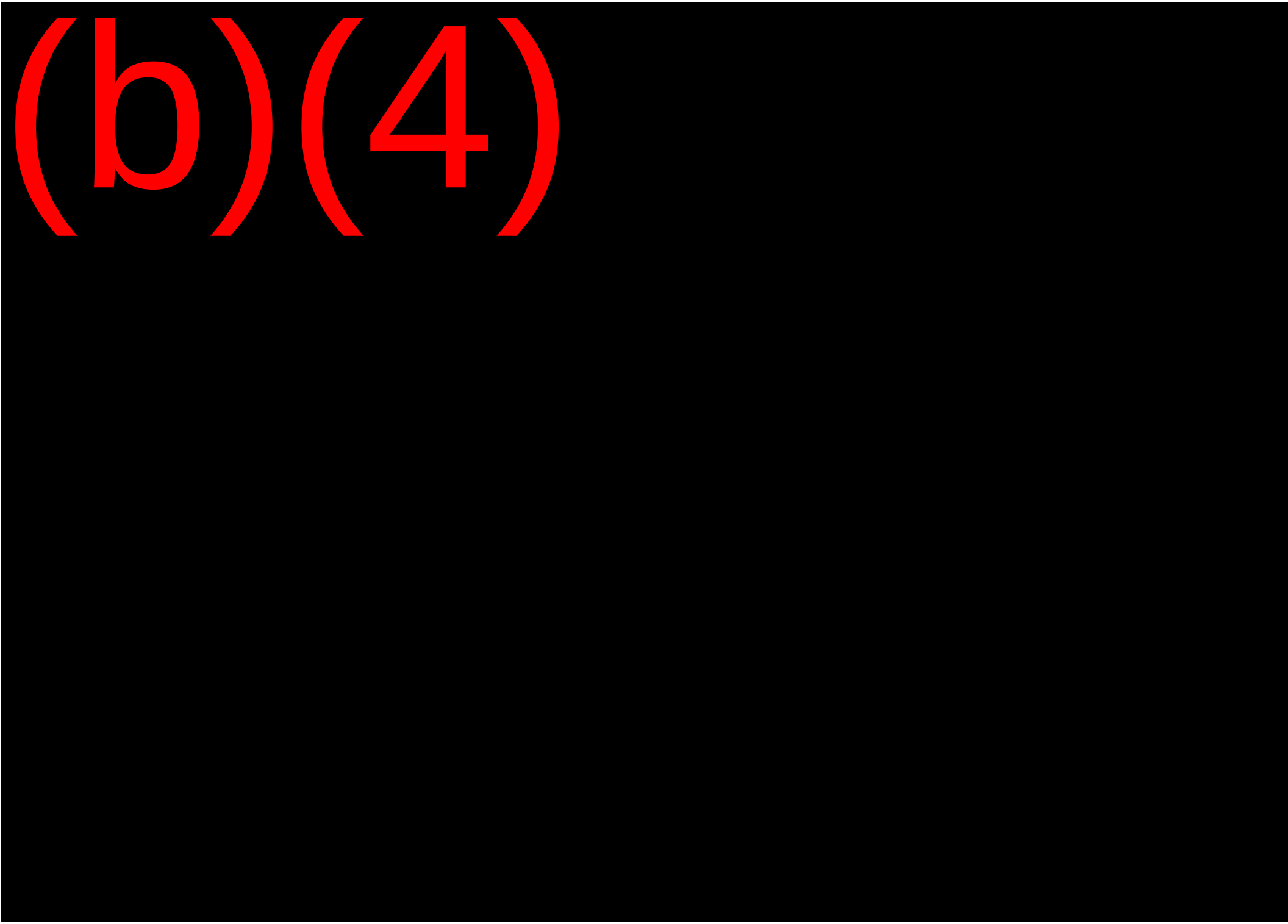
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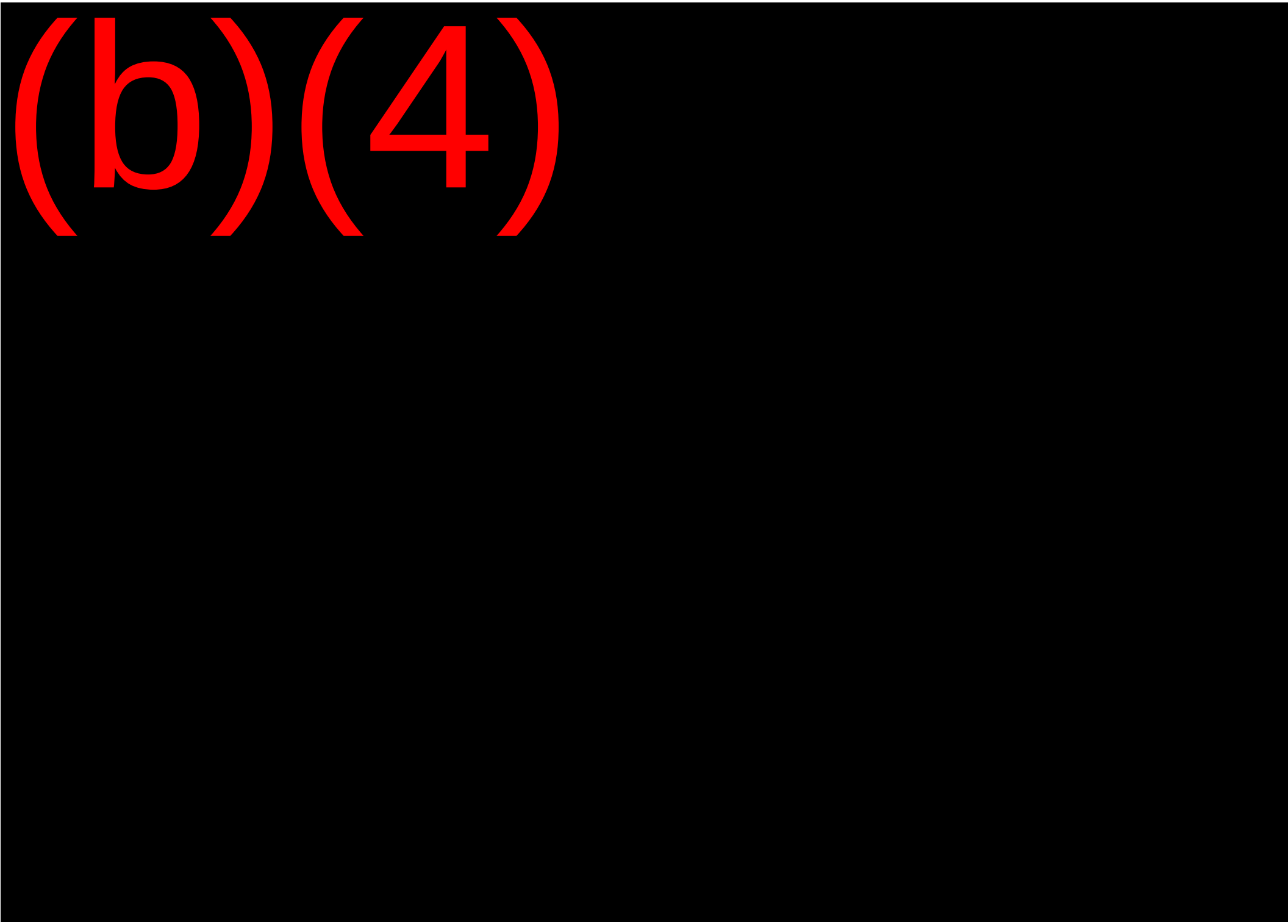
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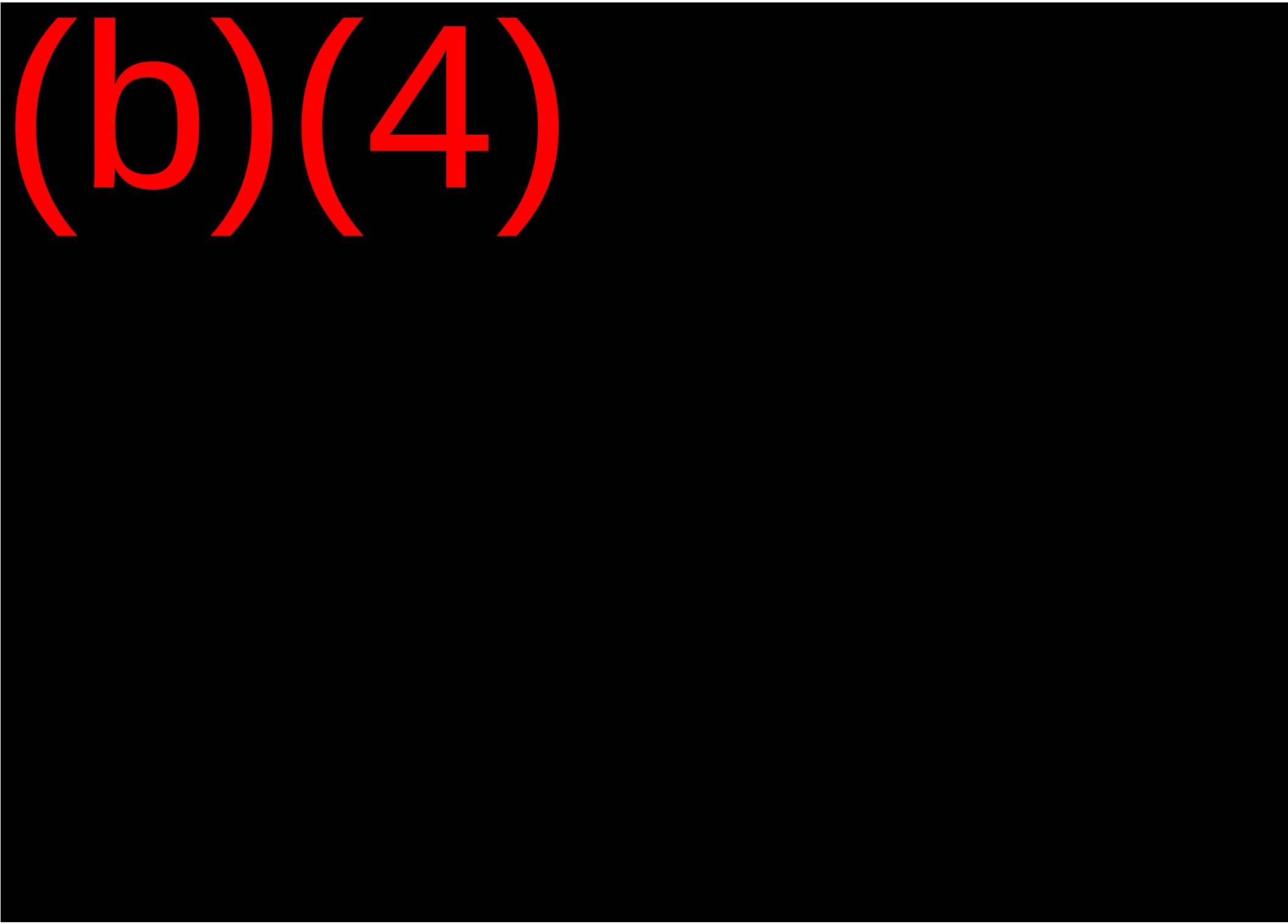
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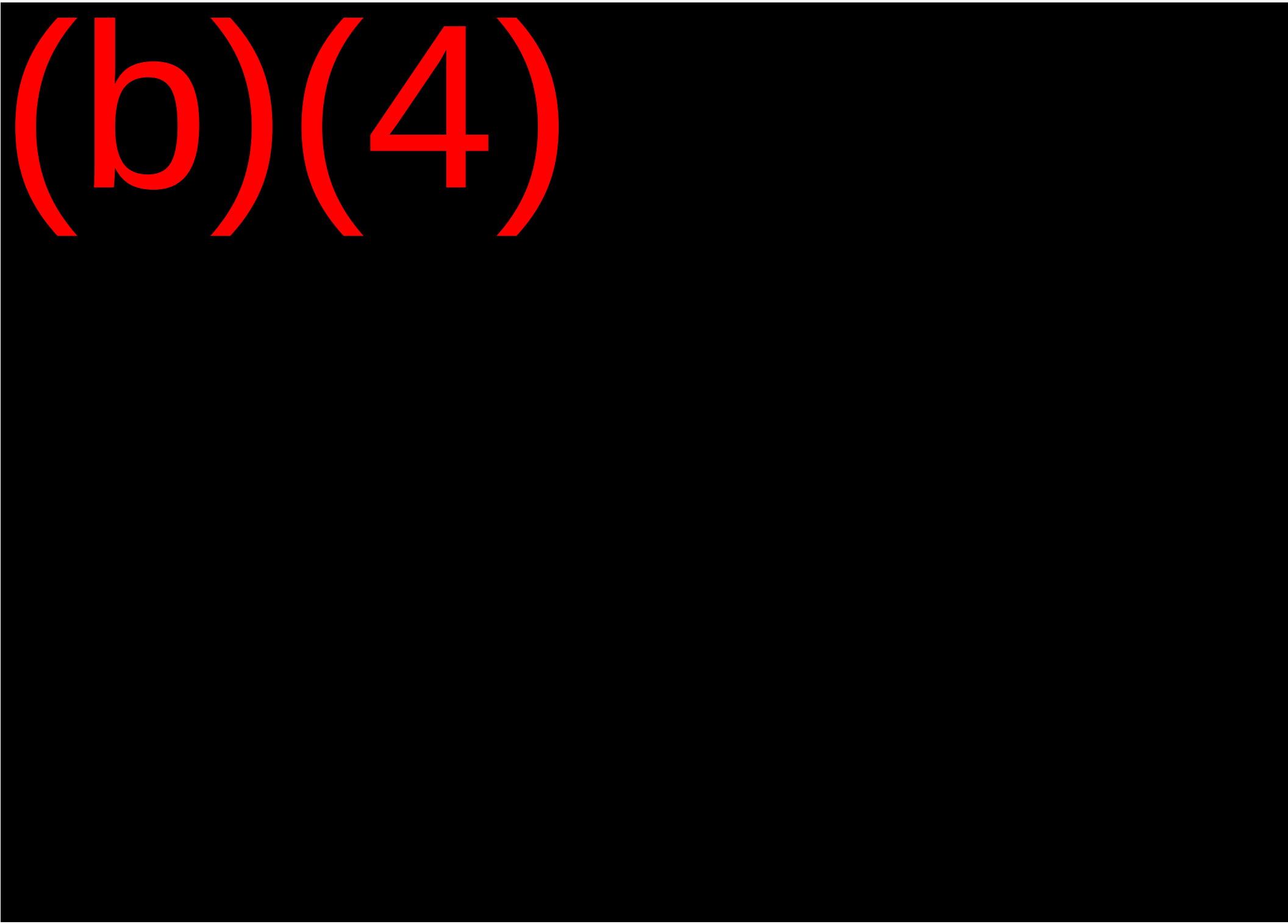
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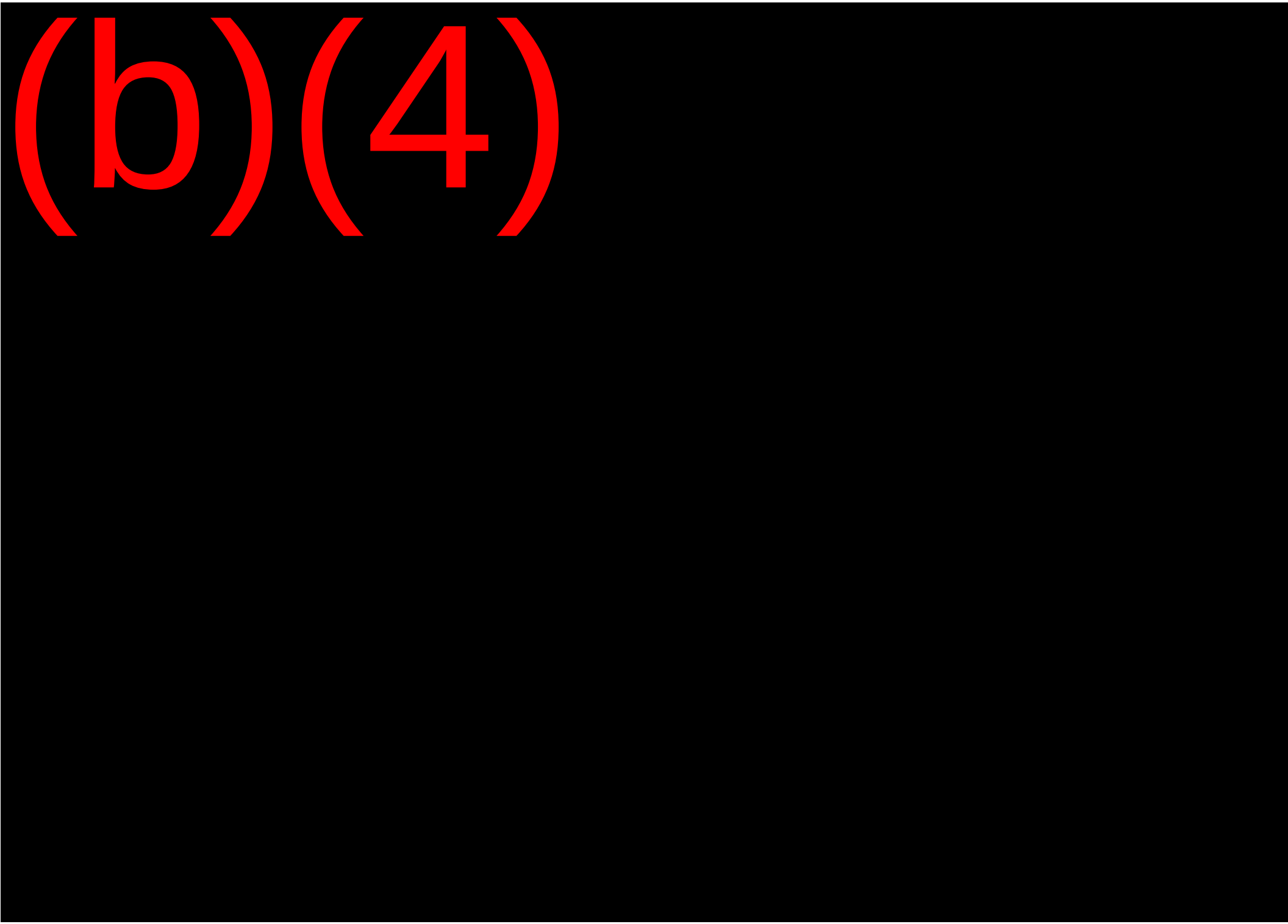
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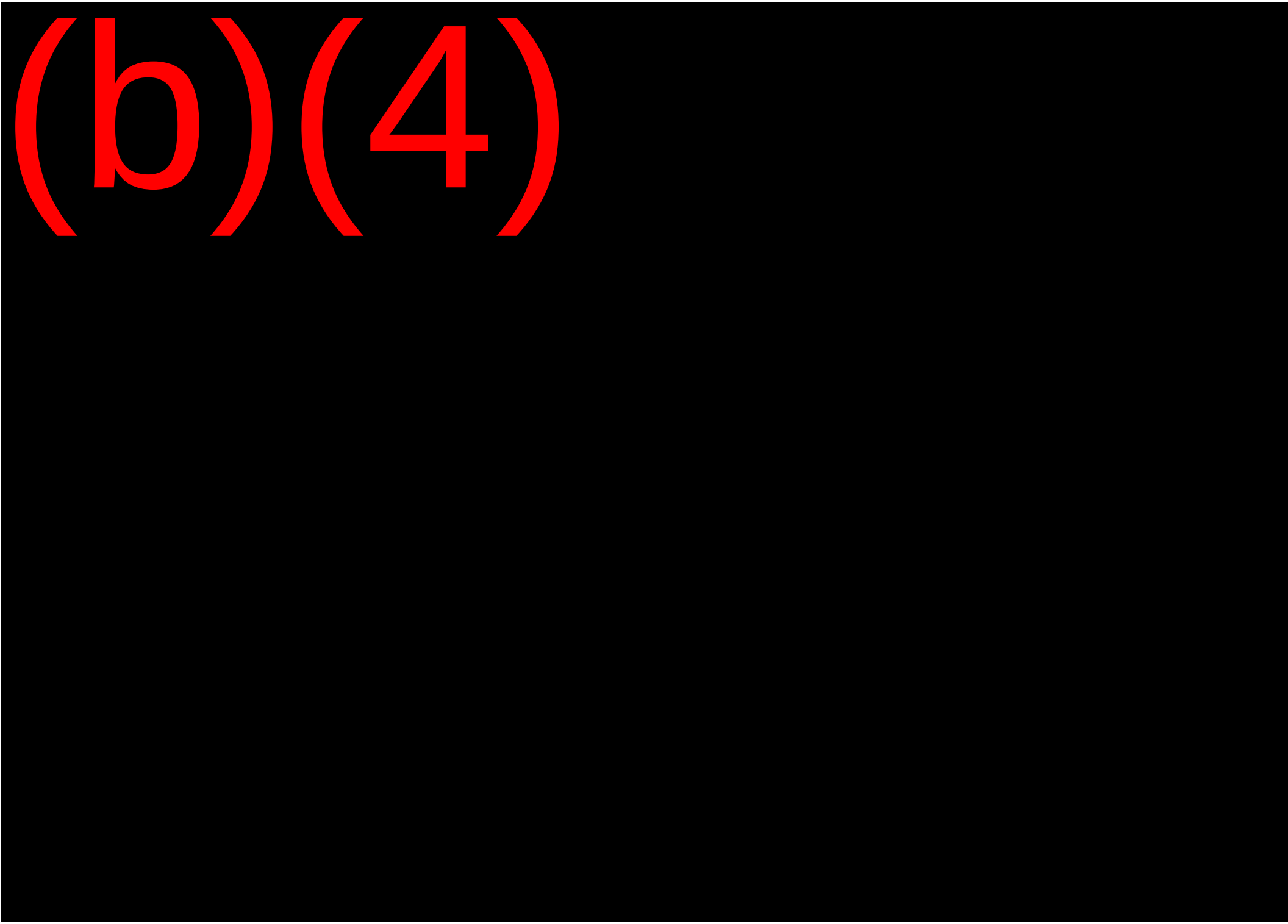
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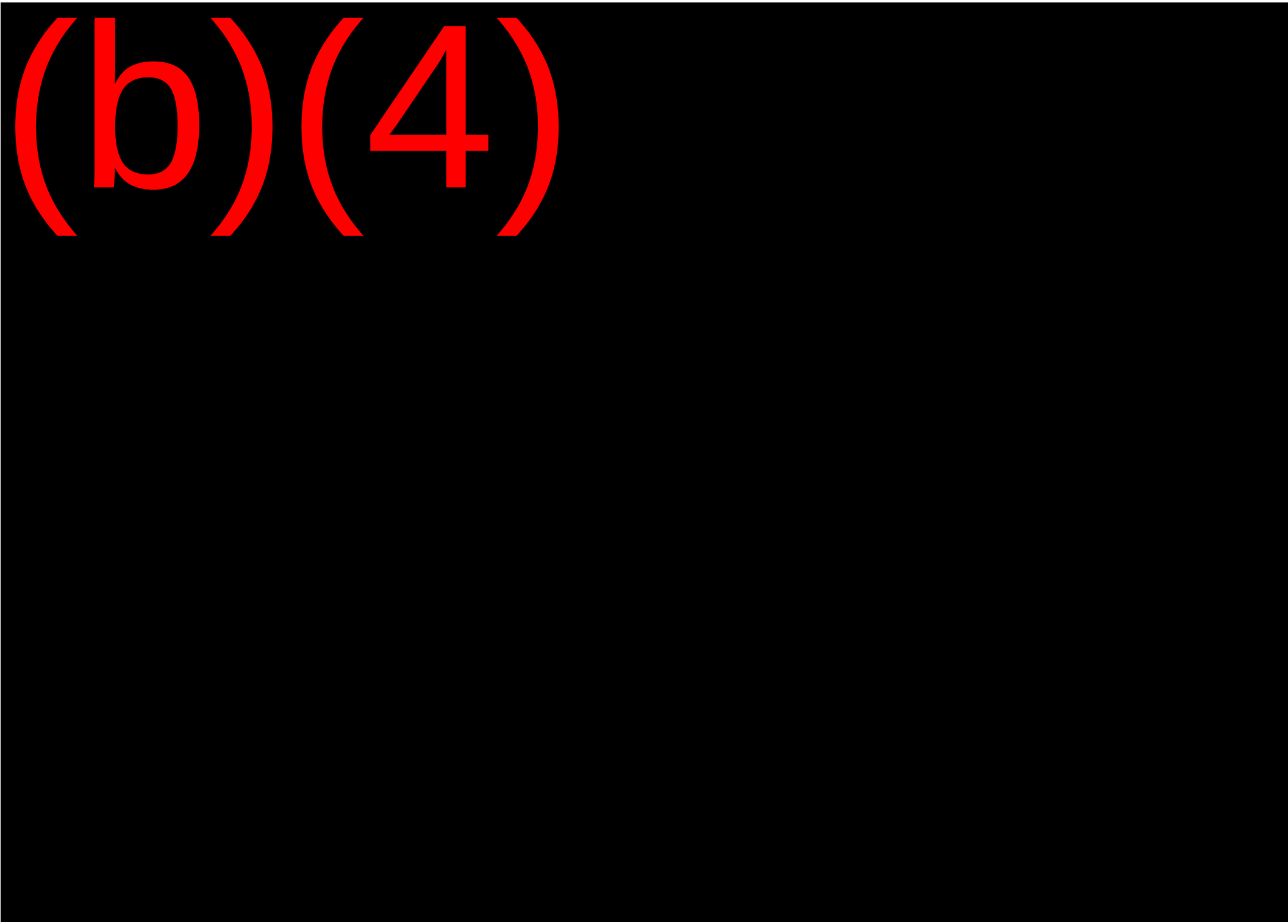
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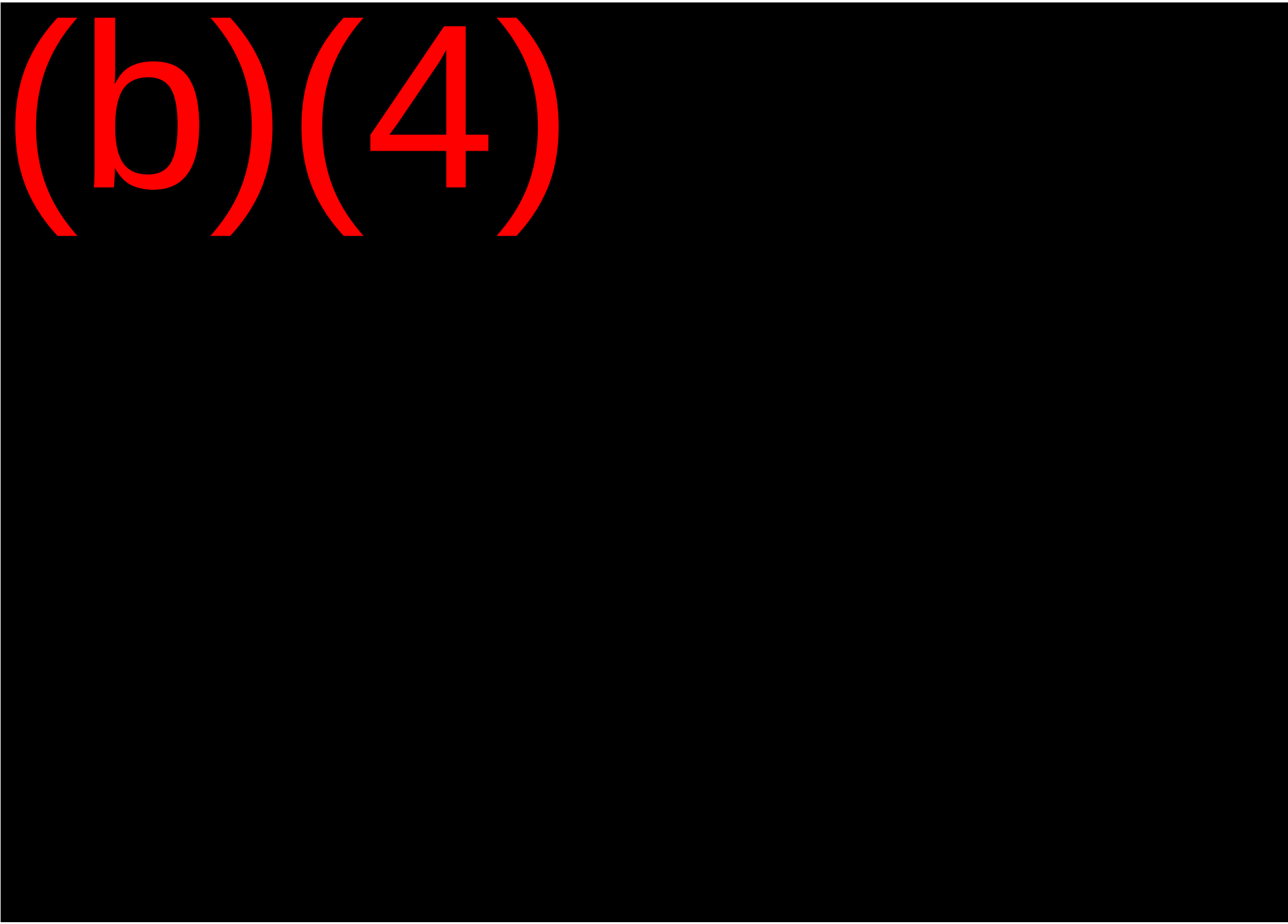
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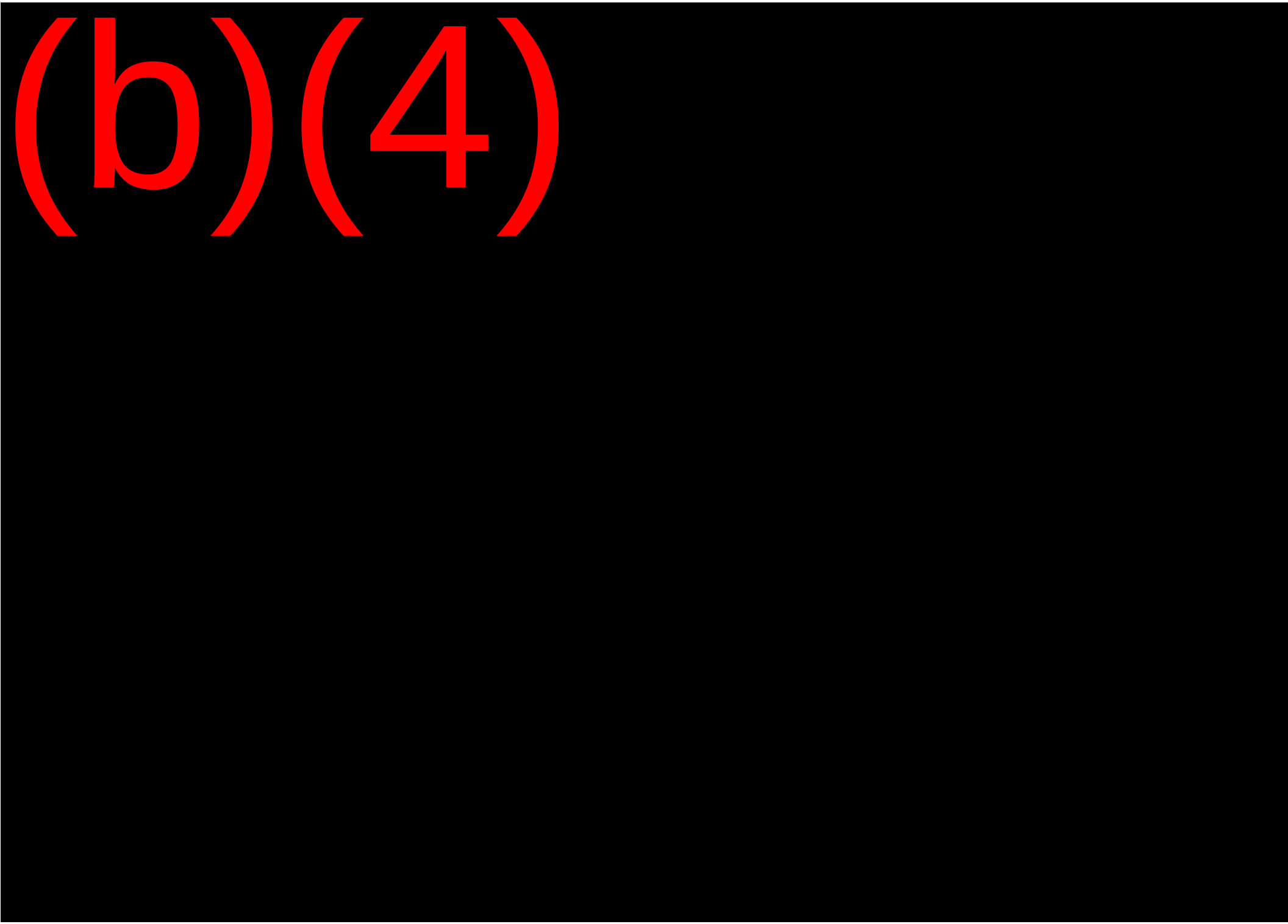
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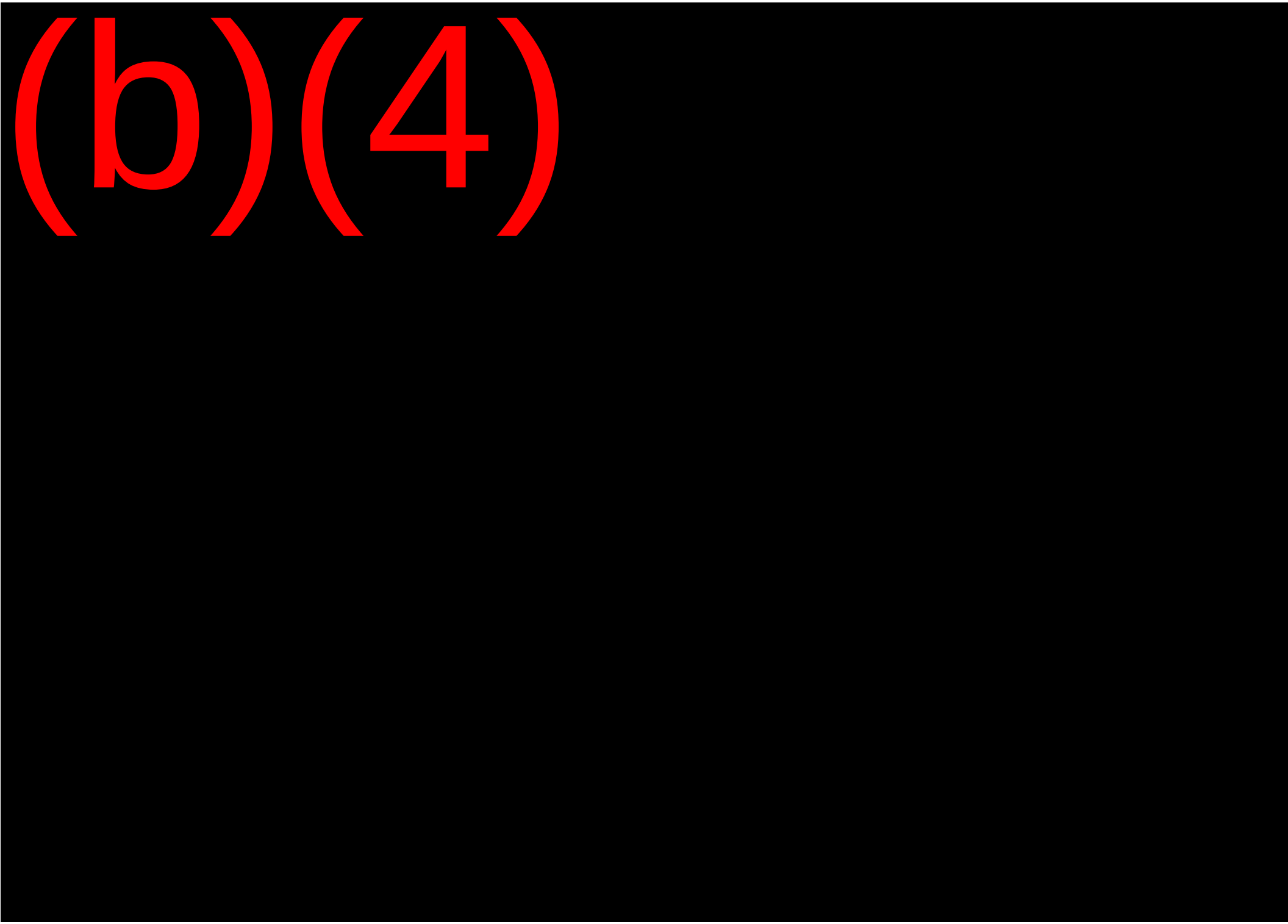
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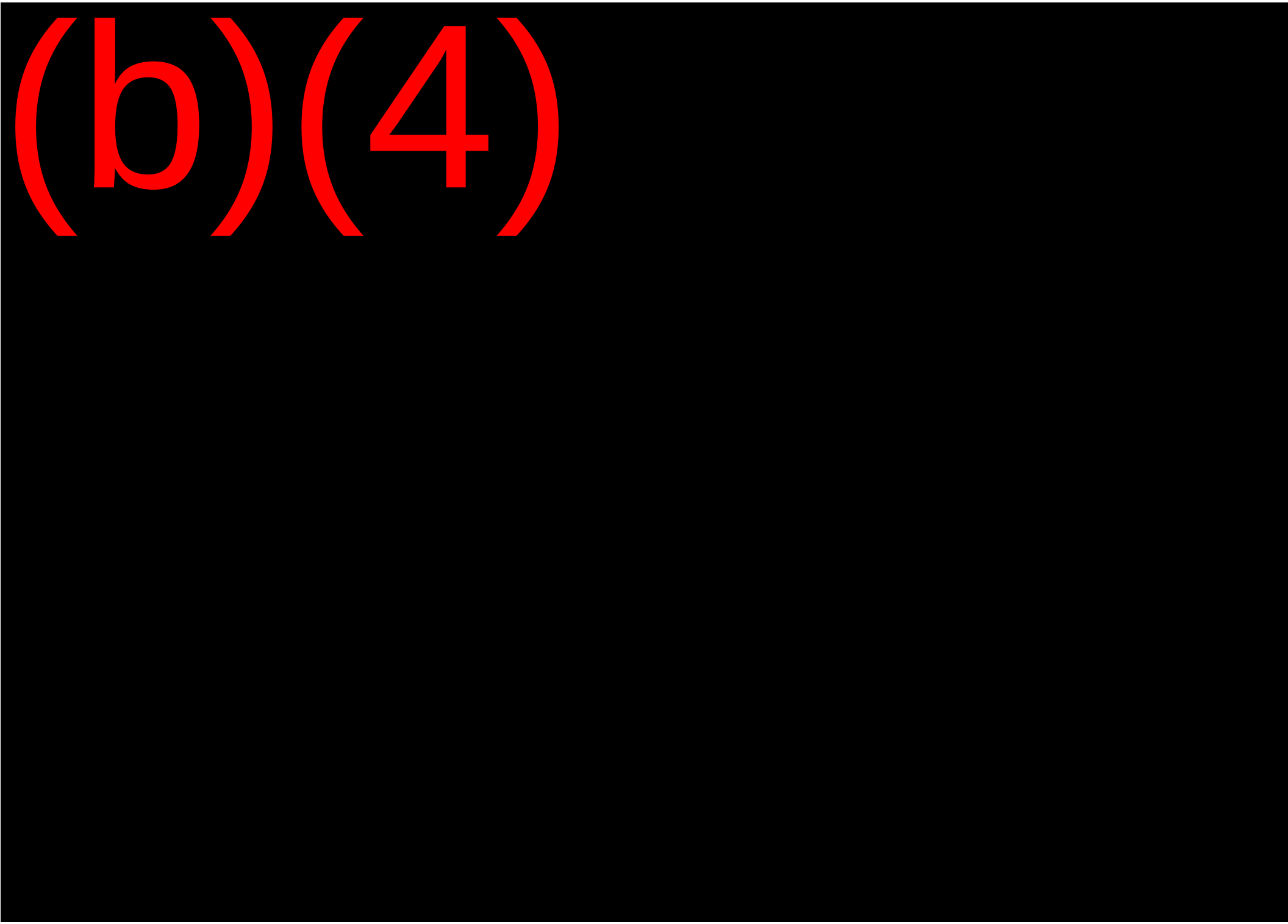
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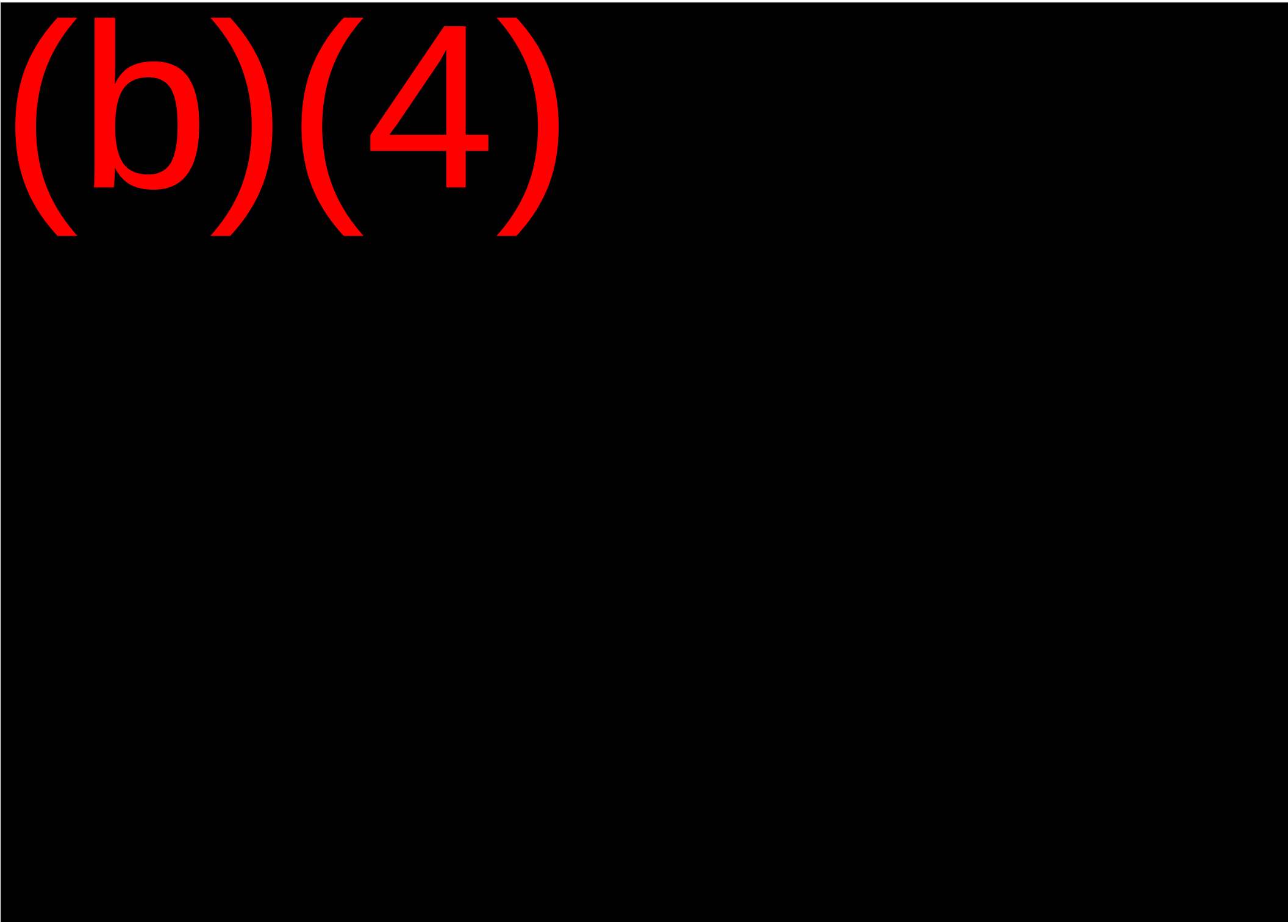
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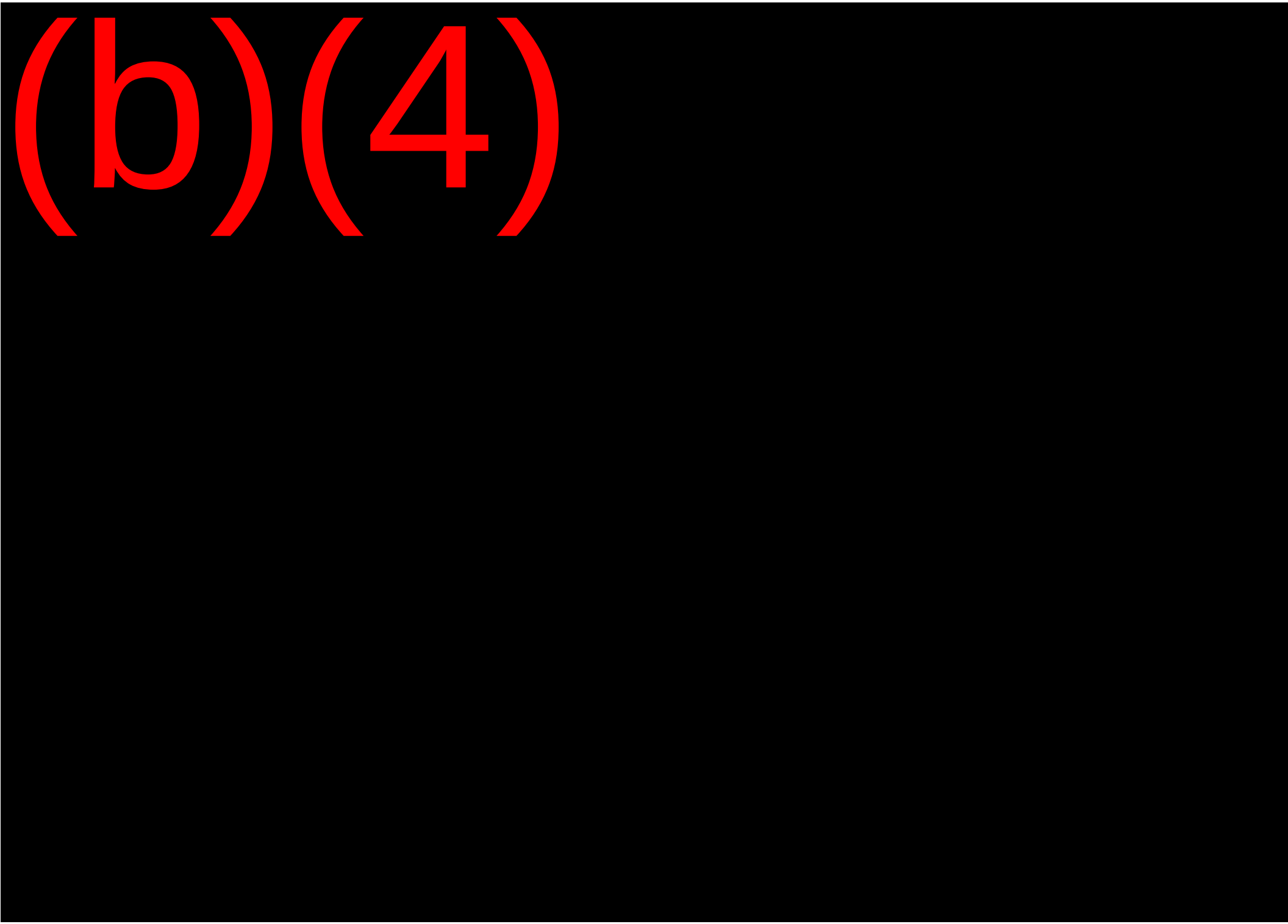
