October 28, 2022

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 REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029

Dear Sir or Madam:

Per the FDA Center for Tobacco Products PMTA and MRTP Annual Report requirements relating to Swedish Match USA, Inc's. ("Swedish Match", "our" or "we") General Snus products, please accept the following combined documents to encompass one PMTA MRTP Postmarket Annual Report submission 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 2021 through October 2022:

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***

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 PM10, PM11, PM12, PM14, PM16 and PM17 dated 6/1/18
Attachment 3B (1-7) – Full Text Articles
    Attachment 3B.1 - XPaper_Aldeek and Sarkar Method Development 2022 separations9030078
    Attachment 3B.2 - XPaper_Antoniewicz_Kabele_2020 journal.pone 0268746 Chronic Snus Use
    Attachment 3B.3 - XPaper_Chen_Xue_Xie_Li JMIR 2022 10(8) e38174 Discussions of Snus
    Attachment 3B.4 - XPaper_Diaz_Kierstead 2022 Online Tobacco Advertising ijerph19084786
    Attachment 3B.5 - XPaper_Emery_Binns_Carter tobaccocontrol 2022 057282
    Attachment 3B.6 - XPaper_Knopp_Kiil Nielsen 2022 Biorelevant In Vitro separations9020052
    Attachment 3B.7 - XPaper_Rahman_Mohamed 2021 jpharmsci.org Discriminatory Dissolution Method
Attachment 4A - 2022-PM10-17 (Manufacturing Deviations) Summary

Document Appendices – Annual Post-Market Surveillance & Studies Report

Appendix 1C (1.1) - Descriptive Tables 14, 14.1, 16-18, & 20-24: General Snus Patterns of Use Study – Wave 4 Study Report **(Excel Attachment)**
Appendix 1C (1.2) - Study Questionnaire: General Snus Patterns of Use Study – Wave 4 Study Report
Appendix 1C (1.2a) Consumer Facing General Snus Patterns of Use Study Baseline to Wave 4
Appendix 1C (1.3) - Study Protocol - General Snus Patterns of Use Study - Version 4
Appendix 1C (1.4) - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 4 Study Report
Appendix 1C (1.5) – Technical Report: General Snus Patterns of Use Study – Wave 4 Study Report DRAFT

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 2022 Trade Media Calendar Advertising Plan **(Excel Attachment)**

Document Appendices – Summary of AFPPH Research Reports

Appendix 3A (1) – Consumer Insights Use Behavior

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 Use Behavior

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 14, 14.1, 16-18, & 20-24: General Snus Patterns of Use Study – Wave 4 Study Report **(Excel Attachment)**
- **Appendix 1C (1.2)** - Study Questionnaire: General Snus Patterns of Use Study – Wave 4 Study Report
  - **Appendix 1C (1.2a)** - Consumer Facing General Snus Patterns of Use Study Baseline to Wave 4
- **Appendix 1C (1.3)** - Study Protocol - General Snus Patterns of Use Study - Version 4
- **Appendix 1C (1.4)** - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 4 Study Report
- **Appendix 1C (1.5)** – Technical Report: General Snus Patterns of Use Study – Wave 4 Study Report DRAFT

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 2022 Trade Media Calendar 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, 2021 – September 30, 2022, we are supplying copies of the revised top, side and bottom label final print proofs which include dimensions, Pantone color numbers, and legible text **(See Appendix 2A (4) -** General Snus Packaging). As this is the seventh 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, due to production of the General Snus products, during the reporting period October 1, 2021 – September 30, 2022.

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, 2021 – September 30, 2022 (**See Attachment 4A -** Annual Reporting Deviations Summary). 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, 2021 – September 30, 2022, 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 PM0000010, 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, 2021 – September 30, 2022, we provide the following research:

1. **Consumer Insights Use Behavior Report - Appendix 3A (1)**

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

- **Appendix 3A (1):** Consumer Insights Use Behavior

Both the 2021 & 2022 submissions included the following: Category and Brand Awareness, Category & Brand Usage, Purchase Dynamics, Demographics

2022: Focused on freshness, history, and originality

- Messaging options, markers/descriptors, and impact on purchase
- Snus storage: importance, how it is stored

- Usage (not included in 2021 submission): Combustible cigarette usage P30D, Brands used 30D, Snus used P30D, Where General is used, Where General is purchased

2021: Focused on MRTP (messaging options, awareness, perception, understanding and impact on purchase)

- Swedish Match is supplying a summary of publications not previously reported (**See Table 1.a**. below). Full text articles are available in **Attachment 3B (1-7) -** Full Text Articles. Swedish Match conducted a literature search of PubMed and Google Scholar using "snus" and "snus 2021" and "snus 2022" to access a general outline of peer reviewed Swedish snus-focused articles published in 2021 and 2022. 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.	Knopp, M. M., Kiil-Nielson, N. K., Masser, A. E., and Staaf, M. (2022): Introducing a Novel Biorelevant In Vitro Dissolution Method for the Assessment of Nicotine Release from Oral Tobacco-Derived Nicotine (OTDN) and Snus Products. *Separations* 2022, *9*(2), 52. Retrieved from: https://doi.org/10.3390/separations9020052 • Authors measured the in vitro release of nicotine from certain smokeless tobacco products, including General Pouched Snus White Portion Large. Authors employed use of artificial saliva using a µDISS Profiler™ dissolution method. The in vitro release data (i.e., biorelevance of the proposed dissolution method) was verified through in vivo nicotine extraction studies on the same products. Nicotine pouches (i.e., ZYN) were also assessed and compared to the General Snus product. • As discussed by the paper, calculations of the difference and similarity factors showed distinct nicotine-release curves for the snus and nicotine pouch products, verifying that the method can discriminate between different product categories. To investigate if the in vitro method could predict in vivo behavior, in vivo nicotine extraction was measured for both products and both time points. No significant differences could be seen within products when comparing in vitro and in vivo data after 15 min and 60 min.
2.	Rahman, Z., Mohamad, E.M., Dharani, S., Khuroo, T., Young, M., Feng, C., Cecil, T., and Khan, M.A. (2022): Development and Validation Of A Discriminatory Dissolution Method for Portioned Moist Snuff and Snus. Journal of Pharmaceutical Sciences Volume 111, Issue 6, June 2022, Pages 1700-1708. Retrieved from: https://doi.org/10.1016/j.xphs.2021.11.019 • Another dissolution study published in 2022 which assessed dissolution rates for snus and nicotine pouch products, with a comparison of the results • A USP Apparatus 4 was employed to develop and validate the method. The method was assessed based on time to reach nicotine dissolution plateau, percentage difference between two profiles at each time point, relative standard deviation (RSD), and *f1* (similarity) and *f2* (dissimilarity) values. • The amount of nicotine dissolved from the nine products varied widely (2.0-3.4, 2.1-4.1, 3.3-4.6, 5.5-6.6, 6.9-9.1, 11.5-14.2, 12.5-14.6, 14.0-15.5, and 15.5-19.6 mg/pouch at 60 min). The developed method produced distinct profiles for all the tested products, which was further confirmed by *f1*>15 and *f2*<50 values.
3.	Chen, J., Xue, S., Xie, Z., Li, D. (2022): Perceptions and Discussions of Snus on Twitter: Observational Study. JMIR Med Inform 2022;10(8):e38174. Retrieved from: doi: 10.2196/38174 • Study assessed public perceptions and discussions of snus on Twitter.

	• Authors collected Twitter posts (tweets) about snus through the Twitter streaming application programming interface from March 11, 2021, to February 26, 2022. Assessment examined change in number of snus-related tweets over time. A sentiment analysis was conducted to examine the sentiments of snus-related tweets. Topic modeling was applied to tweets to determine popular topics. A keyword search and hand-coding were used to understand the health symptoms mentioned in snus-related tweets. • Study revealed that the proportion of snus-related tweets with a positive sentiment was significantly higher than the proportion of negative sentiment tweets (4341/11,631, 37.32% vs 3094/11,631, 26.60%; *P*<.001). Positive tweets focused on snus's harm reduction and snus use being an alternative to smoking. Negative tweets focused on health concerns related to snus. Mouth and respiratory symptoms were the most mentioned health symptoms in snus-related tweets.
4.	Emery, S.L., Binns, S., Carter, C.C., Rose, S.W., and Gostygina, K. (2022): Characterising advertising strategies and expenditures for conventional and newer smokeless tobacco products. *Tobacco Control* Published Online First: 08 July 2022. Retrieved from: doi: 10.1136/tobaccocontrol-2022-057282 • As discussed by the authors, advertising expenditures were collected using Kantar Media's 'Stradegy' tool, which identified 306 smokeless products within Kantar database and collected ad expenditures retrospectively for January 2018–April 2020. Promotional expenditures were aggregated by product category, by month and by designated market area (DMA). • Kantar data analysis returned 28 conventional smokeless tobacco, 22 oral nicotine and 3 snus products (53 total) advertised during the period of observation, with over $71 million spent collectively on promotion. Across categories, more advertising dollars were spent on conventional smokeless products (63%) than newer oral nicotine products (25%) or snus (12%). However, during the later 9-month period from August 2019 to April 2020, oral nicotine products accounted for the majority of monthly ad spending. Most ad spending was placed in the national market ($66.5 million), with Atlanta ($1.1 million), Houston ($1 million) and Las Vegas ($0.8 million) as the top three local DMAs for expenditures. • Advertising expenditures for nicotine pouches have recently exceeded conventional ST product advertising and nicotine pouches are being promoted nationally.
5.	"Special Issue" of Separations: Introduction - Method Development and Applications for Reduced-Risk Products by Fadi Aldeek and Mohamadi A. Sarkar • Citation: *Separations* 2022, *9*(3), 78; https://doi.org/10.3390/separations9030078 This article belongs to the Special Issue Method Development and Applications for Reduced-Risk Products in Separation Science
6.	Antoniewicz, L., Kabele, M., Nilsson, U., Pourazar, J., Rankin, G., Bosson J.A., and Lundbäck, M. (2022): Chronic snus use in healthy males alters endothelial function and increases arterial stiffness. PLoS One. 2022 Jun 3;17(6):e0268746. Retrieved from: doi: 10.1371/journal.pone.0268746. PMID: 35657943; PMCID: PMC9165771. • In a Swedish hospital setting, the arterial stiffness of fifty healthy males (24 snus users, 26 age-matched controls) with a mean age of 44 years was assessed employing both pulse wave velocity and pulse wave analysis. Endothelial vasodilatory function was measured by venous occlusion plethysmography, utilizing intra-arterial administration of acetylcholine, glyceryl trinitrate and bradykinin to further gauge endothelium-dependent and -independent vasodilatory function. • Arterial stiffness was significantly higher in chronic snus users as compared to controls: pulse wave velocity [m/s]: 6.6±0.8 vs 7.1±0.9 resp. (p = 0.026), augmentation index corrected for heart rate [%]: 0.1±13.2 vs 7.3±7.8 resp. (p = 0.023). Endothelial independent vasodilation, i.e. the reaction to glyceryl trinitrate, was significantly lower in snus users as measured by venous occlusion plethysmography. • These findings indicate that long-term use of snus may alter the function of the endothelium and therefore reinforces the assertion that chronic snus use is correlated to an increased risk of

	development of cardiovascular disease.
7.	Diaz, M.C.; Kierstead, E.C.; Edwards, D.; Kim, Y.; Rose, S.W.; Emery, S.; Khatib, B.; Liu, M.; Kostygina, G. (2022): Online Tobacco Advertising and Current Chew, Dip, Snuff and Snus Use among Youth and Young Adults, 2018–2019. *Int. J. Environ. Res. Public Health* 2022, *19*, 4786. Retrieved from: https://doi.org/10.3390/ijerph19084786 • As discussed by the authors: the study objective was to understand the relationship between exposure to online tobacco advertising and current smokeless tobacco use. Three waves of a national probability-based sample of (*n* = 15,985) youth and young adults were used. Analysis controlled for social media use, demographics, tobacco use, average price of smokeless tobacco inclusive of taxes, smoke-free indoor air laws (SFIA) and state tobacco control expenditures. • Study found that frequent exposure to tobacco advertising on social media is associated with greater odds of current smokeless use (aOR: 2.05, 95% CI: 1.62, 2.60). • Study authors concluded that greater exposure to tobacco advertising online is associated with greater odds of smokeless use among surveyed youth and young adults.

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, 2021 – September 30, 2022. 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, 2021 – September 30, 2022. 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, 2021 – September 30, 2022. (**See Attachment 1B** - Annual PMSS Adverse Experiences Report)

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

Data and information on current product users are included in the **Consumer Insights Use Behavior Report - Appendix 3A (1).** Including research (provided above at **Attachment 3B (1-4)**) and sales and distribution data (provided above at **Attachments 1A.1 & 1A.2.**), there is no further product user data for the reporting period October 1, 2021 – September 30, 2022. Likewise, there has been no change in the intended target market for these products for the reporting period October 1, 2021 – September 30, 2022.

Table of Contents - General Snus PMTA MRTP Annual Report 2022

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)

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

Page 7, PM0000010

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)

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.

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 05:59:58 -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)

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, 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)

[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

Page 7, PM0000013

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)

[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)

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 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)

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
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- 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:

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- 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.
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   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)									
			2021 Q4		2022 Q1		2022 Q2		2022 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
		Total General	(b) (4)									
MR0000020	6-09249-62053-8, 6-90249-62024-8, 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										
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Classic Blend Portion White Large (12 ct)										
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										
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Wintergreen Portion White Large										

			Dollar Sales ($1,000's)									
			2021 Q4		2022 Q1		2022 Q2		2022 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
		Total General	(b) (4)									
MR0000020	6-09249-62053-8, 6-90249-62024-8, 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										
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Classic Blend Portion White Large (12 ct)										
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										
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Wintergreen Portion White Large										

Summary of Consumer Contacts (Adverse Experiences)

Product	General Dry Mint Portion Original Mini
SKU Number	4800
FDA Tracking Number	PM0000011
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Complaint Description	Count	Importance
---	---	---	---

Summary of Consumer Contacts (Adverse Experiences)

Product	General Portion Original Large
SKU Number	4880
FDA Tracking Number	PM0000012
Reporting Period	October 1, 2021 to September 30, 2022

Item	Complaint Description	Count	Importance
(b) (4)			

Product	General Portion Original Large
SKU Number	4880
FDA Tracking Number	PM0000012
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Consumer No.	Complaint Received	Complaint Description	Additional Information
(b) (4)				

Summary of Consumer Contacts (Adverse Experiences)

Product	General Mint Portion White Large
SKU Number	4352
FDA Tracking Number	PM0000014
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Complaint Description	Count	Importance
(b) (4)			

Product	General Mint Portion White Large
SKU Number	4352
FDA Tracking Number	PM0000014
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Consumer No.	Complaint Received	Complaint Description	Additional Information
(b) (4)				

Summary of Consumer Contacts (Adverse Experiences)

Product	General Portion White Large
SKU Number	4881
FDA Tracking Number	PM0000016
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Complaint Description	Count	Importance
(b) (4)			

Product	General Portion White Large
SKU Number	4881
FDA Tracking Number	PM0000016
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Consumer No.	Complaint Received	Complaint Description	Additional Information
(b) (4)				

Summary of Consumer Contacts (Adverse Experiences)

Product	General Wintergreen Portion White Large
SKU Number	4882
FDA Tracking Number	PM0000017
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Complaint Description	Count	Importance
(b) (4)			

Product	General Portion Wintergreen White Large
SKU Number	4882
FDA Tracking Number	PM0000017
Reporting Period	October 1, 2021 to September 30, 2022

Item #	Consumer No.	Complaint Received	Complaint Description	Additional Information
(b) (4)				