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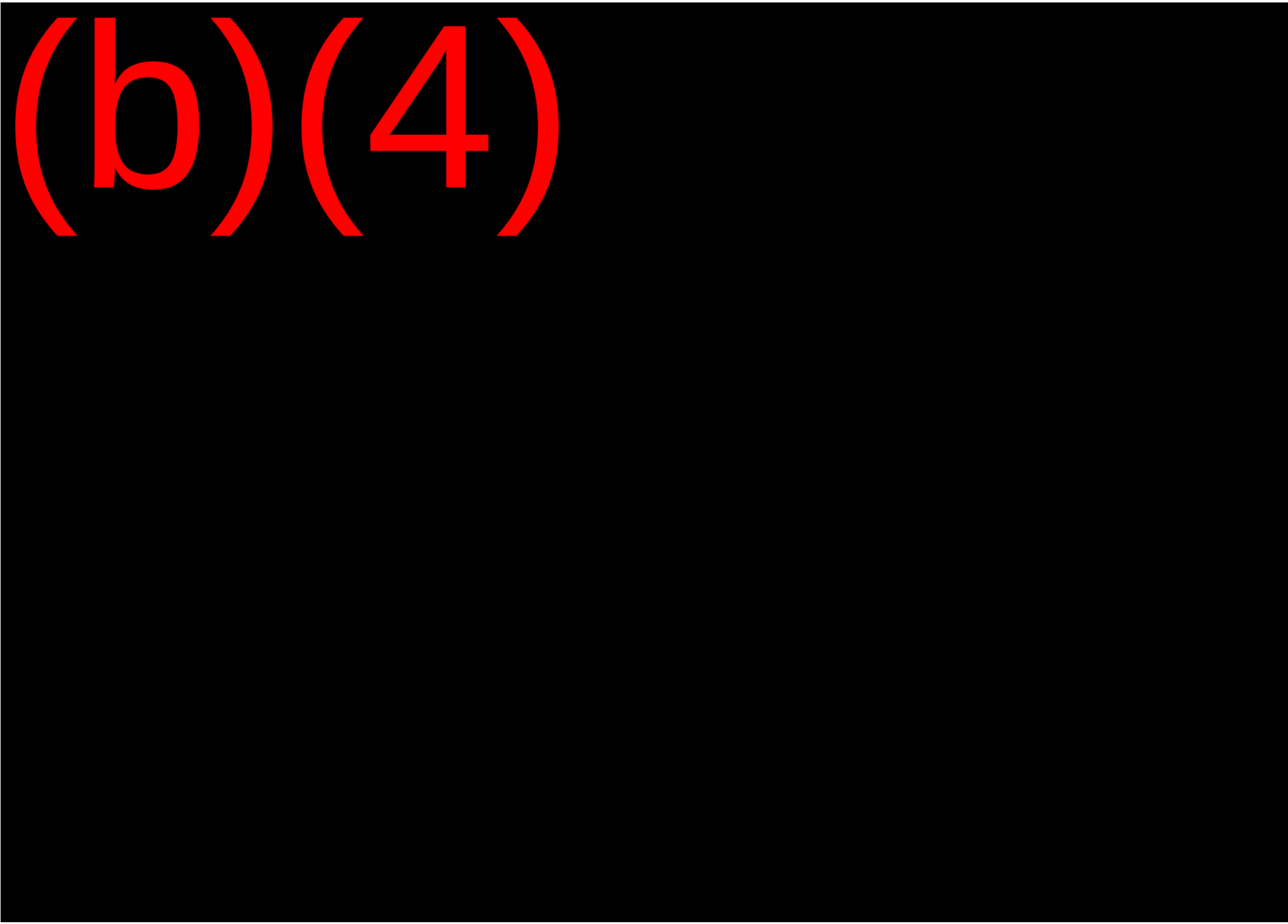
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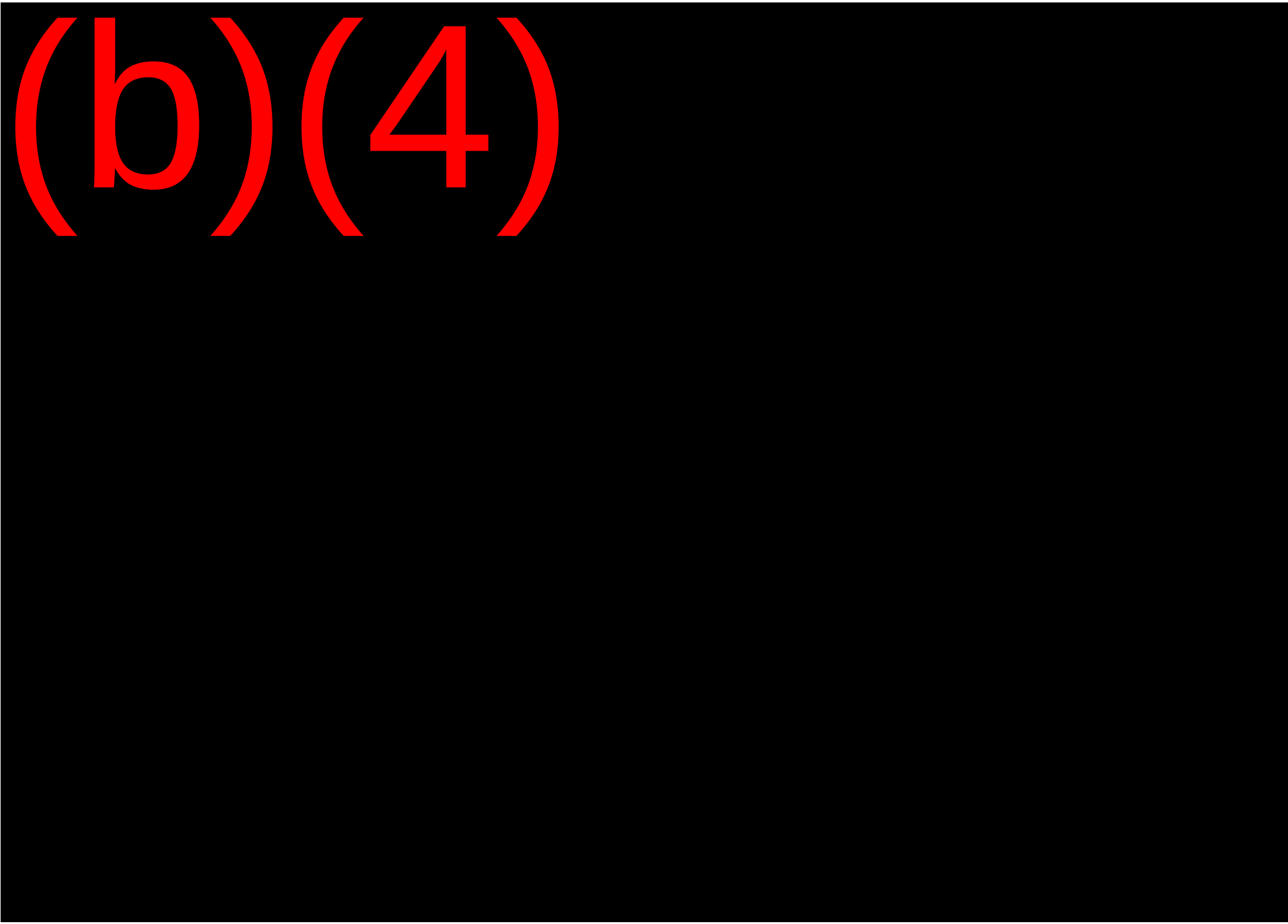
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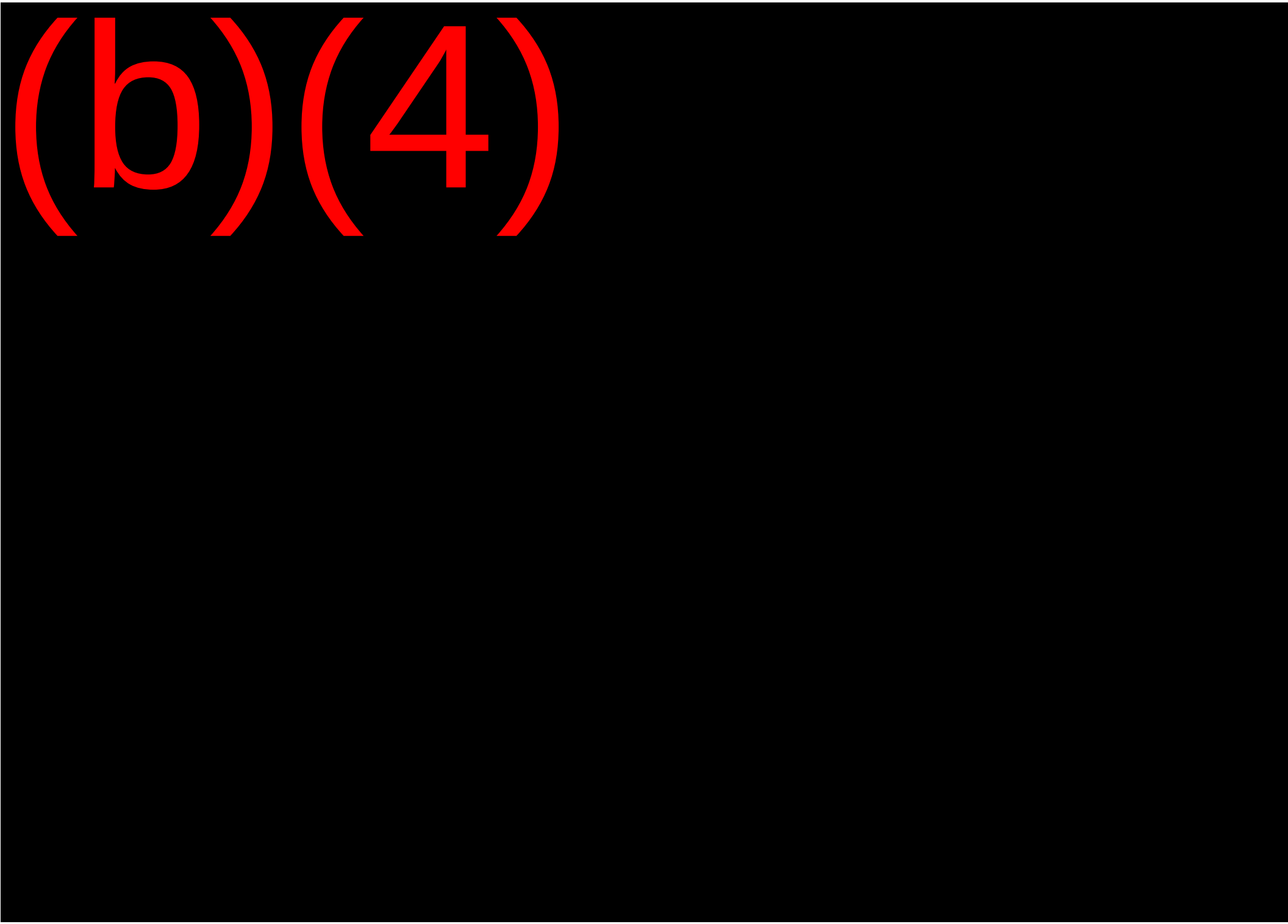
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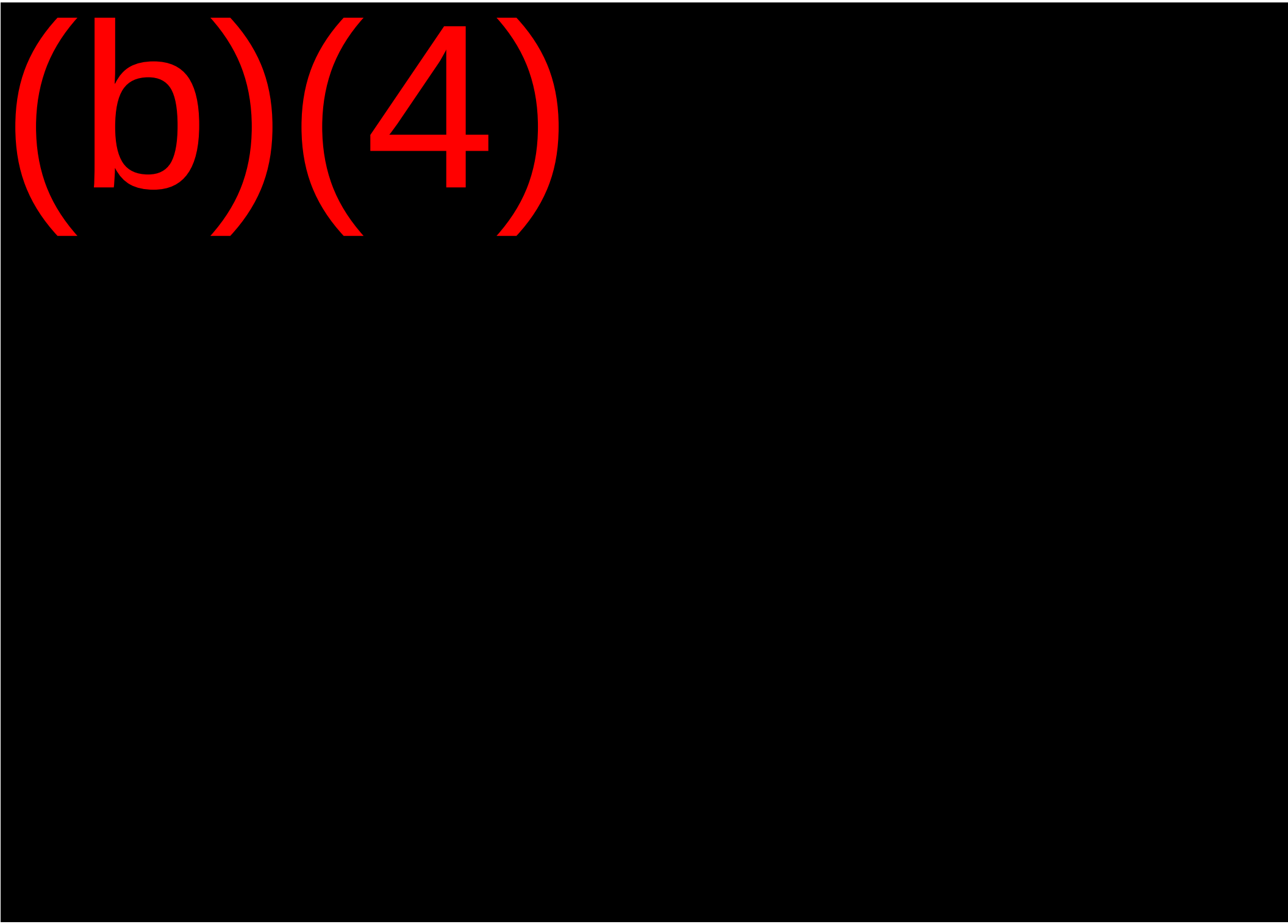
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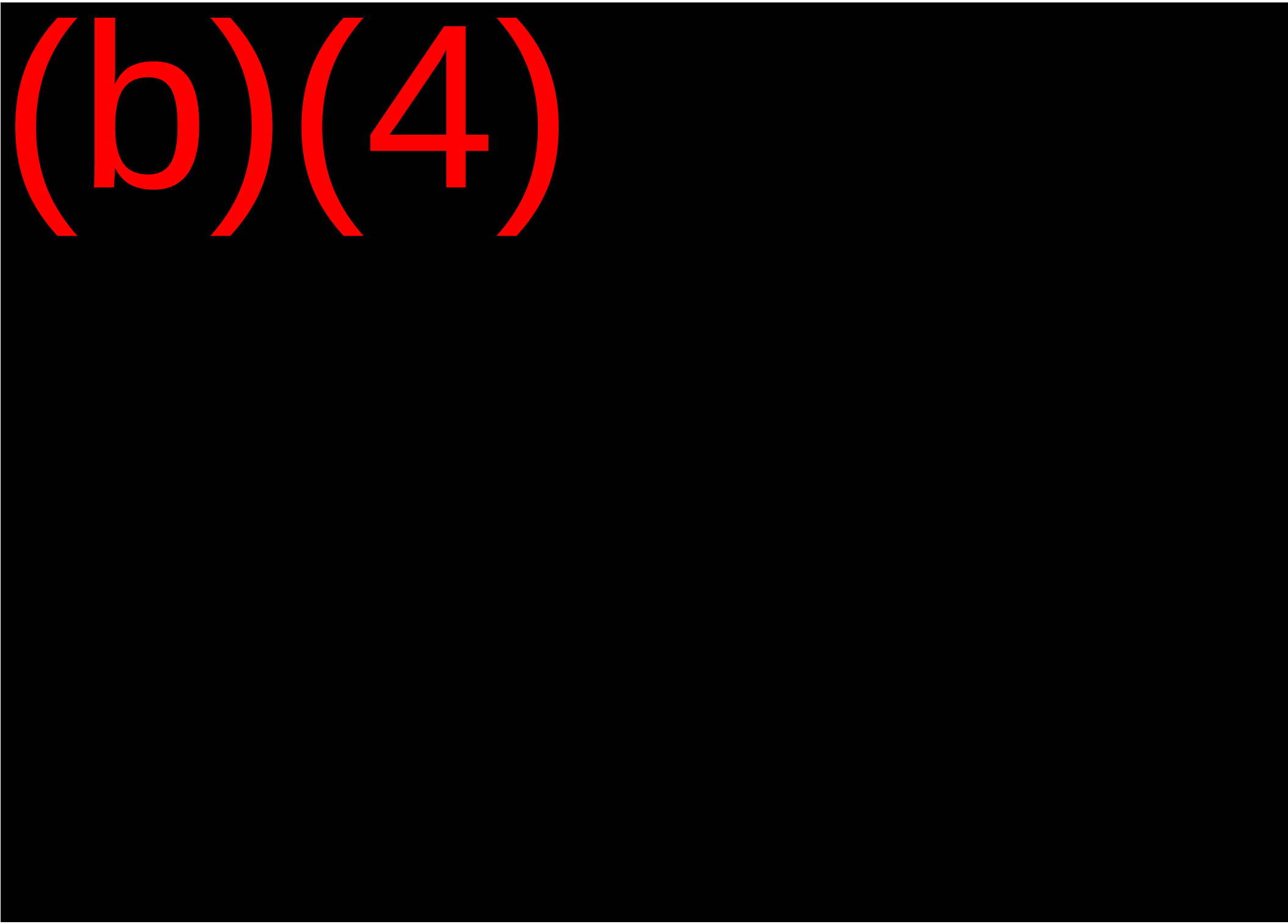
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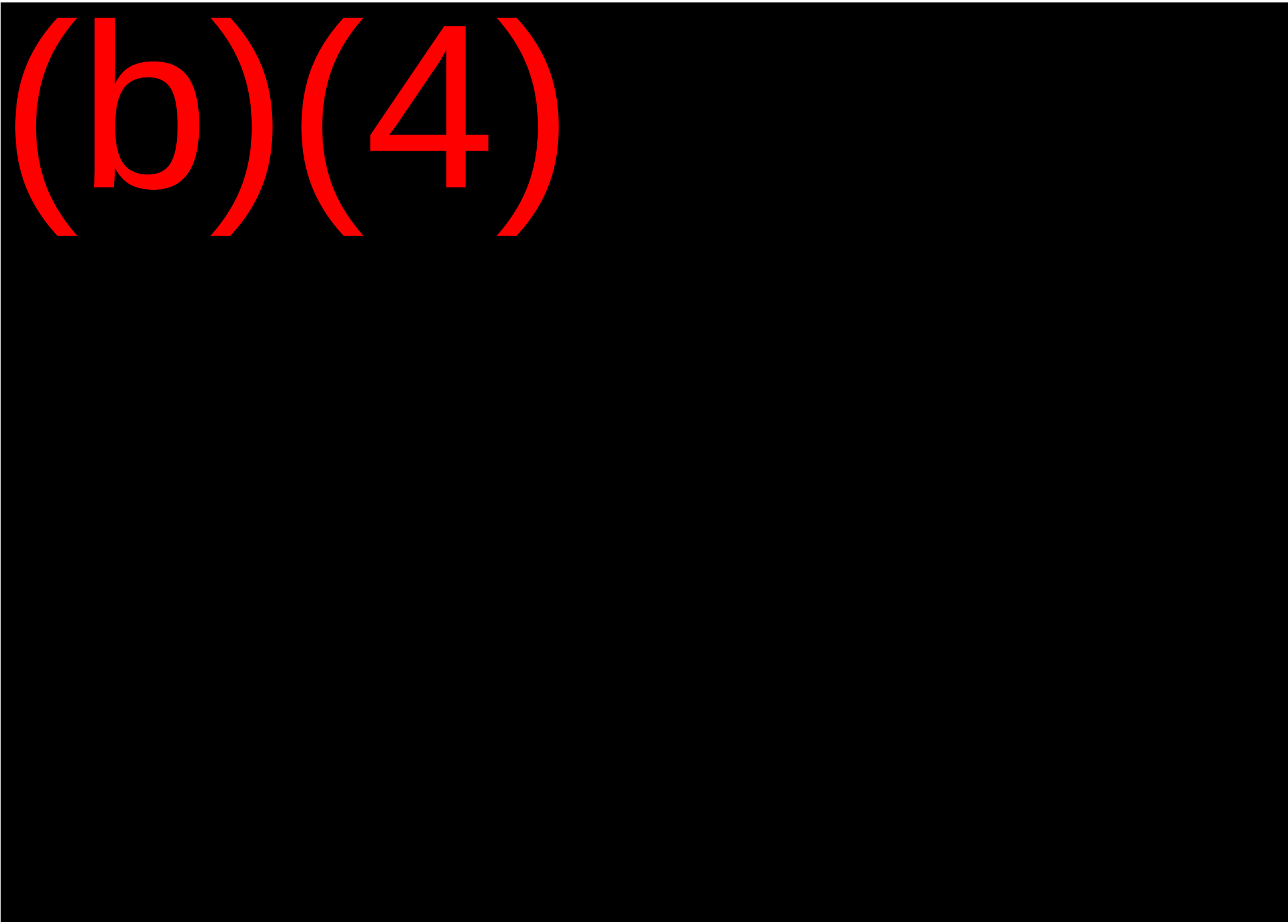
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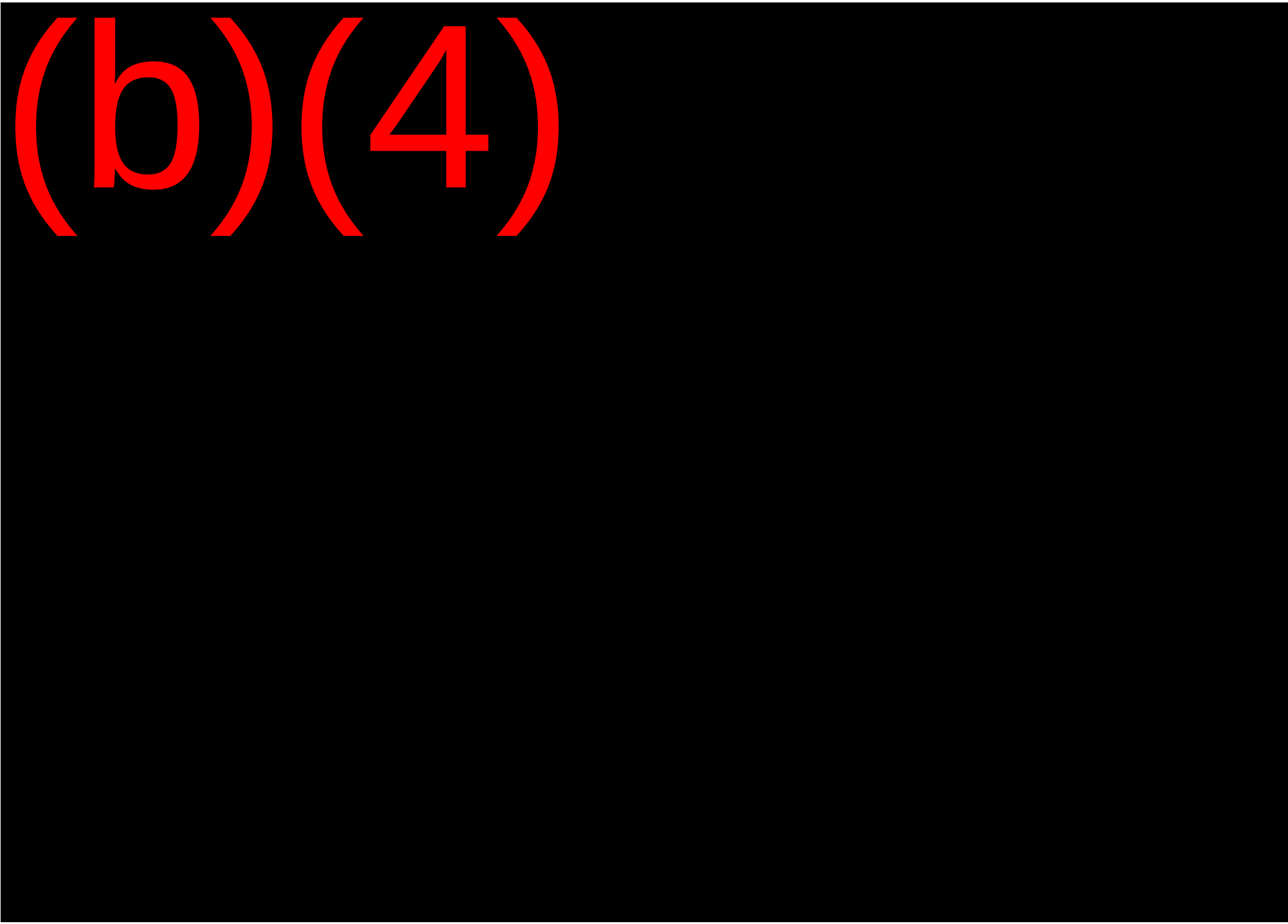
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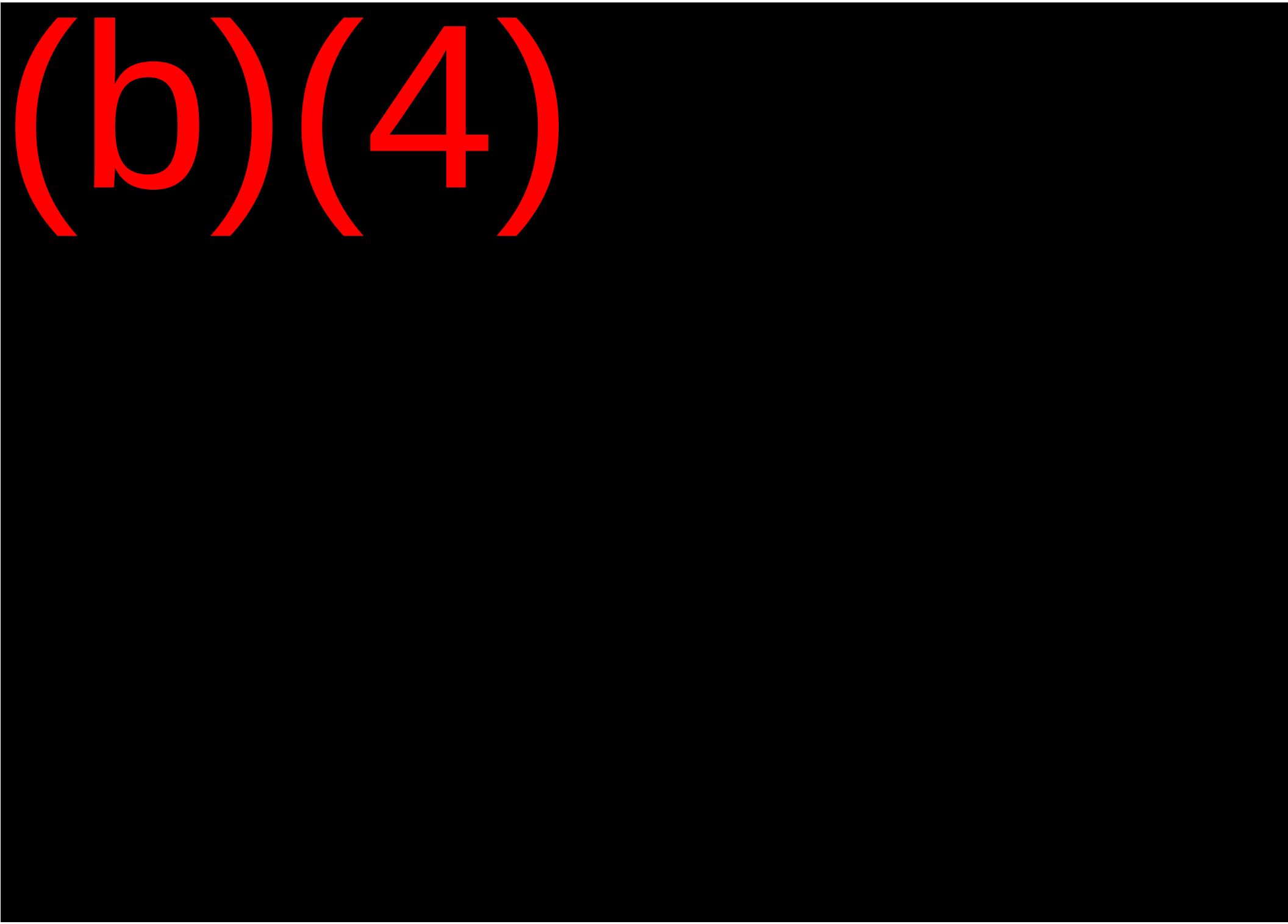
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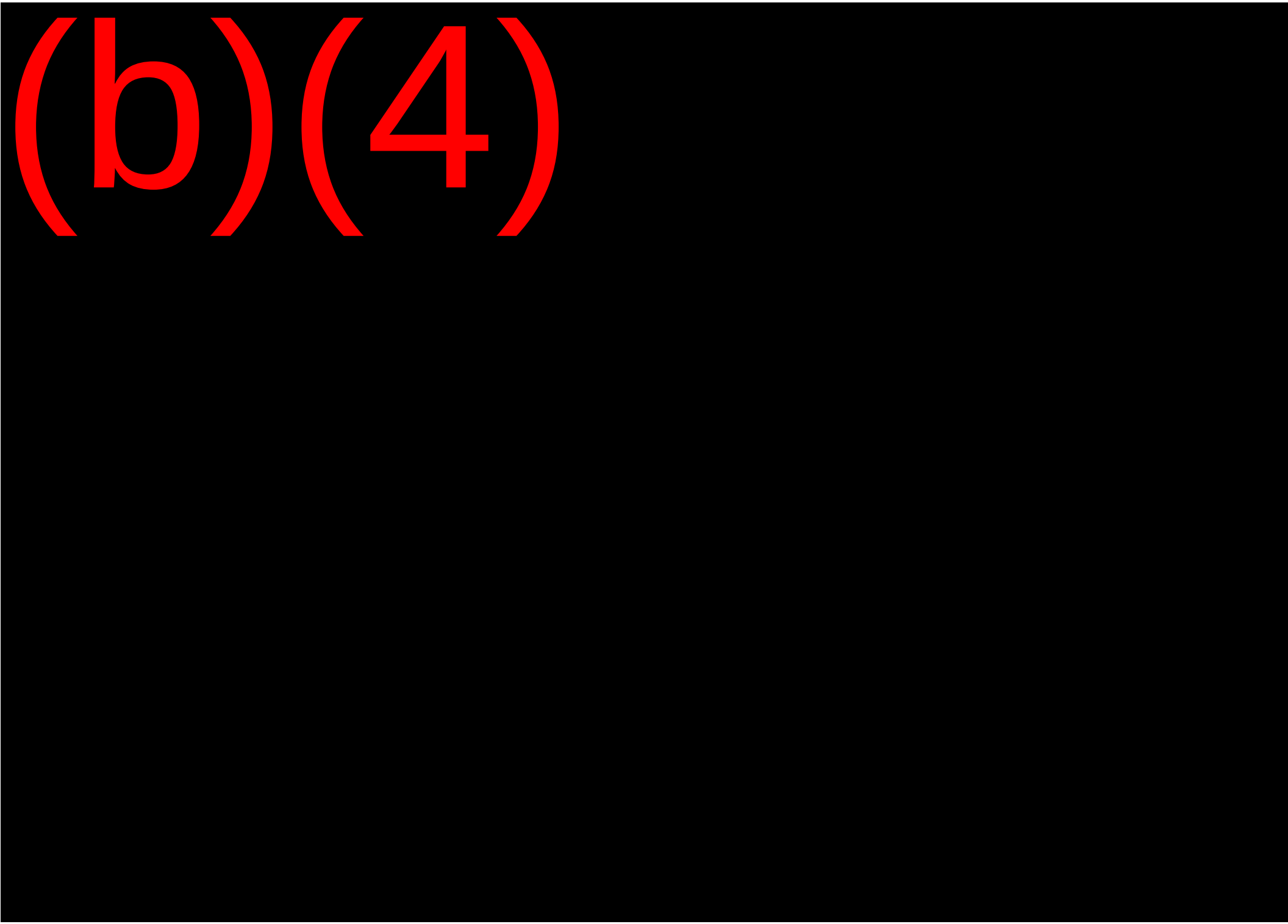
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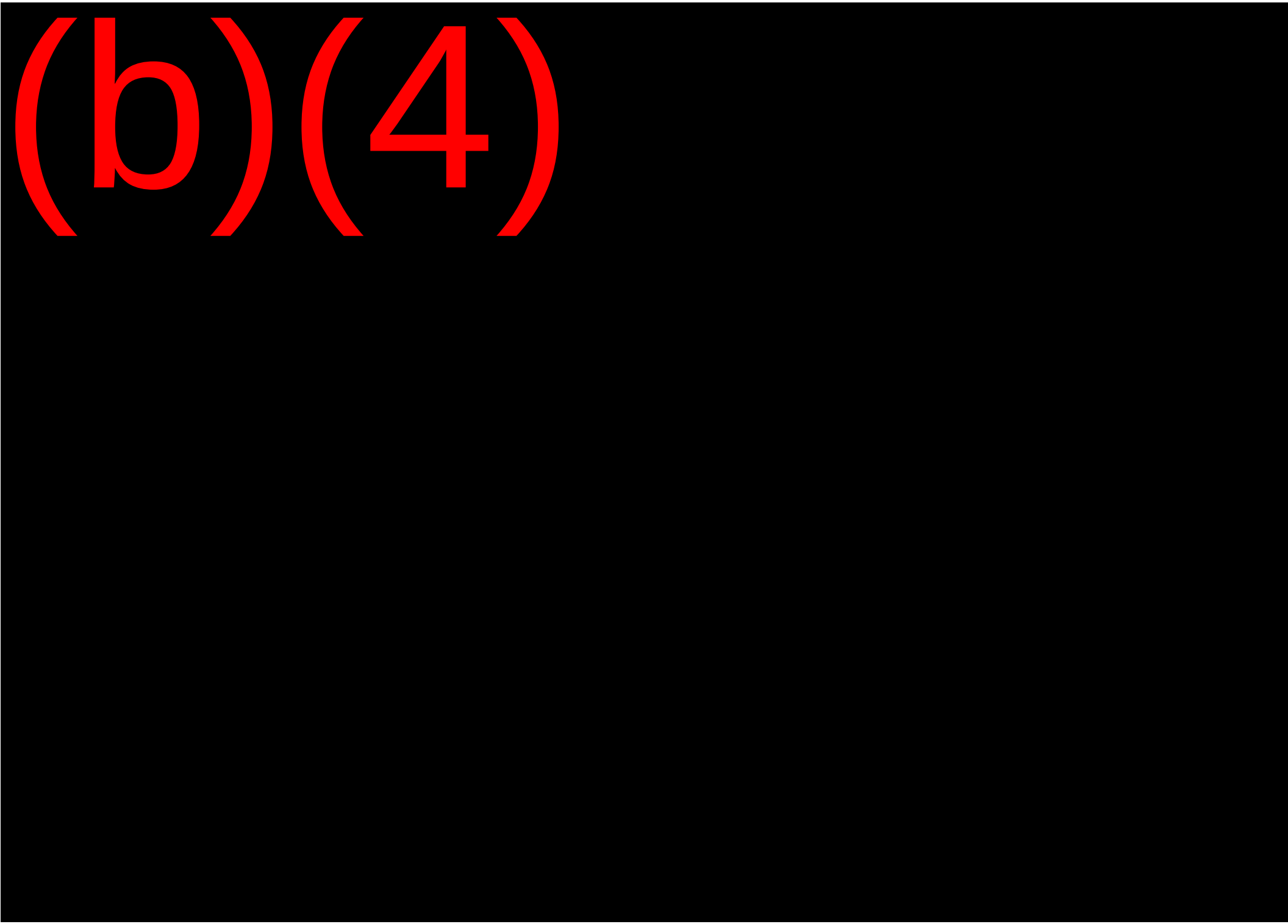
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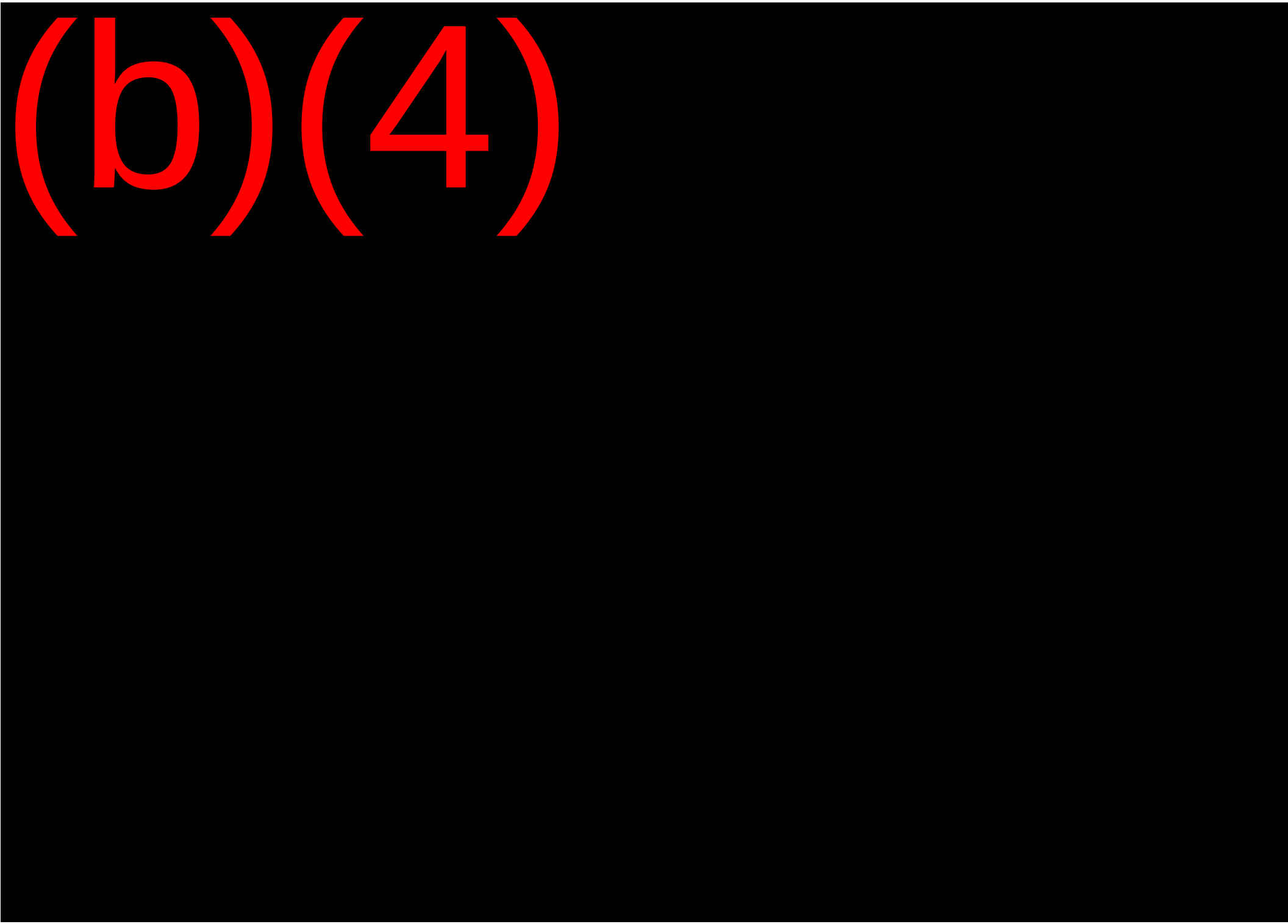
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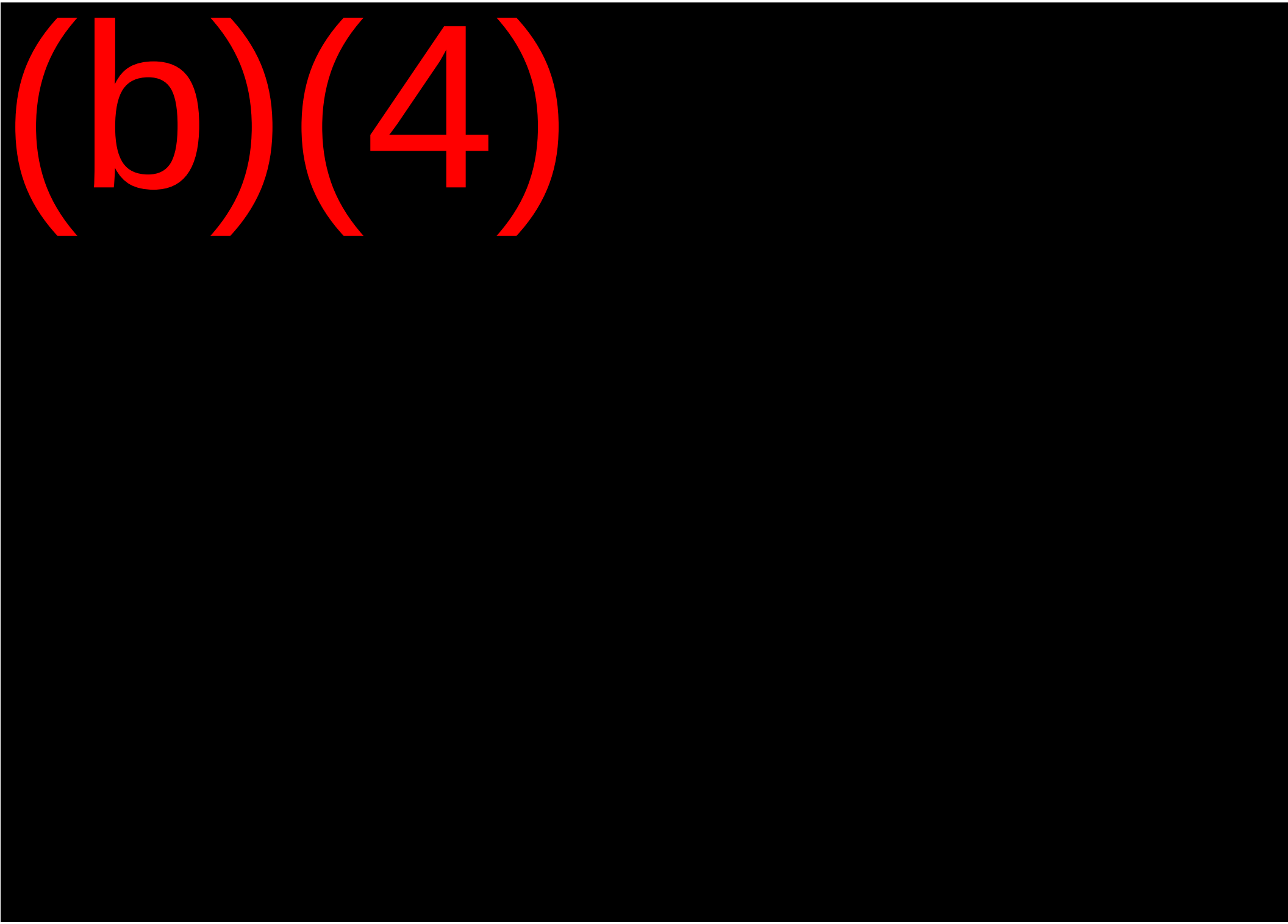
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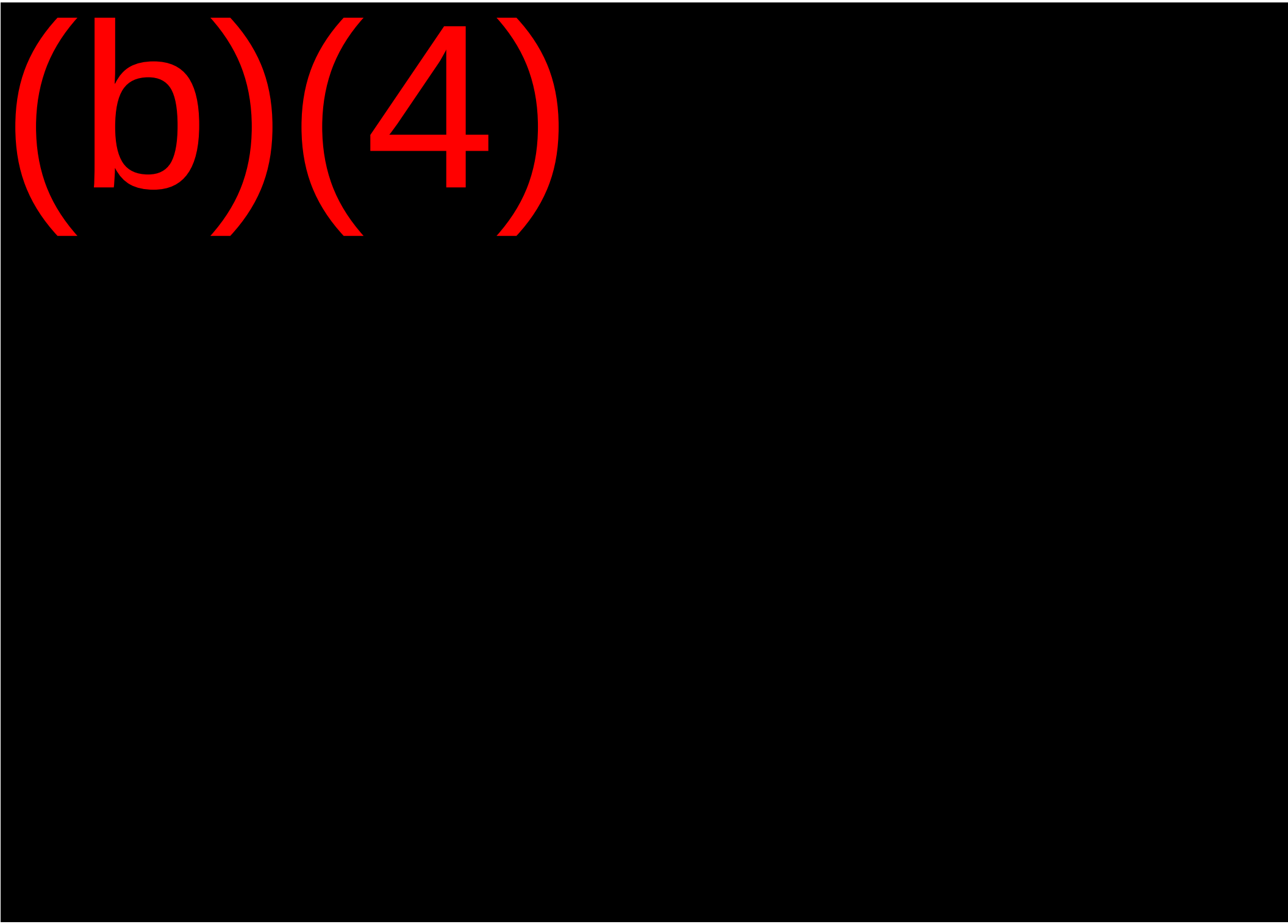
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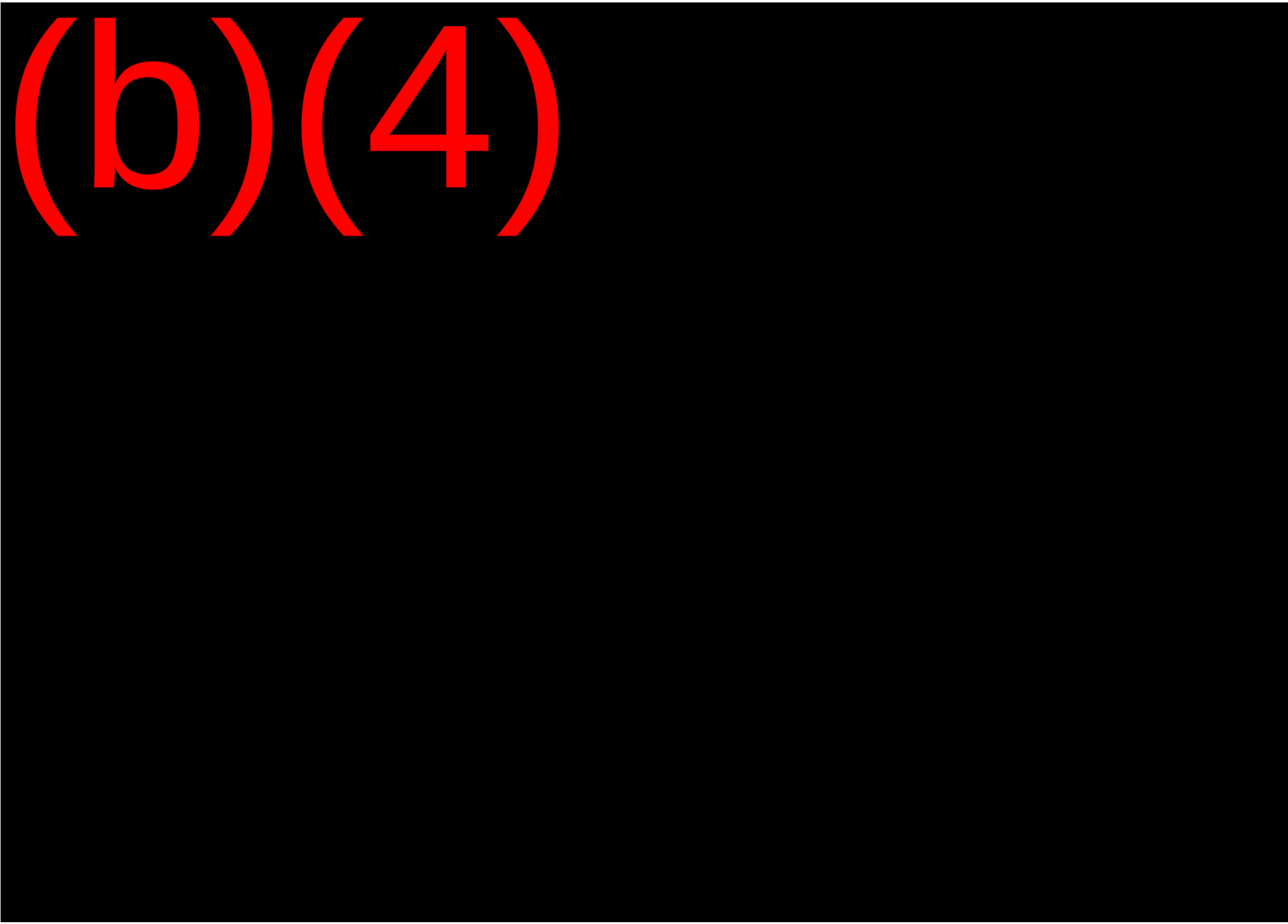
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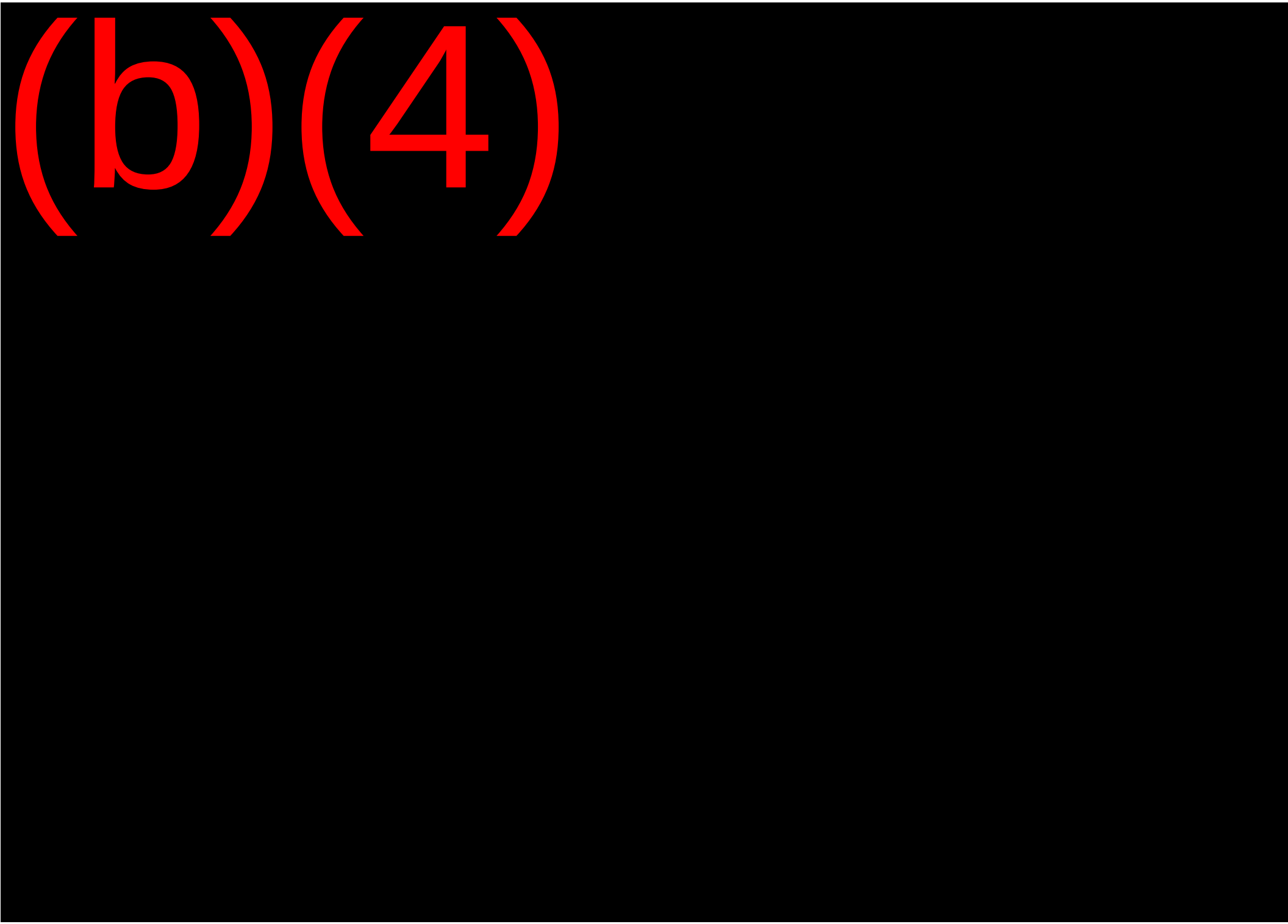
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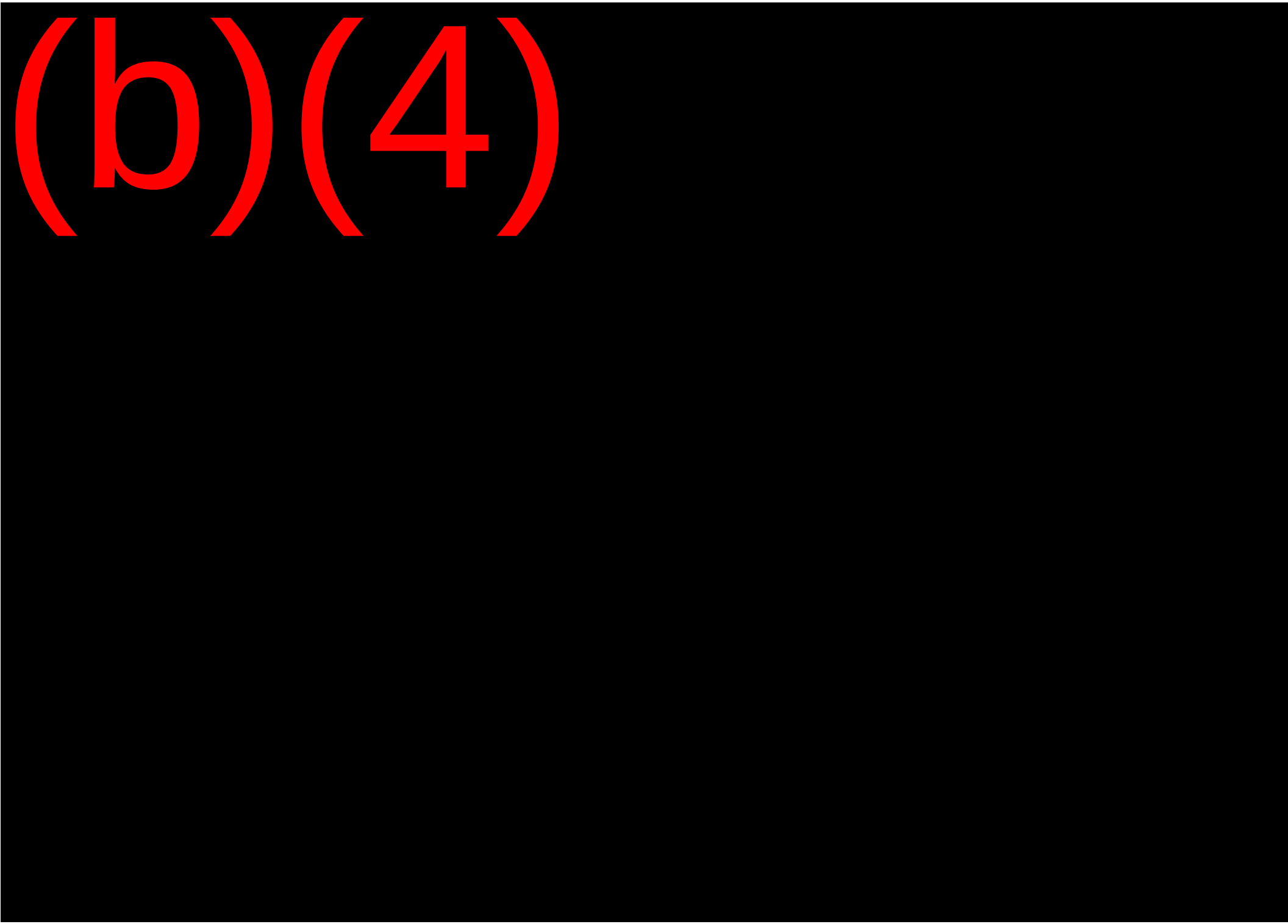
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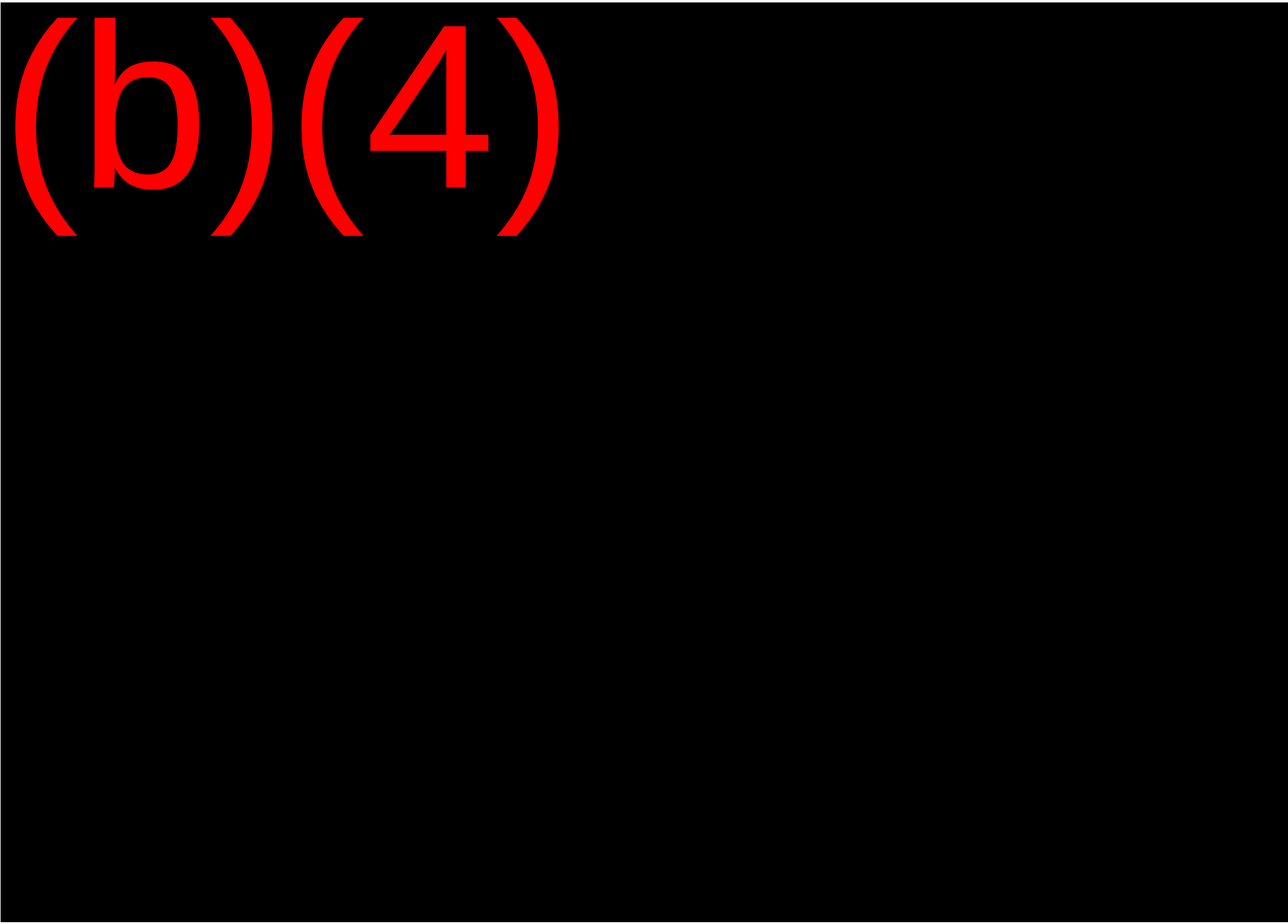
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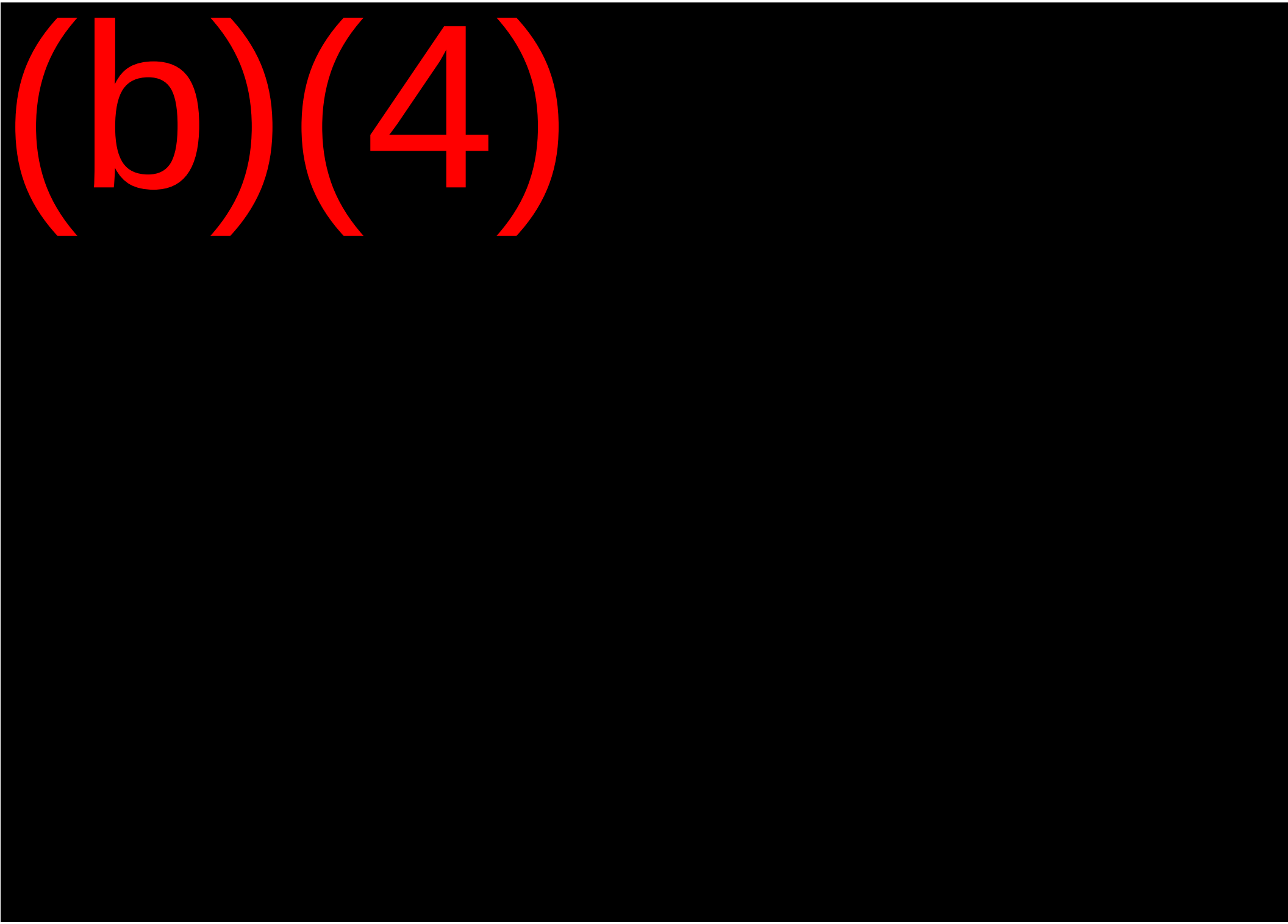
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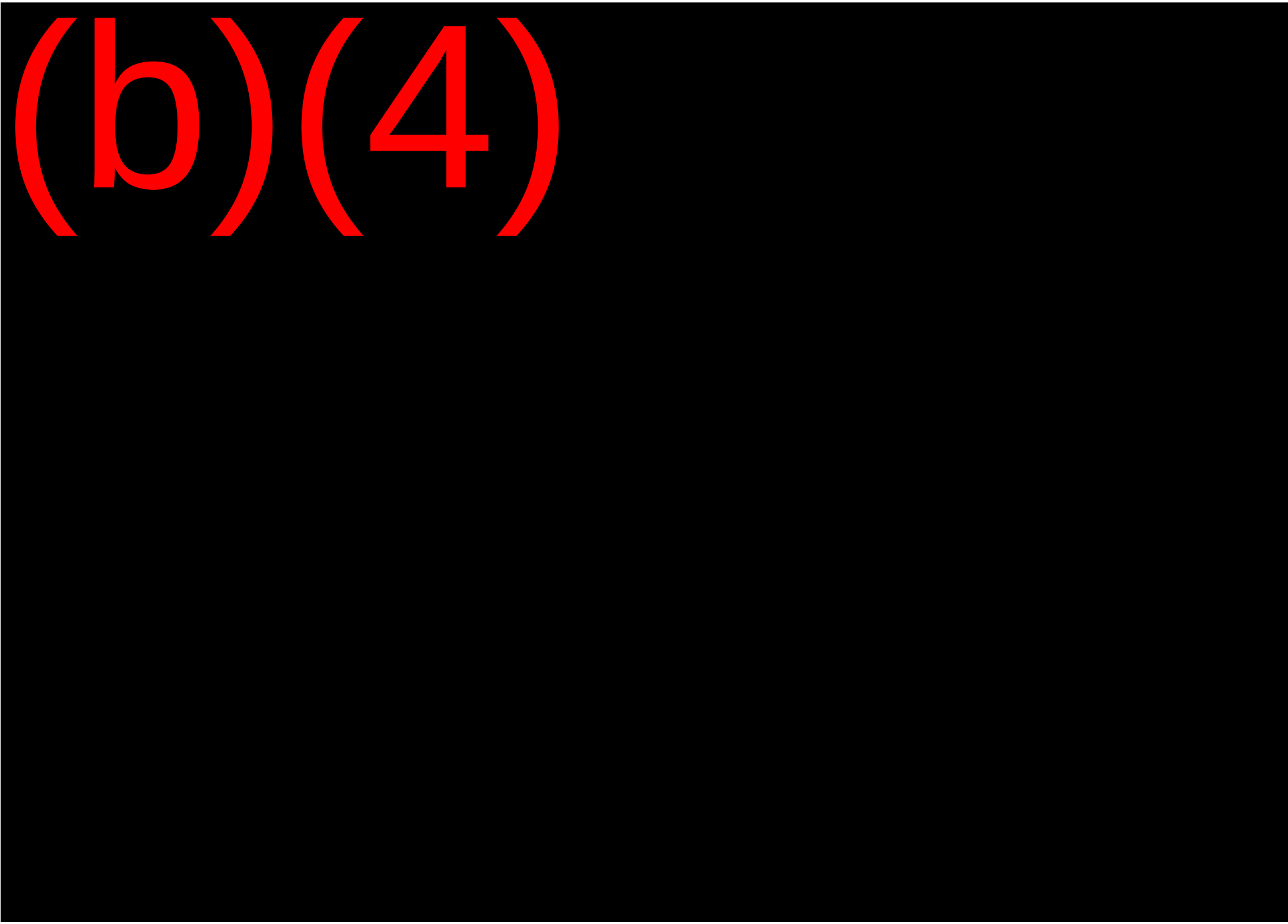
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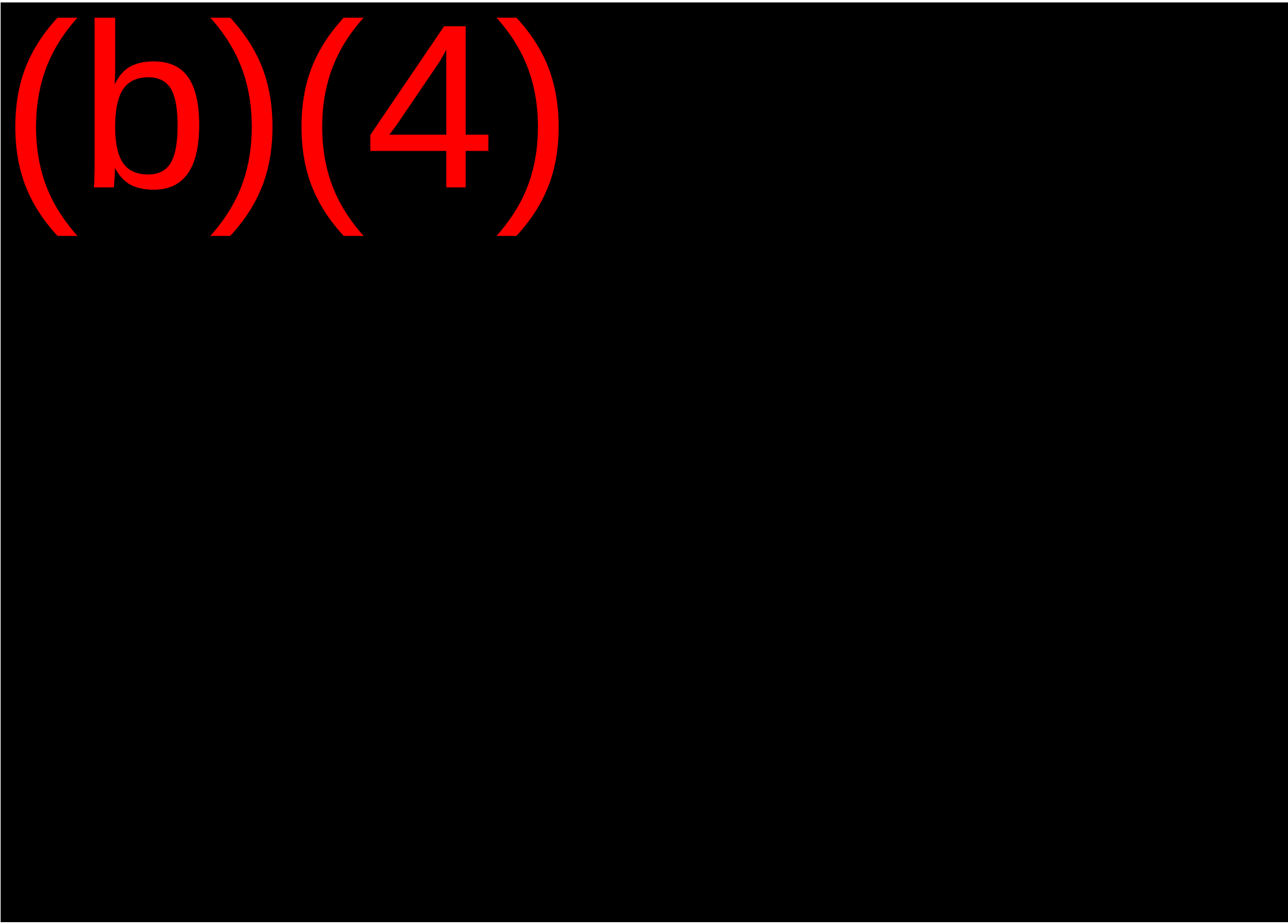
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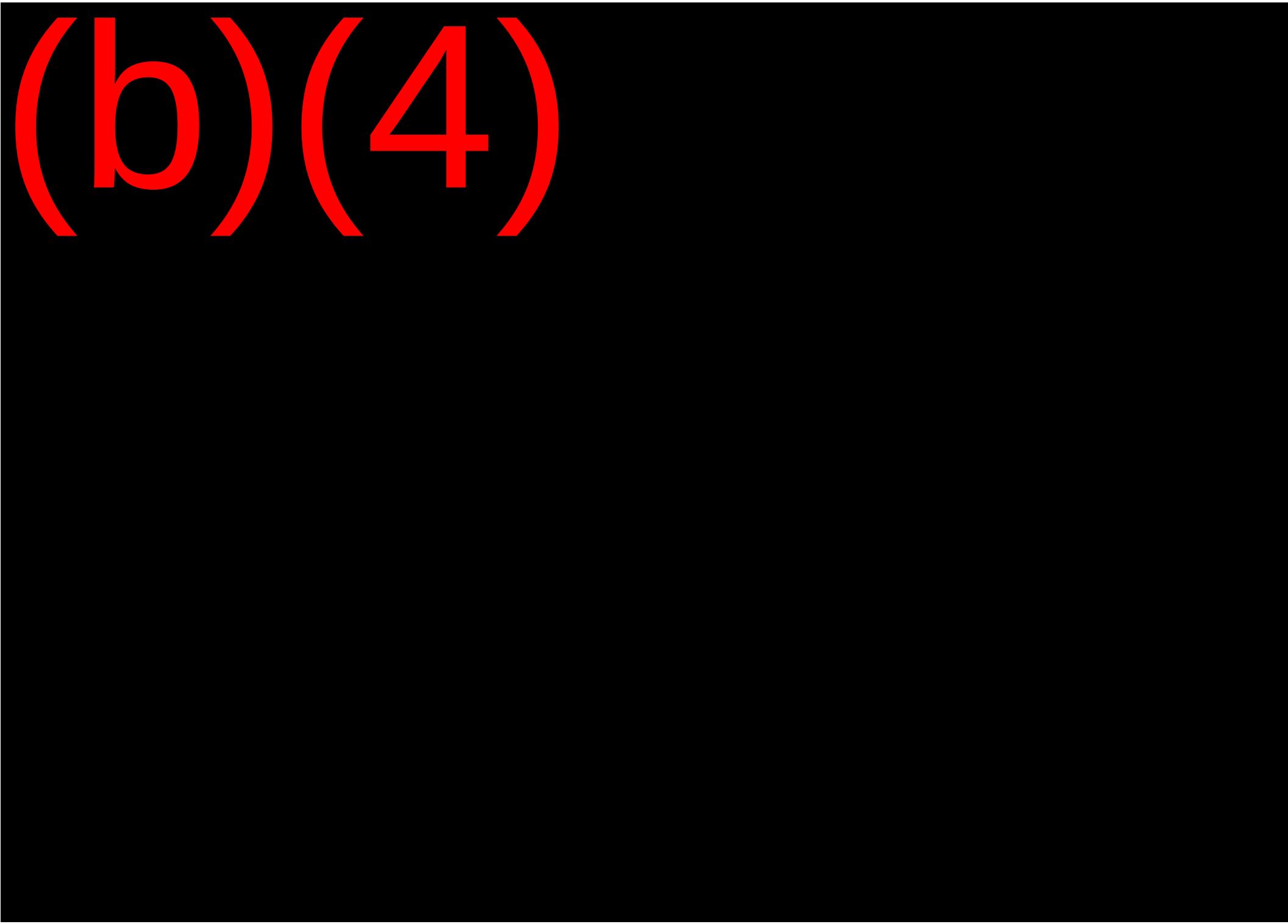
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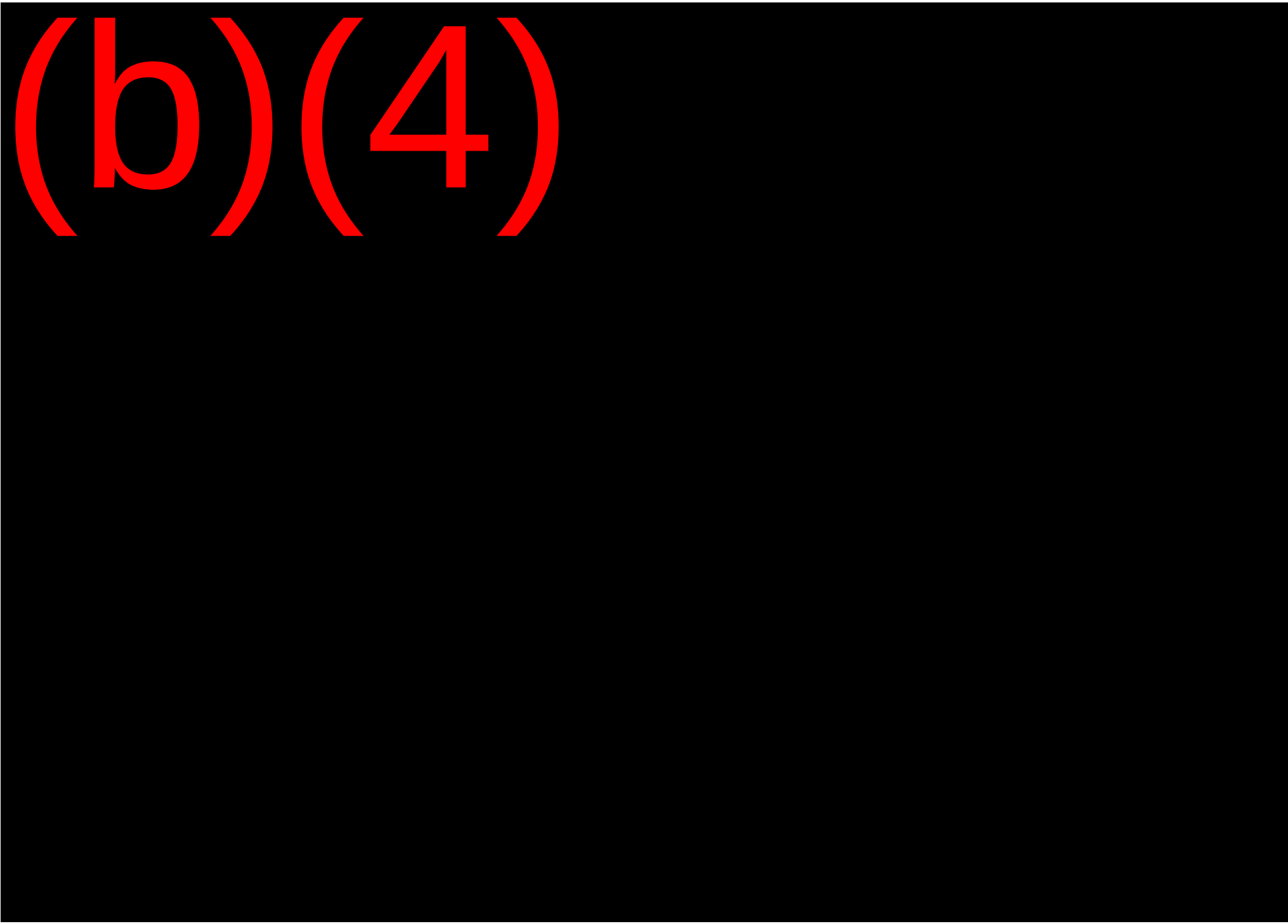
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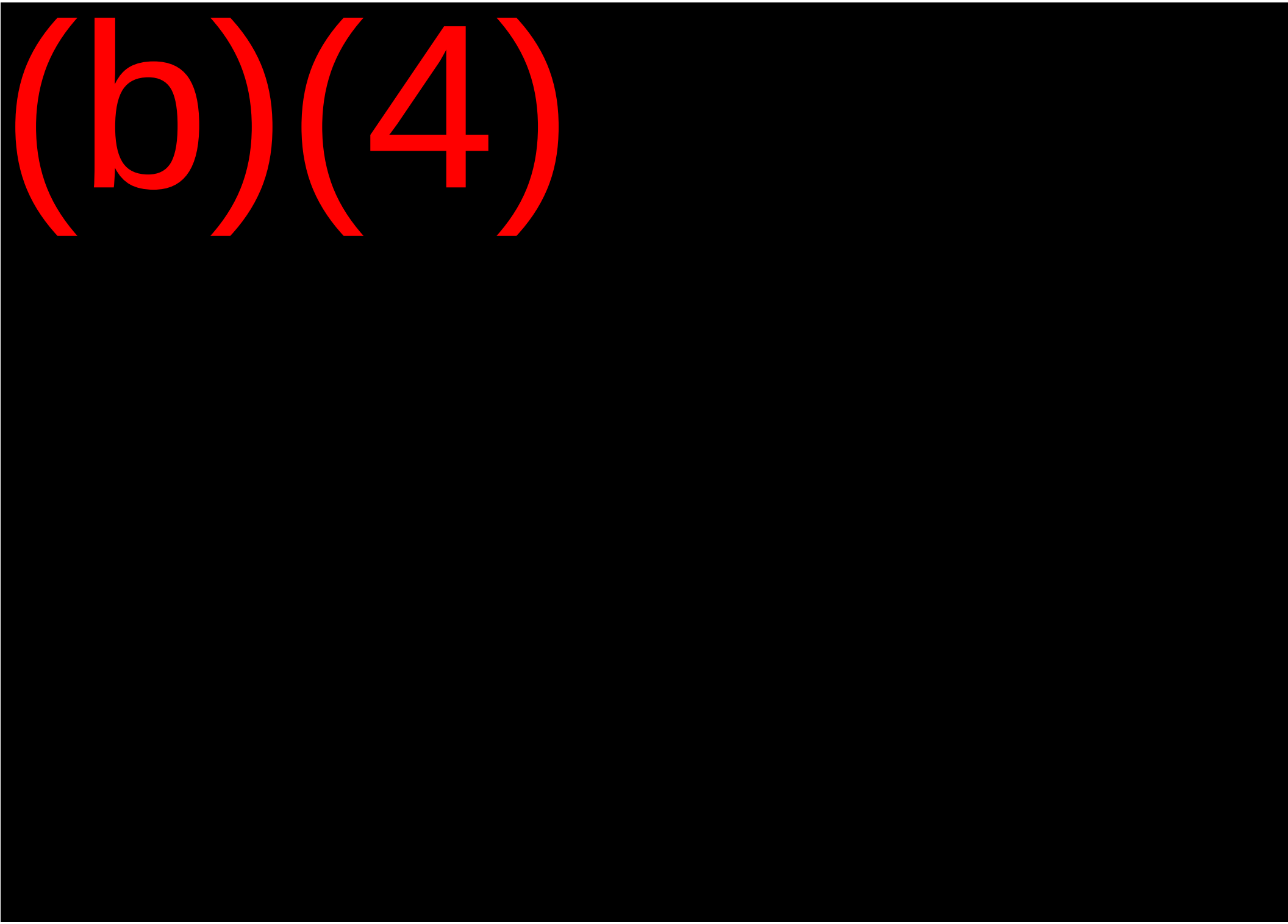