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

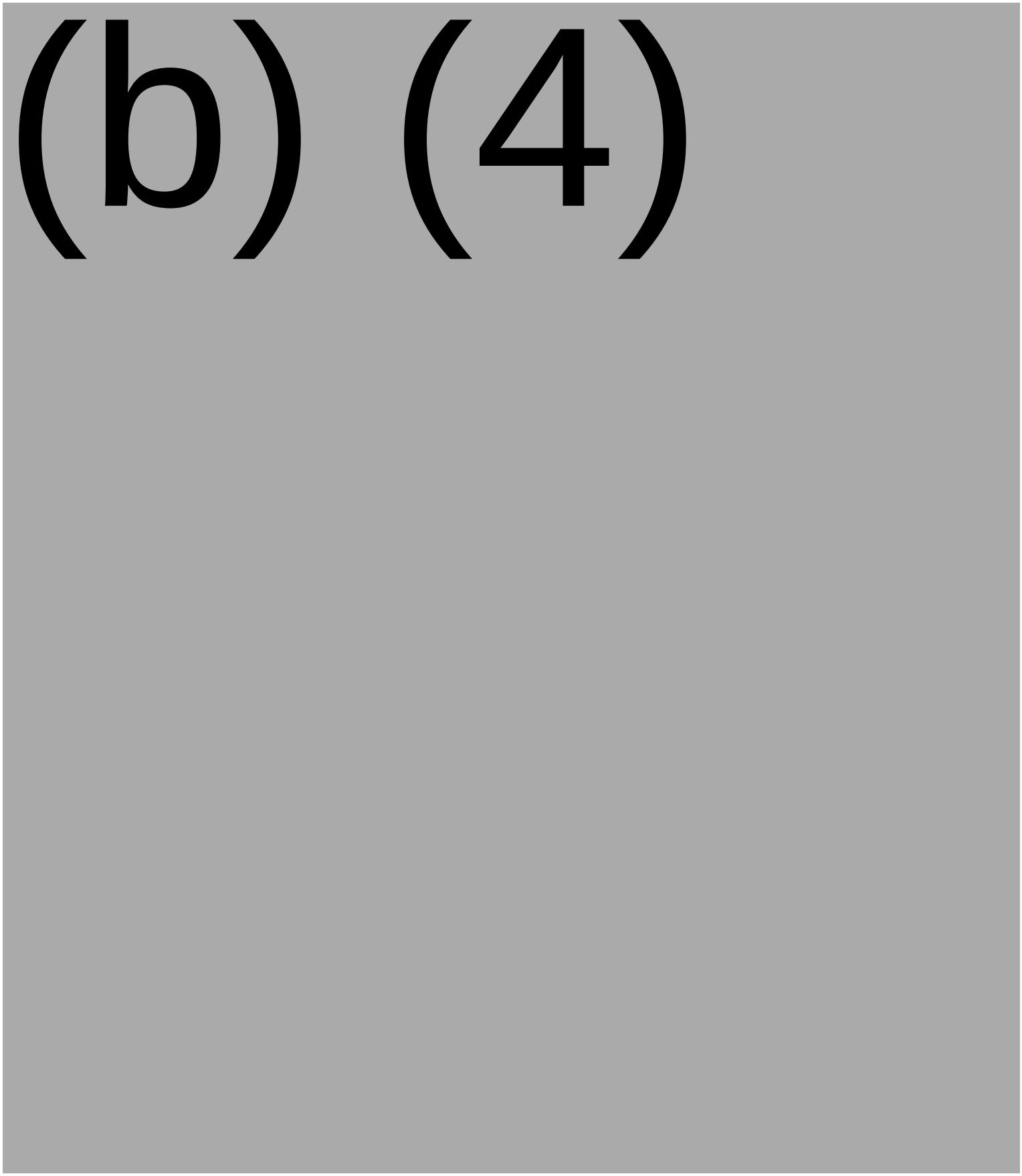
Amendments Received	
Date of Submission:	February 18, 2020
Date of Receipt:	February 18, 2020
Reviewed:	Yes
Status:	Active
Brief Description:	Response to January 17, 2020 FDA Information Request Letter
Date of Submission:	April 1, 2020
Date of Receipt:	April 1, 2020
Reviewed:	Yes
Status:	Active
Brief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

(b) (4)

Appendix 2 to Protocol SMU 19-01GENS

***General* Snus® Patterns of Use Study – Wave 4 Questionnaire**

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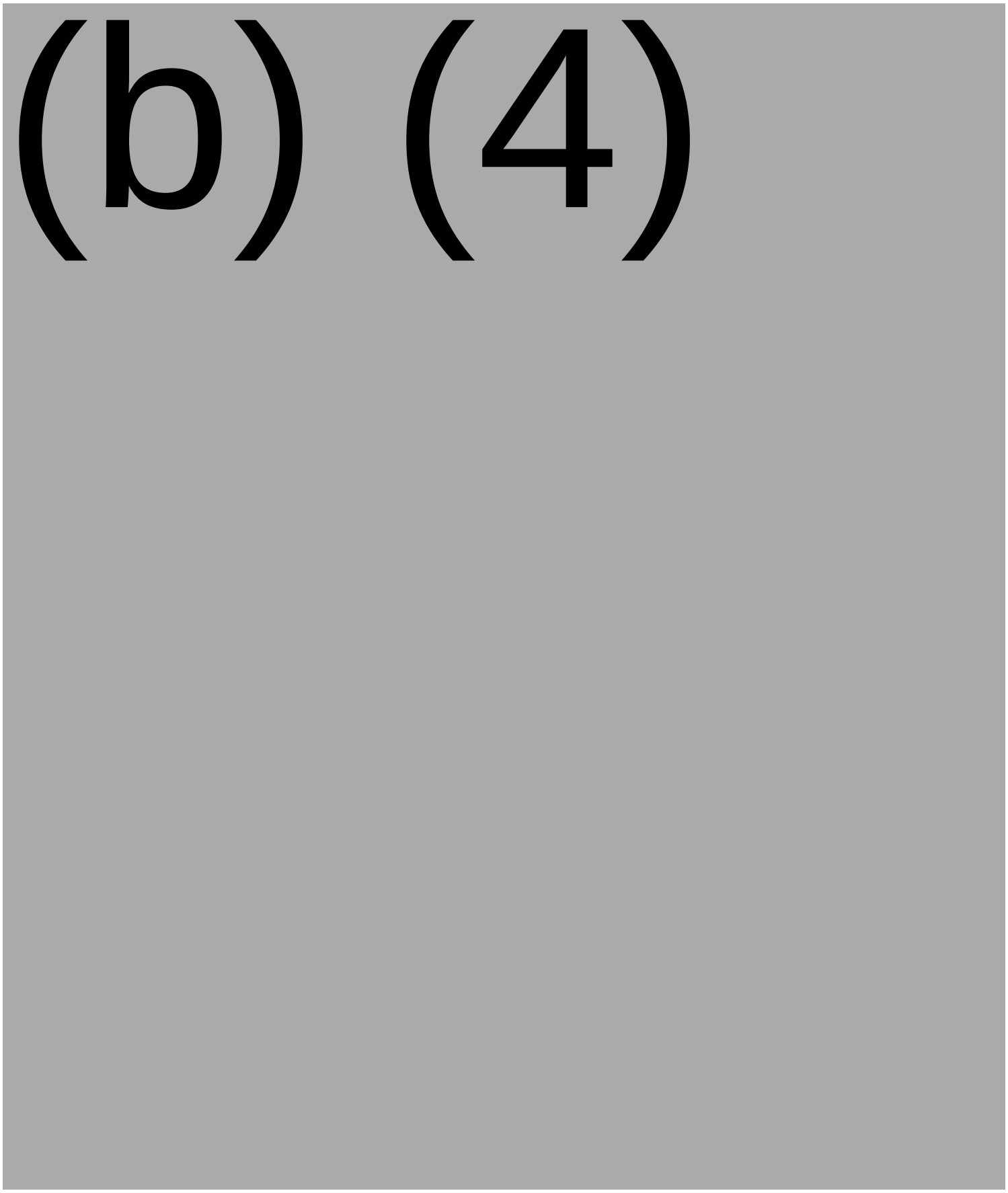
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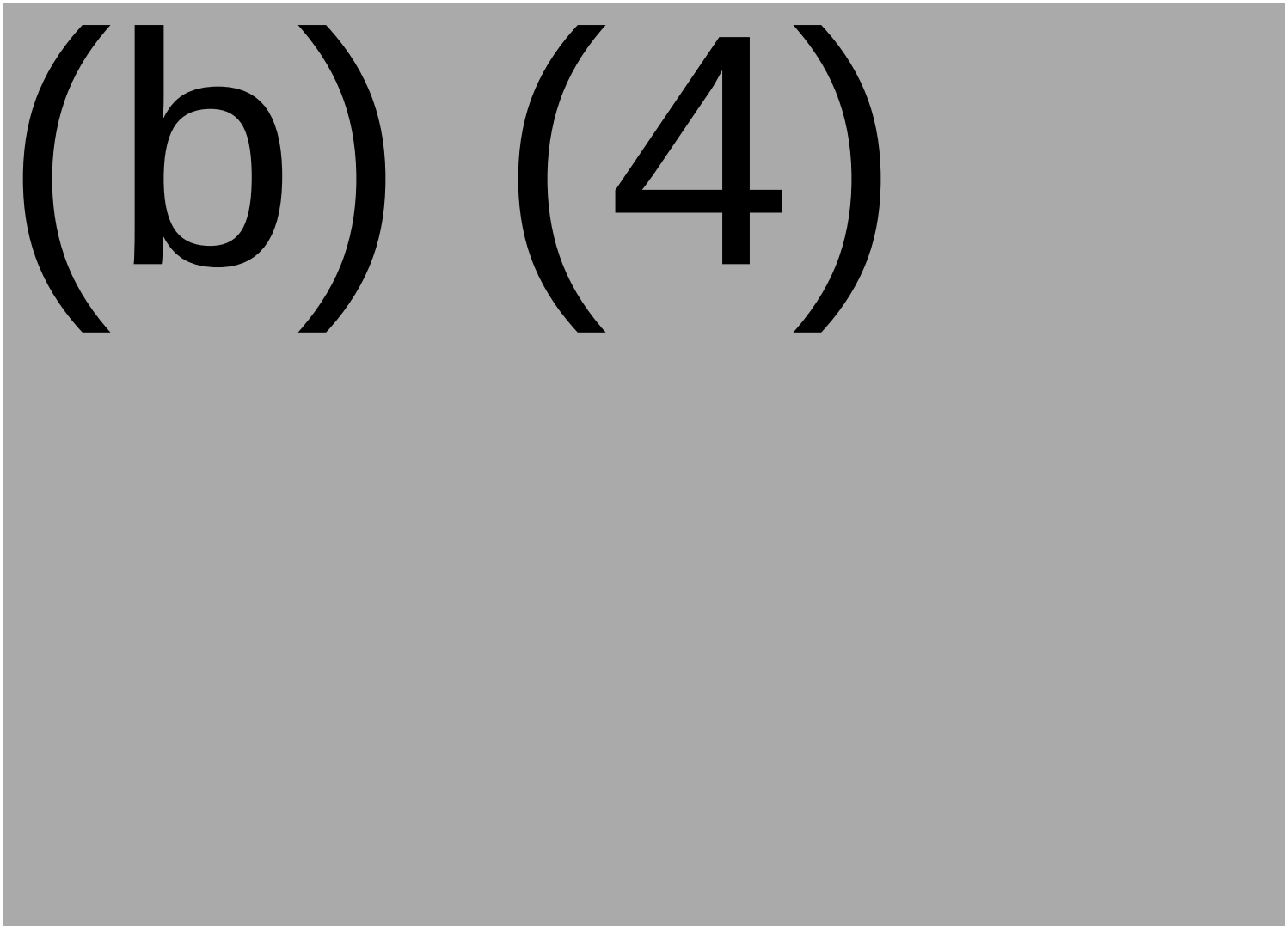
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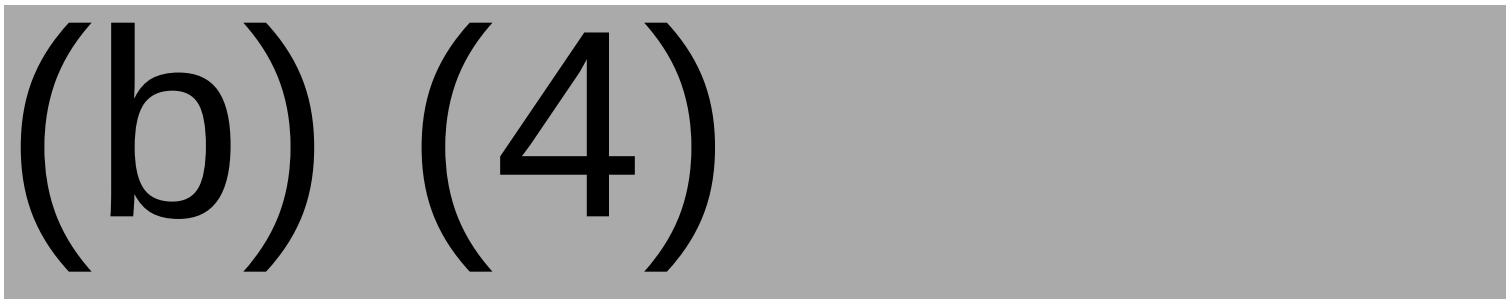
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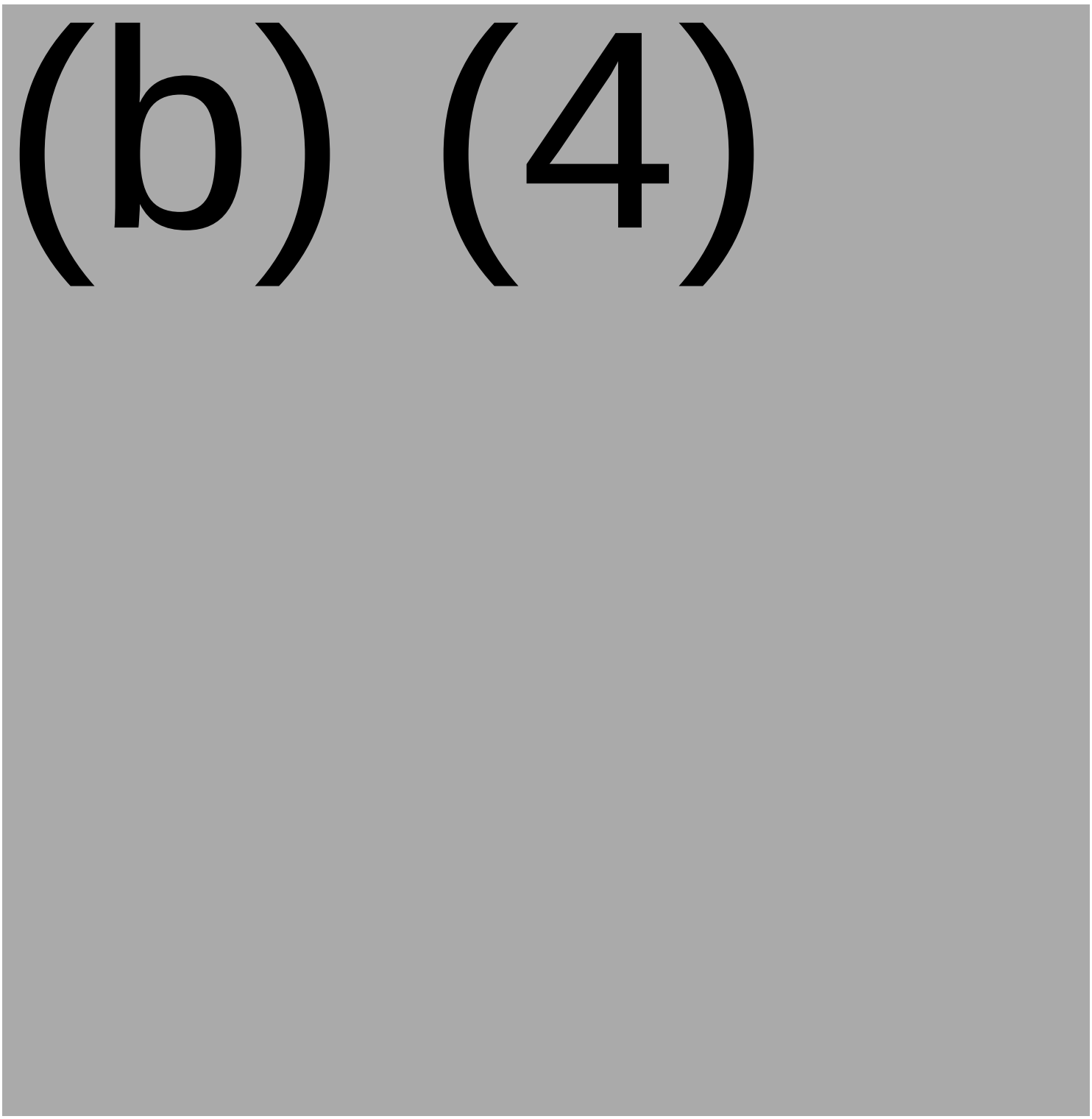
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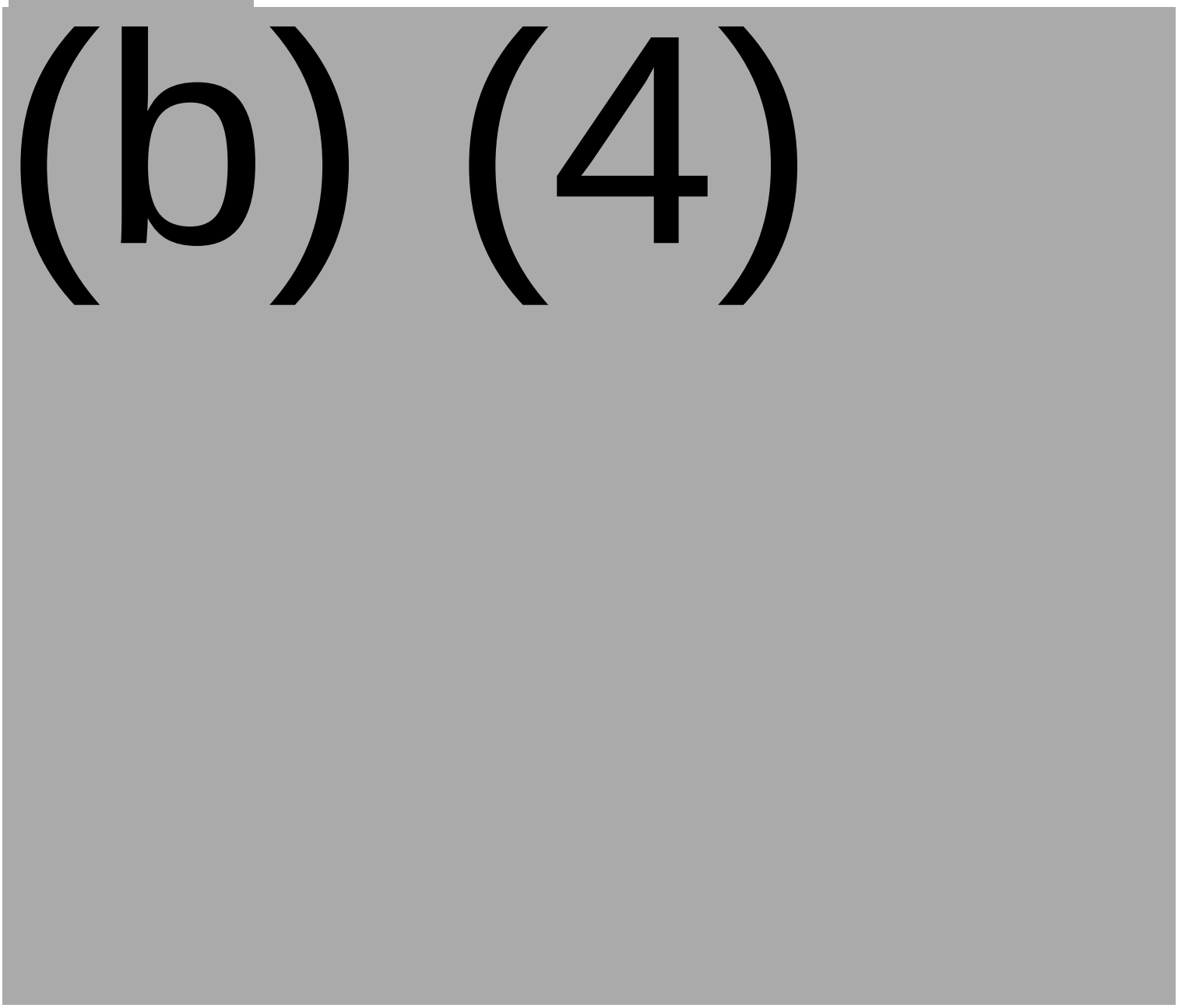
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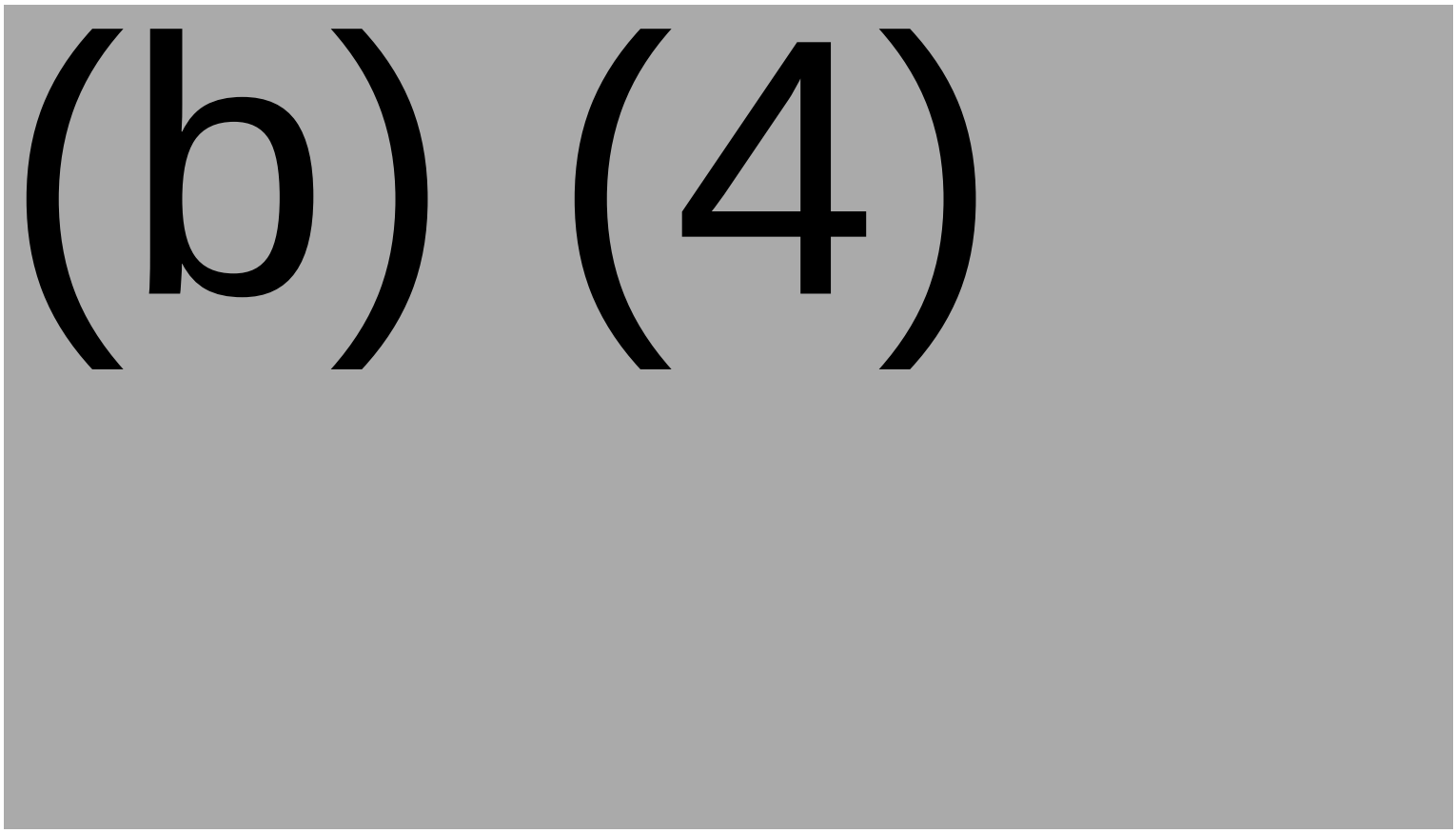
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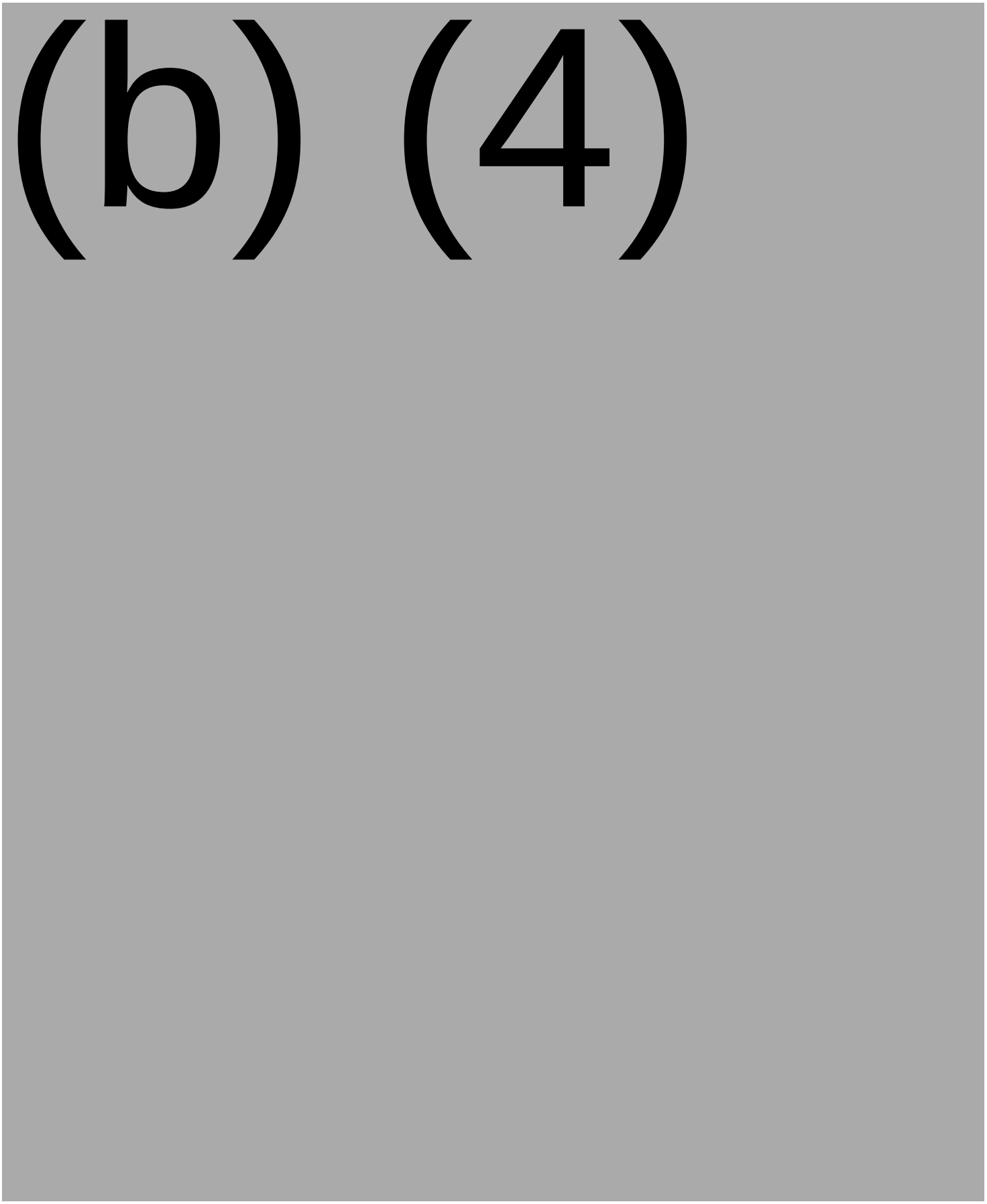
(b) (4)