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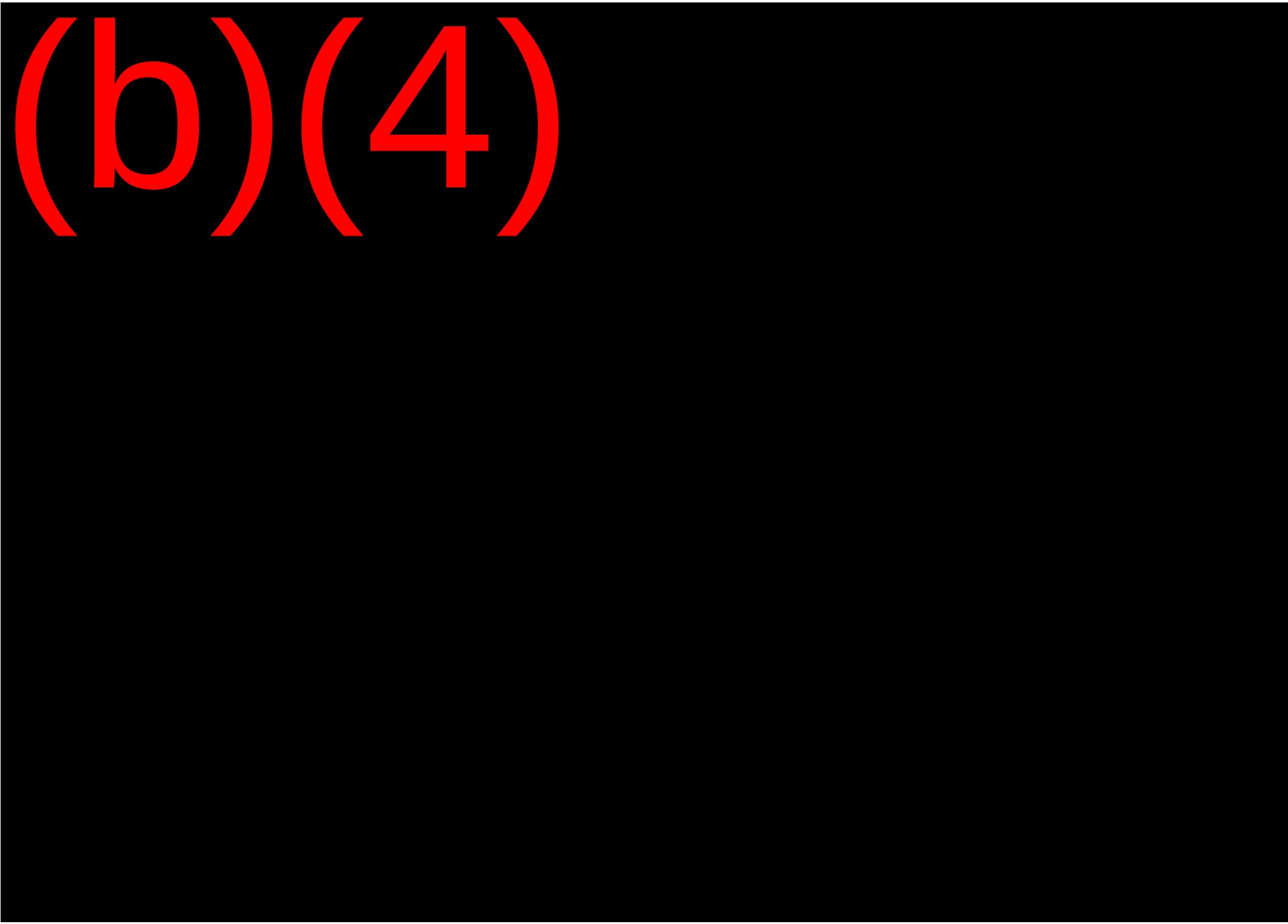
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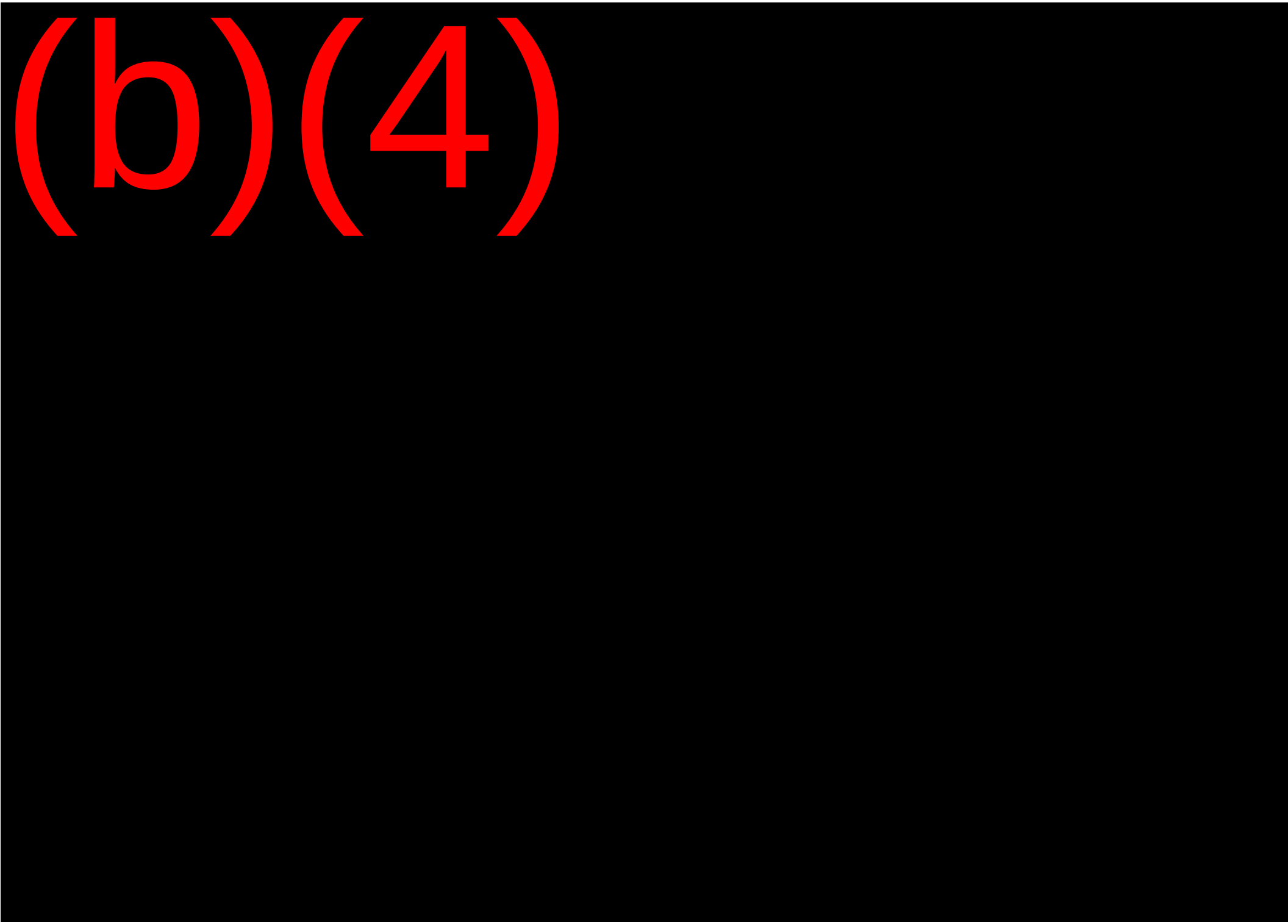
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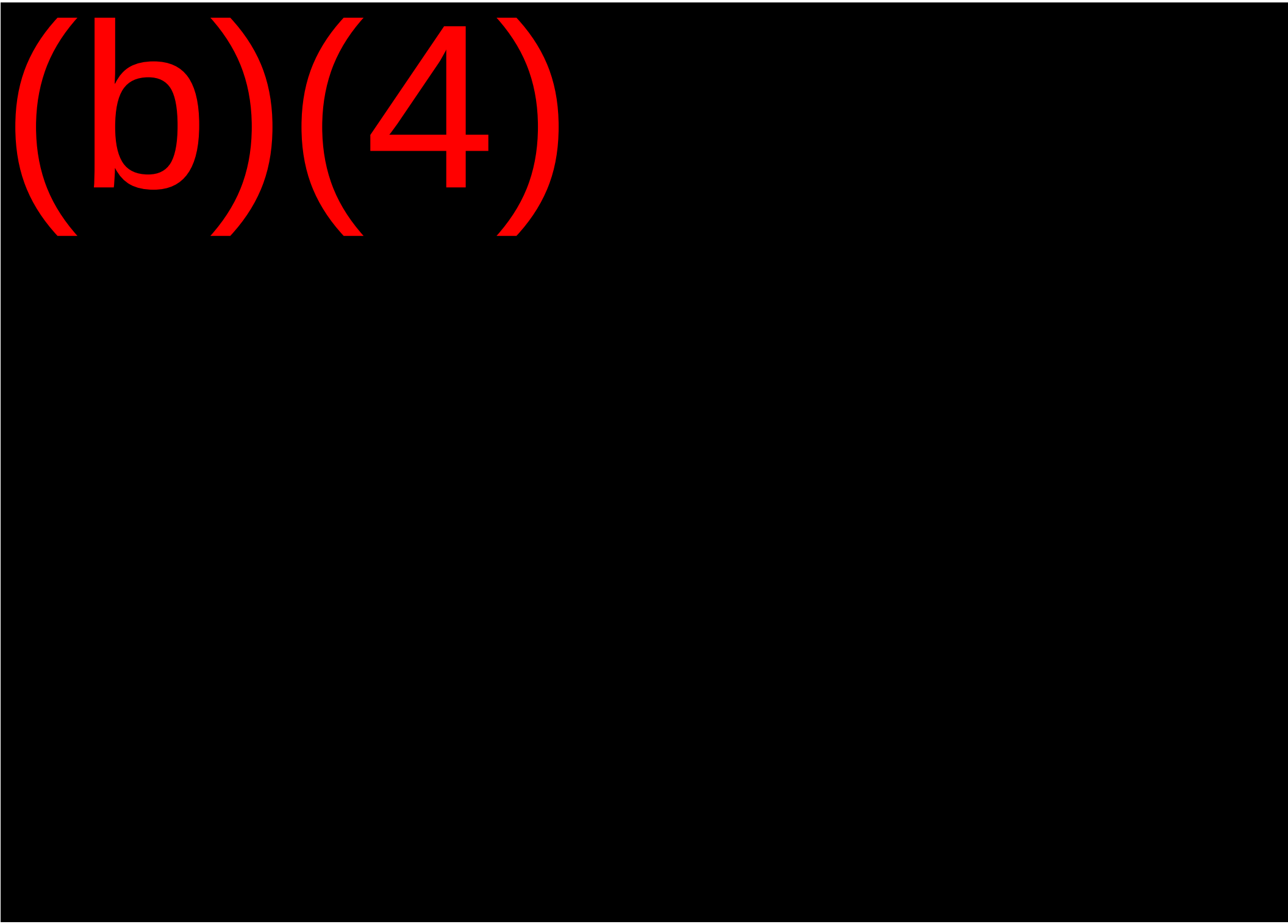
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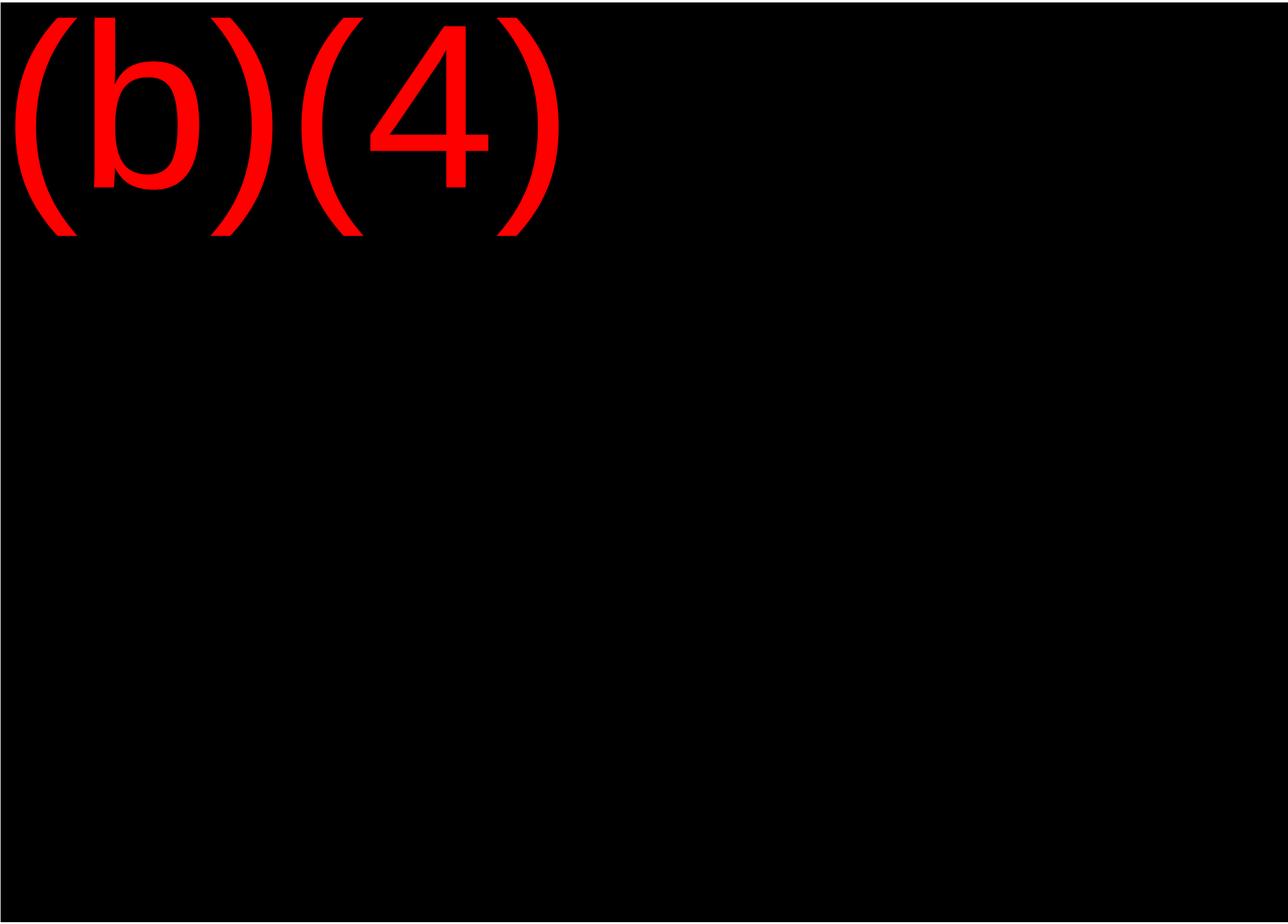
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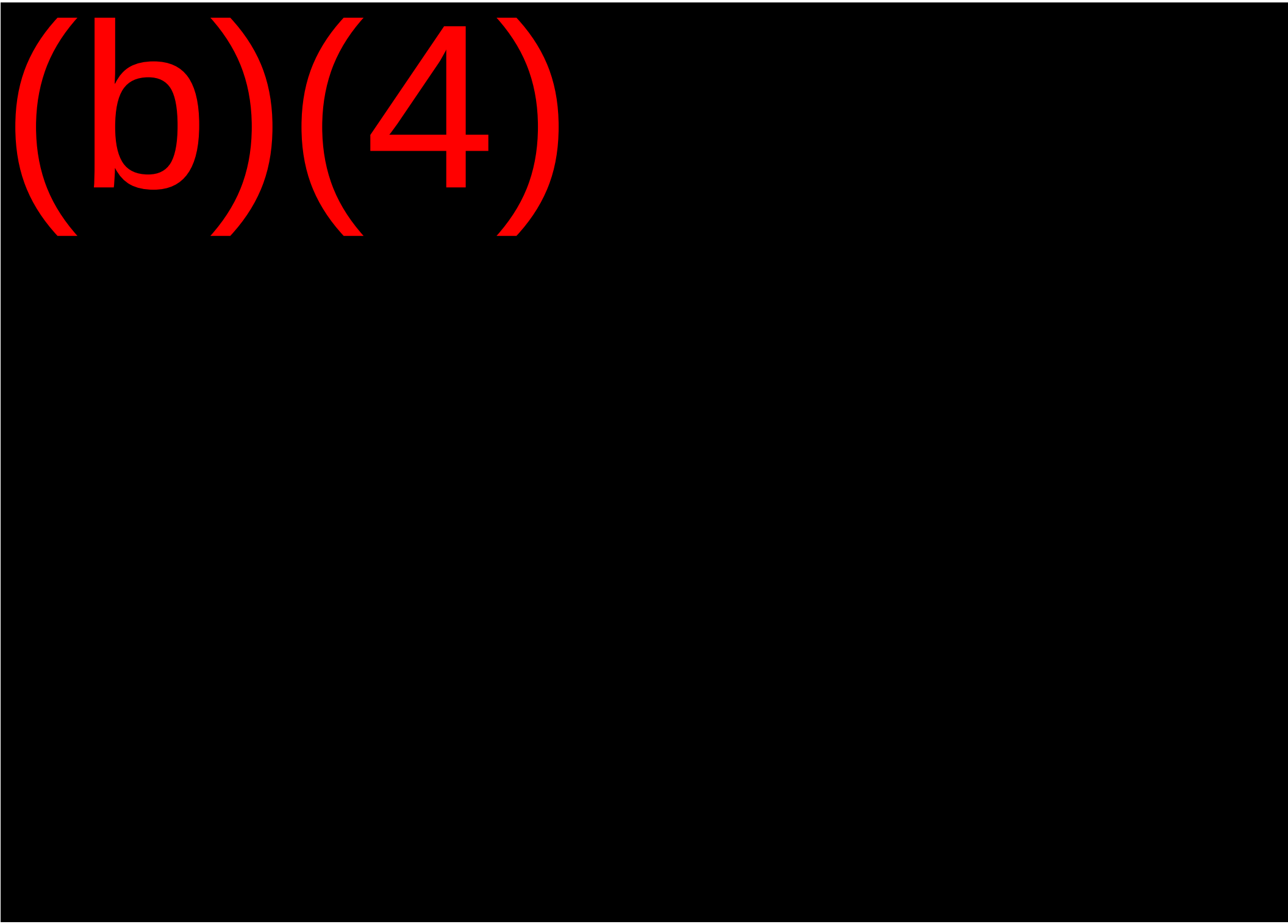
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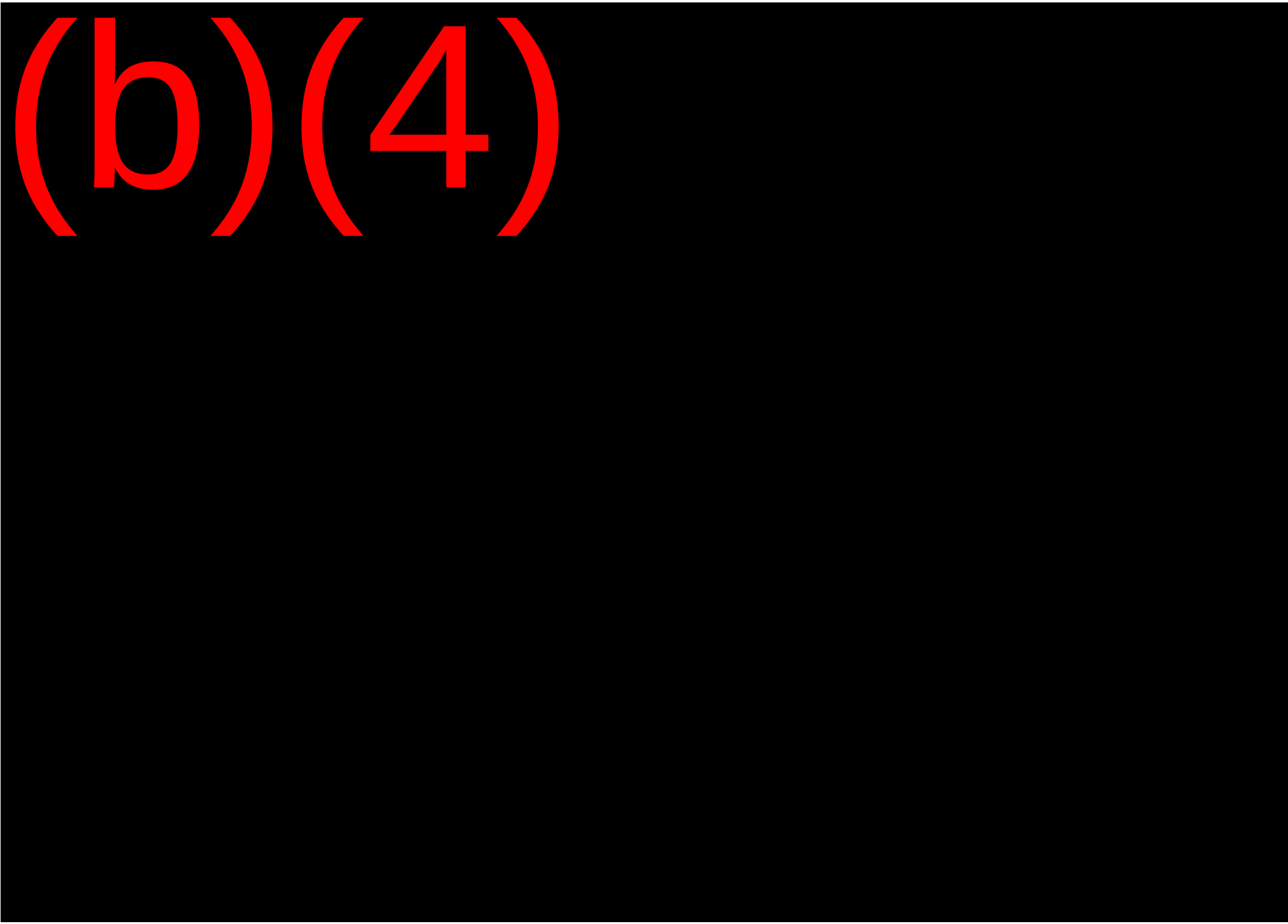
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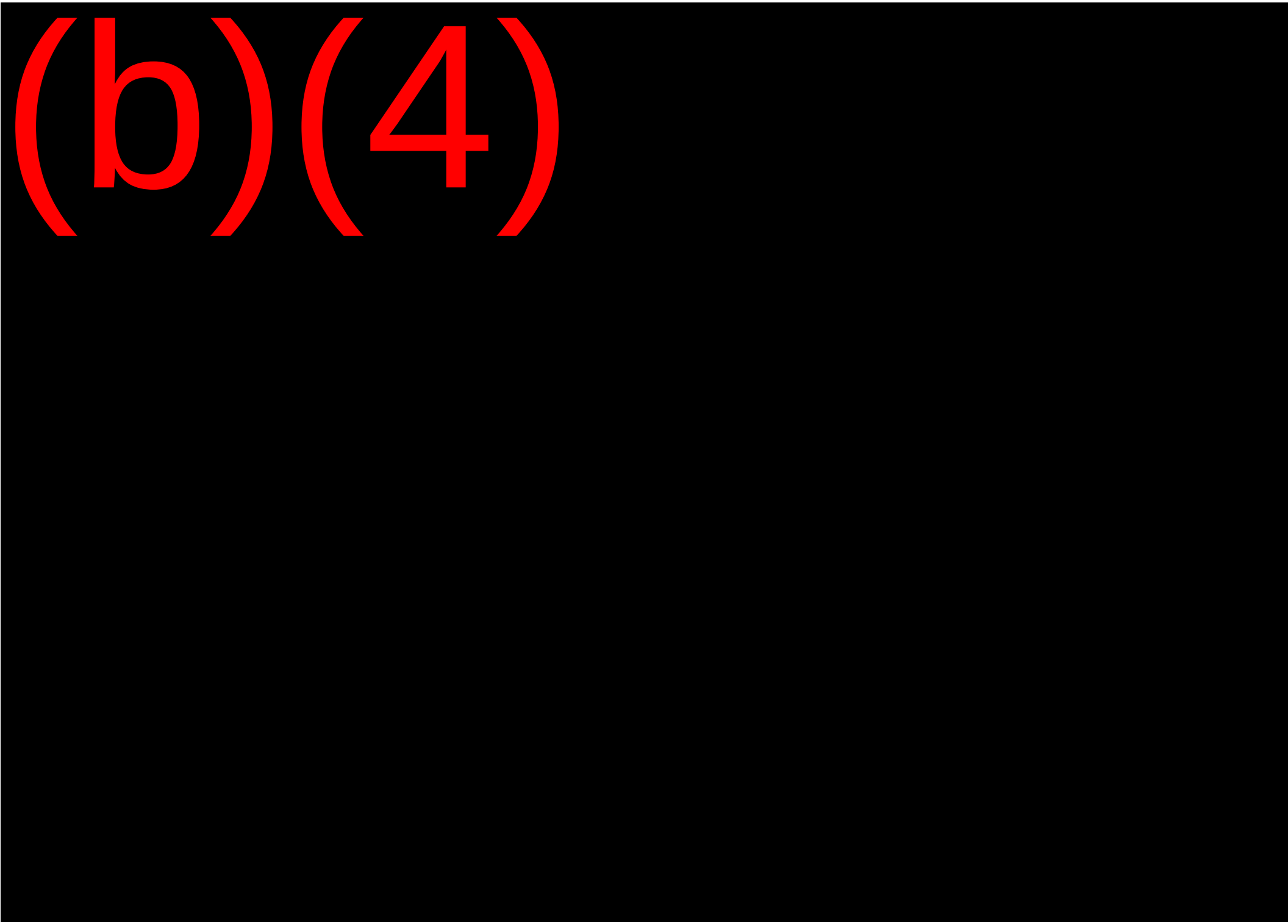
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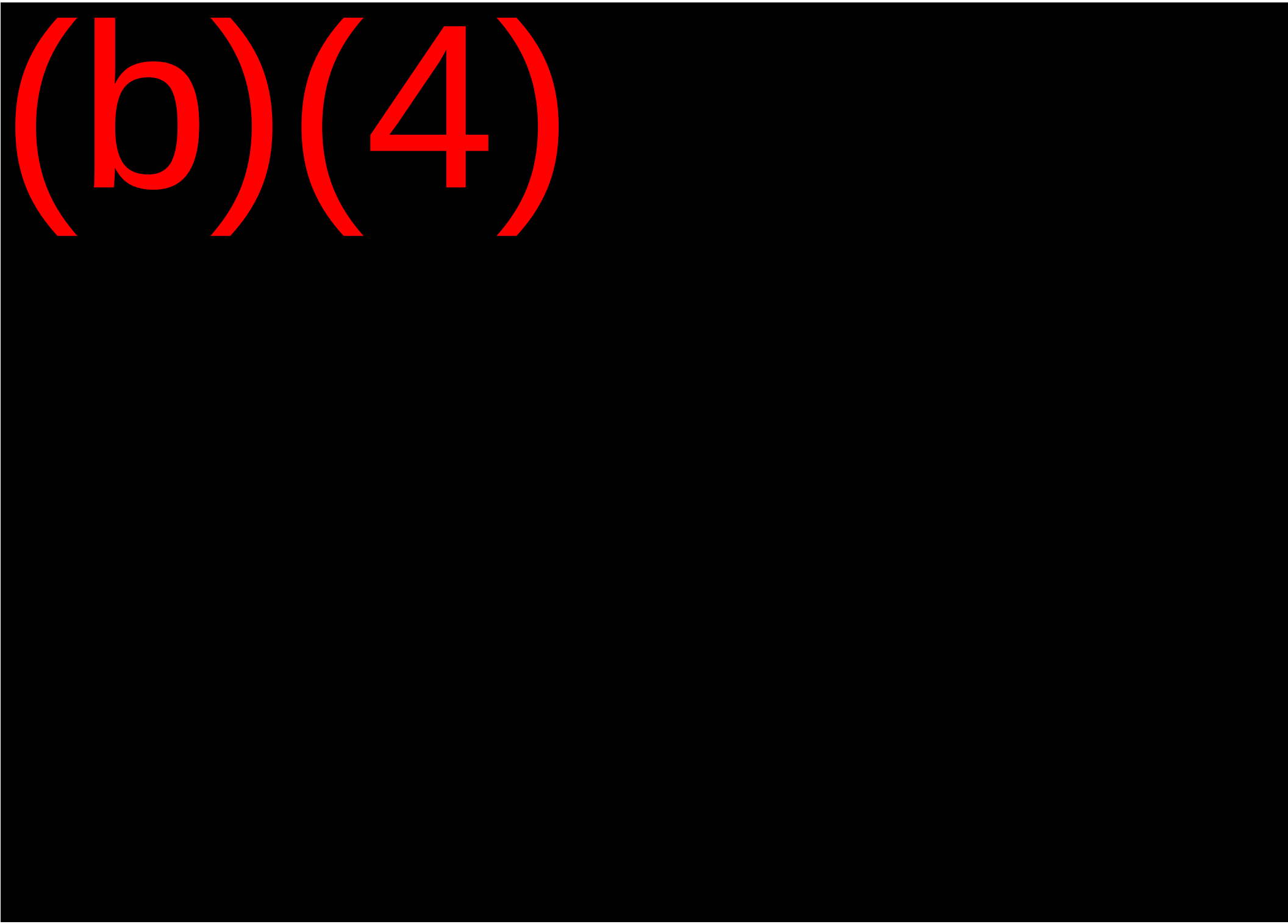
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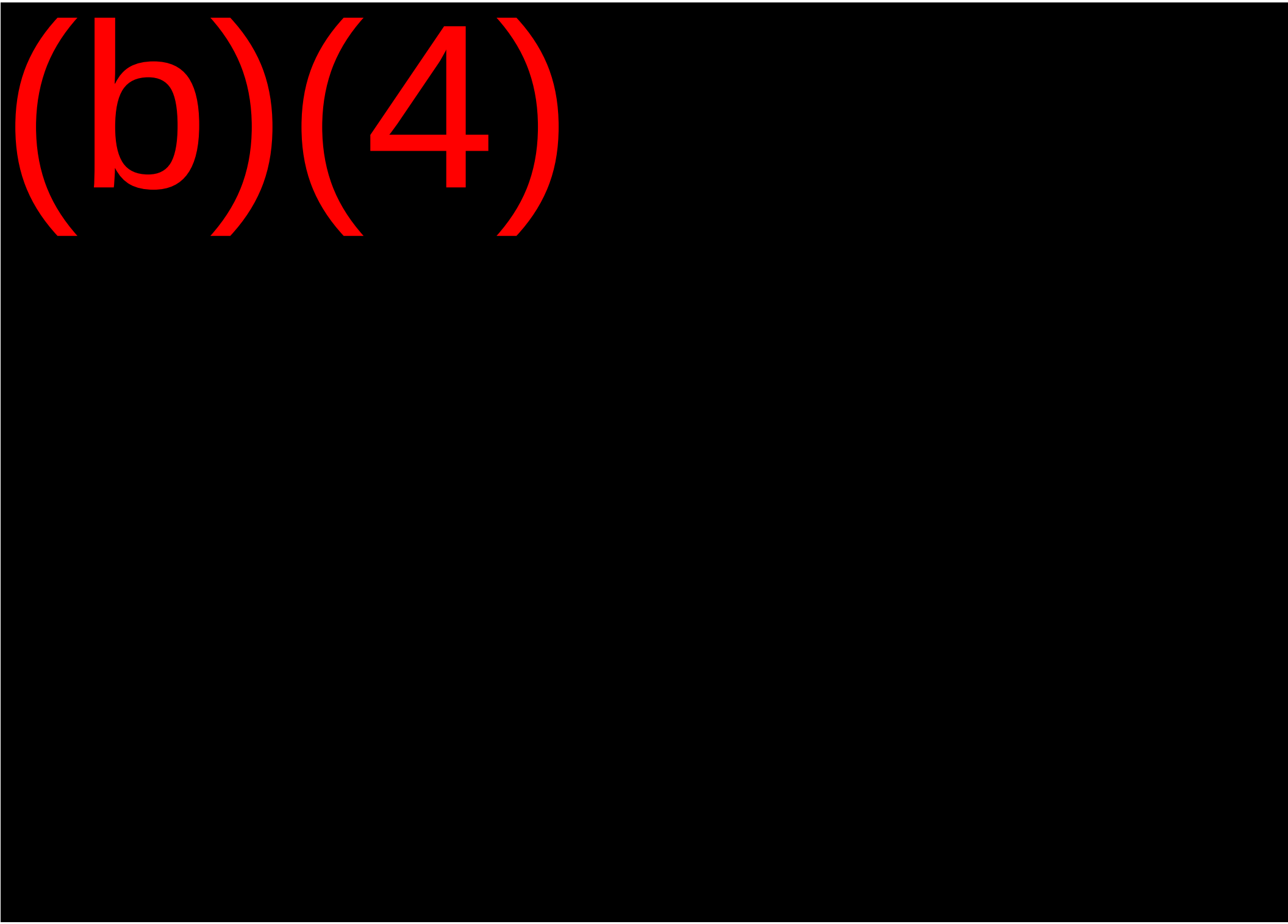
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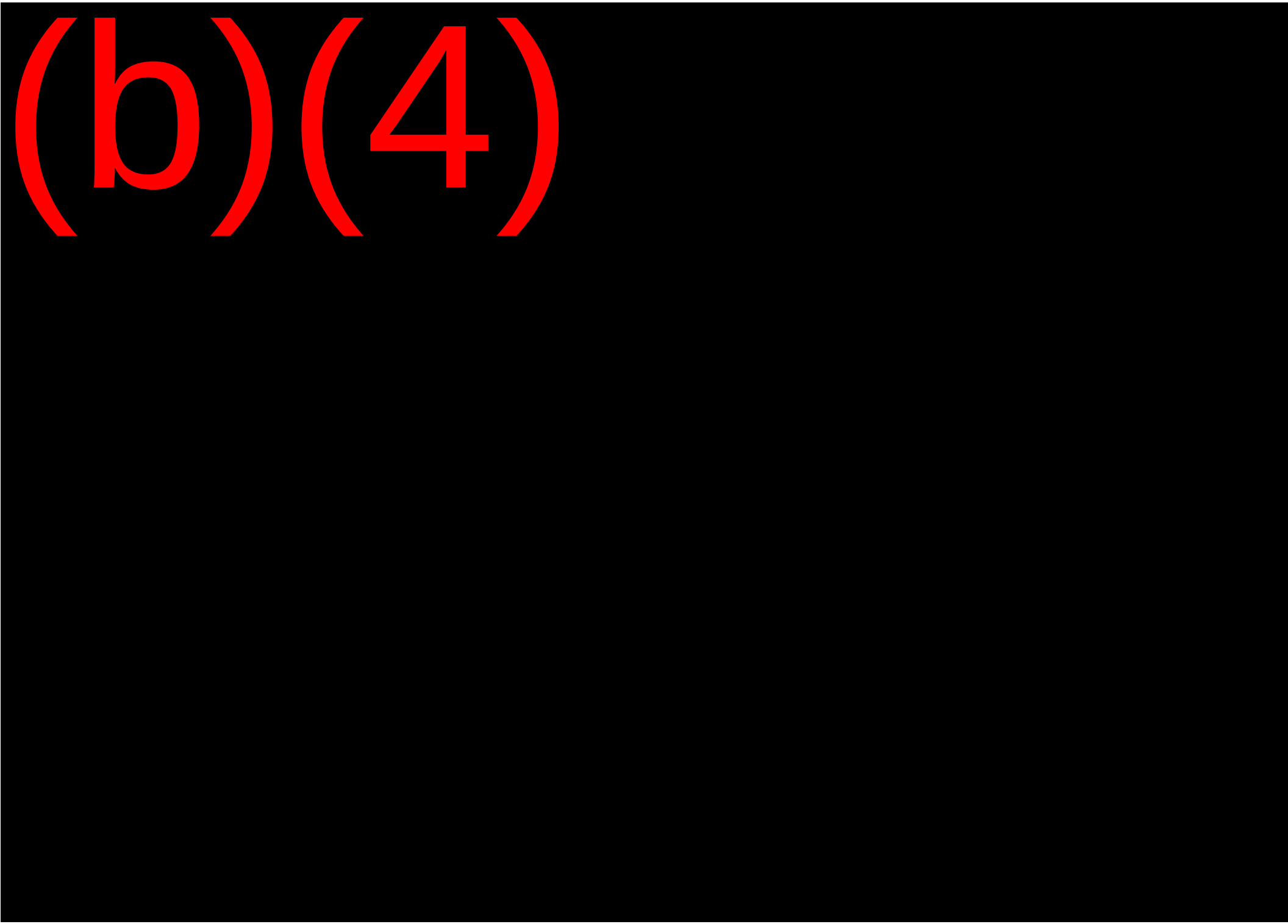
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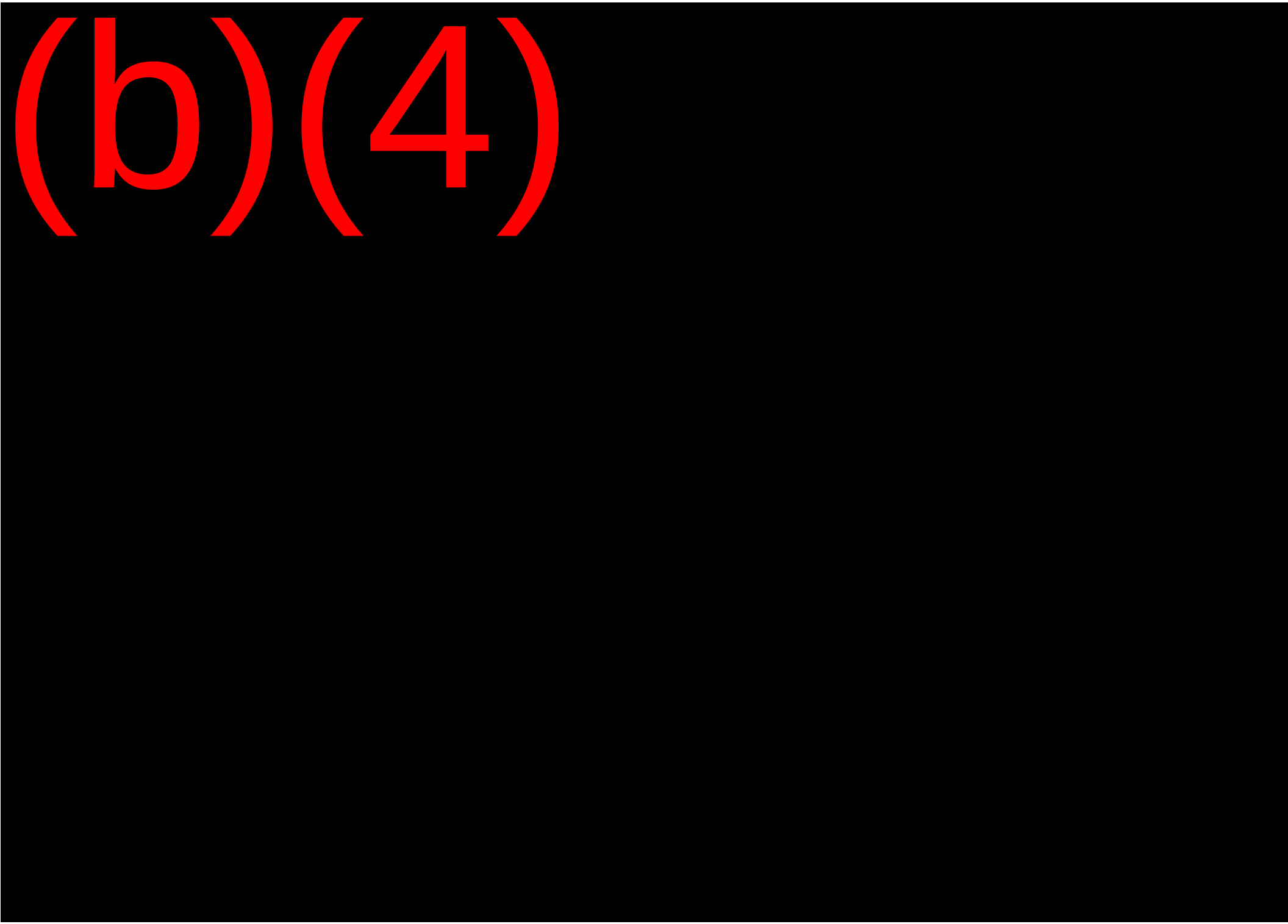
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Harm Perceptions and Beliefs about Potential Modified Risk Tobacco Products

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Abstract: Under US law, tobacco products may be authorized to claim lower exposure to chemicals, or lower risk of health harms. We sought to examine the harm perceptions and beliefs about potential modified risk tobacco products (MRTPs). We recruited 864 adult current and former smokers in August 2019. Participants read a paragraph describing the potential for the FDA to authorize MRTPs and a brief description of MRTPs. The most endorsed beliefs for each product were that they contained nicotine and that they were risky. Believing that e-cigarettes can help smokers quit smoking, that they tasted good, and looked cool were associated with greater odds of intending to try e-cigarettes after controlling for demographic and use factors. For snus, the beliefs that the product was not addictive and tasted good were associated with increased odds of intending to try snus. The beliefs that heated tobacco would taste good and would be a good quit aid was associated with increased odds of intentions to try heated tobacco products. Understanding what the public believes about products currently or potentially authorized to be marketed as modified risk tobacco products can inform communication efforts.

Keywords: alternate tobacco products; e-cigarettes; modified risk tobacco products

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1. Introduction

There is a growing recognition among tobacco control experts that tobacco products pose different levels of risk which exist along a "continuum of risk" [1,2]. Snus (a low nitrosamine type of moist snuff), and e-cigarettes pose significantly fewer health risks to individual users compared to cigarettes, though they are not without risk [2–5]. While switching to products lower on the risk continuum may have the potential for harm reduction among those smokers who are unable or unwilling to quit cigarettes; research indicates that users' perceptions about the comparative risks of tobacco products are often inconsistent with the continuum of risk. Many believe smokeless tobacco (SLT) and e-cigarettes are as harmful or more harmful than tobacco cigarettes [6–8]. Many tobacco control experts have called for more accurate communication about the risks of such products relative to cigarettes [8–10]. Smokers may be receptive to such communications, with about half reporting they would be interested in using a tobacco product that claimed to be less harmful than other tobacco products [11,12].

In response to the health concerns about the harmful health effects of smoking, the tobacco industry began marketing new tobacco products as less harmful compared to traditional cigarettes [13,14]. This history can be traced from the recent efforts to advertise e-cigarettes as a harm reduction alternative to cigarettes, before becoming regulated by the FDA, [15,16] back to falsely claiming that filtered, "low tar," and "light" cigarettes were less harmful than regular cigarettes [17–19]. After decades of misleading reduced risk claims, [20] the 2009 US Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provided a regulatory framework in which tobacco companies could introduce and market tobacco products with lower exposure or risk claims only after a review and obtaining a marketing order from the US Food and Drug Administration (FDA) [21]. Under

the law, products with these claims are "modified risk tobacco products" (MRTPs), defined as products "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" [21]. To date, applications from five brands, including a reduced-nicotine cigarette (22nd century), an electronic heated tobacco product (i.e., IQOS), and three SLT products (i.e., General Snus, Camel Snus, and Copenhagen) have been submitted. The FDA issued the first modified risk order to Swedish Match authorizing a claim that "Using General Snus instead of cigarettes puts you at lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis" in October 2019 [22] In July 2020, FDA authorized an exposure modification claim for IQOS, which states that switching completely from cigarettes to IQOS can "significantly reduce your body's exposure to harmful or potentially harmful chemicals" [23].

The potential impact of MRTP claims on population health may in part depend on whether smokers are exposed to these claims, how they view MRTP claims on their own and in comparison to other tobacco products, and if they perceive them to be salient and truthful [24–26]. Attitudes and beliefs about tobacco products can be considered as either comparative or absolute [27]. Absolute measures of beliefs and perceptions focus on each tobacco product without a comparison product, where comparative measures include a reference to a specific tobacco product, typically cigarettes [28]. Using a theory of reasoned action lens to approach this topic, how the population reacts to these claims will be in part determined by their beliefs, including misbeliefs, about using these products [29]. Health mass media campaigns that follow principles of effective campaigns can have moderate effects on health knowledge, beliefs, attitudes, and behaviors [30,31]. One of these principles is helping campaign designers understand the nature of the behavior, for a campaign can only be effective if the beliefs targeted by the campaign impact the intended behavior.

The purpose of this this study is to provide valuable baseline data about smokers' and former smokers' beliefs about three products that currently have been or have the potential to be authorized as modified risk tobacco products. Specifically, we sought to understand harm perceptions and beliefs about products with the potential to be authorized as MRPTs; examine differences in beliefs about using MRTPs and beliefs about MRTPs in comparison to cigarettes; how MRTP user status impacts the rating of beliefs; and which beliefs are associated with intentions to use MRTPs.

2. Methods

We recruited 864 adult current and former smokers through Dynata to complete an online survey in August 2019, before any products had been authorized as MRTPs and before e-cigarette or vaping product use-associated lung injury (EVALI) was in the news. Participants were considered current smokers if they had smoked at least 100 cigarettes in their lifetime and currently smoke every day or some days, and former smokers if they had smoked at least 100 cigarettes in their lifetime, and currently did not smoke at all [32]. Additionally, participants could not have participated in more than two online surveys about cigarette smoking or other tobacco products in the last three months.

Participants included 450 men and 414 women, with a mean age of 47.5 years. A little more than half of the participants were current smokers or ever-users (i.e., current or former users) of e-cigarettes. Participants were diverse in race, education, and income, though slightly more educated than the population of US smokers (Table 1) [32].

Table 1. Participant characteristics.

Characteristic	Participants (n = 864)
	n (%)
Mean age (SD)	47.5 (17.6)
Gender	
Male	450 (52)
Female	414 (48)
Hispanic	59 (7)
Race	
White	732 (85)
Black or African American	81 (9)
Asian	14 (2)
American Indian, Alaska Native, or Native Hawaiian	34 (4)
Education	
High school or less	283 (33)
Some college	201 (23)
College or higher	380 (44)
Income	
Less than $25,000	187 (22)
Between $25,000 and $49,999	213 (25)
Between $50,000 and $74,999	164 (19)
Between $75,000 and $99,999	126 (15)
Between $100,000 and $149,999	117 (14)
$150,000 or more	55 (6)
Smoking status	
Current smoker	463 (54)
Former smoker	402 (46)
MRTP user status	
Current user	288 (33)
Former user	180 (21)
Never user	393 (45)

Note: Missing data range from 0 to 0.6%.

2.1. Procedures

Participants completed an eligibility survey, answered demographic survey questions, and information about their current smoking including the Fagerstrom scale [33], and the contemplation ladder [34]. Then, participants read a paragraph describing the potential for the FDA to authorize modified risk tobacco products (MRTPs) and a brief description of MRTPs. Participants were randomly assigned to either the control condition, in which they read a description about heat-not burn tobacco, snus, and e-cigarettes, presented in random order (Table 2); or to the corporate social responsibility condition, in which they read the generic description, plus a corporate responsibility statement crafted using press releases and text from IQOS, General Snus, or JUUL's website respectively. There were no differences between the conditions, so the conditions were collapsed for further analysis.

After reading descriptions of MRTPs, and a description of e-cigarettes, snus, and heated tobacco, participants answered questions about awareness, harm perceptions, use, likelihood of use, beliefs, and intentions to use the three products that have potential for, or have already received, authorization for modified risk tobacco product claims. The belief questions were worded using three different variations and participants were randomly assigned one wording variation per product using a Latin square design. The [blinded for review purposes] institutional review board approved the procedures.

Table 2. Tobacco products currently or with the potential to receive modified risk tobacco products (MRTP) authorization and the product descriptions.

Product	Description
E-cigarettes	Electronic or e-cigarettes and other vaping devices, such as pod mods and vape pens, are battery-powered devices that produce vapor instead of smoke. Some look like cigarettes, some are very colorful, and some have tanks that contain liquid. Popular brands of e-cigarettes include JUUL, Blu, Vuse, NJOY, and Flavor Vapes.
Snus	Snus is a type of moist tobacco. It comes in a small pouch that goes under your lip. It does not result in the need for spitting. Popular brands include General snus, Camel Snus, and Swedish Match.
Heated tobacco	Heat-not-burn is a type of tobacco product. It heats the tobacco just enough to release a small amount of smoke without burning the tobacco. Popular brands include IQOS.

2.2. Measures

2.2.1. Awareness

Participants were provided with brief descriptions of e-cigarettes, snus, and heated tobacco and then indicated if they had ever heard of each product. Those who answered yes were considered aware of the product [35,36].

2.2.2. Harm Perceptions

Participants indicated how harmful they thought e-cigarettes, snus, and heated tobacco were to their health on a scale of not at all harmful (coded as 1), to extremely harmful (coded as 4) [35].