(b) (4) -

General Snus MRTP

Post-Market Surveillance

Consumer Facing Materials

(b) (4)

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(b) (4)

Swedish Match USA, Inc.

Protocol for *General* Snus® Patterns of Use Study

Protocol *SMU 19-01GENS*

Status: Approved

Date: 15 June 2020

Prepared by: (b) (4)

Confidentiality Statement

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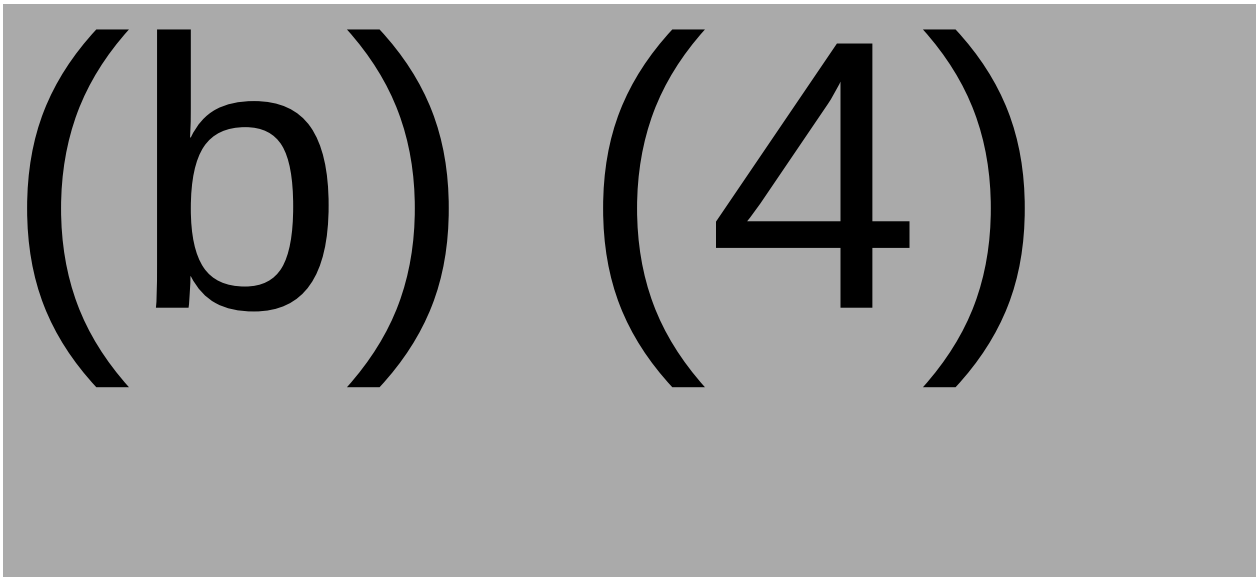
TABLE OF CONTENTS



LIST OF FIGURES

1. ABBREVIATIONS

(b) (4)	(b) (4)
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
(b) (4)	(b) (4)
(b) (4)	(b) (4)
IRB	Institutional Review Board
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
(b) (4)	(b) (4)
PII	Personally Identifiable Information
(b) (4)	(b) (4)
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SMU	Swedish Match USA, Inc.
TNP	Tobacco/Nicotine Product(s)
U.S.	United States

2. RESPONSIBLE PARTIES

2.1. Investigator(s) and Contributors

Investigator: (b) (4)

(b) (4) **r Project Team:**

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

2.2. Sponsor:

Swedish Match USA, Inc.

Tryggve Ljung, Vice President Scientific Affairs

3. SYNOPSIS

Title	***General* Snus® Patterns of Use Study**
Protocol version identifier	Version 4.0 FINAL
Date of last version of protocol	June 15, 2020
Protocol number	SMU 19-01GENS
Author	Tryggve Ljung, MD., Ph.D.

Rationale and background	In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General* Snus®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing[1]. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General* Snus® a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22,2019. This proposed study is planned to be part of the post marketing surveillance following the risk modification order. The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.
Research question and objective	The overarching research questions within this study are as follows: (b) (4) [redacted] **<u>Primary Objectives</u>** (b) (4) [redacted]

	(b) (4) **Secondary Objectives** (b) (4)
Study design	(b) (4)
Population	

	(b) (4)
Data sources	
Study size	
Data analysis	

Milestones	(b) (4)

4. AMENDMENTS AND UPDATES

Number	Date	Section of study protocol	Description of Change	Reason
1				
2				
...				

5. BACKGROUND AND RATIONALE

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *Genera*l Snus®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General* Snus® a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22, 2019. This proposed study is planned to be part of the post marketing surveillance following risk modification order.

The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.