2.2.3. Ever-Use and Frequency of Use

Participants who were aware of a product were asked if they had ever used the product even one or two times. Those who answered that they were unaware, or who had never used the product were coded as never-users. Ever-users were then asked "In the past 30 days, on how many days did you use [product]?" Ever-users who answered that they had not used the product in the last 30 days were coded as former users, those who had used the product in the last 30 days were coded as current users. The heated tobacco and snus items were adapted from the PATH survey item about e-cigarettes [35,36].

2.2.4. Likelihood of Use

All participants were asked "If one of your best friends were to offer you a [product], would you use it?" The 4-point response scale ranged from definitely no (coded as 1) to definitely yes (coded as 4) [35,36].

2.2.5. MRTP Beliefs

The survey first assessed beliefs with an open-ended question asking "What comes to mind when you think about [product]?" Participants were instructed to list up to 5 thoughts about the products. After completing the awareness, harm perceptions, use, and open-ended beliefs for each of the three products, the survey assessed 15 different beliefs about e-cigarettes, snus and heated: tasting good, feeling harsh, being odorless, being easy to use, looking cool, making second hand smoke, being risky, not being addictive, having long term health benefits, causing lung damage, containing nicotine, helping smokers quit, untrustworthy science about the product, appealing to kids, and being expensive (Appendix A). The decision to focus on these beliefs was based on prior qualitative research, surveys on salient beliefs, and examining the MRTP applications and materials made publicly available [12,25,37–45]. The 5-point response scale ranged from strongly disagree (coded as 1) to strongly agree (coded as 5). The survey assessed these beliefs using three wording variations: a comparison to cigarettes, a self-referent, and an absolute statement.

Using a Latin square design, participants were asked about their beliefs for each product using a different wording condition. Group A answered questions about heated tobacco with the comparison wording, the absolute was used for snus, and the self-referent was used for e-cigarettes. Group B answered e-cigarette beliefs with the absolute wording, self-referent wording was used for heated, and comparison wording was used to assess snus beliefs. For group C, beliefs about snus were assessed using the self-referent wording, e-cigarette beliefs were assessed using the comparison wording, and heated tobacco beliefs items used the absolute wording. This design insures that—despite three sets of belief wordings—in each group the respondent always responds to a different wording-product combination without repeating the wording or the product.

Spearman ranked correlations between the absolute wording and the self-referent wording were very high (ρ (rho) = 0.97 to 0.98, $p < 0.001$) for each of the three products indicating that participants did not meaningfully differentiate between the two wordings. The correlation remained high even after subgroup analysis comparing demographic characteristics, smoking status, and user characteristics. The self-referent and absolute wording conditions were collapsed in subsequent analyses.

2.2.6. Intentions to Use MRTP Products

The survey asked if the participant thought they would use e-cigarettes, snus, or heated tobacco in the next year. The 4-point response scale ranged from definitely no (coded as 1) to definitely yes (coded as 4) [35,36].

2.3. Statistical Analysis

Stata version 15 [46] was used to conduct Spearman rank correlations, and descriptive analysis to obtain means and standard deviations. Intention to use potential MRTPs was dichotomized in order to compare responses of "definitely no" (coded as 0), to other responses (coded as 1). We specified multiple logistic regression models in Stata version 15 to assess the intention to use each of the alternative tobacco products. Each model includes scores for each of the 15 beliefs. Each model also controlled for the individual-level covariates including ever use of at least 1 of the products, current smoking status, and sociodemographic characteristics: education, ethnicity, race, and age. We conducted a likelihood-ratio test to evaluate the difference between the model with only the individual-level covariates, and the full model with all 15 beliefs and all the individual-level covariates.

3. Results

3.1. Awareness and Use of Potentially Modified Risk Tobacco Products

E-cigarettes were the most well-known product of the three potentially modified risk tobacco products we asked about, with 97% of participants reporting they had heard of them. Only 12.5% of the participants had heard of heated tobacco (Table 3). Fifty four percent of participants had ever used at least one of the products, the overwhelming majority of current users and former MRTP users were e-cigarette users.

Table 3. Awareness and use of potentially modified risk tobacco products (n = 864).

	E-Cigarettes	Snus	Heated Tobacco
		n (%)	
Aware of product	839 (97)	488 (56)	107 (12)
User status			
Current user	284 (33)	45 (5)	50 (6)
Former user	168 (19)	58 (7)	5 (1)
Never user	412 (48)	758 (88)	806 (93)
Past 30-day use of ever users mean (sd)	6.9 (10.0)	2.0 (3.6)	4.6 (6.3)

Note: Missing data range from 0 to 0.6%.

3.2. Harm Perceptions and Likelihood of Use for Potentially Modified Risk Tobacco Products

Mean perceptions of harm were 2.60 (sd = 0.92) for heated tobacco, 2.67 (sd = 0.90) for e-cigarettes, and 2.81 (sd = 0.90) for snus ($F = 18.93$, $p < 0.01$), post-hoc analysis indicated that the participants had higher harm perceptions for snus compared to each of the other two products ($p > 0.05$). The likelihood to use was lowest for snus with a mean of 1.5 (sd = 0.84), for heated tobacco the mean was 1.80 (sd = 0.95), and for e-cigarettes the mean likelihood to use was highest at 2.1 (sd = 1.13) ($F = 76.7$, $p < 0.01$). Post-hoc analysis indicated that the mean likelihood to use each product was significantly different from the other two products ($p < 0.01$).

3.3. E-Cigarette Beliefs

3.3.1. Beliefs about Using E-Cigarettes

The three most endorsed beliefs about using e-cigarettes were that they contained nicotine (M = 3.98, SD = 0.93), they were risky (M = 3.89, SD = 1.01), and that they caused lung damage (M = 3.87, SD = 0.95). Participants were least likely to endorse the beliefs that e-cigarettes had long-term health benefits (M = 2.56, SD = 1.40), that they were cool (M = 2.38, SD = 1.22), and that there were not addictive (M = 2.23, SD = 1.18; Table 4).

3.3.2. Beliefs about E-Cigarettes in Comparison to Cigarettes

When a comparison to cigarettes was invoked, participants most commonly endorsed the belief that e-cigarettes appealed to kids (M = 3.57, SD = 1.18), that the science about e-cigarettes could not be trusted (M = 3.44, SD = 1.14), and that e-cigarettes were expensive (M = 3.29, SD = 1.03). Similar to their beliefs about using e-cigarettes, participants were least likely to endorse the beliefs that e-cigarettes were cool (M = 2.59, SD = 1.17), had long-term health benefits (M = 2.51, SD = 1.33), and were not addictive when compared to cigarettes (M = 2.29, SD = 1.15; Table 4).

3.3.3. Differences between MRTP User Groups

The correlation of the rankings of beliefs about using e-cigarettes between never, former, and current was high (Rho > 0.73; $p < 0.001$) and not independent from each other. The correlation of the rankings of beliefs about e-cigarettes compared to cigarettes between never and current users (Rho= −0.09; $p = 0.74$) and former users and current users (Rho= 0.41; $p = 0.13$) was low, and independent of each other. Current users most highly rated belief was that the e-cigarettes taste good compared to cigarettes (mean = 3.8, SD= 1.03), among former-users it came in the middle, rated 5th highest (M= 3.10, SD = 1.20), and among never users it was rated 10th (m = 2.86, SD = 0.96). Current users lowest rated belief was that e-cigarettes were risky compared to cigarettes (M= 2.58, SD = 1.08), former users rated it 6th (M = 3.06, SD = 1.10) and never users rated it 5th (M = 3.27, SD = 3.27). Former users and never-users' lowest rated belief was that e-cigarettes were not addictive compared to cigarettes ($M_{former} = 1.92$, SD = 0.96; $M_{never} = 2.03$, SD = 0.99), whereas current users rated it 10th (M = 2.93, SD = 1.23). Never users highest rated belief is that the science about e-cigarettes is untrustworthy compared to cigarettes (M = 3.82, SD = 1.01) compared to current users, who rated it 9th highest (M = 3.04, SD = 1.17), and former users who rated it 4th highest (M = 3.23, SD = 1.11).

3.4. Snus Beliefs

3.4.1. Beliefs about Using Snus

The three most endorsed beliefs about using snus were that it contains nicotine (M = 3.98, SD = 0.93), that it is risky (M = 3.95, SD = 0.97), and that it does not make second-hand smoke (M = 3.60, SD = 1.09). Participants were least likely to endorse the beliefs that snus tasted good (M = 2.48, SD = 1.08), that it was not addictive (M = 2.20, SD = 1.16), and that it was cool (M = 2.05, SD = 1.14; Table 4).

Table 4. Mean belief endorsement for the 15 close-ended belief items about e-cigarettes, snus, and heated tobacco n = 864.

	E-Cigarette Self	E-Cigarette Comparison	Snus Self	Snus Comparison	Heated Tobacco Self	Heated Tobacco Comparison
			Mean (SD)			
Taste good	3.09 (1.10)	3.21 (1.11)	2.48 (1.08)	2.67 (1.05)	2.78 (0.96)	2.85 (0.84)
Feel harsh	3.14 (0.94)	2.88 (0.95)	3.45 (0.96)	3.12 (0.86)	3.35 (0.86)	3.06 (0.79)
Odorless	2.69 (1.09)	2.83 (1.16)	2.96 (1.05)	3.13 (1.00)	2.68 (0.94)	2.81 (0.94)
Easy	3.61 (0.98)	3.16 (1.10)	3.19 (1.03)	3.17 (1.00)	3.01 (0.94)	2.96 (0.93)
Cool	2.38 (1.22)	2.59 (1.17)	2.06 (1.14)	2.28 (1.02)	2.30 (1.18)	2.67 (1.04)
No second-hand smoke	2.80 (1.13)	3.23 (1.22)	3.60 (1.09)	3.73 (1.05)	2.69 (1.01)	3.08 (0.98)
Risky	3.89 (1.01)	3.01 (1.04)	3.95 (0.97)	3.22 (0.93)	3.76 (0.99)	3.12 (0.91)
Not addictive	2.23 (1.18)	2.29 (1.15)	2.20 (1.16)	2.40 (1.11)	2.35 (1.09)	2.60 (1.12)
Health benefits	2.56 (1.40)	2.51 (1.33)	2.52 (1.38)	2.70 (1.32)	2.59 (1.31)	2.66 (1.15)
Lung damage	3.87 (0.95)	3.08 (1.12)	3.19 (1.11)	2.89 (1.00)	3.63 (0.96)	3.13 (0.92)
Nicotine	3.98 (0.93)	2.97 (0.91)	3.98 (0.93)	3.10 (0.80)	3.80 (0.96)	3.07 (0.78)
Quit	2.69 (1.19)	2.86 (1.22)	2.56 (1.05)	2.53 (1.07)	2.48 (1.01)	2.66 (1.02)
Untrustworthy sci	3.50 (1.08)	3.44 (1.14)	3.41 (1.05)	3.25 (1.08)	3.45 (1.09)	3.41 (0.98)
Kid appeal	3.68 (1.08)	3.57 (1.18)	2.89 (1.21)	2.96 (1.07)	3.04 (1.12)	3.30 (1.05)
Expensive	3.70 (1.05)	3.29 (1.03)	3.58 (0.96)	3.23 (0.88)	3.56 (0.95)	3.43 (0.83)

Note. Belief scale was from strongly disagree (coded as 1) to strongly agree (coded as 5). The same participants did not answer both wording variations for the same product.

3.4.2. Beliefs about Snus in Comparison to Cigarettes

When a comparison to cigarettes was invoked, participants most commonly endorsed the belief that snus produced no second-hand smoke (M = 3.73, SD = 1.05), that the science about snus was untrustworthy (M = 3.25, SD =1.08), and that snus was expensive compared to cigarettes (M = 3.23, SD = 1.08). Like their beliefs about using snus, participants were least likely to endorse the beliefs that snus cool (M = 2.28, SD = 1.02), was not addictive compared to cigarettes (M = 2.40, SD = 1.11) and would help smokers quit smoking (M = 2.53, SD = 1.07; Table 4).

3.4.3. Differences between MRTP User Groups

The rankings of beliefs between users of MRTPs was high for snus ($Rhos_{self} > 0.89$; $p < 0.001$; $Rhos_{comparison} > 0.74$; $p < 0.01$), and not independent of one another.

3.5. Heated Tobacco Beliefs

3.5.1. Beliefs about Using Heated Tobacco

The three most endorsed beliefs about using heated tobacco was that it contains nicotine (M = 3.80, SD = 0.96), that it is risky (M = 3.76, SD = 0.99), and that it causes lung damage (M = 3.63, SD = 0.96). Participants were least likely to endorse the beliefs that heated tobacco would help smokers quit (M = 2.48, SD = 1.08), that it was not addictive (M = 2.20, SD = 1.16), and that it was cool (M = 2.30, SD = 1.18; Table 4).

3.5.2. Beliefs about Heated Tobacco in Comparison to Cigarettes

When a comparison to cigarettes was invoked, participants most commonly endorsed the belief that heated tobacco was expensive (M = 3.43, SD = 0.83), that the science about heated tobacco was untrustworthy (M = 3.41, SD = 0.98), and that heated tobacco products were appealing to kids compared to cigarettes (M = 3.30, SD =1.05). Like their beliefs about using heated tobacco products, participants were least likely to endorse the beliefs that heated tobacco had long-term benefits (M = 2.66, SD = 1.15), were not addictive compared to cigarettes (M = 2.60, SD = 1.12) and would help smokers quit smoking (M = 2.66, SD = 1.02; Table 4).

3.5.3. Differences between MRTP User Groups

The rankings of beliefs between never, former, and current users of MRTPs were high for heated tobacco products ($Rhos_{self} > 0.96$; $p < 0.001$), and not independent of each other. The correlation of the rankings of beliefs about heated tobacco compared to cigarettes between current and never users (Rho = 0.45, $p = 0.09$) and current and former users (Rho = 0.69, $p = 0.004$) were moderate. For the belief that heated tobacco would not create second-hand smoke compared to cigarettes, current users and former users rated it 2nd and 3rd highest, respectively ($M_{current}$ = 3.33, SD = 1.01; M_{former} = 3.21, SD = 1.00). In comparison, never-users rated the belief 9th highest (M = 2.84, SD = 0.89). Current users rated the belief that heated tobacco would cause lung damage 13th (M = 3.04, SD = 1.04) compared to former MRTP users who rated it 7th (M = 3.00, SD = 0.89) and never MRTP users who rated it 4th (M = 3.26, SD = 0.82). Both former and never MRTP users rated the belief that heated tobacco was risky compared to cigarettes 5th (M_{never} = 3.19, SD = 0.85; M_{former} = 3.08, SD = 0.82), whereas current MRTP users rated it 10th (M = 3.06, SD = 1.04).

3.6. Beliefs from Open Ended Responses

Participants were instructed to list up to 5 thoughts about the products. This was done to ensure that we did not miss any widespread beliefs in our set of 15 close-ended responses that followed. After discarding nonsensical responses (e.g., hdakhjk), and don't know responses (e.g., "don't know," "none," "n/a"), we coded responses as one of the 15 close ended beliefs, or as a new response. New responses were then coded into new belief groupings. When participants were asked to list their beliefs about snus and heated tobacco, the most common responses were about non-lung health concerns or benefits, the

most common open-ended responses about e-cigarettes were about risk and safety. Among the beliefs not asked about in the close-ended portion, participants listed general affective reactions (e.g., gross, eww) for all three products. For heated tobacco and snus, participants commonly listed associations they made with the product (e.g., baseball, chew, hookah, vaping) (Table 5).

3.7. Intentions to Use Potentially Modified Risk Tobacco Products

For all products and wording conditions, including beliefs increased the models' fit compared to models that only included the demographic control variables.

3.7.1. E-Cigarettes

Believing that e-cigarettes can help smokers quit smoking (OR = 1.61), that they tasted good (OR = 1.56), and looked cool (OR = 1.42) were associated with greater odds of intending to try e-cigarettes after controlling for demographic and use factors. Believing that the science about e-cigarettes was untrustworthy was associated with lower odds of intending to try e-cigarettes (OR = 0.61).

3.7.2. Snus

The belief that the product was not addictive (OR = 2.07) and tasted good (OR = 1.45) were associated with increased odds of intending to try snus. Believing that the science about snus was untrustworthy (OR = 0.59) and that the product was risky (OR = 0.63) was associated with lower odds of intending to try snus.

3.7.3. Heated Tobacco

The belief that heated tobacco would taste good (OR = 2.92) and would be a good quit aid (OR = 1.72) was associated with increased odds of intentions to try heat-not burn tobacco products. Believing that heated was expensive was associated with lower odds of intending to try (OR = 0.67; Table 6).

Table 5. The top five most common open-ended response categories and example statements for three types of potentially modified risk tobacco product.

	Snus		Heated Tobacco		E-Cigarettes	
	Category	**Example Statements**	**Category**	**Example Statements**	**Category**	**Example Statements**
1	Non-lung health concerns or benefits (*n* = 452)	"Bad for gums" "mouth cancer" "unhealthy"	Non-lung health concerns or benefits (*n* = 201)	"causes cancer," "causes diseases," "harmful" "it still isn't good for your body" "death"	Risk or safety (*n* = 217)	"Dangerous," "A little safer," "Not safe," "Harmful," "Might blow up," "potentially completely harmless"
2	Affective reactions * (*n* = 278)	"bad," "good," "great," ew," "gross" "yuck"	Affective reactions * (*n* = 110)	"bad," "disgusting" "enjoyable," "ewww," "good"	Non-lung health concerns or benefits (*n* = 183)	"Deadly," "Health concerns," "Bad for you," "can still cause cancer," "brain damage," "healthier"
3	Associations * (*n* = 134)	"chew," "dip," "guys," "baseball," "spitting," "tobacco"	Risk or safety (*n* = 108)	"it sounds a little safer than a cigarette," "it could be less risky than smoking," "harmful," "harmless"	Affective reactions * (*n* = 115)	"awesome," "bad," "fun," "good," "not good," "gross," "nasty"
4	Risk or safety (*n* = 82)	"safer than cigarettes," "very harmful," "just another unhealthy tobacco product"	Association * (*n* = 93)	"clean," "hookah," "e-cigarettes," "it's still tobacco," "vaping"	Cost (*n* = 100)	"expensive," "cheaper," "costly," "price," "waste of money," "cheaper in the long run"
5	Taste (*n* = 70)	"gross taste," "bad taste in mouth," "needs flavor," "it's tasty," "minty"	Coolness (*n* = 48)	"Cool," "socially unacceptable," "silly," "stupid," "elegant"	Taste (*n* = 98)	"different flavors," "great taste," "bad taste," "sweet," "tastier"

* denotes categories that were not included in the close-ended belief options.

Table 6. Multiple logistic regression adjusted odds ratio of any intention to use e-cigarettes, snus, or heated tobacco, *n* = 864.

	E-Cigarettes		**Snus**		**Heated Tobacco**	
	Self (*n* = 553)	**Comparison (*n* = 275)**	**Self (*n* = 547)**	**Comparison (*n* = 268)**	**Self (*n* = 541)**	**Comparison (*n* = 274)**
Beliefs	aOR [CI]		aOR [CI]		aOR [CI]	
Taste good	1.56 * [1.15 to 2.11]	2.33 * [1.43 to 3.78]	1.45 * [1.01 to 2.08]	1.51 [0.97 to 2.35]	2.92 * [1.91 to 4.47]	1.65 [0.87 to 3.12]
Feel harsh	0.97 [0.69 to 1.37]	0.66 [0.38 to 1.13]	0.64 * [0.43 to 0.96]	0.78 [0.43 to 1.42]	1.05 [0.71 to 1.55]	0.75 [0.37 to 1.53]
Odorless	0.93 [0.70 to 1.25]	0.85 [0.55 to 1.30]	1.40 [0.99 to 1.99]	1.41 [0.86 to 2.31]	0.78 [0.52 to 1.18]	0.91 [0.56 to 1.48]
Easy to use	1.42 [1.00 to 2.03]	1.54 [0.94 to 2.51]	1.22 [0.83 to 1.79]	1.15 [0.71 to 1.84]	1.25 [0.87 to 1.82]	1.26 [0.75 to 2.12]
Look cool /make me look cool	1.42 * [1.09 to 1.86]	1.01 [0.65 to 1.56]	1.24 [0.90 to 1.71]	1.57 [0.99 to 2.48]	1.25 [0.92 to 1.70]	1.92 * [1.19 to 3.09]
No shs made	1.26 [0.95 to 1.66]	1.32 [0.85 to 2.06]	0.68 * [0.47 to 0.97]	0.64 [0.39 to 1.03]	1.17 [0.81 to 1.67]	1.51 [0.94 to 2.43]
Risky	0.80 [0.56 to 1.14]	0.71 [0.42 to 1.19]	0.63 * [0.42 to 0.94]	1.30 [0.75 to 2.26]	0.88 [0.62 to 1.25]	0.58 [0.32 to 1.04]
Not addictive	0.91 [0.70 to 1.19]	1.32 [0.81 to 2.13]	2.07 * [1.50 to 2.85]	0.90 [0.57 to 1.42]	0.97 [0.68 to 1.40]	1.21 [0.79 to 1.84]
Long-term health benefits	1.14 [0.93 to 1.39]	0.97 [0.67 to 1.40]	1.03 [0.78 to 1.36]	1.13 [0.79 to 1.63]	1.39 * [1.09 to 1.76]	1.39 [0.92 to 2.10]
Cause lung damage/get lung damage	0.86 [0.58 to 1.27]	1.02 [0.62 to 1.68]	0.91 [0.64 to 1.29]	1.25 [0.77 to 2.04]	0.78 [0.55 to 1.10]	0.82 [0.50 to 1.35]
Has nicotine	0.79 [0.57 to 1.09]	0.76 [0.44 to 1.32]	1.02 [0.69 to 1.51]	0.50* [0.28 to 0.90]	0.91 [0.65 to 1.29]	1.42 [0.76 to 2.64]
Quit aid	1.61 * [1.23 to 2.11]	1.52 [0.97 to 2.38]	1.57 * [1.07 to 2.31]	1.93 * [1.19 to 3.11]	1.72 * [1.21 to 2.44]	0.83 [0.52 to 1.31]
Untrustworthy product science	0.61 * [0.46 to 0.81]	0.60 * [0.38 to 0.94]	0.59 * [0.41 to 0.84]	0.69 [0.44 to 1.08]	0.76 [0.55 to 1.05]	0.53 * [0.32 to 0.87]

Table 6. *Cont.*

	E-Cigarettes		Snus		Heated Tobacco	
	Self (*n* = 553)	**Comparison (*n* = 275)**	**Self (*n* = 547)**	**Comparison (*n* = 268)**	**Self (*n* = 541)**	**Comparison (*n* = 274)**
Kid appeal	1.29 [0.97 to 1.72]	1.00 [0.67 to 1.51]	0.87 [0.63 to 1.21]	0.87 [0.56 to 1.35]	1.37 [1.02 to 1.85]	0.98 [0.63 to 1.52]
Expensive	0.99 [0.75 to 1.31]	0.75 [0.48 to 1.17]	1.20 [0.82 to 1.74]	1.33 [0.73 to 2.45]	0.67 * [0.47 to 0.96]	1.26 [0.77 to 2.06]
Demographic controls						
Ever MRTP use	4.93 * [2.78 to 8.76]	2.82 [1.22 to 6.54]	3.08 * [1.56 to 6.07]	6.27 * [2.66 to 14.79]	4.31 * [2.38 to 7.80]	2.62 * [1.10 to 6.24]
Current smoker	5.12 * [2.86 to 9.15]	17.94 * [6.71 to 47.92]	4.77 * [2.49 to 9.16]	5.70 * [2.29 to 14.18]	10.57 * [5.64 to 19.79]	3.95 * [1.82 to 8.60]
White	3.37 *[1.56 to 7.28]	0.57 [0.14 to 2.39]	1.38 [0.62 to 3.04]	1.19 [0.41 to 3.40]	0.89 [0.41 to 1.93]	2.49 [0.89 to 6.94]
Age in years	0.96 * [0.95 to 0.98]	0.97 [0.94 to 1.00]	0.97 * [0.95 to 0.99]	0.97 [0.95 to 1.00]	0.98 * [0.96 to 0.99]	0.97 * [0.95 to 1.00]
Hispanic	1.02 [0.36 to 2.87]	2.42 [0.19 to 30.72]	3.29 * [1.03 to 10.50]	0.64 [0.16 to 2.55]	1.01 [0.33 to 3.07]	2.92 [0.74 to 11.59]
Any college	1.47 [0.83 to 2.63]	2.16 [0.88 to 5.32]	1.35 [0.72 to 2.53]	1.66 [0.76 to 3.64]	1.77 [0.99 to 3.18]	1.24 [0.56 to 2.77]
Pseudo R^2 (all variables)	0.50	0.57	0.51	0.42	0.50	0.41
Pseudo R^2 (controls only)	0.33	0.40	0.25	0.26	0.30	0.24
Likelihood-ratio test	126.0 *	65.7 *	169.8 *	51.6 *	142.8 *	61.0 *

Note. Outcome was any intention to use the tobacco product. Adjusted models control for all variables in the table. Demographic control variables are dichotomous except for age. Likelihood-ratio test reports the LR chi2 difference between the full model and the model with controls only. Missing data were handled with listwise deletion and ranged from 2% to 6%. aOR = adjusted odds ratio. CI = 95% confidence interval. * $p < 0.05$.

4. Discussion

In order for modified risk tobacco products to live up to their harm reduction potential, two things must be true simultaneously: MTRPs cannot entice nonsmokers to start using them when they otherwise would have never used a tobacco product, and they cannot spur smokers to switch to them when they otherwise would have quit tobacco completely. They will have the greatest public health impact if they move people down the risk continuum who would have otherwise remained a user of the riskier product. This maybe particularly salient as the US moves to put pictorial tobacco warnings on cigarette packs. As these warnings increase intentions to quit smoking, this may increase interest in switching to a less harmful product [47].

The results of this study demonstrate that adult smokers and former smokers have different awareness, harm perceptions, and beliefs the three products they assessed. This is consistent with prior cross-sectional research showing that the public views some products as more harmful than others [6,48]. This paper adds to this literature by including perceptions and beliefs about heated tobacco alongside e-cigarettes and snus. This sample of current and former smokers perceived heated tobacco as less harmful than snus, but not significantly different from e-cigarettes. Prior research with Canadian respondents found that over half of the respondents perceived IQOS as equally or more harmful than e-cigarettes [49]. Given the importance of moving people down the risk continuum, the differences in beliefs about using the products and the products when compared to cigarettes are of particular importance and interest. Across all three products, the most endorsed beliefs were that the products contained nicotine, which is true, and that they are risky, and the least endorsed beliefs all included that the products were not addictive. The participants overall, did not demonstrate any glaring misbeliefs about using any of the three products. When a comparison to cigarettes was invoked, the most endorsed beliefs were about trustworthiness of the science, appeal of the product to kids, and the cost.

The correlations of the rankings between different user groups were high for beliefs about using all three products. However, when the comparison to cigarettes was invoked, participants with different MRTP use history differ in their endorsements of the 15 beliefs about e-cigarettes and heated tobacco. Current users of MRTPs were less likely to endorse beliefs about risk and lung damage compared to never and former users. The fact that there are differences between never, former, and current users is consistent with research demonstrating the role of involvement on message processing and attitude change [50]. Because current users have more of a stake in the safety of these products than never users, they are likely more attentive to the information, and as a result are affected in different ways, they also are motivated to believe that the products are safe, since they are currently using them.

One of the limitations of this study is that it was a convenience sample that cannot be generalized to the larger US population. While the demographics are similar to those of US smokers, our population was slightly more educated than the population of US smokers. Another limitation is that it is a cross-sectional study and only captures these beliefs at a very specific point in time. As previously mentioned, these data were collected before EVALI news was widespread, and before a global pandemic featuring a respiratory illness (COVID-19) interrupted everyone's daily lives and routines. While it is encouraging that some of our findings are similar to other large nationally representative longitudinal studies, [6,36,39,49] replicability of these findings with a larger and longitudinal sample would be ideal.

5. Conclusions

For all three products, believing that MRTPs taste good and can be used as a quit aid are associated with greater intentions to try MRTPs. This is consistent with prior work which found that young adults who held a baseline belief that e-cigarettes could help people quit were more likely to report experimenting with e-cigarettes at follow-up [39]. Beliefs that the science about the product was untrustworthy was associated with reduced

intentions to try the product. However, each product had its own unique sets of beliefs associated with trying the products. This paper contributes to the growing literature about beliefs and perceptions of e-cigarettes, snus, and heated tobacco. It contributes to our understanding of what the public believes about products currently or potentially authorized to be marketed as modified risk tobacco products. This understanding can inform the planning and development stages of communication campaigns.

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Appendix A. Beliefs and Wording Variations

1. Taste good	
Compared to regular cigarettes, [product] will taste better	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] will taste good.	4. Agree
If I use [product], I will find that it tastes good.	5. Strongly agree
2. Feel harsh	
Compared to smoking regular cigarettes, [product] will feel harsher.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] will feel harsh.	4. Agree
If I use [product], it will feel harsh to me.	5. Strongly agree
3. Odorless	
Compared to regular cigarettes, [product] will be odorless.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] will be odorless.	4. Agree
If I use [product], I will find that it is odorless.	5. Strongly agree
4. Easy	
Compared to regular cigarettes, [product] will be easier to use.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will be easy.	4. Agree
If I use [product], I will find it easy to use.	5. Strongly agree

5. Cool	
Compared to regular cigarettes, [product] will look cooler.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will look cool.	4. Agree
If I use [product], it will make me look cool.	5. Strongly agree
6. No shs	
Compared to regular cigarettes, [product] will make less second-hand smoke.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will not make second-hand smoke.	4. Agree
I will not make second-hand smoke if I use [product].	5. Strongly agree
7. Risky	
Compared to regular cigarettes, [product] will be riskier.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will be risky.	4. Agree
It will be risky for me to use [product].	5. Strongly agree
8. Not addictive	
Compared to regular cigarettes, [product] will not be as addictive.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will not be addictive.	4. Agree
If I use [product], I will not become addicted.	5. Strongly agree
9. Health benefits	
Compared to regular cigarettes, [product] will have long-term health benefits.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will have long-term health benefits.	4. Agree
If I use [product], it will have long term health benefits.	5. Strongly agree
10. Lung damage	
Compared to regular cigarettes, [product] will be more likely to cause lung damage.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will cause lung damage.	4. Agree
If I use [product], I will be more likely to get damaged lungs.	5. Strongly agree
11. Nicotine	
Compared to regular cigarettes, [product] has more nicotine.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] has nicotine.	4. Agree
If I use [product], I will get a dose of nicotine.	5. Strongly agree

12. Quit	
Compared to regular cigarettes, [product] will help smokers quit smoking.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
Using [product] will help smokers quit smoking.	4. Agree
If I use [product], it will help me quit smoking.	5. Strongly agree
13. Untrustworthy science	
Compared to regular cigarettes, the science about [product] cannot be trusted.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
The science about [product] cannot be trusted.	4. Agree
I cannot trust the science about [product].	5. Strongly agree
14. Kid appeal	
Compared to regular cigarettes, [product] will be more appealing to kids.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] will be appealing to kids.	4. Agree
If I use [product], my use will help make it appealing to kids.	5. Strongly agree
15. Expensive	
Compared to regular cigarettes, [product] will be more expensive.	1. Strongly disagree 2. Disagree 3. Neither disagree nor agree
[product] will be expensive.	4. Agree
If I use [product], it will be expensive for me.	5. Strongly agree

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Brief Report

Smokers' Exposure to Perceived Modified Risk Claims for E-Cigarettes, Snus, and Smokeless Tobacco in the United States

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Abstract

Introduction: Based on arguments for harm reduction and health benefits, tobacco companies in the United States can apply for regulatory authorization to make "modified risk tobacco product" (MRTP) marketing claims. The impact of future MRTP claims may depend on whether they are noticed, believed, and lead to smokers switching products. This study provides baseline data about smokers' exposure to perceived MRTP claims ahead of any MRTP authorizations.

Aims and Methods: We analyzed measures from Wave 3 of the US-based Population Assessment of Tobacco and Health (PATH) study which asked smokers to indicate if they had seen any e-cigarettes, snus, or other smokeless tobacco (SLT) products that claim to be "less harmful" in the past 12 months, and their likelihood of using products with these claims in the next 30 days.

Results: Significantly fewer smokers noted having seen snus (5.1%) or other SLT (5.6%) with "less harmful" claims compared with e-cigarettes (29.1%). For each product, the prevalence of MRTP claim exposure was higher among smokers who perceived the product to be less harmful than smoking, who currently used the product, and who had higher rates of tobacco advertising exposure at the point of sale. Among smokers who noticed products with "less harmful" claims, about one-quarter said they would use them in the future (24%–27%).

Conclusions: Ahead of any Food & Drug Administration (FDA) authorization for MRTP claims, some smokers already perceive exposure to "less harmful" claims for e-cigarettes, but few do for SLT. MRTP claims may motivate some smokers to use these products.

Implications: This study provides new baseline data about smokers' perceived exposure to MRTP claims in the United States ahead of any regulatory claim authorization. Using data from Wave 3 of the US PATH study, we found that some smokers already perceive exposure to "less harmful" claims for e-cigarettes (29%), but few do for SLT (5%–6%). Among smokers who noticed products with "less harmful" claims, about one-quarter said they would use them in the future (24%–27%), suggesting MRTP claims may motivate some smokers to use products described as "less harmful."

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Introduction

There is a growing recognition that different tobacco products pose different levels of risk and fall along a "continuum of risk."[1,2] Though not harmless, moist snuff smokeless tobacco, snus (a low nitrosamine type of moist snuff), and e-cigarettes pose significantly fewer health risks to individual users than cigarettes.[2–5] Thus, switching to these products may offer the potential for *harm reduction* for smokers who are unable or unwilling to quit nicotine. However, research indicates that consumers' perceptions about the comparative risks of tobacco products are often inconsistent with the continuum of risk. Many believe smokeless tobacco (SLT) and e-cigarettes are as harmful or more harmful than tobacco cigarettes.[6–8] As such, many tobacco control professionals have called for more accurate communication about the risks of such products relative to cigarettes.[8–10] Smokers may be receptive to such communications, with about half reporting they would be interested in using a tobacco product that claimed to be less harmful than other tobacco products.[11,12]

In the United States, tobacco companies are not permitted to make these types of comparative or "modified risk tobacco product" (MRTP) claims in their marketing or product labeling without authorization from the Food & Drug Administration (FDA). To date, applications from five brands, including a reduced-nicotine cigarette (22nd century), an electronic heated tobacco product (IQOS), and three SLT products (General Snus, Camel Snus, Copenhagen, Denmark) have been submitted. In October 2019, the FDA issued the first modified risk order to Swedish Match authorizing a claim that "Using General Snus instead of cigarettes puts you at lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."[13] In July 2020, FDA authorized an exposure modification claim for IQOS, which states that switching completely from cigarettes to IQOS can "significantly reduces your body's exposure to harmful or potentially harmful chemicals."[14]

The potential impact of MRTP claims on population health may in part depend on whether smokers are exposed to these claims, perceive them to be salient and truthful,[15–17] and are motivated to try and completely switch to these products. This study provides baseline data about smokers' reported exposure to and potential behavioral response to MRTP claims for snus, other SLT, and e-cigarettes in the context of a regulatory landscape when no such claims had been authorized but ahead of several potential MRTP claim authorizations.

Methods

We analyzed data from the publicly available Wave 3 adult dataset of the Population Assessment of Tobacco and Health (PATH) study. The PATH study is a household-based, nationally representative, longitudinal cohort study of adults (ages 18+) and youth (12–17 years). The study uses audio computer-assisted self-interviews (ACASI) available in English and Spanish to collect self-reported information on tobacco use patterns and associated health behaviors. Recruitment for the Wave 1 cohort employed a stratified address-based, area-probability sampling design—Wave 1 methods details are published elsewhere.[18] Wave 3 data were collected from October 2015 through October 2016 and included responses from 28 148 adults, with an unweighted response rate of 78%. This analysis is limited to responses from 9013 current established smokers in the sample (ie, those who have used 100 cigarettes in their lifetime and now report smoking cigarettes some days or every day), the primary intended audience for nicotine harm reduction products/messages.