6. OBJECTIVES

The overarching research questions within this study are as follows: (b) (4)

6.1. Primary Objectives:

(b) (4) :

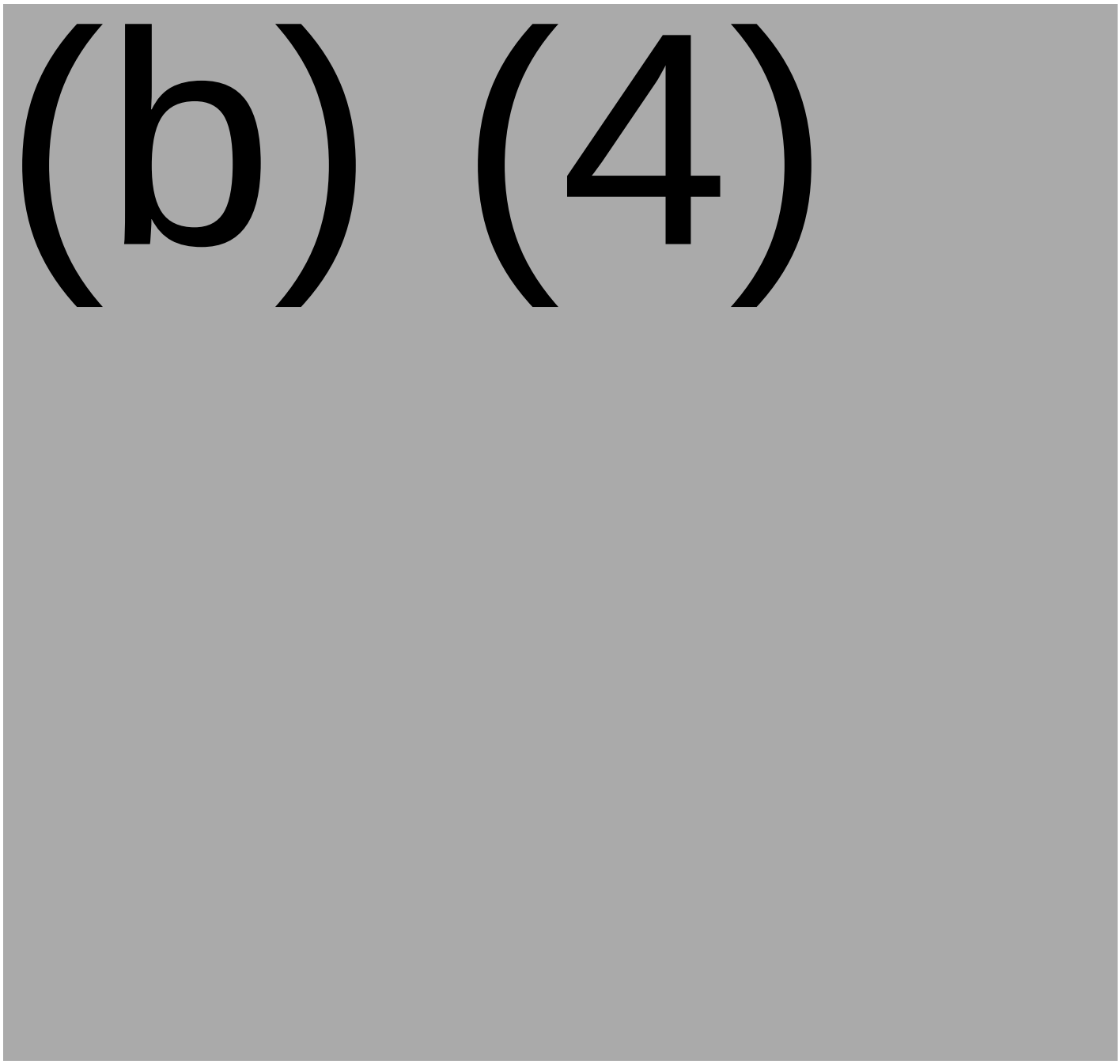
(b) (4)

6.2. Secondary Objectives:

(b) (4)

7. RESEARCH METHODS

7.1. Data Source



7.2. Study Design

(b) (4)

Figure 1: Summary of Research Phases

(b) (4)

7.3. Study Population

(b) (4)

7.4. Sample Size

(b) (4)

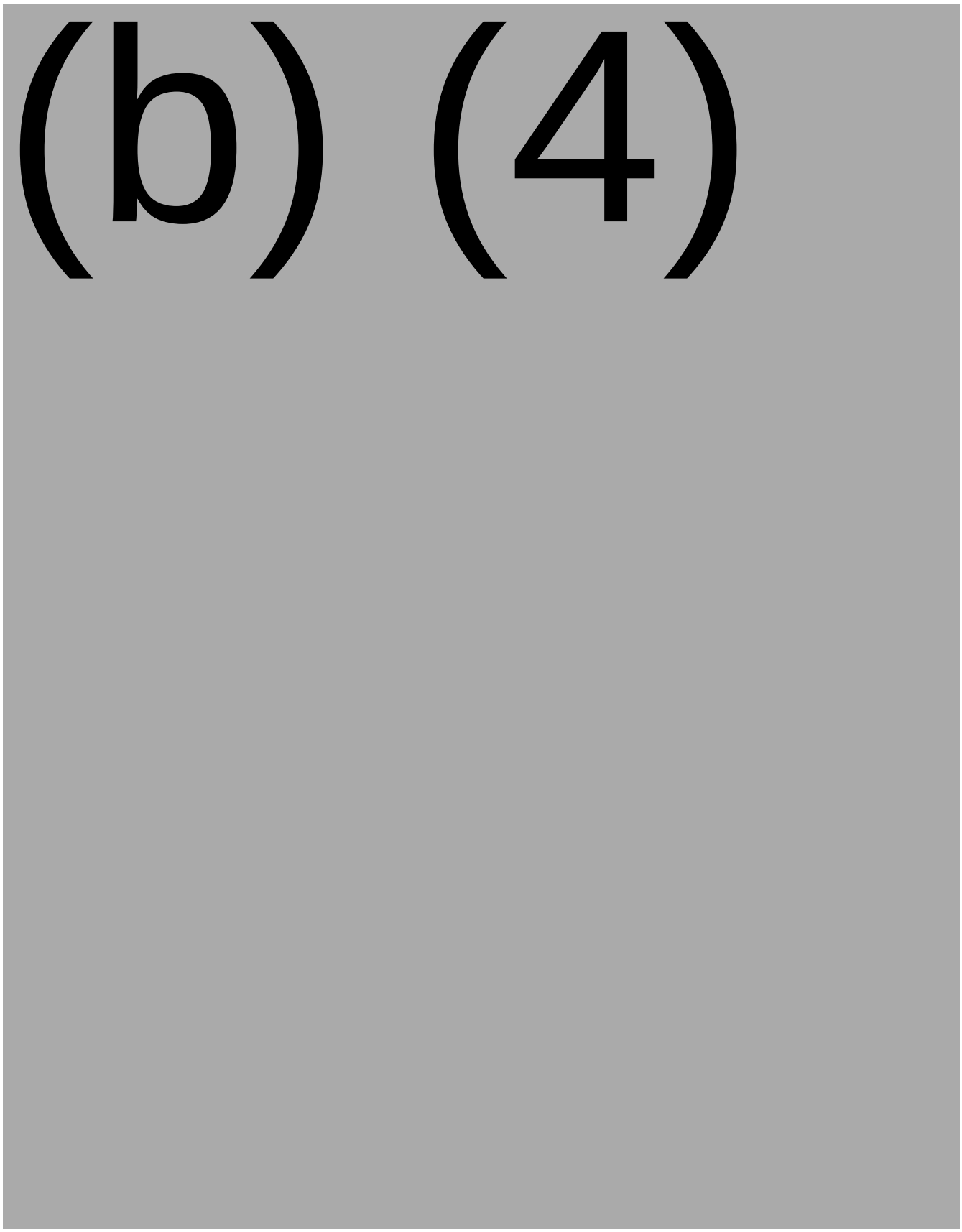
7.4.1. Sample Selection: Inclusion Criteria

(b) (4)

7.4.2. Sample Selection: Exclusion Criteria

(b) (4)

(b) (4)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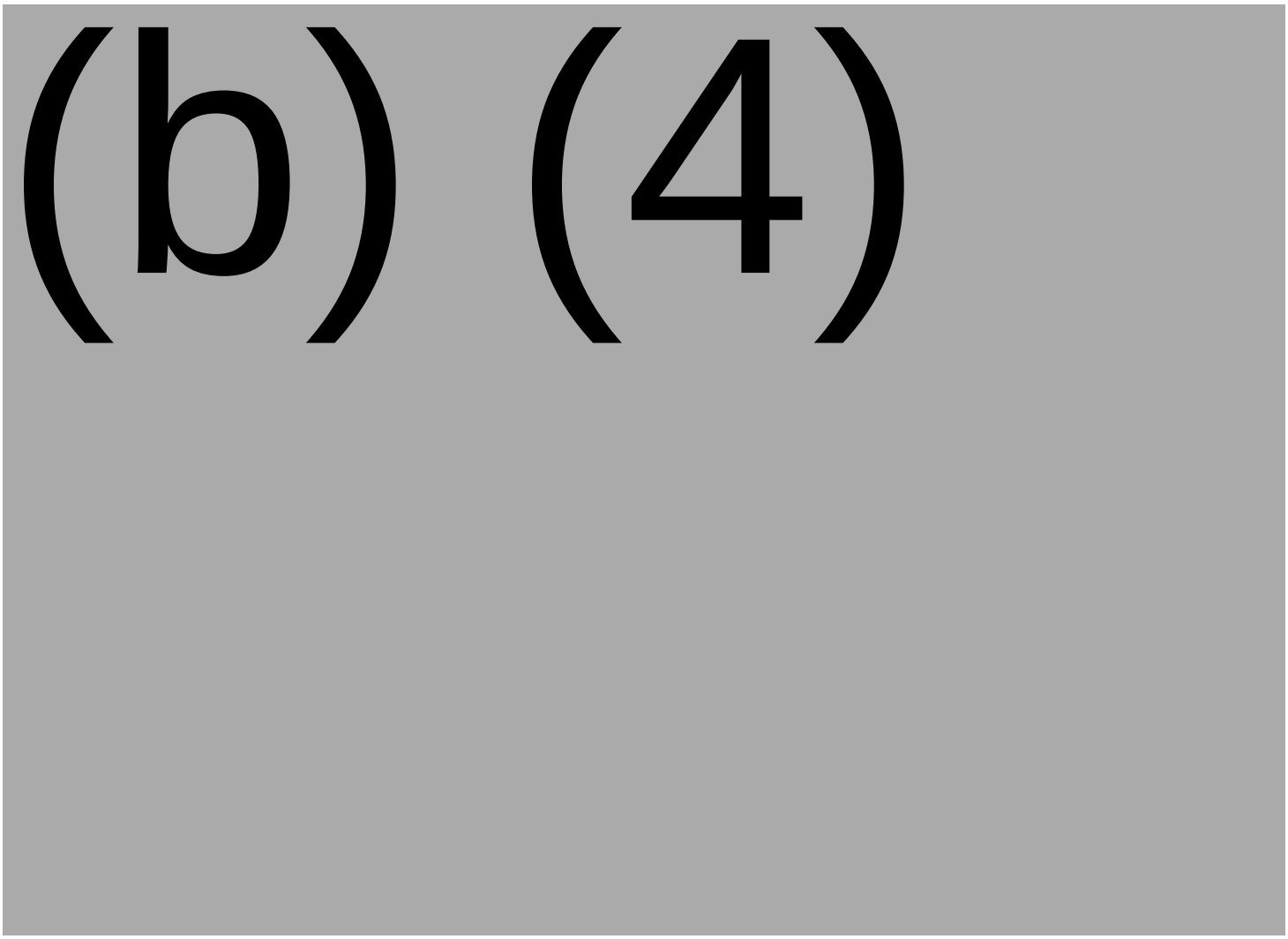
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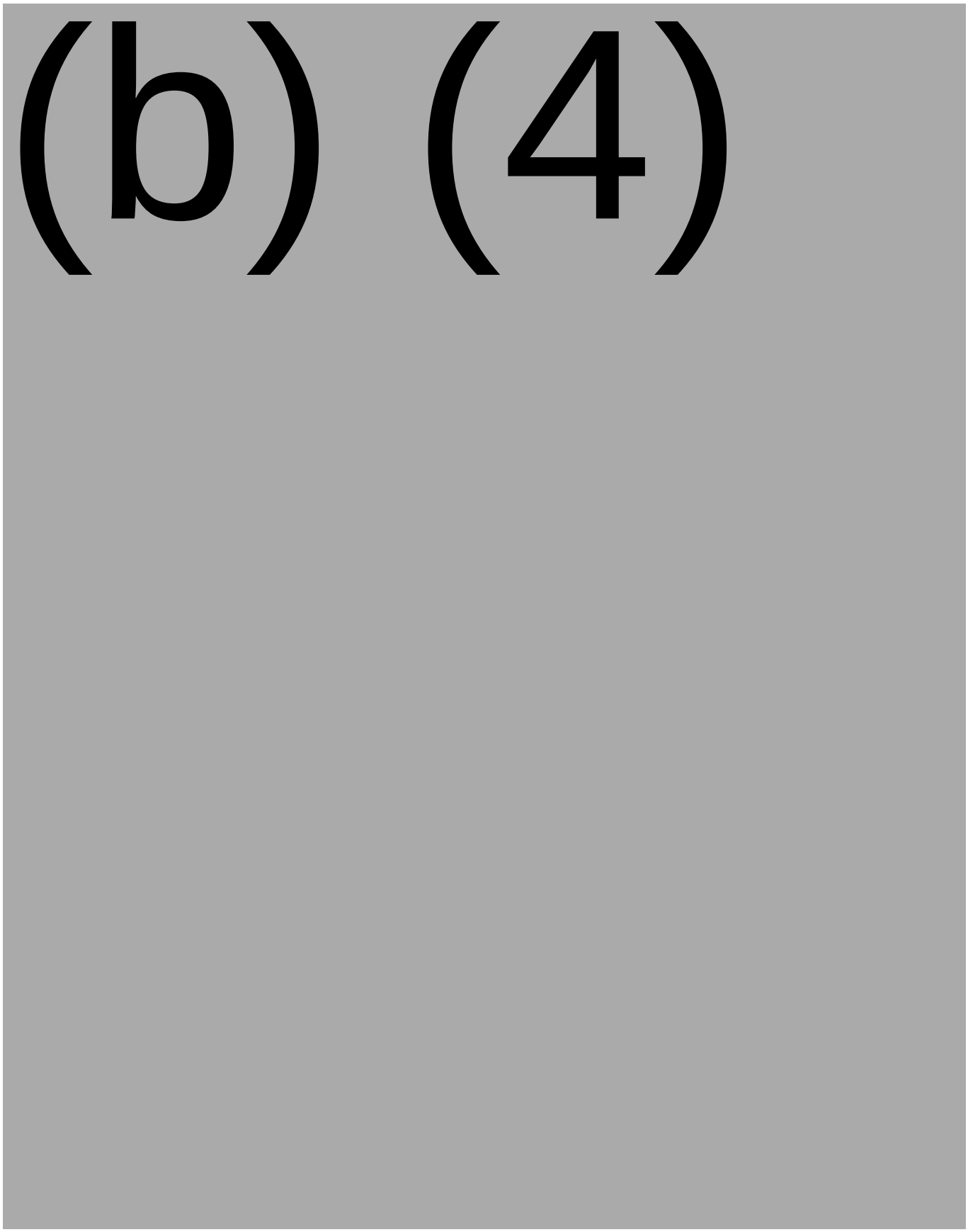
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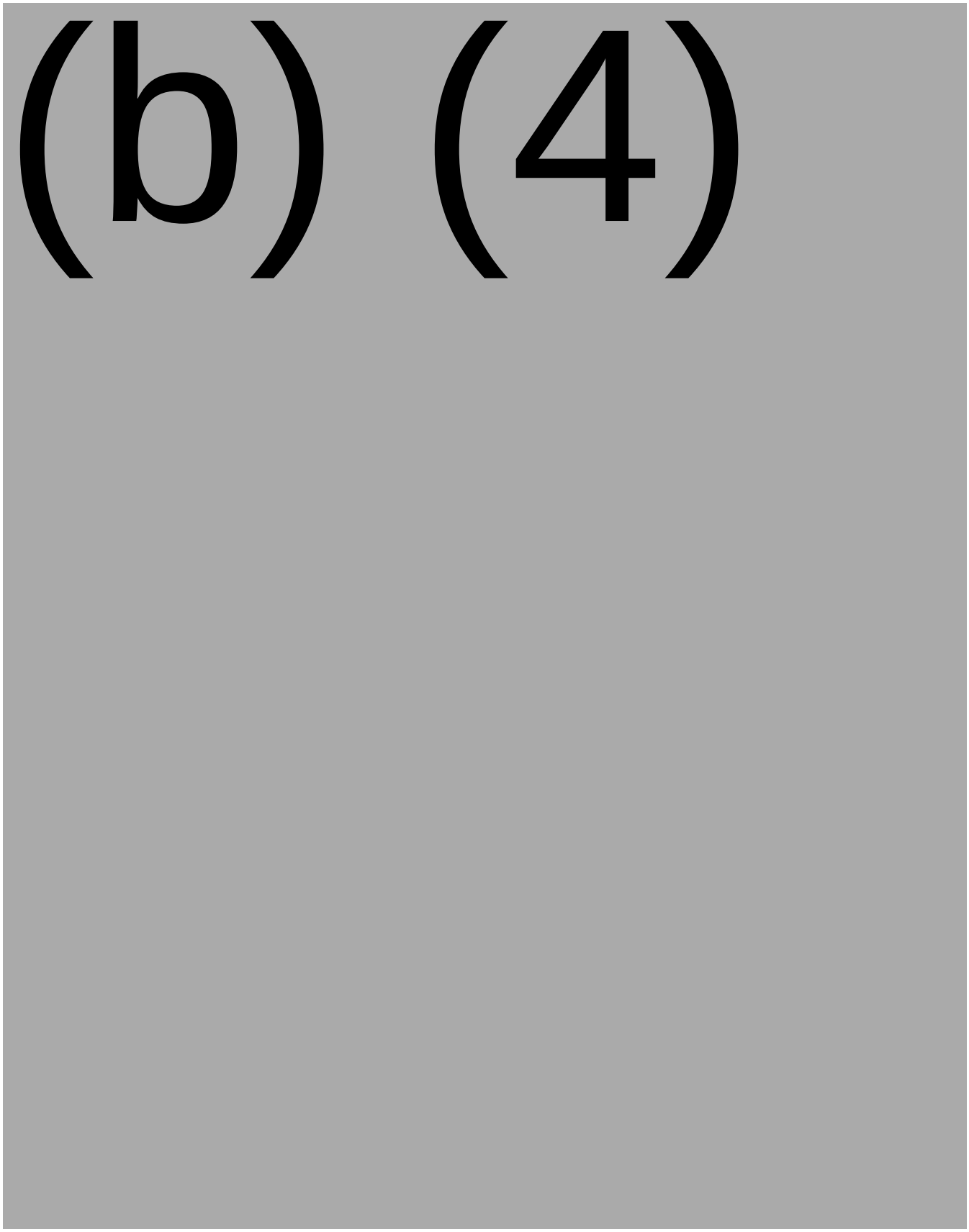
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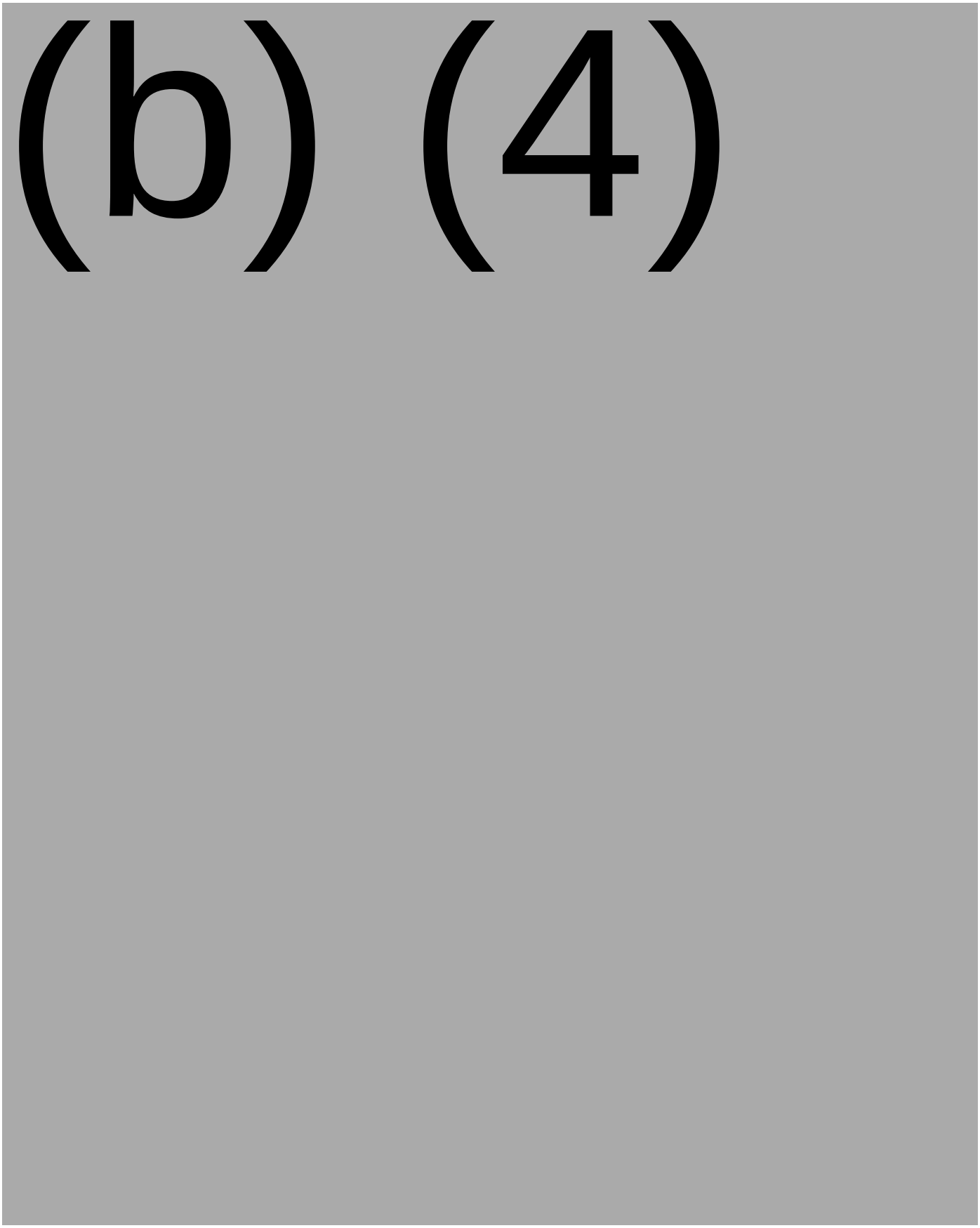