Measures

Primary measures included those about respondents' reported exposure to perceived MRTP claims and likelihood to use the products with these claims. Specifically, we examined responses to three questions that asked respondents to indicate whether, in the past 12 months, they had seen "any e-cigarettes or other electronic nicotine products that claim to be less harmful?," "any snus products that claim to be less harmful?," and "any smokeless tobacco products (such as dip, spit or chew) that claim to be less harmful?" Provided response options were "yes" and "no." Those who responded "yes" were asked a follow-up question about likelihood of using that product: "How likely is it that you will use one of these [e-cigarettes or other electronic nicotine products; snus products; smokeless tobacco products (such as dip, spit or chew)] that claim to be less harmful in the next 30 days?" Response options were dichotomized as very/somewhat likely or very/somewhat unlikely during analysis. These measures were asked for the first time on Wave 3.

Covariates included demographics and variables related to tobacco use, perceived product harmfulness relative to cigarettes, and exposure to tobacco marketing (see Supplementary Table S1). Current users of e-cigarettes, snus pouches, and other SLT were defined as those who reported using these products some days or every day. Harm perception measures asked whether using each product type was less harmful, about the same or more harmful than smoking cigarettes (dichotomized as "less harmful" versus "same or more harmful" during analysis). As an indicator of exposure to tobacco marketing, we included a question that asked participants "In the past 30 days, have you noticed tobacco ads or promotions on store windows or inside stores where tobacco is sold? (Yes/No)." We also included parallel product-specific marketing exposure measures that asked participants to indicate if they had received any discounts or coupons for e-cigarettes, snus pouches, and other SLT.

Analyses

We used PATH Wave 3 single wave survey weights (as recommended in the PATH User Guide)[19] to generate prevalence estimates and adjusted odds ratios (AORs) of reported exposure to perceived e-cigarette, snus, and SLT MRTP claims and likelihood of using one of these products. The weighting procedures adjusted for oversampling and nonresponse, yielding nationally representative estimates of the noninstitutionalized, adult civilian US population in 2015–2016. Individuals missing the outcomes or covariates included in a table were excluded from those analyses. We developed multivariable logistic regression models for exposure to a perceived MRTP claim and use likelihood for each of the three products, adjusting for participants' sociodemographic and non-cigarette tobacco use characteristics. We also included as covariates PATH measures from the Global Appraisal of Individual Needs–Short Screener (GAIN-SS) that assess internalizing mental health related problems (eg, symptoms of anxiety and depression) and externalizing problems (eg, lying and violent behavior). Model 1 (claim exposure) also adjusted for engagement with product marketing (eg, receiving coupons). We collapsed variable levels when sample sizes for that variable and the outcome restricted analyses (eg, race). All analyses were conducted in Stata/SE version 16.0.

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Results

Exposure to Perceived MRTP Claims

Overall, 29.3% of current smokers indicated having seen e-cigarettes claiming to be "less harmful" while significantly fewer reported having seen snus (5.1%) or other SLT (5.6%) with such claims (Supplementary Table S1).

The odds of noticing e-cigarette MRTP claims did not differ by sex for e-cigarettes but were significantly higher among males versus females for snus (AOR = 1.4) and other SLT (AOR = 1.2) (Supplementary Table S1). For all three products, the prevalence of noticing MRTP claims was highest among the 18–24- and 25–34-year age groups. The odds of claim exposure were lower among black versus white smokers for e-cigarettes, but higher among black versus white smokers for snus and other SLT. The odds of noticing e-cigarette MRTP claims were lower for those with less education, but those with less education had higher odds of noticing snus and SLT claims. Odds of noticing e-cigarette claims were also higher among those with high levels of externalizing symptoms (AOR = 1.3).

For each product type, the odds of exposure to perceived MRTP claims for that product were significantly higher among product users versus nonusers (e-cigarettes, AOR = 1.3; snus, AOR = 1.6; other SLT, AOR = 1.4). In terms of risk perceptions, the prevalence of claim exposure was also significantly higher among those who perceived the product to be "less harmful" than smoking compared with "as or more harmful" for each product type (e-cigarettes, 34.4% versus 27.9%; snus, 10.2% versus 4.7%; other SLT, 11.4% versus 5.2%). Claim exposure was also significantly higher among smokers who reported exposure to tobacco advertising at the point of sale in the past 12 months versus those who did not (e-cigarettes, AOR = 2.1; snus, AOR = 1.6; other SLT, AOR = 1.9). Receiving product-specific discounts or coupons was also associated with greater odds for noticing MRTP claims for e-cigarettes and SLT (AOR = 2.1).

Product Use Likelihood

Among smokers who reported noticing MRTP claims for e-cigarettes, snus, and other SLT, the percentage who indicated they would likely use these "less harmful" products was similar—e-cigarettes (25.1%), snus (27.6%), and other SLT (25.7%) (Supplementary Table S2). Use likelihood did not significantly vary by age or race/ethnicity and was significantly higher for males versus females for snus only (AOR = 2.2). The reported prevalence and odds of likelihood of using snus (AOR = 2.7) and other SLT (AOR = 3.1) with "less harmful" claims were significantly higher among lesbian, gay or bi-sexual (LGB) smokers versus straight smokers.

Not surprisingly the prevalence and odds of being "likely to use" one of these products were higher among current smokers who already used these products, with the highest likelihood reported for e-cigarettes (AOR = 8.1), followed by snus (AOR = 2.3). Among smokers who noticed a claim, the prevalence of "likely to use" responses for each product was also significantly higher among those smokers who thought the product was less harmful than smoking versus equally or more harmful than smoking.

Discussion

This study of adult smokers in the United States found that, prior to any FDA authorization for the use of MRTP claims, few reported exposure to "less harmful" claims for snus or other SLT products, while almost 30% of smokers reported seeing such claims for e-cigarettes. Among smokers who did notice such claims, the proportion who said they would likely use these "less harmful" e-cigarettes, snus, or other smokeless products was similar (25%–28%).

This study also found that modified risk claim exposure was more prevalent among those with perceptions that those products are less harmful than smoking. As a cross-sectional study, it is not clear if these lower harm perceptions may have been influenced by MRTP message exposure, or if existing lower harm perceptions about these products made respondents more attuned to messages perceived as consistent with their existing beliefs. However, we found that over a quarter of smokers who do *not* believe e-cigarettes are less harmful still reported seeing e-cigarettes claiming to be "less harmful." This suggests these reported exposures cannot be fully explained by existing beliefs.

The difference in exposure to perceived MRTP claims for e-cigarettes versus snus and other SLT products may potentially be due in part to differences in their marketing. Previous analyses of e-cigarette marketing sources have documented their (unauthorized) use of implied and explicit modified risk messages.[20,21] However, participants may have also considered messages from nonindustry sources in their responses, such as friends, social media posts, or the press, which has notably focused more on e-cigarettes than SLT.[22,23] In contrast, smokers' low existing exposure to "less harmful" claims for snus and other SLT are consistent with a general lack of awareness about the relative harms of these products compared with cigarettes.[6,7]

Ultimately, smokers' potential for tobacco harm reduction depends on whether they completely switch to lower harm products. We found that some smokers exposed to less harmful messages for e-cigarettes, snus, and other SLT were also interested in using these products in the future. Given that most of these smokers were already co-using cigarettes and the alternative product, it is important that future MRTP communications make clear that harm reduction is conditional on complete product switching, not dual product use.[24]

Study limitations include reliance on a self-reported measure of claim exposure which may have been interpreted in variable ways, including communication from nonindustry sources. Analyses were also limited to current smokers. Future research should also consider claim exposure among nonsmokers (including young adults and former smokers) and, importantly, whether this translates into product uptake among these groups.

In conclusion, this baseline study found that smokers in the United States more frequently report exposure to modified risk claims for e-cigarettes than for snus or SLT, prior to any FDA authorization for such claims. Exposure to such claims may motivate some smokers to use these lower harm products. Future research should continue to examine perceived exposure to MRTP messages as the US tobacco regulatory landscape and MRTP marketing evolves.

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr.

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Declaration of Interests

The authors declare no conflict of interest. The content is solely the responsibility of the authors and does not necessarily represent the official views of the funding organizations.

Authors' Contributions

OAW obtained funding for the study and led writing of the manuscript. JP led data analysis and contributed to data interpretation, manuscript writing, and editing. RJO contributed to data analysis planning and manuscript writing and editing. All authors approved the final manuscript.

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'95% less harmful'? Exploring reactions to quantitative modified risk claims for snus and e-cigarettes

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ABSTRACT

Objectives Studies examining perceptions of 'modified risk tobacco product' (MRTP) messages for e-cigarettes and smokeless tobacco have indicated consumers want statistics and quantification of harm reduction. However, limited research exists on reactions to quantitative MRTP messages.

Design We conducted 12 focus groups in the USA in 2019—6 focused on e-cigarette messages and 6 on snus messages. Eight groups were with current smokers (ages 21–66) and four with young adult (ages 18–25) non-smokers (n=57). Participants discussed messages stating that use of snus and vaping products have been estimated by scientists to be about 90% and 95% less harmful than smoking cigarettes, respectively.

Results Several participants agreed the messages strongly communicated that the products are less harmful than cigarettes, were attention getting and could be 'convincing'. However, participants expressed scepticism about the source and accuracy of the stated figures, and some noted the claims could be misleading and attractive to young people. Comments also reflected some claim misunderstandings (eg, that e-cigarettes only pose a 5% chance of harm). Participants also agreed that stating e-cigarette risks 'are unlikely to exceed 5% of cigarette smoking harms' was confusing and less impactful than the '95% less harmful' wording.

Conclusions Quantitative claims suggesting high levels of reduced risk when comparing e-cigarettes or smokeless tobacco/snus relative to cigarettes may be successful in gaining attention and being persuasive for some audiences, particularly, if from more credible sources. However, message developers, users and evaluators should be mindful of message limitations and aim to mitigate unintended consequences.

INTRODUCTION

Although quitting all tobacco and nicotine products is the safest way to reduce harm from smoking, harm reduction approaches may include encouraging smokers unable or unwilling to quit all nicotine products to switch to less harmful alternatives.[1–3] Snus and electronic cigarettes (or 'e-cigarettes') are two types of international products considered to have reduced or modified risks (MR), and thus potential for harm reduction (ie, be potential 'MR tobacco products').[2–6] Snus is a type of low nitrosamine smokeless tobacco (SLT) long used in Scandinavian countries and has been associated with lower risks for several diseases relative to smoking, including lung cancer, oral cancer, respiratory disease and heart disease.[6–13] E-cigarettes are newer products for which potential long term health risks are not known, but studies and reviews have suggested that smokers who completely switch to e-cigarettes can reduce their exposure to numerous toxicants, suggesting their harm reduction potential.[5 14–16]

However, research across several counties also suggests that many smokers mistakenly perceive these products to be as harmful as cigarettes rather than less harmful, prompting calls for better relative-risk communication.[17–24] In some countries, 'MR' messages about non-combusted products are already in use or being considered.[25] For example, in the US one snus brand has received regulatory authorisation to make a claim about reduced disease risks[6] and claims for other smokeless brands are under review.[26] Health Canada previously commissioned research to study potential claims for authorised use by e-cigarette companies.[27] And in the UK, Public Health England (PHE) has included the message that e-cigarettes are 'at least 95% less harmful than smoking' in public statements and health campaigns.[28 29] The quantitative MR message used by PHE is notable given that previous qualitative studies have suggested consumers desire specific information in MR messages, including statistics and quantification of harm reduction magnitude.[27 30–32] Although a few qualitative studies have begun exploring some quantitative claims about reduced exposure to constituents (eg, 'cigarette smoke contains nine times more toxic ingredients than e-cigarette vapour'),[27 30] we are not aware of any qualitative studies that have examined consumer understanding and perceptions of quantified MR claims (such as the '95% less harmful' message).

In this study, we explored reactions to quantitative claims which stated that using snus and vaping products have been estimated to be 90% and 95% less harmful than cigarette smoking, respectively, as has been suggested in previous international expert review studies,[3–5 33 34] and similar to the e-cigarette message used in the UK. Two previous expert panels estimated the risk of low-nitrosamine SLT (such as snus) to be about 5%–10% as harmful as cigarettes (considering a range of harm including morbidity, mortality and dependence),[4 33] and one of these estimated e-cigarettes to be about 4% as harmful.[4] A 2016 review by the Royal College of Physicians in the UK supported this e-cigarette estimate and stated that the long term health risks associated with e-cigarettes 'are unlikely to exceed 5% of those associated with smoked tobacco products.'[3] A 2015 report commissioned by PHE stated that 'there is a need to publicise the current best estimate that

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using e-cigarettes is around 95% safer than smoking,'[34] and a 2018 PHE follow-up review concluded that 'stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping.'[5]

To contribute to the literature on this topic, we examined perceptions of these quantitative MR statements with adult smokers, the main intended audience of MR messages for harm reduction purposes. We also included young adult (YA) non-smokers (following recommendations for MR claim research)[35 36] given that exposure to such messages may produce no harm reduction benefit for this group while potentially introducing harm if messages are misperceived as suggesting those products are safe and lead to product use. Research also suggests younger non-smokers are more likely to initiate MR products than older non-smokers.[37 38] This study was conducted in the USA, where snus is available but infrequently used to date[39 40] and where e-cigarettes have helped some smokers quit,[14 41] but are most frequently used by young people.[14]

METHODS

Participants and recruitment

We explored reactions to the 90%/95% claims as part of a broader focus group study that also examined other MR messages.[32] Six groups focused on snus claims and six on e-cigarette/vaping claims (12 groups total). Within each set of six groups, four groups included adult current smokers (ie, smoked 100 cigarettes and now smoke every day or some days) and two with YA non-smokers. Given discussion of multiple messages, groups sizes were kept small (with 3–6 participants per group)[42 43] (N=57 participants, 32 smokers, 25 YA non-smokers). Across all groups we aimed to recruit participants who were not current regular (ie, daily) users of e-cigarettes or SLT, although they may have used these in the past or be occasional users. Due to recruitment error, one smoker in the snus groups did indicate daily SLT use and one smoker in the e-cigarette groups indicated daily e-cigarette use. Another smoker in the e-cigarette groups reported occasional e-cigarette use during screening, but daily use during the session. Inclusion criteria also included being at least 18 years old and able to read and speak English.

Groups were held on campus of a large northeastern US public university. Participants were recruited from postings on a website (Craigslist), University employee listservs, and flyers in local neighbourhoods. Groups were conducted between August and October 2019.

Study procedures and analyses

In each group, participants viewed and discussed three main 'base' claims about snus or e-cigarettes (and some variations of each) one at a time. Messages were presented to participants as text-only statements on an overhead projector and in individual packets. When presented, messages were not attributed to any particular source, and participants were told at the beginning of the session that the statements they were going to view could potentially be used in channels like tobacco company advertisements as well as educational campaigns by health related organisations. The first base claim was a qualitative MR claim indicating that switching to snus can 'greatly' reduce risk for several diseases, or that switching to e-cigarettes can 'greatly reduce harms to your health'. The second base claim was a modified exposure claim indicating that snus or e-cigarettes contain fewer harmful chemicals than cigarette smoke. Responses to these messages have been described elsewhere.[32] The present analysis focuses on the third base claim discussed, which, depending on product group, stated that scientists have estimated that using snus or vaping products exclusively is about 90% (snus) or 95% (vaping) less harmful than smoking cigarettes (see table 1).

Table 1 Quantitative modified risk (MR) claims discussed during focus group sessions

Message type	Snus groups (n=6)	E-cigarette groups (n=6)
Quantitative MR base claim	If you smoke, consider this—scientists have estimated that using snus exclusively is about 90% less harmful than smoking cigarettes.	If you smoke, consider this—scientists have estimated that using vaping products exclusively is about 95% less harmful than smoking cigarettes.
MR claim variations		
Use of lower no	Ask: What if this didn't say 90% but a lower number (eg, 30%? 50%–70%?) Asked in: ► Three smoker groups. ► 1 YA non-smoker group.	Ask: What if this didn't say 95% but a lower number (eg, 30%? 50%? 70%) Asked in: ► Four smoker groups. ► 1 YA non-smoker group.
With reference to more specific type of risk reduction (ie, death)	Scientists have estimated that using snus exclusively is about 90% less likely to result in death from tobacco use compared with smoking cigarettes. Asked in: ► Two smoker groups. ► 1 YA non-smoker group.	Scientists have estimated that using vaping products exclusively is about 95% less likely to result in death from tobacco use compared with smoking cigarettes. Asked in: ► Two smoker groups. ► 2 YA non-smoker groups. 95% less likely to result in death from a tobacco-related disease compared with smoking cigarettes. ► Asked in two smoker groups.
With alternative framing (e-cigarette smoker groups only)		If you smoke, consider this—scientists have estimated that the harms of using vaping products exclusively is unlikely to exceed 5% of the harm of smoking cigarettes. ► Asked in all four smoker groups.

YA, young adult.

To facilitate discussion, participants were asked to rate this message on a scale of 1–10 about (1) how clearly it communicated that the product is less harmful than smoking, (2) whether it is clear and easy to understand, (3) how clearly it communicates that there are still harms associated with the product and (4) how much it would encourage them to completely switch to the product (in smoker groups) or start using the product (in YA groups). After initial discussion of this base claim, groups also discussed some message/wording variations of it (time permitting), including reactions to replacing 90/95% with a lower number (eg, 30%, 50%) and an alternative claim version with more specific wording—'90/95% less likely to result in death from tobacco use' or 'from a tobacco related disease' (table 1). Smokers in the e-cigarette groups also considered a version with different framing ('…using vaping products exclusively is unlikely to exceed 5% of the harm of smoking cigarettes,') (table 1). Procedures were adapted from a study conducted for Health Canada exploring reactions to concept e-cigarette/vaping MR messages.[27]

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During debriefing, the Principal Investigator (PI) explained that the statements were concept messages and not approved for use by industries in the USA, reviewed known risks about snus and e-cigarettes, underscored the importance of switching completely for potential harm reduction benefits, and provided a list of smoking cessation resources. Because the e-cigarette groups were in progress during an outbreak of e-cigarette or vaping product use-associated lung injury (EVALI) in the US during the fall of 2019,[44] debriefing in these groups also consisted of a handout and discussion about EVALI information and recommendations from the US Food and Drug Administration and Centers for Disease Control at that time. Each participant received a US$50 gift card.

We used a thematic analysis approach to analyzing the data. Sessions were transcribed and then preliminary research memos were written by two research team members who participated in the sessions (OAW and MR) based on initial observations during the sessions (the first opportunity to 'get to know the data') and repeated transcript readings.[45] During this iterative process of reading and note-taking, a list of thematic and content codes was developed, and guide describing the codes. Data extracts in the research memos were annotated with these draft codes to further exemplify them. After discussion and agreement on these codes and definitions by OAW and MR, OAW independently coded four transcripts using Atlas.ti qualitative software and MR reviewed these coded transcripts. After discussing any disagreements, MR independently coded the remaining transcripts. Drafts of the results were then further developed, revised and refined based on reviews of the coded transcripts (by OAW and MR) and agreement that the results narrative fairly represented the data.[45] Illustrative quotes were selected (in some cases edited for brevity and clarity) to exemplify emergent themes and response patterns.

RESULTS

About 65% of participants were female, 50% were white (23% Asian, 16% Black/African American, 11% other race) and 12% Hispanic. Highest level of education completed varied as follows: high school degree or completion of General Educational Development tests (30%); some college or technical school (32%); at least college degree (37%). Smokers' average age was 44 (range 21–66) and YAs' average age was 20 (range 18–25). Most smoker participants (84%) smoked daily and for at least 10 years (80%). Most (81%) smokers and 56% of YAs had tried e-cigarettes/vaping before; fewer said they now vaped some days (smokers, 25%; YAs, 20%) or daily (n=2 smokers, 6%). About 23% of smokers and 8% of YAs had ever tried SLT - 3 smokers (10%) indicated they now use SLT some days and 1 smoker indicated daily SLT use.

Across smoker and YA groups, participants agreed that the 95%/90% less harmful claim clearly communicates that using e-cigarettes/snus is less harmful than smoking and easy to understand, and several smokers had favourable immediate reactions, noting the claim would capture their attention:

> …this sentence would definitely make me swap out cigarettes for vapes. I'd like to know where it's less harmful. Is it just in the lung? Is it heart disease? …is it things that go along with smoking in general? Just as a sentence by itself, it would catch my eye. (e-cigarette group, female smoker)

Several participants reacted favourably because they felt it provided a more 'precise' or specific picture of how much less harmful the product was, and was perceived by some as providing 'facts' or 'evidence':

> It's giving me a percentage of less harmful than cigarettes…Those are pretty good percentages…I do like it because it gives me some facts. (snus group, female smoker)

Some smokers and YAs also noted that the 95%/90% less harmful claim seemed more eye-catching and impactful than the other harm and exposure reduction claims viewed earlier during the sessions:

> This is the best one yet. I think the 90 percent thing is really bold and clear, and that puts the image in your head right away of how much snus are better than cigarettes. I don't think the other ones achieve that… (snus group, male YA)
>
> The number jumps out at you before all the other words …and the rest of the sentence almost doesn't matter anymore. It's just that 95 percent less, and that's what you end up focusing on. So I mean there's a lot of power in that. (e-cigarette group, female YA)

Statement understanding and interpretation

Several participants across groups noted that they thought the 95%/90% less harmful claims suggested that e-cigarettes or snus are 'a lot safer' or 'way better' than cigarettes, exposed you to fewer carcinogens, were less likely to cause you to 'die early' and less likely 'to give the bigger diseases that are associated' with smoking, such as lung illnesses and cancer ('95% better chances of not getting lung cancer,' female smoker). However, some smokers and YAs noted that the statement was too vague and did not specify what type of harms were reduced:

> …And to say that it's 95 percent less harmful, harmful to what? Your health, to the environment, to other people? …I also don't think it's very clear …. (e-cigarette group, female smoker)

Participants across groups (including YAs) generally correctly understood what the phrase using snus or vaping products 'exclusively' was intended to mean ('I think it just means you're not using any other tobacco products, you're just using snus,' male smoker). However, several participants made comments that suggested they did not correctly understand or were confused by the numeric information:

> I completely dislike the percentage. A lot of the people they cannot understand percentage, so the information will not be as clear. If you give me a number of 7000 or whatever numbers, perfect. Percentages? (snus group, female smoker)

Some participants also appeared to misinterpret the number to suggest their absolute risk of harm:

> There's a ten percent that will cause damage to my body. (snus group, female smoker)
>
> …it said, '95 percent. There's five percent still harmful to your health… (e-cigarette group, female YA)

Believability issues

Across groups, participants also noted that even though the statement clearly communicated reduced harm and 'sounded good', they did not necessarily believe it. Several smokers and YAs were sceptical about the magnitude of the number (95%/90%), which appeared to detract from its believability (see box 1, A). For e-cigarettes, this also seemed influenced by the fact that e-cigarettes require inhalation:

> I don't think it seems believable…Makes no sense to me. You're still putting something into your lungs… (e-cigarette group, female smoker)

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Box 1 Believability-related reactions to quantitative snus and e-cigarette modified risk claims

A. Scepticism about the high stated magnitude of lower risk
- 'I don't think it seems believable. How can you say it's 95% less harmful than smoking cigarettes when 100 percent would be not smoking at all? Makes no sense to me. You're still putting something into your lungs…' (e-cigarette group, female smoker).
- 'It just seems like a really, really stark difference between smoking cigarettes and vaping, and from what I know about vaping, I know that it like easily gets you an addiction, and it still exposes you to harmful chemicals. So like…95% less harmful is a really large difference.' (e-cigarette group, female young adult (YA)).
- 'I mean, do they actually know that, that it would be 90% less harmful?' (snus group, female smoker).
- '…I usually just really—all tobacco products together as just equally being harmful, so just seeing that this is 90% less harmful, it's just surprising to me…I wouldn't believe it at first glance no.' (snus group, female YA).

B. Scepticism based on product unfamiliarity or perceived novelty
- 'I mean it's always for the reason being that knowledge wise it's only been out for a few years. How would they know already?' (e-cigarette group, male smoker).
- '…how do they already know that it's not gonna be harmful to anybody? I mean, I never heard of it so how many people use this stuff? I don't know. I just don't get it.' (snus group, male smoker).

C. Scepticism about the source of the cited estimates
- '…Who's the scientist and who are these people?' (e-cigarette group, female smoker).
- '…it says less harmful, 95%. I don't know who came up with that. I don't know if it's necessarily true. Pretty sure it's not…' (e-cigarette group, female smoker).
- '…it could possibly be one of these scientists who get paid by these guys. It's impressive but I don't know if it's believable…' (snus group, male smoker).

D. Scepticism that claims sounds like a 'sales pitch' or 'marketing tactic'
- 'It just goes back to me thinking that 'please buy our products' basically.' (e-cigarette group, male smoker).
- '… 'using vaping products exclusively', that was a trigger word for me because it sounds like a marketing thing as opposed to an actual scientific fact.' (e-cigarette group, female smoker).
- 'I feel it's like the Tylenol commercials, when they say two out of three doctors recommends Tylenol. It's just advertising and over exaggerations to me like they do with every product. So that doesn't mean much to me reading that.' (snus group, female smoker).

E. Scepticism about the terms 'estimated' or 'about'
- 'So the first word that I stopped at was estimated 'cause scientists really don't know. They're just estimating. That's a guess.' (e-cigarette group, female smoker).
- 'It sounds good, but it also says estimated… you don't want your money estimated…You don't want your paycheck estimated, so why would you want something about your health to be 'estimated?' (e-cigarette group, female smoker).
- '…why would scientists be estimating, anyway? Isn't that their job to figure it out?' (snus group, female smoker).
- 'I don't like that they used the word 'estimated' and 'about', because it just makes it seem not believable. Like it makes it seem like kind of made that up…' (e-cigarette group, male YA).

F. Scepticism about e-cigarette claim because of news about e-cigarette and vaping related lung illnesses (EVALI)
- 'I think it's a bit hard to believe, but that just might be bias because we've seen so much of it lately on the news, but again, it's really concerning that people are using it for that short of a time, and you're having such a great health impact that that just makes me feel like, okay, so what if it is 95% less? There's still a big risk. People are still being harmed.' (e-cigarette group, female YA).
- '…I'm trying to be objective that if I didn't hear anything in the news about what vaping does, the recent information.' (e-cigarette group, female smoker).

Believability was also related to lack of product familiarity/perceived novelty, and some scepticism and questions about the source of the statistics and their intentions. Some noted that the claims sounded like a sales pitch or a 'marketing' tactic (box 1, B–D). For some participants across groups, statement believability also related to use of the word 'estimated' or 'about' in the claim (box 1, E). However, some acknowledged that this seemed honest and at least could give people a 'ballpark' idea:

> …maybe it's not actually 90, it might be 80, but it's not 20. So, you know, it's giving me at least a ballpark. (snus group, female smoker)

For some, e-cigarette statement believability was also influenced by recent news reports about vaping and lung related illnesses/EVALI (box 1, F). One person also doubted that the e-cigarette statement could be true because e-cigarettes were completely composed of chemicals, unlike tobacco cigarettes:

> …because vaping products are all chemicals…It's difficult for me to believe that smoking only chemicals is less dangerous or is 95 percent less harmful than if I were to go out and roll my own cigarettes where it's just putting tobacco and using papers. (e-cigarette group, male smoker)

Communicates that the products are still harmful

Across groups, smokers and YAs also agreed that the statement more clearly communicated about *reduced harm* from vaping/snus than it did that there are still harms associated with vaping/using snus. Although in general 'less harmful' was understood to mean some level of harm was still possible, some commented

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that the statements might be seen as almost providing a 'guarantee' or could be somewhat 'misleading' (because cigarettes are extremely harmful):

> Well, cigarettes are very, very harmful, and something that's 95% less harmful would still be pretty harmful. (e-cigarette group, female smoker)
> It's almost like a 100—you're gonna have no ill health at all if you vape instead of smoking… (e-cigarette group, female smoker)

Similarly, some YAs noted that the statement made e-cigarettes or snus seem relatively harmless:

> If it's like only 5% as harmful, like you're probably fine. (e-cigarette group, male YA)
> …They're just putting snus in this spot, like, 'Oh, this is such a great and close to harmless replacement to smoking. (snus group, male YA)

Motivation to use product

Although several smokers suggested the statement would make them interested in the product, product reluctance was related to statement believability ('Well, we have to have proven fact for me to believe it.', e-cigarette group, female smoker), and concerns that the product would still pose harm ('I think for me to be convinced you would have to say it's 100%', snus group, female smoker). However, disinterest in switching to the product was also related to perceived difficulty in changing to a new product at their age, habit, or hesitance to switch to another addiction:

> Ninety-five percent is great. It's a fabulous number. But I still wouldn't change my mind…I prefer my cigarettes….I honestly don't think anything is gonna make me stop unless it's me… (e-cigarette group, female smoker)

Some smokers and YAs also noted that the claims could be appealing to young people or other non-smokers ('…kids would love that statement,' e-cigarette group, female smoker):

> I mean I just think that that 90 percent figure there is really the hallmark of this claim and that's…going to possibly attract people who aren't even smoking in the first place. So it would be a pretty smart tactic of them to use something like this in marketing their product. (snus group, male YA)

However, interest in using the products continued to be low among YA participants, but some thought the 95%/90% claims might be more likely to peak their interest to try them than the other claims viewed earlier:

> …still low chances of me wanting to try it, but this something specifically did raise my chances from the previous statements. (snus group, female YA)

Alternative wording/versions

Lower number

Participants across groups had mixed reactions to having a lower percentage number/estimate in the claim. Some thought a number lower than 95%/90% (such as 50%) would seem more believable:

> Well, 95 percent just seems so absurd. Fifty percent, I could go with that….I'd probably have to go do a little investigating, but 95 percent…I just kinda dismiss it…(female smoker, e-cigarette group)

However, some seemed to misinterpret use of 50% in the claim as suggesting '50/50' chance of harm. In addition, while some suggested that 'any amount less is better', others noted a lower number (like 30%) would be a non-starter, and that the stated percentage still needed to be high enough (above 50%) to be considered:

> It [50%] wouldn't have nearly as big an impact…like if you said like 75 to 80 percent, that's not only believable, but it's also kind of attainable, until you get even more data to prove that it's above 80 percent. (male smoker, e-cigarette group)

Less likely to result in death/tobacco related disease

Some smokers had positive/favourable reactions to the 'less likely to result in death from tobacco use' or 'from a tobacco-related disease' alternative statements (table 1), with some noting this wording might be more 'eye-catching' and effective:

> Well, that might make me use snus. Yeah, because if it's less likely for me to result in death… (snus group, male smoker)

Some YAs also thought this version could be less appealing to young people/non-smokers. However, some thought the message was too extreme and some were unclear what was meant by 'tobacco related diseases' (suggesting 'smoking diseases' might be clearer). Some noted that it is the chemicals in e-cigarettes and tobacco (including nicotine) that is the problem, not tobacco itself:

> …tobacco isn't the problem. It's what they put in the tobacco that's the problem. So that makes the second statement kinda untrue altogether… (e-cigarette group, female smoker)

In the e-cigarette groups, some participants also seemed confused by the reference to reduction in 'tobacco-related diseases', since e-cigarettes do not contain tobacco.

Unlikely to exceed 5% of smoking harms

Lastly, smokers in the e-cigarette groups consistently found the wording of the 'unlikely to exceed 5% of the harm' message variation (table 1) to be more difficult to understand ('I don't even know what the hell that means', female smoker) and thought it required more cognitive effort ('You have to really put thought into the sentence', female smoker). Some participants also misinterpreted the statement, thinking it suggested vaping was only 5% better or safer and thus almost as harmful as cigarettes:

> I wouldn't even accept a 5% commission let alone—you're just helping me 5%.' (e-cigarette group, female smoker)

Several participants agreed after some consideration that the statement essentially provided the same information, but worded or framed in a different way. However, several participants across groups agreed that the '95% less harmful message' would be more attention grabbing, clearer and have more impact than the 5% message:

> Well, if you read it [5% message] quickly, which is how we read most advertisements, commercials, it just it takes you longer to kind of—you have to actually read this one thoroughly and think about it, because it's not as powerful as the other one…When you see 95 percent less harmful, I mean, right away, your eyes can just kind of digest that in a couple seconds. (e-cigarette group, female smoker)
> But the 95 percent hits it home a little better because now you're saying what am I saving? I'm saving 95 percent of my harm. Here you're saying, I'm gonna have 5 percent of what I had before—it just doesn't have the same effect. (e-cigarette group, female smoker)

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DISCUSSION

To our knowledge, this is the first qualitative study to examine reactions to quantitative claims suggesting substantially lower health risk (90%, 95%) from snus and e-cigarettes. Although data were collected in the USA, results may also have relevance for other countries using or considering these types of messages. Results suggest that these types of numeric claims may be attention grabbing, quickly communicate that these products are substantially less harmful than cigarettes, and potentially appeal to some smokers compared with other types of MR claims. However, results also suggest challenges with message believability, and some potential issues with misunderstanding and appeal to young people.

With respect to believability, participants were generally sceptical that the claims were 'too good to be true.' This scepticism appeared to be based on the high magnitude of the presented numbers, perceptions that the products were 'too new', and perceptions that the claims conflicted with other product information they had heard and their existing beliefs. This type of cognitive anchoring bias, which can lead individuals to judge new information based on existing 'anchored' beliefs/knowledge,[46] may limit smokers' receptivity to MR messages. In addition, although some smokers suggested a lower, more modest number may be more believable, it is unclear whether there is a numeric 'sweet spot' that, in addition to being accurate or agreed on, is also believable and motivating. On the other hand, we observed that although YA non-smokers were also generally sceptical of the claims, including the magnitude, some did express a perception that the claims made the product seem relatively harmless and potentially appealing to young people, which could suggest some risk for unintended effects.

It is also worth noting that participants' scepticism at the high estimates presented are not unreasonable, given that these figures are in fact estimates based on a limited set of studies and data, and are not universally accepted in the tobacco control community. Indeed, the 95% e-cigarette message has been a source of some debate/controversy among scientists themselves.[47 48] Furthermore, the broadly stated 90%/95% claims we examined do not capture the fact that risk estimates may differ significantly for particular health conditions. For example, the Levy *et al* study found that while estimates for total mortality relative risks associated with low-nitrosamine SLT fell between 5%–10% of the risk of smoking, estimates were lower for lung cancer (2%–3%) and higher for oral cancer (15%–30% of risk of smoking).[33] In addition, these numbers may not represent actual levels of reduced harm for smokers who *switch* to these products, given that these estimates are based on consideration of exclusive product use, not switching. These numbers may also not reflect accurate reduction in certain risks that are common to all non-medicinal nicotine products, such as addiction or harms to fetal development among pregnant smokers. These important nuances can be difficult to communicate in short standalone written messages.

This study also suggested some comprehension issues related to numeracy. Indeed, previous research has documented that people struggle with mathematical statements about risk, particularly with odds and percentages.[46 49] Our results also suggest potential framing effects of quantitative MR message understanding and appeal, with smokers reacting more favourably to the more positive message that e-cigarettes are '95% less harmful' (which emphasises a 'less harmful' benefit) than to the more negatively framed message that emphasises the potential harm from e-cigarettes (about 5% of that from smoking cigarettes). Previous literature has shown that when comparing positive and negative frames of risk information, positive frames lead to lower risk perceptions.[46 50] Although this may help encourage harm reduction for smokers, our results also suggested that this framing and message could have some unintentional appeal with YA non-smokers. Future research could also explore additional framing comparisons of quantitative MR messages, such as those emphasising the magnitude of risk reduction relative to smoking ('90% less harmful than smoking) vs those emphasising the relative risk of smoking (eg, 'smoking is about 10 times more harmful than using snus').

Finally, while the 95%/90% figures remain estimates and may not be completely agreed on or precisely understood, these messages may leave audiences with the 'gist' that these products are believed to be, at least by some experts, substantially less harmful than cigarettes. According to the fuzzy-trace-theory of medical decision making, people often interpret the 'bottom-line meaning' of numeric information in a qualitative way, and use this 'gist' information, rather than exact precise numbers, in decision-making.[51] Indeed, as described by one participant, the figures may not be exactly right but give a 'ballpark' idea and were interpreted by participants as meaning that the products are 'way better' or 'a lot safer'. While some participants commented that the statements were misleading, many appropriately perceived these figures to be estimates rather than as hard facts or guaranteed reductions.