(b) (4)

(b) (4)

8. PROTECTION OF HUMAN SUBJECTS

(b) (4)

8.1. Regulatory authority approvals/authorizations

The study will be carried out in accordance with CTP guidance on data for human studies designed to evaluate the risks and benefits to the population as a whole[1]. (b) (4)

8.1.1. Institutional review board (IRB)

(b) (4)

.

8.1.2. Respondent information and consent

(b) (4)

8.1.3. Confidentiality

SMU as well as all investigators ensure adherence to applicable data privacy protection regulation.

(b) (4)

All records identifying the subject will be kept confidential and will not be made publicly available.

(b) (4)

9. REFERENCES

1. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products. Applications for Premarket Review of New Tobacco Products: Draft Guidance. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products; 2011

2. 2010 US Census Regions and Divisions. Available at: **HTTPS://WWW2.CENSUS.GOV/GEO/PDFS/MAPS-DATA/MAPS/REFERENCE/US_REGDIV.PDF**

3. Ministry of Health, Labour, and Welfare and Ministry of Education, Culture, Sports, Science and Technology. Ethical Guidelines for Medical and Health Research Involving Human Subjects. 2015.

4. United States Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse, and United States Department of Health and Human Services. Food and Drug Administration. Center for Tobacco Products. Population Assessment of Tobacco and Health (PATH) Study. ICPSR36231-v13. Ann Arbor, MI: Inter-university Consortium for Political and Social Research, 2017-06-19. Available at: **HTTPS://DOI.ORG/10.3886/ICPSR36231.V13**

5. Booker et al. A systematic review of the effect of retention methods in population-based cohort studies. BMC Public Health 2011, 11:249

6. Teague et al. BMC Medical Research Methodology. Retention strategies in longitudinal cohort studies: a systematic review and meta analysis. 2018 18:151

7. National Cancer Institute. Health Information National Trends Survey (HINTS) 2005 Survey Instrument. Accessed February 2018. Available at: **HTTPS://HINTS.CANCER.GOV/VIEW-QUESTIONS-TOPICS/QUESTION-DETAILS.ASPX?PK_CYCLE=1&QID=444**

10. ATTACHMENTS

10.1. Attachment 1: (b) (4)

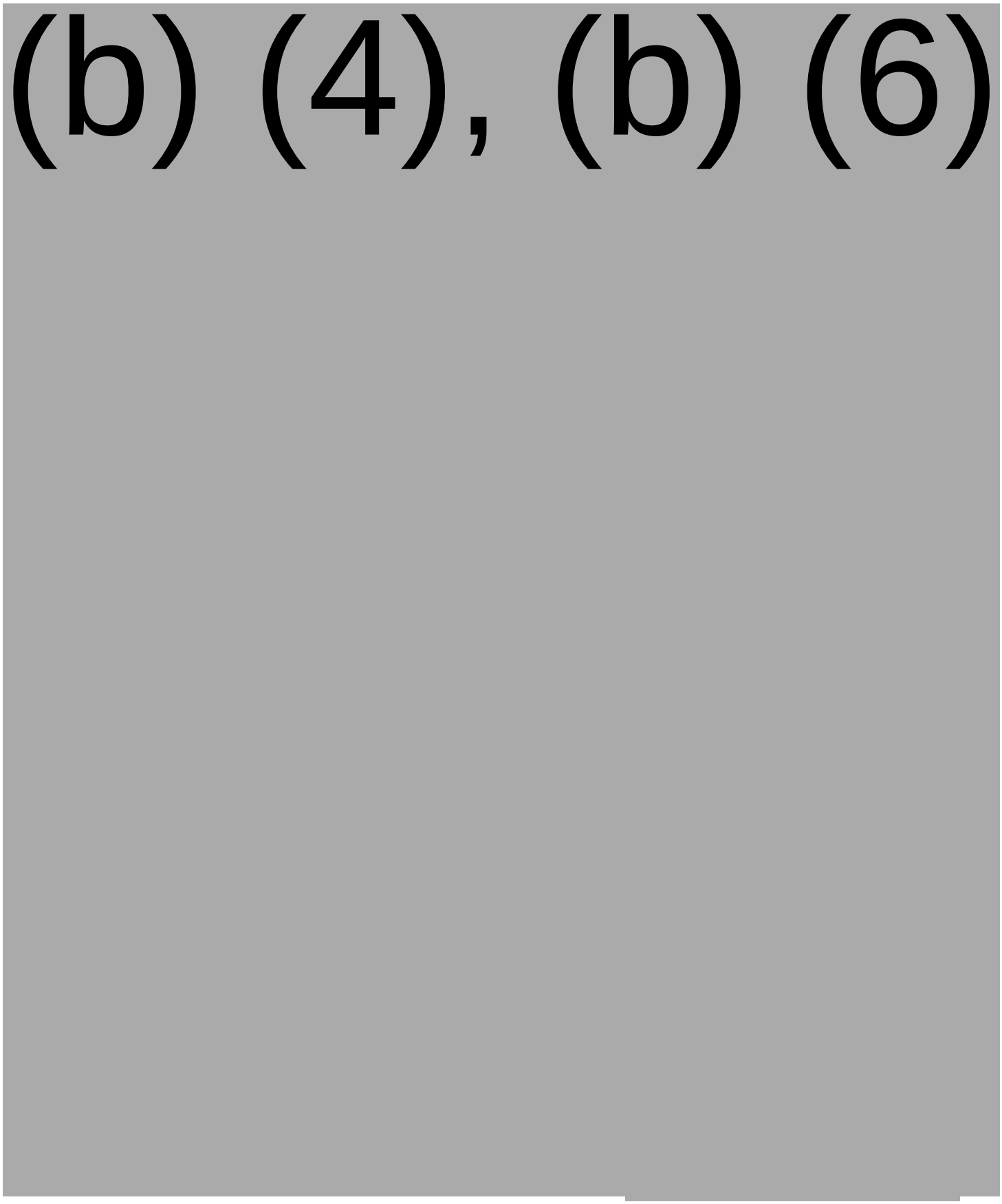
10.2. Attachment (b) (4)

10.3. Attachment 3: (b) (4)

(b) (4) .

(b) (4)

(b) (4), (b) (6)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Swedish Match USA, Inc.

Statistical Analysis Plan

***General* Snus® Patterns of Use Study**

SMU 19-01GENS

Status: Approved
Date: 24 March 2020
Prepared by: (b) (4)

Confidentiality Statement

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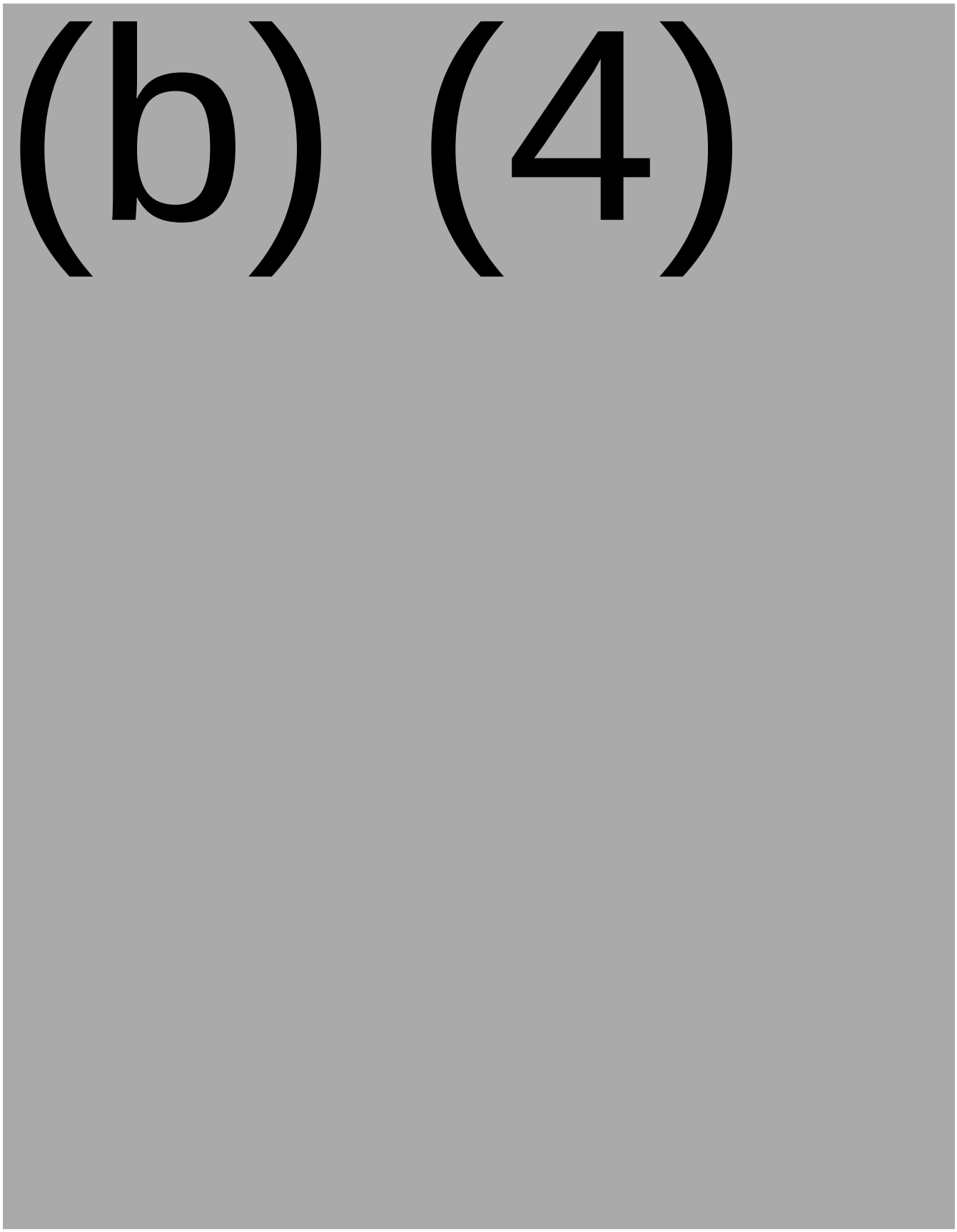
Swedish Match USA, its parent and affiliate companies

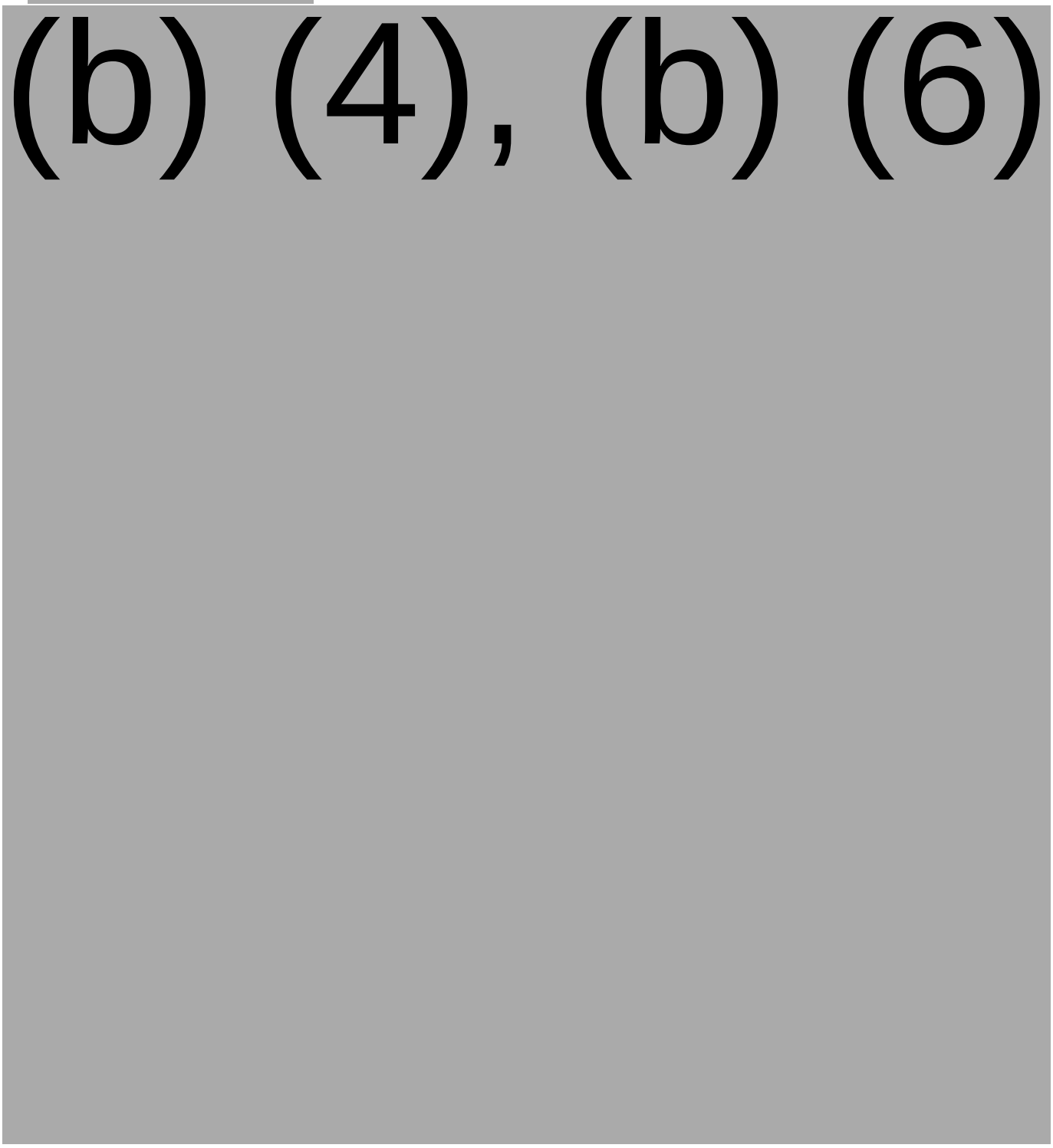
TABLE OF CONTENTS

LIST OF TABLES



1. LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviations	Definition
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
(b) (4)	(b) (4)
(b) (4)	(b) (4)
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
MTSS	Motivation To Stop Scale
(b) (4)	(b) (4)
PMTA	Premarket Tobacco Product Application
(b) (4)	(b) (4)
SAP	Statistical Analysis Plan
SAS®	Statistical Analysis System
SMNA	Swedish Match North America
SMU	Swedish Match USA, Inc.
(b) (4)	
U.S.	United States


(b) (4), (b) (6)

4. BACKGROUND AND RATIONALE

In 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law, giving the FDA the power to regulate the tobacco industry and establishing the Center for Tobacco Products (CTP) within the FDA. This law gives the CTP authority to regulate the marketing/advertising content and sale of tobacco/nicotine products[a] (TNP). The FDA requires that the marketing of a new tobacco product be appropriate for the protection of the public health as determined "on the basis of well-controlled investigations" (Section 910).[1]

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General* Snus®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General* Snus® a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22, 2019. This proposed study is planned to be part of the post marketing surveillance following risk modification order.

The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.

5. OBJECTIVES

The overarching research questions within this study are as follows: (b) (4)

.

5.1 Primary Objectives

(b) (4)

.

[a] "(b) (6)

.

(b) (4)

5.2 Secondary Objectives

(b) (4)

6. OVERALL STUDY DESIGN

6.1 Study Design

(b) (4)

Figure 1: Summary of Research Phases

(b) (4)

(b) (4)

6.2 Study Cohorts

(b) (4)

6.2.1 Subject Selection: Inclusion Criteria

(b) (4)

6.2.2 Subject Selection: Exclusion Criteria

(b) (4)

6.3 Study Sample Size

(b) (4)

6.4 Variables of Relevance to the Study

6.4.1 Outcomes

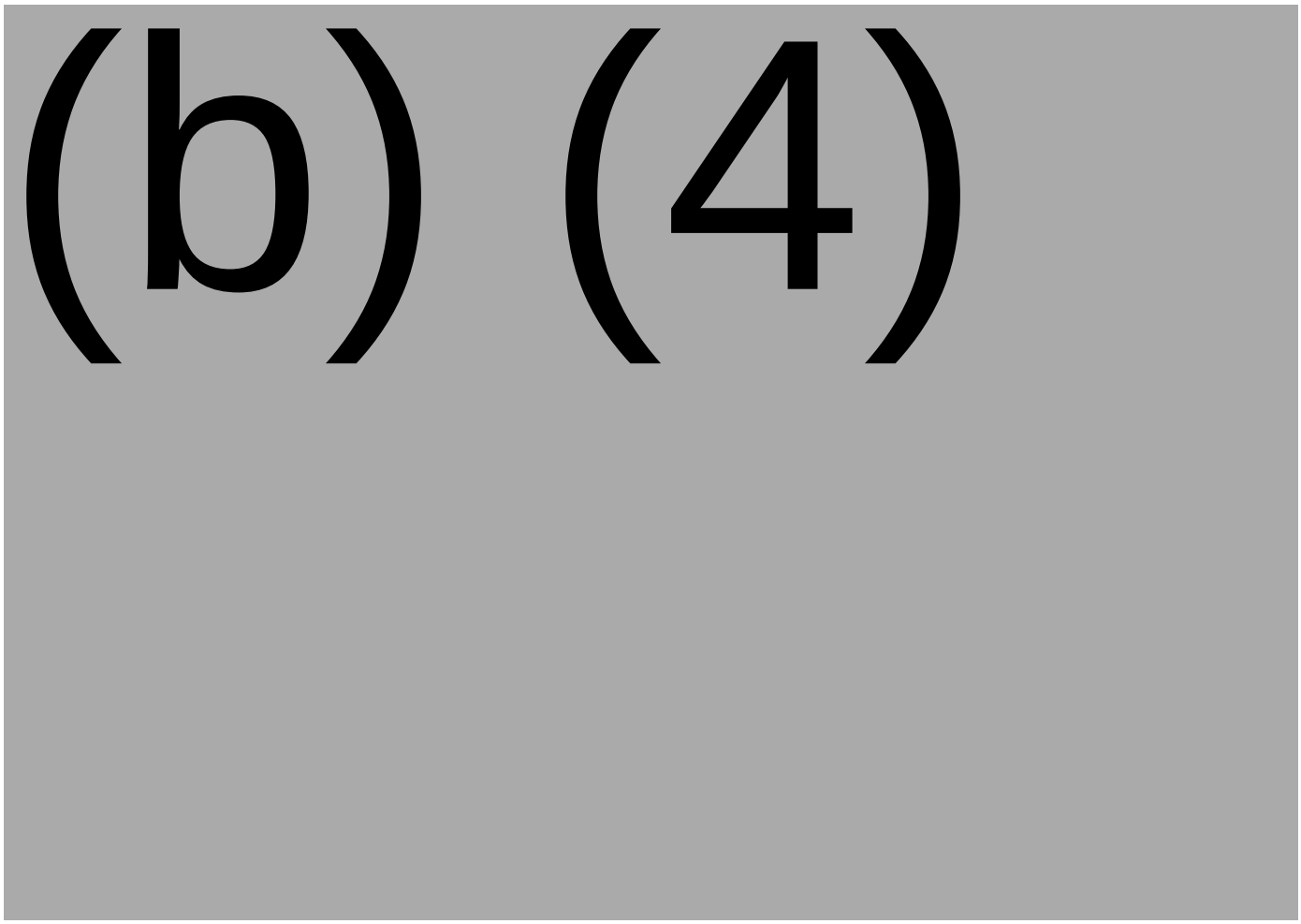
Primary Objectives

(b) (4)

(b) (4)

Secondary Objectives

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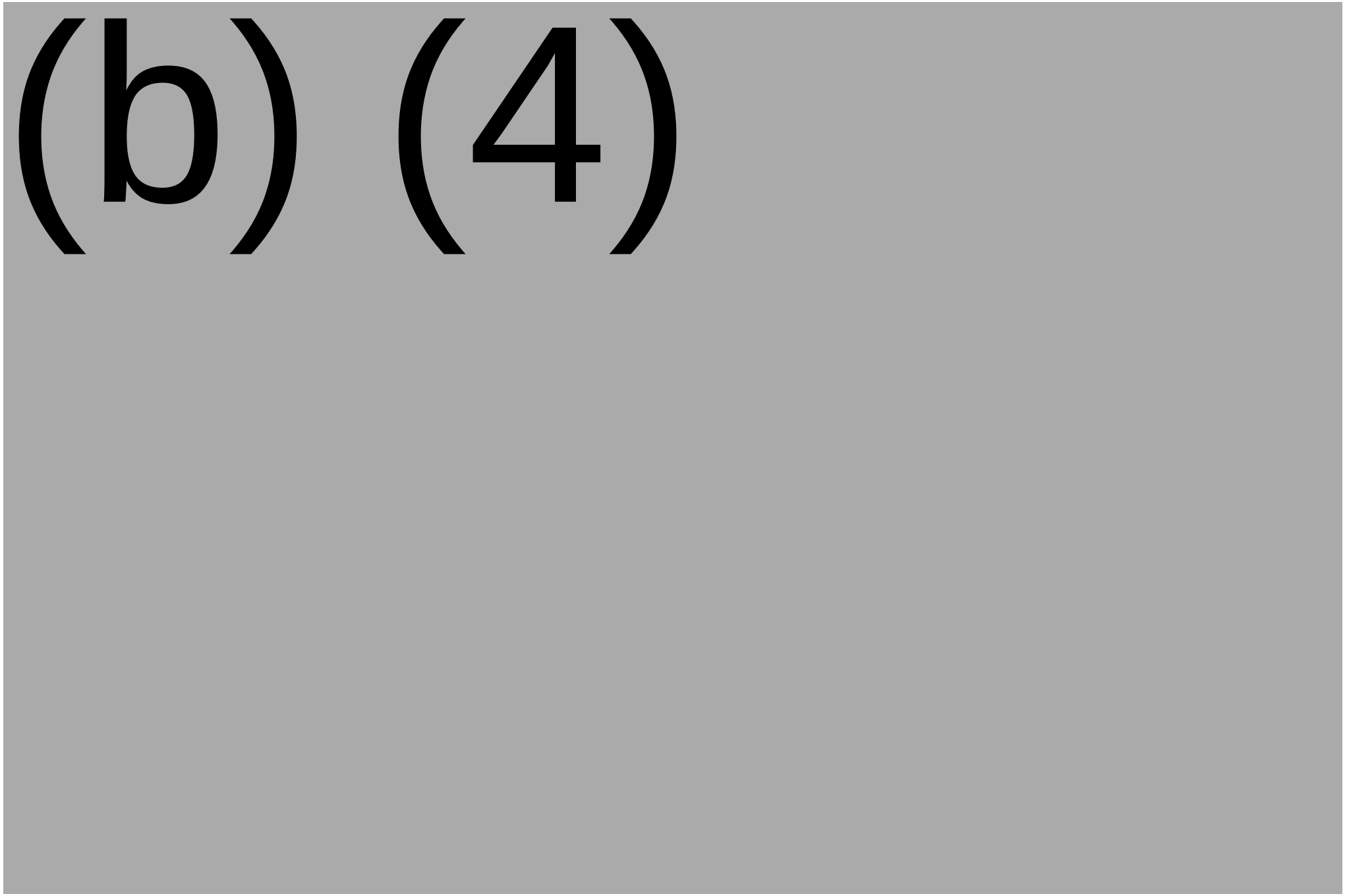
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(b) (4)

6.4.2 Respondent Characteristics

Socio-demographic Variables

(b) (4)

6.5 Time Points of Importance

(b) (4)

7. STATISTICAL ANALYSIS

7.1 Presentation of Analysis Results

(b) (4)

7.2 Study Analysis

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7.3 Socio-demographic Characteristics

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7.4 Primary Objectives

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7.5 Secondary Objectives

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8. STATISTICAL AND ANALYTICAL ISSUES

8.1 Data Capture and Management

8.1.1 Data Capture

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8.2 Handling of Missing Data

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8.3 Identification of Outliers