Study limitations include the use of a small convenience sample, and potential order and priming effects, given that the 90%/95% messages were discussed last in group sessions. It is also worth noting that participants were not naïve to these products, particularly e-cigarettes (including many ever triers and some current users), and we previously documented that negative and unsatisfying product experiences also appeared to influence their future product interest.[32] Future research may benefit from additional studies comparing reactions to different types of MR messages, and how they may vary by audience type and product experience.

Overall, quantitative claims suggesting high levels of reduced risk when comparing e-cigarettes or SLT/snus relative to cigarettes may be successful in gaining attention, communicating reduced-risk quickly, and being persuasive for some audiences, particularly if attributed to more credible sources. However, health professionals and health organisations should be mindful of the limitations of such claims, particularly if presented as standalone messages, and aim to mitigate unintended consequences.

What this paper adds

- Qualitative studies examining perceptions of reduced or 'modified risk' (MR) messages about e-cigarettes and smokeless tobacco have indicated consumers want statistics and to know 'how much' less harmful such products are, that is, a quantification of harm reduction. Some organisations have used such messages (eg, that e-cigarettes are 95% less harmful than cigarettes).
- However, limited research exists on consumers' understanding and perceptions of these types of quantitative MR messages.
- Our results from focus groups in the USA suggest that quantitative claims suggesting high levels of reduced harm (90%, 95%) from snus and e-cigarettes may be attention grabbing, quickly communicate that these products are substantially less harmful than cigarettes, and potentially appeal to some smokers compared with other types of MR tobacco product claims. However, results also suggest challenges with message believability, and some potential issues with misunderstanding and appeal to young people.

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Snus and Alcohol: Mutually Rewarding Effects in the Brain? A Matched Controlled Population Study

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ABSTRACT

BACKGROUND: The use of moist smokeless tobacco (snus) is increasing in the U.S. and other Western countries, and especially among young people. Snus is associated with several health problems, but the relationship between use of snus and alcohol is scarcely explored. Neuro-cognitive and psychological research suggest an association due to possible mutually rewarding effects in the limbic brain. We investigated this issue in a matched controlled population study.

METHODS: Matched control group design where drinking habits and alcohol consumption in a group of users of snus (n = 1043, mean age = 35.20; n men = 749, n women = 294) were compared to a control group of non-users matched on age and gender (n = 1043, mean age = 35.65; n men = 749, n women = 294). In addition, we registered background variables such as level of education, income, self-perceived general, dental health, mental health, current depressive symptoms, and BMI. In estimation of alcohol consumption, the background variables were used as covariates in factorial analyses of variance (ANCOVA).

RESULTS: Users of snus had lower level of education, lower income, poorer general, dental, and mental health status than non-users, but there were no differences in BMI. Differences in mental health status were related to drinking habits. Users of snus had a higher frequency of drinking, higher frequency of intoxication, and showed more excess drinking. Controlled for background variables users of snus had a 25.2% higher estimated yearly consumption of alcohol in terms of standard units of alcohol on the weekdays, 26.4% higher on weekends and a 60.2% higher yearly excess consumption.

CONCLUSION: Users of snus had an elevated alcohol consumption and another drinking style than non-users. The findings are discussed according to neuro-cognitive and psychopharmacological mechanisms, reward learning and conditioning. The results have implications for prevention, treatment and rehabilitation of alcohol and nicotine dependence.

KEYWORDS: Snus, smoking, alcohol, addiction, reward

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Introduction

Moist smokeless tobacco, snus (sometimes denoted Swedish snus) is a psychoactive substance containing nicotine with rewarding and cognitive effects mainly caused by nicotine acting on the nicotinic ACh receptors (nAChRS) in the nervous system and other internal organs in the body with ACh receptors.[1,2] Snus also contains several other constituents including water, salt, humectants, tobacco-specific nitrosamines etc. Nicotine causes increased psychological reward and probably withdrawal relief[3] and is strongly addictive.[4] Physical tolerance and dependency develops quickly.[5] In Scandinavia, snus is taken orally in small portions (pads). The daily dosage for men and women in the age 16 to 74 is typically 10 portions, yielding a total exposition in the mouth of approximately 63 to 80 mg nicotine,[6] that is, ca. 3650 portions per year for 1 person. The pads are taken out after some time and become waste, which also could create an environmental problem. More than 100 million boxes containing over 2 billion portions were consumed in Norway last year.[7] The use of snus seems to increase in Western and Nordic countries, whereas tobacco smoking shows a decreasing trend.[6,8,9] Snus is prohibited in EU member states, except Sweden, but not in the US and Norway. Use of snus will probably increase also in the US in the coming years due to increased availability, more smokeless products and marketing.[10,11]

In Norway snus use has been increasing since the late 1990's and especially among young people. There is male preponderance and today 20% of adult men and 5% of women are daily users of snus, whereas in the age group 16 to 24, 25% of the men and 15% of the women use snus daily.[6] The increase among young adults is not surprising since snus use is linked to norm-challenging behaviour, risk-related life-style and team sports,[12,13] clearly showing the impact of cultural factors. Use of snus is also associated with sociodemographic factors such as lower income and lower level of education.[14] However, twin-studies suggest that snus initiation is also influenced by genetic factors.[15]

Snus seems to have a positive effect on quitting smoking,[16] and probably a harm reduction effect on tobacco-related diseases.[17] On the other hand, mental health problems are linked to snus, and especially among young people,[18] as well as increased drinking.[19] Several other health problems are also

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reported. A recent review of the research literature describes cardiovascular, malignant, dental, gastro-intestinal, diabetic, metabolic, mental disorders, and pregnancy outcomes.[6] Alcohol habits of users of snus were not discussed in that review, which was unexpected since a large longitudinal Swedish community study (10 years follow-up) on a middle aged cohort (n = 21 037) found that snus users had an increased risk for development of alcohol dependence.[20] These results strongly suggest an elevated alcohol consumption among snus users. Moreover, many users of snus are former and dual users of tobacco,[21] which also is linked to increased drinking, a relationship that has been known for years. For instance, general population studies have shown that tobacco smokers drink almost twice as much as non-smokers,[22] findings also corroborated from other research areas such as clustered health risk habits,[23-25] lifestyle choice[26] and health behaviour.[27]

The widespread combined use of nicotine and alcohol suggests enhanced reward learning, since brain areas affected by alcohol and nicotine such as nucleus accumbens, striatum and prefrontal cortex and involving dopamine systems[28-30] also are involved in reward learning.[31] Nicotine and alcohol seem to increase dopamine production in targeted brain areas.[32] Furthermore, psychopharmacological evidence proposes that nicotine reduces the intoxicative and sedative effects of alcohol, which, again, might potentiate mutual rewarding effects.[33,34]

However, the combined use of nicotine and alcohol in the general population might be a more complex issue than effects of neuro-cognitive and psychopharmacological mechanisms. The syndrome model of addiction suggested by Shaffer et al[35] could be a useful point of departure to understand better this addictive behaviour. This theoretical approach describes three common superordinate categories: distal antecedents (eg, genetic and neurobiological risk, psychosocial risk factors), premorbid factors (eg, proximal antecedents such as psychosocial events) and shared manifestations, but different expressions for various types of addictions such as smoking, drinking, gambling, and drug use. This syndrome model also includes neurobiological factors such as the dopaminergic reward systems, neuro-cognitive and memory systems, and mental health issues.

The psychosocial and neurobiological antecedents seem to be especially relevant for understanding the use of snus and alcohol in the general population. For instance, lower education among snus users could be regarded as a distal psychosocial antecedent, that is, creating risk factors in terms of social norms, sociocultural closeness, social modelling and positive attitudes toward use snus, comparable to what has been seen in smoking.[36,37] Likewise, meso-limbic dopaminergic structures could be seen as distal neurobiological antecedents since these systems convey the neuro-cognitive interaction between nicotine and alcohol in the limbic brain, which could result in a dual use of alcohol and snus due to mutual rewarding effects.[33] Taken together, the presented evidence suggests that increased alcohol consumption is to be expected among snus users and their drinking habits specifically should be subject to further empirical research.

The aim of the current study was to investigate alcohol consumption and drinking habits in a sample of users of snus compared to a sample of non-users matched on age and gender. We examined frequency of drinking in the weekdays (Monday-Thursday), in the weekends (Friday-Sunday), frequency of intoxication and frequency of excess drinking (more than 6 standard units of alcohol per drinking occasion). In addition, we estimated the yearly alcohol consumption in terms of units of alcohol for weekdays, for weekends, and the yearly excess consumption controlled for health-related and sociodemographic background variables.

Methods

Participants and procedure

Data was extracted from the Norwegian Survey on Living Conditions – Health, Care, Social Relations 2015 (n = 8164) administered by the Norwegian Centre for Research Data (NSD). The survey was conducted by computer assisted telephone interviews (CATI) and comprised a wide range of topics, including living conditions, labour, health, education, economy, and is representative of the almost Caucasian adult Norwegian population.[38] That survey also included one question about how often they were using snus. The answers were registered on a Likert scale: 1 = Daily, 2 = Now and then, 3 = Never, 4 = Will not answer, 5 = Do not know. Totally, 741 reported that they were using snus daily (9.1%), 302 (3.7%) now and then, 26 (0.3% would not answer the question and 7 (0.1%) did not know. To get a better distribution of age and gender, we included both the daily users and the now-and-then users in the snus sample, total n = 1043; n men = 749 (71.8%), n women = 294 (28.2%); M_{age} = 35.20 years, SD = 14.03.

The majority of the total sample, n = 7088 (86.8%), never used snus; n men = 3345 (47.2%), n women = 3743 (52.8%). In addition, 26 would not answer the question (0.3%) and 7 did not know (0.1%). M_{age} for the total sample was 49.5 years, SD = 18.6. Due to the differences in age and gender between the users and non-users of snus, we randomly selected (the random sampling procedure from the Statistical Package for the Social Sciences) from that sample (n = 7088) a control group of non-users matched with the snus group on age and gender, total n = 1043, n men = 749 (71.8%), n = 294 (28.2%), M_{age} = 35.65, SD = 11.53.

Measures

Alcohol and smoking habits. Firstly, the participants were asked if they had an alcoholic drink of any kind or smoked the last 12 months. The answers were registered on a dichotomic scale: 1 = Yes, 2 = No.

Secondly, they were asked about the frequency of drinking alcohol the last 12 months. The answers were registered on a 4-point Likert scale: 1 = Daily, 2 = Weekly, 3 = Several times a month, 4 = Less than monthly.

The third question assessed the frequency of drinking in the weekdays Monday to Thursday. The answers were registered

on a 5-point Likert scale: 1 = All 4 days, 2 = On 3 of 4 days, 3 = 2 of 4 days, 4 = 1 of 4 days, 5 = None of the days.

Fourthly, they were asked about the number of standard units of alcohol consumed on weekdays (volume and category explained more detailed to the respondents): 1 = 16 or more units, 2 = 10-15 units, 3 = 6-9 units, 4 = 4-5 units, 5 = 3 units, 6 = 2 units, 7 = 1 unit, 8 = 0 units. This scale was transformed to another interval scale to give a more direct estimate of units of alcohol using the arithmetic mean values of the intervals as estimates. For instance, the interval 2 = 10-15 units was transformed into 12.5, resulting in the following final scale: 1 = 16 units, 2 = 12.5 units, 3 = 7.5 units, 4 = 4.5 units, 5 = 3 units, 6 = 2 units, 7 = 1 unit, 8 = 0 units. One standard unit is comparable to 1 small bottle of beer (0.33 l), 1 glass of wine, or 1 drink of liquor and corresponds to 1.5 cl or 12.5 g pure alcohol.[39] We estimated the amount of weekdays consumption according to this QF-formula (Quantity x Frequency): Number of units typically consumed in the weekdays × frequency of drinking: 1 = All 4 days, 2 = 3 of the 4 days, 3 = 2 of the 4 days, 4 = 1 of 4 days, 5 = None of the days. Yearly weekday consumption was calculated as weekday consumption × 52 (number of weeks).

The fifth question registered the frequency of drinking in weekends (Friday-Sunday): 1 = All 3 days, 2 = On 2 of 3 days, 3 = 1 of 3 days, 4 = None of the days.

The sixth question assessed the amount of alcohol typically consumed on a weekend day in terms of standard units of alcohol: 1 = 16 or more units, 2 = 10-15 units, 3 = 6-9 units, 4 = 4-5 units, 5 = 3 units, 6 = 2 units, 7 = 1 unit, 8 = 0 units). This scale was also transformed to the same interval scale as used in question 4: For instance, the interval 2 = 10-15 units was transformed into 12.5, resulting in the following final scale: 1 = 16 units, 2 = 12.5 units, 3 = 7.5 units, 4 = 4.5 units, 5 = 3 units, 6 = 2 units, 7 = 1 unit, 8 = 0 units. From the answers we estimated the amount of alcohol consumption in the weekends in terms of standard units of alcohol according to the following QF measure: Number of units typically consumed on a weekend drinking occasion × frequency of weekend drinking: 1 = All 3 days, 2 = On 2 of 3 days, 3 = 1 of 3 days, 4 = None of the days. The yearly weekend alcohol consumption was calculated as weekend consumption × 52.

The seventh question registered how often they had been drinking so much that they got a clear sense of intoxication: 1 = Daily, 2 = Weekly, 3 = Monthly – several times, 4 = Less than monthly, 5 = Never.

The eighth questions registered excess alcohol consumption by asking how often they had been drinking 6 standard units of alcohol or more: 1 = Daily, 2 = Weekly, 3 = Several times a month, 4 = Monthly or less, 5 = Never. From the answers we estimated the yearly amount of excess consumption according to this QF-formula: 6 units × frequency of drinking: 1 = Daily (almost every day – 340 days), 2 = Weekly (2-3 times a week – 130 days), 3 = Several times a month (approximately once a week – 52 days), 4 = Monthly or less (12 days) and 5 = Never (0 days).[22] For example, drinking 6 units daily will result in a yearly estimated excess consumption of 2040 units of alcohol (6 × 340 days).

When we calculated the yearly consumption in the weekdays, weekends and excess consumption we first included both those who reported drinking and no drinking (0 units), that is, the total samples in both groups. Secondly, we included only those who reported drinking (more than 1 unit ie, selected samples). Thus, respondents who did not drink were excluded from the second analyses. In the Table 5 we present the results for both analyses.

Body mass index and self-perceived general and dental health status. Body Mass Index (BMI) is a frequently used screening method for weight classification and is related to a number of disease outcomes, including depression.[40] BMI was calculated as self-reported weight in kilograms divided by the square of height in metres (kg/m^2).

Self-perceived health is a valid and widely used indicator of general health status in many research areas.[41-44] In the current study self-perceived General health and Dental health status were assessed with the questions 'How is your health in general. Is it. . .' and 'How is your dental health. Is it. . .?' The answers were registered on a 5-point Likert scale 1 = Very good, to 5 = Very bad.[38,45]

General mental health and depressive symptoms. The Symptom Check List-10 (SCL-10) was used for assessment of general mental health (last 2 weeks). This is a shorter form of SCL-25, and has been shown to be valid, reliable and as a screening instrument almost as good as the SCL-25 version. The answers were registered on a 4-point Likert scale: 1 = Not at all, 4 = Very much. Clinical cut-off is set at a score above 1.75.[46]

Current depressive symptoms (last 2 weeks) was registered according to the adapted European version (PHQ-8) of the depression scale taken from the Patient Health Questionnaire (PHQ-9) by Spitzer et al.[47] The 8 questions were answered on a 4-point Likert scale: 1 = Not at all to 4 = Nearly every day and calculated into a clinical index: 1 = None, 2 = Mild, 3 = Moderate, 4 = Moderately severe, 5 = Severe.[45]

Educational status and monthly income. Level of education was registered according to the Norwegian Standard Classification of Education[48] using the following scale: 0 = No education; 1 = Elementary school, 1-7 years; 2 = Secondary school, 8-10 years; 3 = College, 11-12 years; 4 = College + 1 year; 5 = College and supplementary education; 6 = University, high school, 14-17 years; 7 = University, high school, 18-19 years; 8 = PhD.

Information about income in NOK (Norwegian krone; 1 USD = p. t. approximately 8.5 NOK) was retrieved from the Norwegian Tax Administration (2014) and calculated as net monthly income (HHINCOME) according to the standard set by the European Union.[49] The monthly income was registered on an interval scale: 1 = NOK 0-19999, 2 = NOK 20 000-39 999, 3 = NOK 40 000-59 999 etc. This scale was recoded into

Table 1. Sociodemographic and health-related background variables for users and non-users of snus.

	USERS OF SNUS		NON-USERS		
	MEAN	SD	MEAN	SD	*P* VALUE
Self-perceived general health	1.90	0.80	1.79	0.80	.002
Current depression	1.39	0.76	1.24	0.56	.000
Self-perceived dental health	2.15	0.87	1.98	0.85	.000
SCL-10	1.29	0.53	1.22	0.47	.002
BMI	25.29	3.99	25.55	6.95	.302
Education	4.81	1.57	5.06	1.60	.001
Monthly income	48653.85	28694.93	52005.79	27910.29	.007

Self-perceived general health: 1 = very good, 5 = very bad; current depression: 1 = none, 2 = mild, 3 = moderate, 4 = moderately severe, 5 = severe; dental health: 1 = very good, 5 = very bad; education: 0 = no education; 1 = elementary school, 1 to 7 years; 2 = secondary school, 8 to 10 years; 3 = college, 11 to 12 years; 4 = college + 1 year; 5 = college and supplementary education; 6 = university, high school, 14 to 17 years; 7 = university, high school, 18 to 19 years; 8 = PhD; monthly income = mean values in NOK for the households; n users of snus = 983 to 1043, n non-users = 913 to 1043.

another interval scale by using the arithmetic mean values of each interval to calculate the net monthly income. For instance, 1 = 0-19 999 was recoded as 1 = 10 000, 2 = 20 000-39 999 was recoded into 2 = 30 000, 3 = 40 000-59 999 was recoded into 3 = 50 000 etc. In this way we could directly show monthly income in NOK.

Data analyses

We used the SPSS Version 26 to analyse the data and applied Pearson Chi-squares to test differences between the groups for the variables assessing drinking habits in dichotomic scales (eg, drinking alcohol and smoking last 12 months (1 = Yes, 2 = No) and Likert scales with few intervals (eg, frequency of drinking last 12 months, during the week, during weekends, frequency of feeling intoxicated, excess drinking). Possible differences in socioeconomic and health-related background variables (self-perceived general and dental health status, current depression, SCL-10, educational status, and net monthly income) were tested using factorial analysis of variance (ANOVA) with use of snus as the independent variable (1 = Yes, 2 = No). Differences in alcohol consumption in terms of estimated standard units of alcohol were tested using factorial analyses of variance controlled for socioeconomic and health – related background variables: smoking, self-evaluated general and dental health status, current depression, general mental health (SCL-10), level of education and net monthly income, using these variables as covariates in a factorial model (ANCOVA). Dependent variables were estimated yearly consumption during weekdays, weekends and yearly excess consumption for the total samples and selected subsamples and the independent variable (fixed factor) was use of snus (1 = Yes, 2 = No).

Ethics

All participants consented according to Norwegian law and recommendations. The data applied in the analysis in this publication are based on 'Health, Care and Social Relations, Survey on Living Conditions, 2015, Regions'. The survey was financed by The Norwegian Directorate of Health. The data are provided by Statistics Norway, and prepared and made available by NSD – Norwegian Centre for Research Data. Neither Statistics Norway, The Norwegian Directorate of Health nor NSD are responsible for the analysis/interpretation of the data presented here.

Results

Table 1 shows the sociodemographic and health-related background variables for users and non-users of snus.

Compared to non-users the users of snus reported significantly worse self-perceived general health, $F(1,2083) = 9.85$, $P = .002$, $\eta^2 = .005$, Observed Power = .880, self-evaluated dental health $F(1,2079) = 19.35$, $P = .000$, $\eta^2 = .009$, Observed Power = .993, and they had a higher current depression score, $F(1,2070) = 24.71$, $P = .000$, $\eta^2 = .012$, Observed Power = .999. The snus group also had slightly poorer general mental health status (SCL-10), $F(1,2084) = 9.43$, $P = .002$, $\eta^2 = .004$, Observed Power = .866, lower level of education $F(1,1894) = 11.89$, $P = .001$, $\eta^2 = .006$, Observed Power = .931, and lower net monthly income $F(1,2075) = 28$, $P = .007$, $\eta^2 = .003$, Observed Power = .770. There were no significant differences between the groups in BMI, $F(1,2060) = 1.07$, $P = .302$, but the mean values of both groups were within the overweight category (BMI 25-29.9[50]). The differences in mental health status (SCL-10) between the groups were no longer significant when we controlled for yearly alcohol consumption and drinking habits in ANCOVA (see Table 5): $F(1,1319) = 3.254$, $P = .071$. However, there were still significant differences in self-perceived general health $F(1,1312) = 5.238$, $P = .022$, $\eta^2 = .004$, Observed Power = .628, dental health (although marginal): $F(1,1311) = 3.994$, $P = .046$, $\eta^2 = .003$, Observed Power = .515, and current depression: $F(1,1305) = 14.768$, $P = .000$, $\eta^2 = .011$, Observed Power = .970.

Table 2. Frequency of smoking and drinking alcohol the last 12 months for users and non-users of snus.

	USERS OF SNUS		NON-USERS	
	N	%	N	%
Drinking alcohol	978	93.8	862	88.2
Not drinking	65	6.2	181	17.4
Smoking	261	25.0	207	19.8
Not smoking	782	75.0	836	80.2
Frequency of drinking				
Daily	27	2.8	6	0.7
Weekly	350	35.8	254	29.6
Monthly – several times	336	34.4	570	31.1
Less than monthly	264	27.0	628	34.2

Smoking: Yes/No; drinking alcohol: Yes/No; drinking or smoking last 12 months: $P = .000$; frequency of drinking: $P = .000$; total n users of snus = 1043; total n non-users = 1043.

Smoking and drinking

Table 2 shows drinking and smoking for users and non-users of snus the last 12 months (yes/no).

Most of the participants in both groups had been drinking alcohol the last year, but significantly more users (93.8%) than non-users (82.5%), χ^2 (1) = 62.01, $P = .000$; Cramer's V = .172. Similarly, 25% of the snus users had been smoking last year, compared to 19.8% for non-users χ^2 (1) = 8.03, $P = .005$; Cramer's V = .062. Users of snus also drank alcohol more frequently than non-users; χ^2 (3) = 26.91, $P = .000$; Cramer's V = .121. 38.6% of the snus users reported drinking on a daily-weekly basis, compared to 30.3% of the not users, whilst 27% and 34.2% drank less than monthly among users and non-users, respectively.

Table 3 shows the results for drinking habits during the weekdays Monday to Thursday and weekend days Friday to Sunday for users and non-users of snus.

There were no differences in frequency of drinking during the weekdays (Monday-Thursday) between the 2 groups, $\chi^2(4) = 5.26$, $P = .262$, Cramer's V = .054. However, during the weekend (Friday-Sunday) users of snus tended to drink more frequently than non-users, $\chi^2(3) = 18.83$, $P = .000$, Cramer's V = .102. For example, 66% were drinking on one of the days, compared to 60.2% of non-users, and only 8% of snus users were not drinking alcohol during weekends, compared to 14.2% of non-users.

Excess drinking

Table 4 describes the differences between the groups in drinking style, that is, drinking so much that they felt intoxicated and frequency of excess drinking, that is, 6 units of alcohol or more on a drinking occasion.

Table 3. Frequency of drinking alcohol during the weekdays Monday to Thursday and weekend days Friday-Sunday for users and non-users of snus.

	USERS OF SNUS		NON-USERS	
	N	%	N	%
Monday-Thursday				
All 4 days	4	0.4	6	0.2
3 of 4 days	8	0.8	8	0.9
2 of 4 days	39	4.1	24	2.8
1 of 4 days	145	15.3	110	12.9
None of the days	754	79.4	706	82.7
Friday-Sunday				
All 3 days	20	2.1	23	2.7
2 of 3 days	227	23.9	192	22.5
1 of 3 days	627	66.0	517	60.6
None of the days	76	8.0	121	14.2

Monday-Thursday: no significant differences; Friday-Sunday: $P = .000$; total n users of snus = 954 to 1043, total n non-users = 854 to 1043.

Table 4. Frequency of consuming an amount of alcohol on a drinking occasion resulting in a feeling of drunkenness and frequency of excess drinking, that is, more than 6 units of alcohol per drinking occasion.

	USERS OF SNUS		NON-USERS	
	N	%	N	%
Felt intoxicated				
Daily	2	0.3	1	0.2
Weekly	38	4.8	10	1.8
Monthly – several times	111	14.1	39	6.9
Less than monthly	559	71.0	434	77.0
Never	77	9.8	80	14.2
More than 6 units				
Daily	3	0.3	2	0.2
Weekly	54	5.6	22	2.6
Monthly – several times	190	19.5	85	9.9
Less than monthly	540	55.6	456	53.1
Never	185	19.0	293	34.1

Felt intoxicated: $P = .000$; more than 6 units: $P = .000$; total n users of snus = 1043, total n non-users = 1043.

Users of snus felt intoxicated significantly more often than non-users, χ^2 (4) = 30.10, $P = .000$, Cramer's V = .152. Totally, 19.2% of the snus users reported being intoxicated on a daily-weekly-monthly basis compared to 8.9% of non-users. 14.2% of

Table 5. Estimated yearly alcohol consumption in terms of standard units for weekdays (Monday-Thursday), weekends (Friday-Sunday) and excess drinking (6 units or more) controlled for sociodemographic and health-related background variables (self-perceived general health, dental health, current depression, SCL-10, smoking, level of education, net monthly income). Factorial ANCOVA for the total samples and the selected subsamples of users and non-users of snus.

	USERS OF SNUS			NON-USERS				
	MEAN	SE	CI 95%	MEAN	SE	CI 95%	%	*P* VALUE
Weekdays total	211.95	14.35	183.80-240.10	169.26	14.78	140.31-198.26	25.2	.039
Weekends total	332.40	9.24	314.27-350.52	262.93	9.93	243.45-282.40	26.4	.000
6 units total	152.98	6.45	139.44-164.73	94.91	7.02	81.15-108.67	60.2	.000
Weekdays selected	1099.85	23.58	1053.46-1146.24	1139.17	27.52	1084.99-1193.34	3.5	.282
Weekends selected	362.27	9.48	343.67-380.87	304.07	10.48	283.52-324.62	19.1	.000
6 units selected	187.27	7.70	172.15-202.38	139.56	9.02	121.51-157.61	34.2	.000

Abbreviations: CI 95%: 95% confidence intervals; SE: standard error; %: percent differences in units of alcohol consumed between the users and non-users of snus; total n users of snus = 882 to 1043, total n non-users of snus = 765 to 1043; weekdays selected samples: n users of snus = 182, n non-users = 134; weekend selected samples: n users of snus = 808, n non-users = 663; 6 units or more selected samples: n users of snus: 741, n non-users = 521.

non-users never felt intoxicated compared to 9.8% of snus users. There were also differences in excess drinking. Users of snus consumed 6 units or more frequently than non-users, χ^2 (4) = 78.45, *P* = .000, Cramer's V = .207. Totally, 25.4% of users reported excess drinking on a daily-weekly-monthly basis compared to 12.7% of non-users. 19% of the snus group never reported excess drinking, compared to 34.1% among non-users.

Estimated yearly alcohol consumption in weekdays, weekends and total yearly excess consumption

In Table 5 we present the results of the factorial ANCOVA analyses for the estimated yearly consumption in weekdays (Monday-Thursday), weekends (Friday-Sunday) and the yearly excess consumption (6 units of alcohol or more per drinking occasion) controlled for smoking and sociodemographic and health-related background variables.

Most of the total sample did not drink during weekdays (82.0%), 9.5% did not drink during the weekends, and 22.9% reported no excessive consumption.

Compared to non-users users of snus had 25.2 % higher yearly estimated consumption in the weekdays (42.7 more units), F(1,1836) = 4.25, *P* = .039, Observed Power = .540; 26.4% higher weekend consumption (69.5 units), F(8,1638) = 25.94, *P* = .000, Observed Power = .999, and 60.2% higher excess consumption (57.1 units), F(8,1671) = 35.60, *P* = .000, Observed Power = 1.000. Totally, a significantly higher consumption for all 3 measures when we looked at the total samples. The results for the subsamples (those who did not drink were excluded) confirmed the general picture, except consumption in weekdays (Monday-Thursday) where there was no significant difference between the users of snus and non-users, F(1,307) = 1.61, *P* = .282. The weekend consumption for the selected samples (Friday-Sunday) was 19.1% higher for the users of snus (58.2 units), F(1,1462) = 16.76, *P* = .000, Observed Power = .983, and the estimated yearly excess consumption was 34.2% higher (47.7 units), F(1,1253) = 15.67, *P* = .000, Observed Power = .977.

Discussion

The current study has investigated alcohol consumption and drinking habits in a sample of users of snus compared to a sample of non-users matched on age and gender. We examined frequency of drinking in the weekdays, in the weekends, frequency of intoxication, and frequency of excess drinking. We also estimated the yearly alcohol consumption in terms of units of alcohol for weekdays, for weekends, and the yearly excess consumption controlled for relevant sociodemographic and health-related background variables.

Most of the findings on socioeconomic and health-related background variables were as expected. Lower level of education and income among users of snus is a common finding in the research literature,[14] evidence suggesting socio-cultural and lifestyle differences between the 2 groups.[13] We also found slightly worse self-perceived general and dental health status and higher current depression scores among users of snus. Since use of snus is associated with several somatic and dental health risks[6,51-53] it is not surprising that their self-perceived general and dental health status is poorer, also after controlling for alcohol consumption.

Users of snus had higher scores on SCL-10 and current depression than non-users, but none of the scores were above clinical cut-off. It is, however, interesting that the differences in SCL-10 disappeared when we controlled for drinking habits, indicating that alcohol consumption accounted for the self-reported reduced mental health. This is not surprising since the association between use of alcohol and mental health disorders is well known from clinical investigations,[54,55] but our findings also show an association at sub-clinical level. An implication of this finding is that alcohol consumption should always be measured

when SCL-10 or comparable screening instruments are used to assess general mental health status in general populations. Drinking habits could influence self-reports of mental health. On the other hand, and somewhat unexpected, differences in current depressive symptoms were not affected by the drinking habits of snus users. However, several studies have shown an association between nicotine and depression, so the finding that users of snus had an elevated depression score could reflect more complex underlying population and genetic factors.[56]

As expected, users of snus showed more dual use of tobacco and alcohol than non-users, they were more often intoxicated, had a higher alcohol consumption and more risky drinking style. Mutual reward learning could be one explanation, as suggested in the model of Shaffer et al[35] emphasizing the role of learning and memory in the hippocampus, emotion regulation in the amygdala and the rewarding role of dopamine-systems interacting with nicotine and alcohol. Since 2004 when the model was presented, there has been a considerable scientific development in psychopharmacology and neuroscience describing these systems, especially in understanding the alcohol-nicotine interaction in the limbic brain. As shown in the thorough review by Adams,[33] alcohol and nicotine have mutual potentiating rewarding effects and, in addition, the intoxication and sedative effects of alcohol seem to be reduced by nicotine. Together, these two mechanisms could cause a powerful reward learning effect that is, the probability of intake of alcohol when using snus increases, or vice versa. Hence, these neuro cognitive and psychopharmacological factors in combination with conditional learning could be essential in maintaining the dual use of snus and alcohol. The underlying neurobiological structures are probably the mesolimbic dopaminergic pathways conveying the cross-reinforcement process (reward) whereas the nicotine acetylcholine receptor (nAChR) in combination with genetic susceptibility factors could induce cross-tolerance.[33] Furthermore, cross-reward and cross-tolerance effects also seem to be influenced by learning and memory. Experimental research indicate a conditioned modulatory effect of drug-associated environmental context in development of cross-tolerance.[57] These findings suggest that situational factors are important. Reward learning is dependent upon activity in the dopaminergic systems, and dopamine agonists enhance reward learning and novelty seeking.[58] Since snus contains nicotine, snus can be regarded as a dopamine agonist. Epidemiological findings lend support to this assumption since snus users have a lowered risk of Parkinson disease,[59] a disorder associated with dopamine dysregulation.[60] Thus, snus could facilitate reward learning which again could lead to increased drinking due to the cross-reward and cross-tolerance effects of nicotine and alcohol.[33]

Snus users are also typically former tobacco smokers and often dual users,[21] as also shown in the current study where 25% of the snus users reported that they had smoked the last 12 months compared to 19.8% among non-users. We would, thereby, expect similar drinking habits among users of snus and tobacco smokers that is, an elevated alcohol consumption.[22,61,62] Furthermore, it is well documented that nicotine is a very addictive psychoactive substance[63] and development of the full nicotine dependence syndrome (in adolescents) can occur within less than two years of tobacco use onset. Symptoms such as increased tolerance, impaired control and withdrawal reactions are commonly reported.[64] Previous studies have also documented that users of snus have symptoms of nicotine dependence comparable to cigarette smokers, and that dual users report the highest prevalence of withdrawal symptoms.[4] Hence, increased drinking among users of snus in our sample could be related both to positive (reward) and negative reinforcing effects of alcohol (alleviation of withdrawal reactions) in combination with nicotine addiction. This suggestion is supported by recent epidemiological research showing that tobacco use is a preceding correlate of alcohol problems.[65]

Taken together, controlled for background variables related to alcohol consumption the combined effect of cross-reinforcement and cross-tolerance for nicotine and alcohol in combination with learning and conditioning could be underlying common factors explaining a dual use of snus and alcohol. These effects also have implications for treatment and rehabilitation. As shown in the current study, snus users show unhealthy drinking habits (more often felt drunk, more excess drinking) which could place them at risk for development of more severe drinking problems later on in life.[66,67] Doctors and health care workers should be aware of this risk, especially with respect to prevention of alcohol problems. A successful reduction in drinking is probably difficult to obtain if the use of snus or tobacco continues as usual due to the cross-reward and cross-tolerance effects of nicotine and alcohol. It would be hard to reduce the intake of one of the drugs, and not the other; intake of both should be reduced. Similarly, nicotine dependency related to snus or tobacco use could be difficult to treat successfully unless attention also is paid to the users elevated alcohol consumption. As suggested by Adams[33] a combined treatment of tobacco and alcohol dependence could, therefore, be more clinically efficient than focus on the separate drugs.

Limitations of this study

The sample of snus users were taken from a representative sample of the adult Norwegian population. The sample of snus users is therefore ethnically very homogenous and not biased in terms of selection. We also used a matched control group design, and these two factors make our investigation methodologically robust. However, there are limitations. The participants were white Caucasians, but, to the best of our knowledge, there is no reason to assume that rewarding effects in the limbic system of nicotine and alcohol is linked to ethnicity. We have also rather crude measures of alcohol consumption and more detailed data such as categories of alcohol (e.g., beer, wine, liquor) and amounts consumed in each category would be preferable. Categorical data would allow us to estimate

alcohol consumption more precisely. Assessment of behaviour profiles and mental health status are also quite limited, and it has been shown that personality factors revealing impulsivity and risky behaviour seem to be associated with increased drinking.[68,69] These factors could also be linked to use of snus. Future investigations should, therefore, include a more detailed assessment of mental health, personality factors and behaviour. Finally, although the data were obtained through computer assisted telephone interviews (CATI) and not based on questionnaires completed by the participants, the data were basically self-reported and that is another limitation.

Conclusion

As expected, there were significant differences between users of snus and non-users in several socioeconomic and health-related background variables (eg, self-perceived general health, dental health, current depression, general mental health, education, and income). The differences in general mental health (SCL-10) were related to drinking habits. More snus users had been smoking and drinking alcohol in the last 12-months than non-users, they had a higher frequency of drinking, higher frequency of intoxication, and higher frequency of excess drinking (6 standard units or more). Controlled for smoking and background variables, users of snus also had a 25.2% higher estimated yearly consumption of alcohol in terms of standard units of alcohol on the weekdays, 26.4% higher on weekends and a 60.2% higher yearly excess consumption. The results also have implications for prevention, treatment and rehabilitation of alcohol and nicotine dependence.

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Author Contributions

RGW developed the concept for the study and was responsible for the data analyses. VPW contributed to the neuropsychological and clinical analyses. Both authors contributed to the interpretation of the data, edited the final draft of the manuscript, and approved the version to be published.

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