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10. TABLE SHELLS

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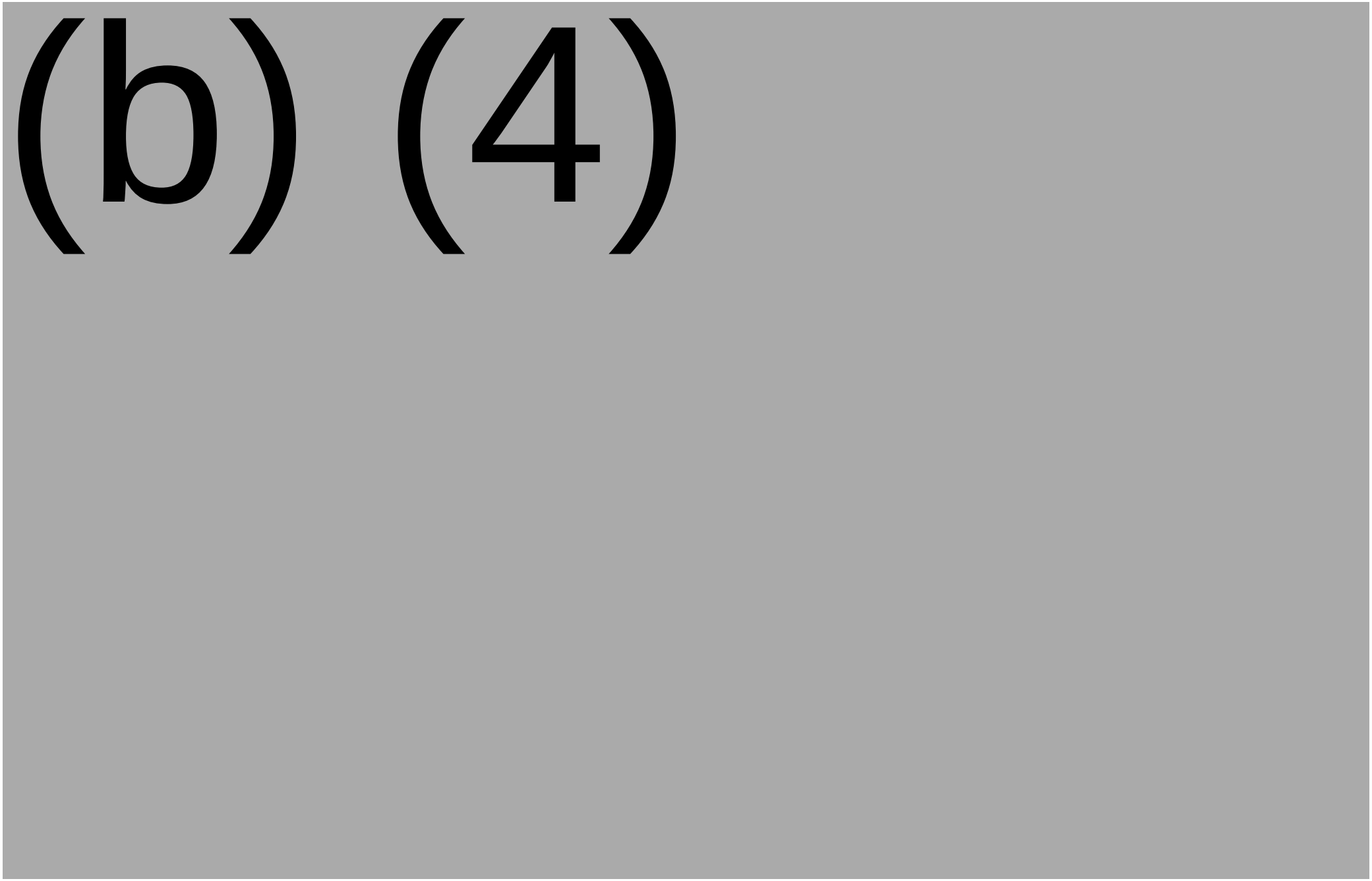
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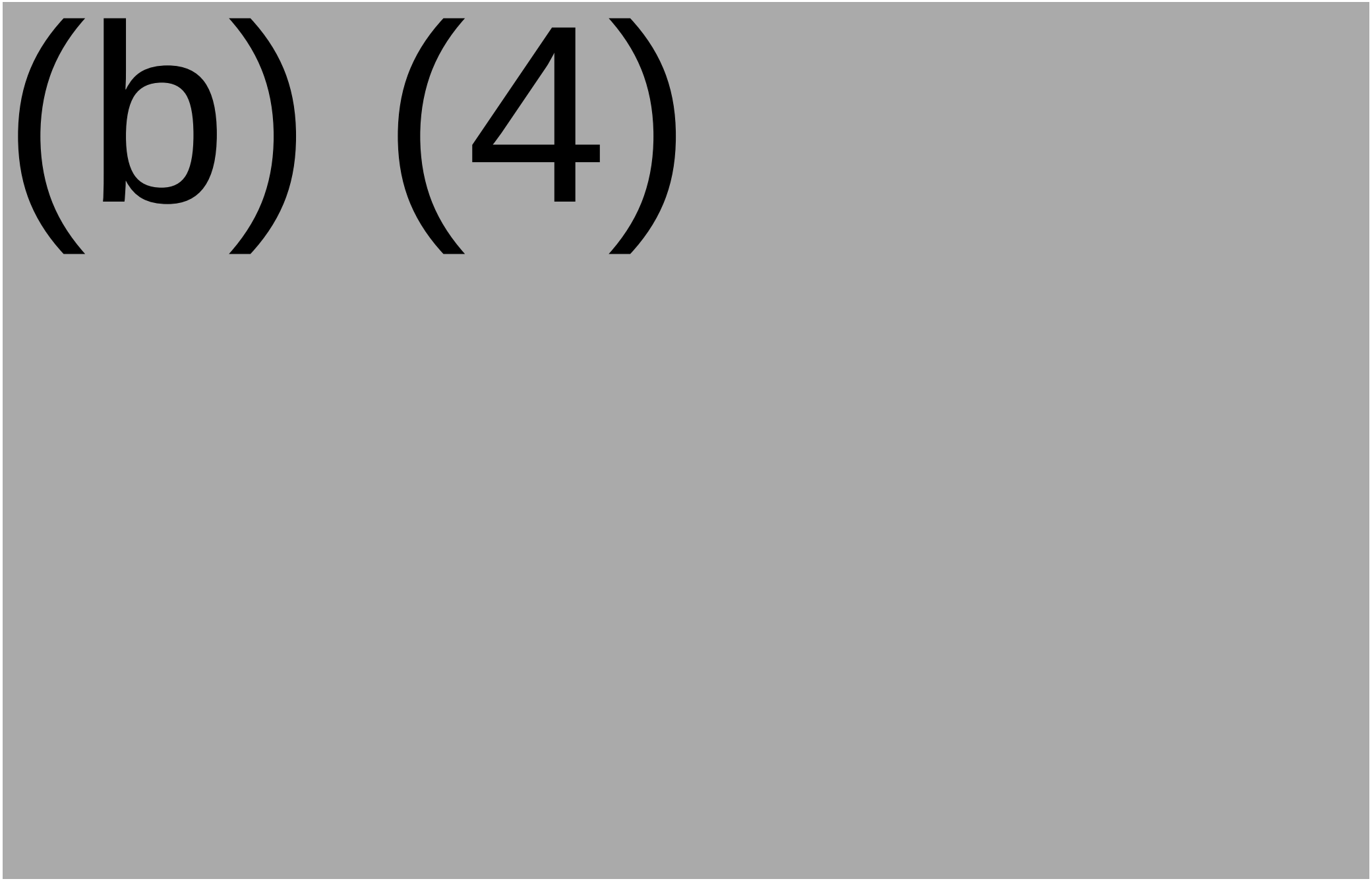
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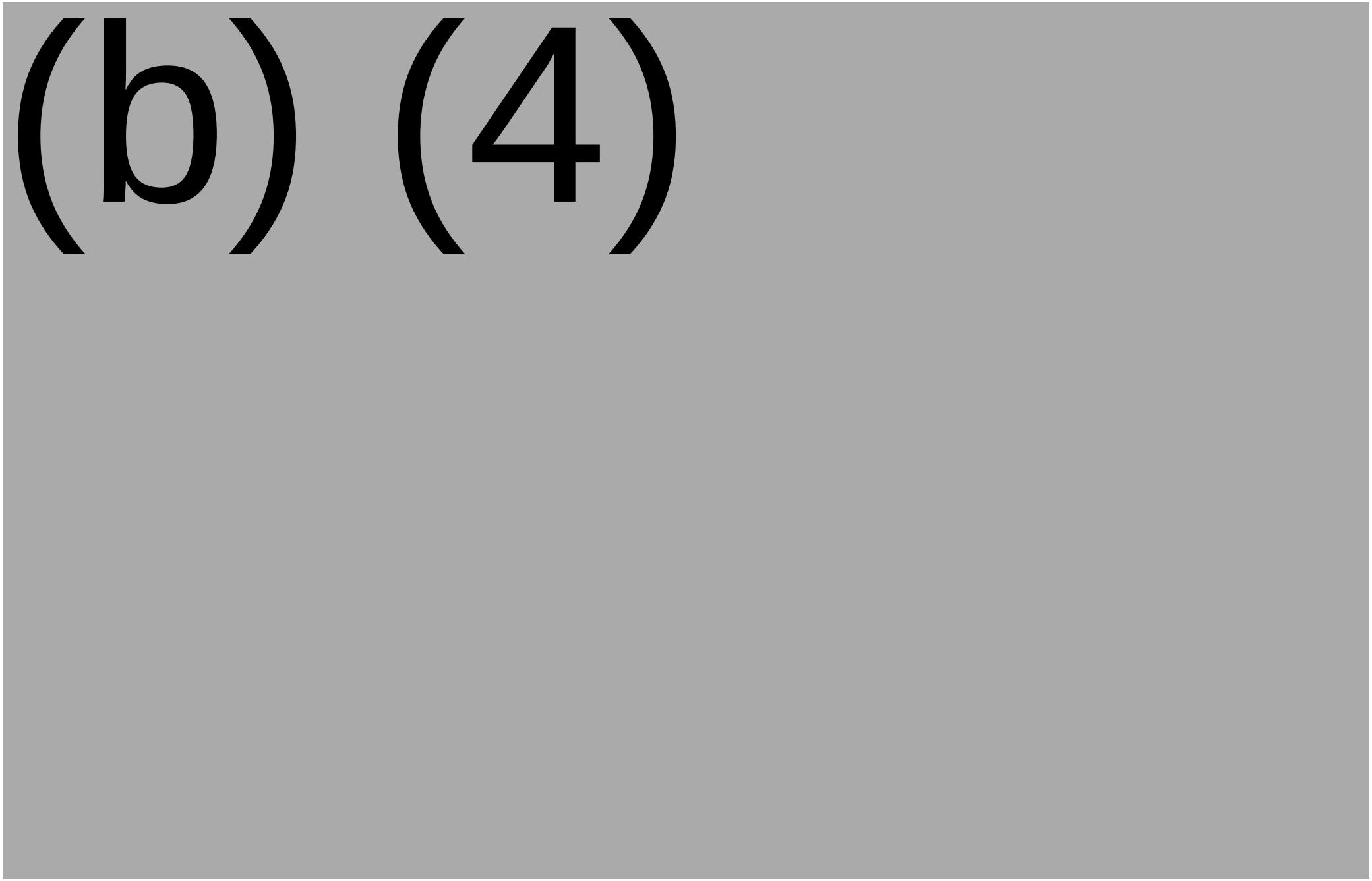
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11. ATTACHMENTS

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Swedish Match®

General Snus® Patterns of Use Study

Wave 4 Technical Report – DRAFT

Swedish Match North America Protocol Number: SMU 19-01 GENS

(b) (4) Protocol Number: 161103844

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Document Version | Date Finalized	Version 0.1 | 26 October 2022
Principal Investigator	(b) (4), (b) (6)
Document Author	
Sponsor Contact	Tryggve Ljung, MD, PhD Vice President Swedish Match AB – Scientific Affairs Phone: (b) (6) Email: (b) (6)

SIGNATURES OF RESPONSIBLE PARTIES

SWEDISH MATCH NORTH AMERICA

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Tryggve Ljung, MD, PhD | Sponsor Signatory
Vice President of Scientific Affairs
(b) (6)

Date Signed

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Brian E. Erkkila, PhD | Sponsor Signatory
Director of Regulatory Science
(b) (6)

Date Signed

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Date Signed

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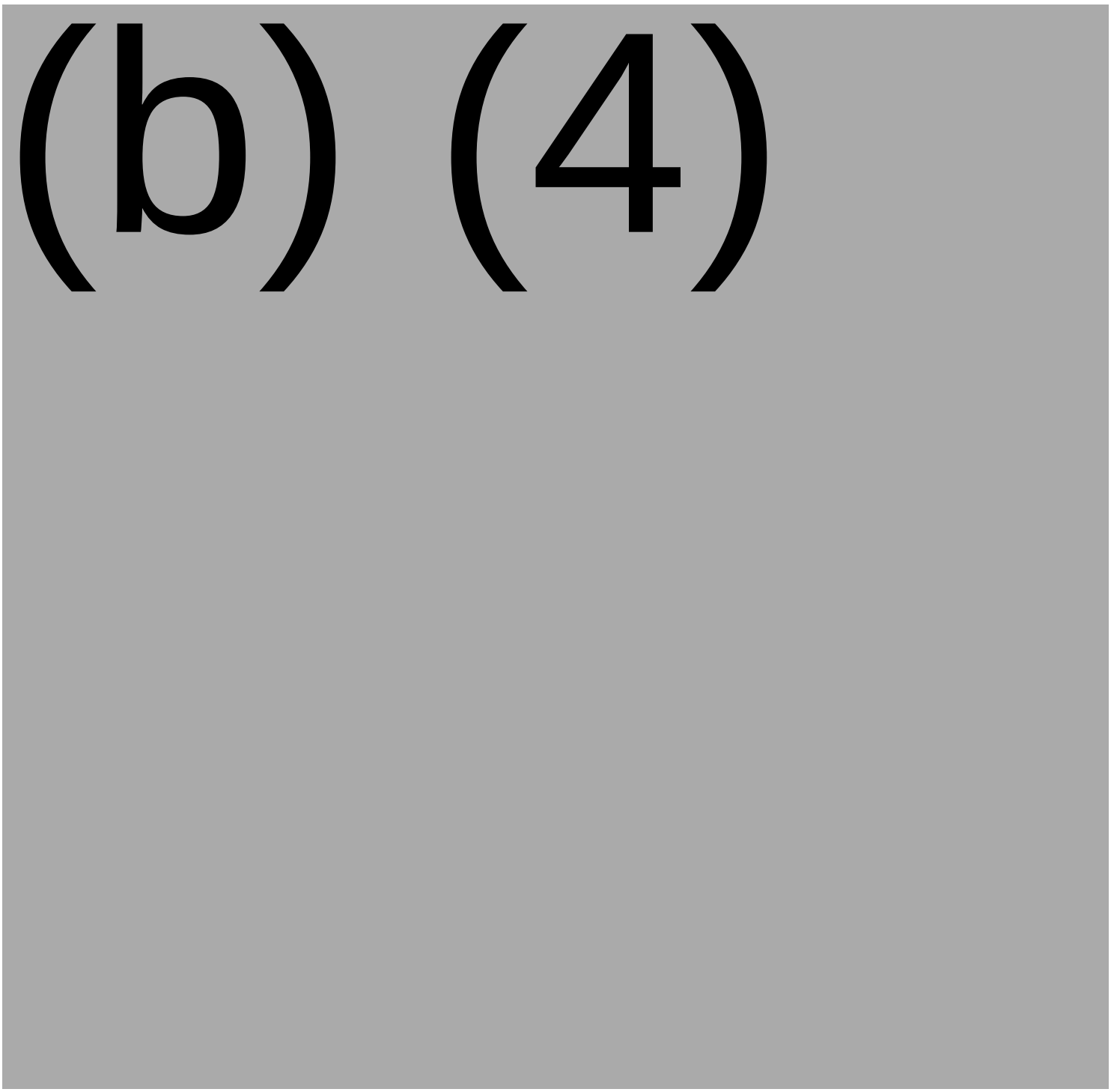
Date Signed

EXECUTIVE SUMMARY



(b) (4) PROJECT TEAM

Project Team Member	Responsibility
(b) (4)	Principal Investigator
Associate Principal Research Consultant	Research Director
(b) (4), (b) (6)	Research Advisor
Research Scientist	Medical Writer
(b) (4), (b) (6)	Statistics Advisor
Biostatistician	Data Analysis
(b) (4), (b) (6)	Statistics Advisor
Senior Biostatistician	Data Analysis
(b) (4), (b) (6)	Document Management
Research Manager	Quality Assurance
(b) (4)	Engagement Services
General Managing Director	Research Operations
(b) (4), (b) (6)	Research Advisor
(b) (4), (b) (6)	Client Partner

DOCUMENT HISTORY

Document Version	Document Status	Version Date	Reason for and Description of Change	Changed By
(b) (4)				

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

Abbreviation	Definition
FDA	FDA Food and Drug Administration
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
(b) (4)	(b) (4)
(b) (4)	(b) (4)
PMTA	Premarket Tobacco Product Application
SAP	Statistical Analysis Plan
SMNA	Swedish Match North America, LLC
(b) (4)	(b) (4)
U.S.	United States

1. BACKGROUND & RATIONALE

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General* Snus®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General* Snus® a MRTP designation, providing guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on 17 September 2018, and the FDA granted the risk modification order on 22 October 2019. The *General* Snus® Patterns of Use Study (the study) is for post-marketing surveillance reporting following the granted risk modification order.

2. STUDY OBJECTIVES

The overarching research questions for this study were the following:

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2.1 PRIMARY OBJECTIVES

The primary objectives of the study were the following:

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2.2 SECONDARY OBJECTIVES

The secondary objectives of the study were the following:

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3. OVERVIEW OF RESEARCH METHODS

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3.1 INCLUSION CRITERIA

Respondents had to meet each of the following criteria to be included in the study:

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3.2 EXCLUSION CRITERIA

Respondents who met of the following criteria were excluded from the study:

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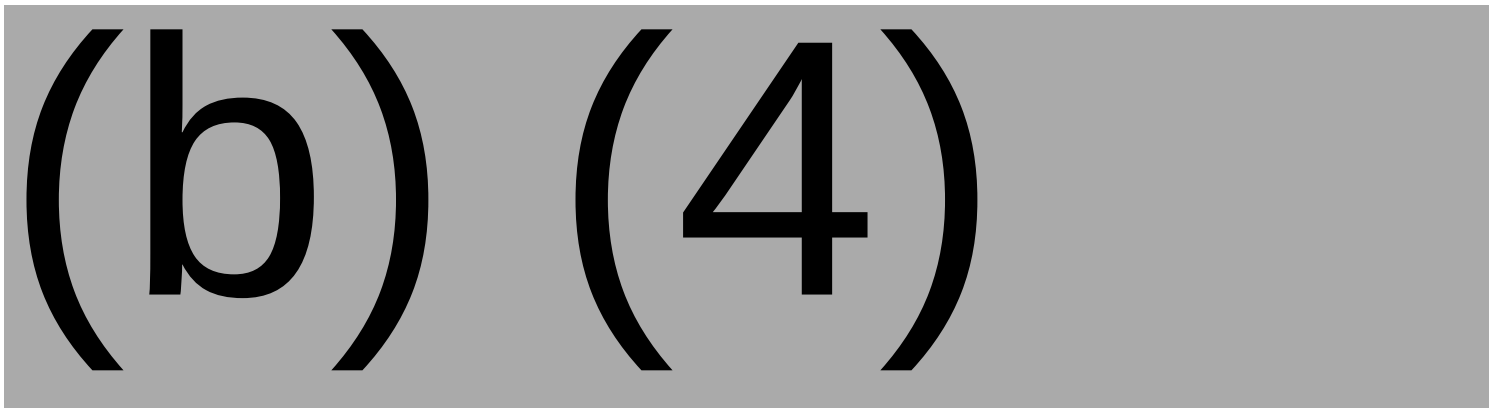
4. OVERVIEW OF ANALYSIS METHODS

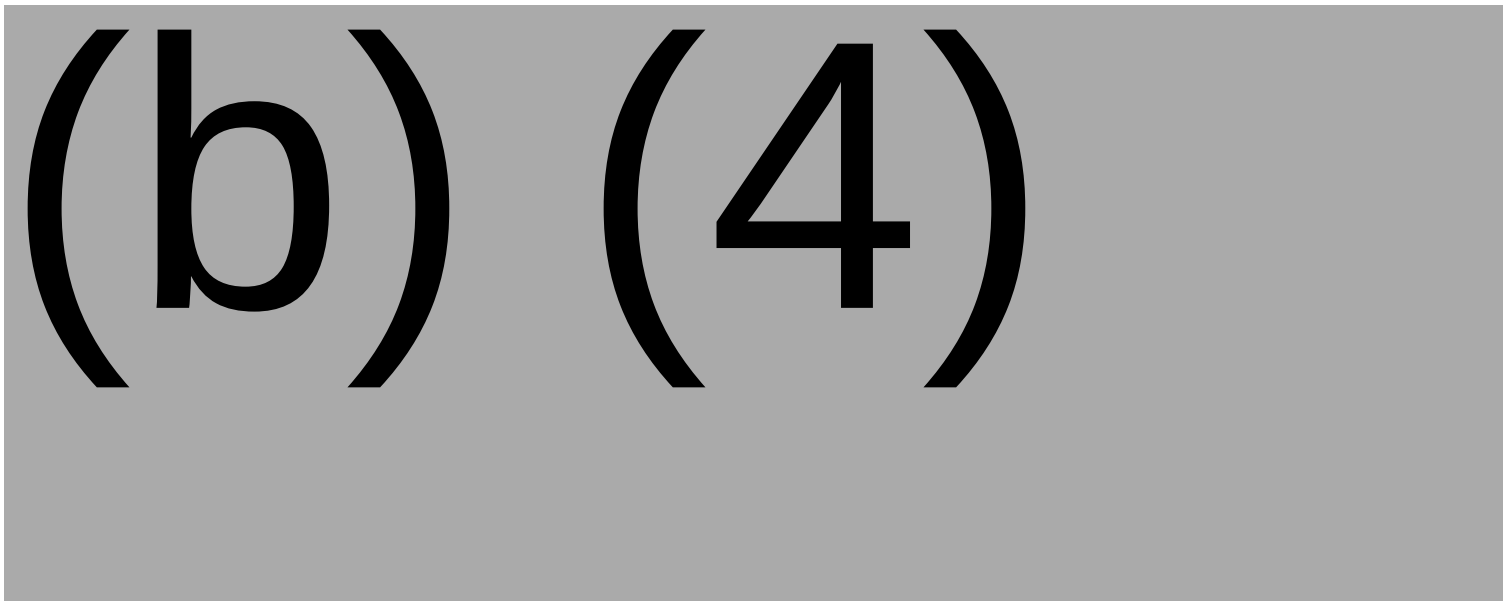


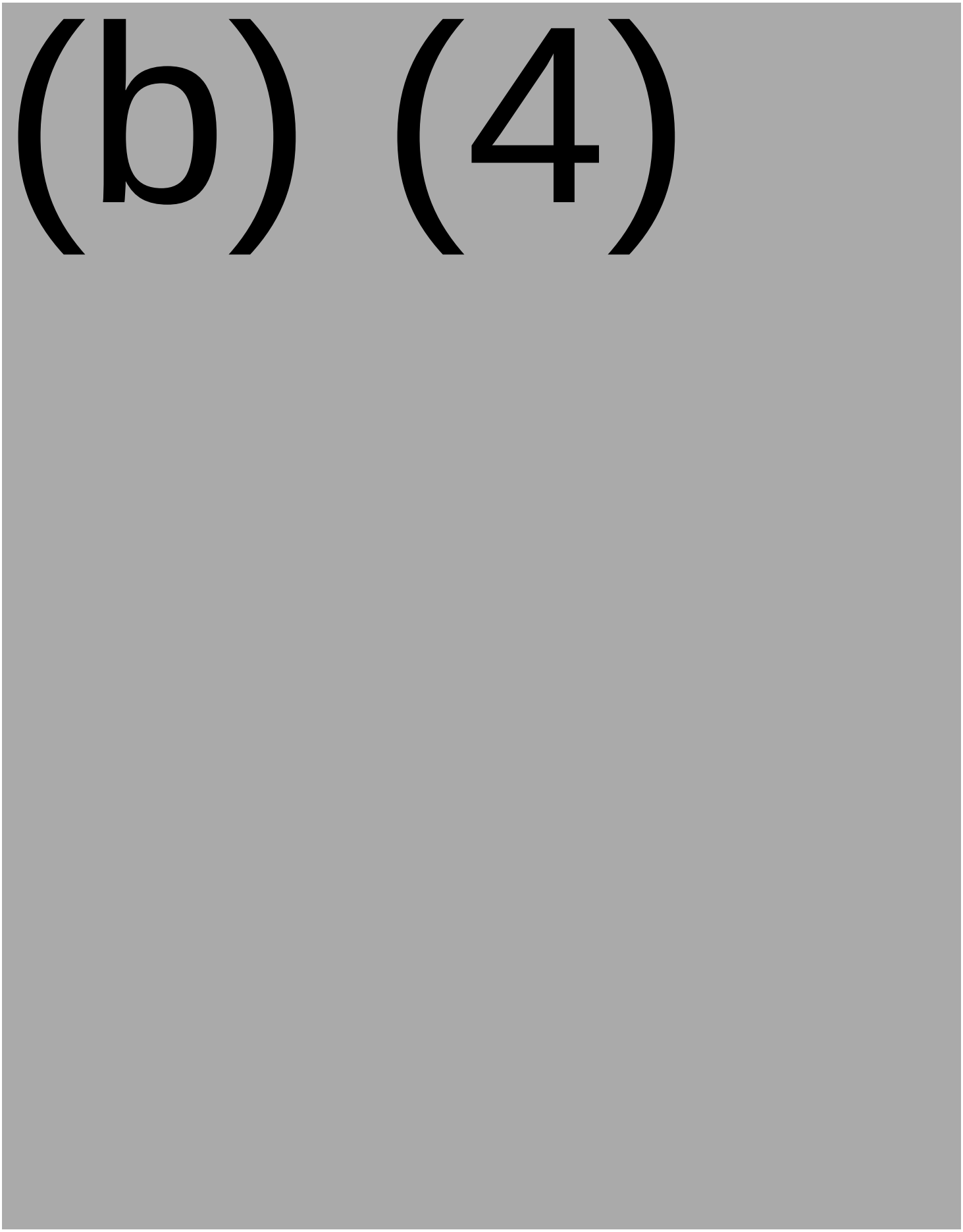
5. WAVE 4 FIELDING SUMMARY

5.1 STUDY FIELDING SUMMARY

6. WAVE 4 STUDY RESULTS

6.1 DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS AT WAVE 4

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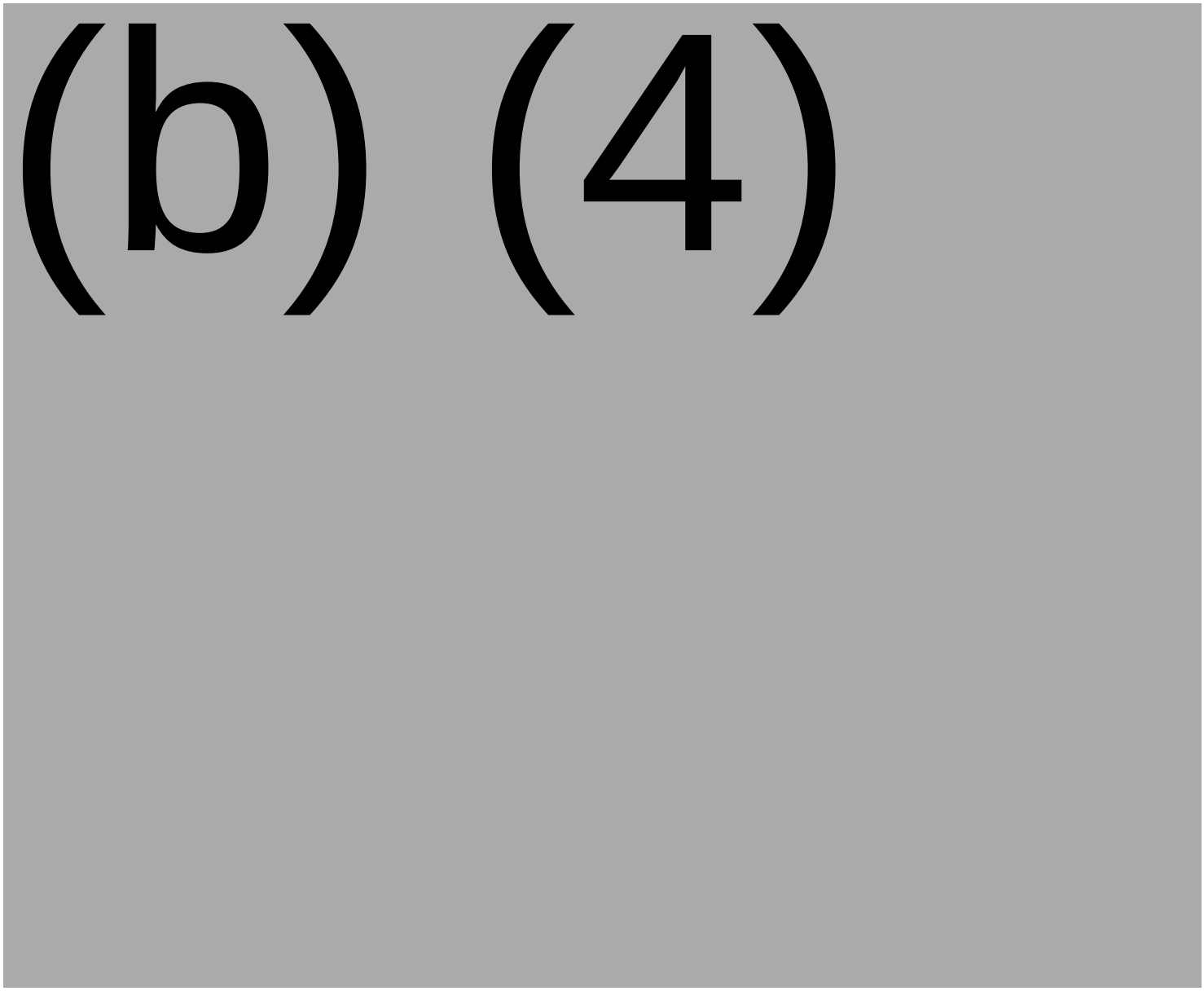
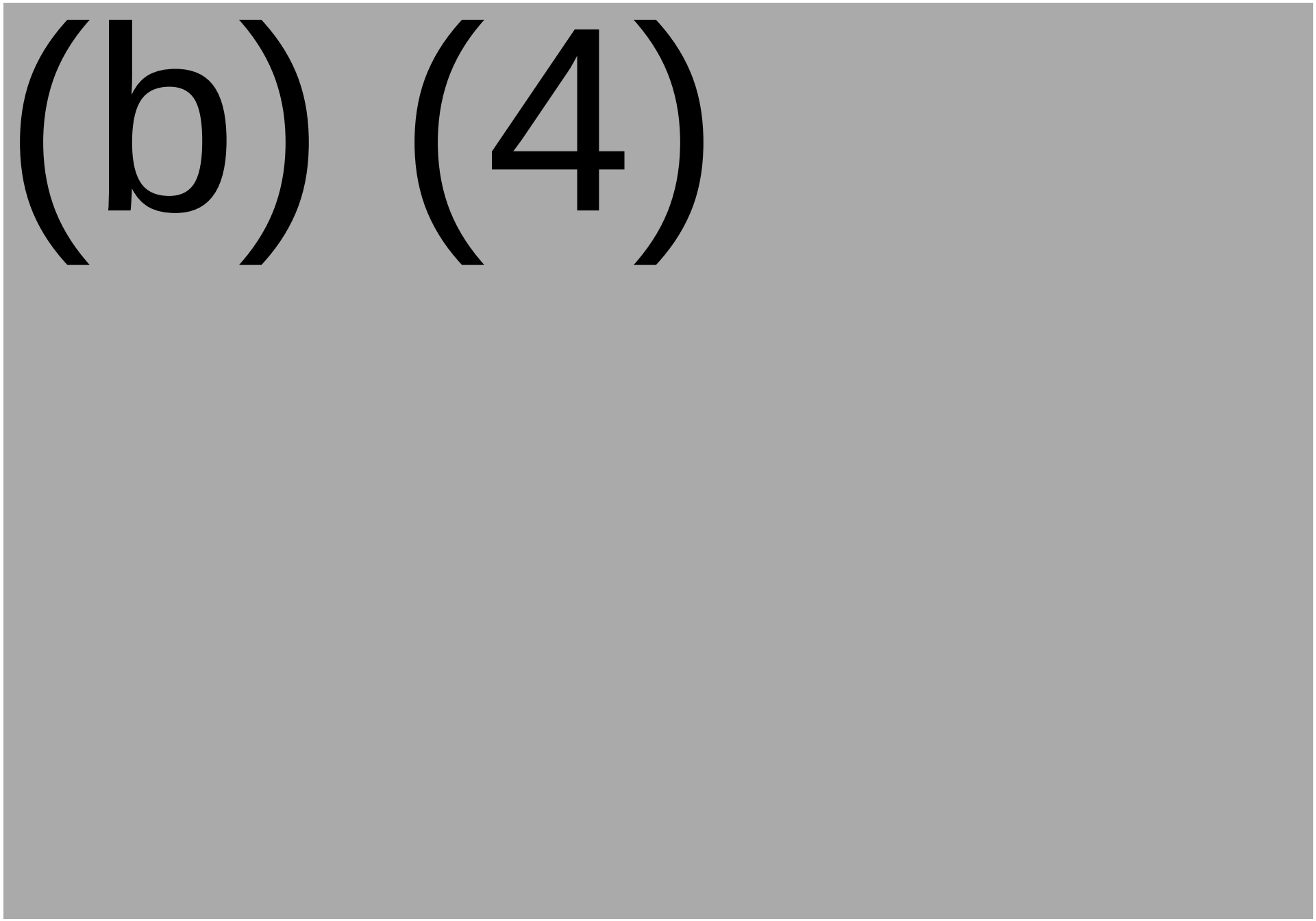
6.2 WAVE 4 RESULTS FOR PRIMARY OBJECTIVES

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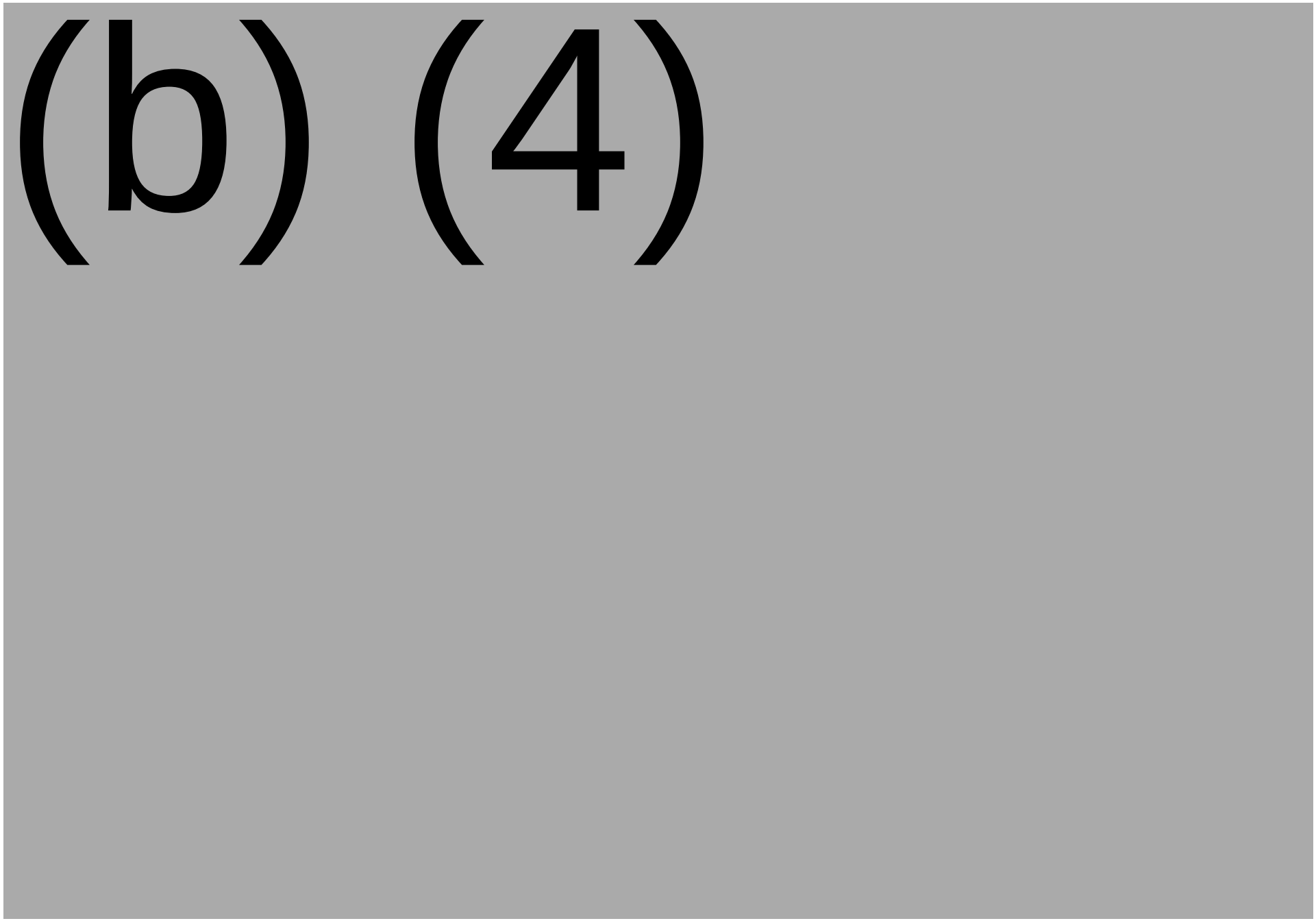
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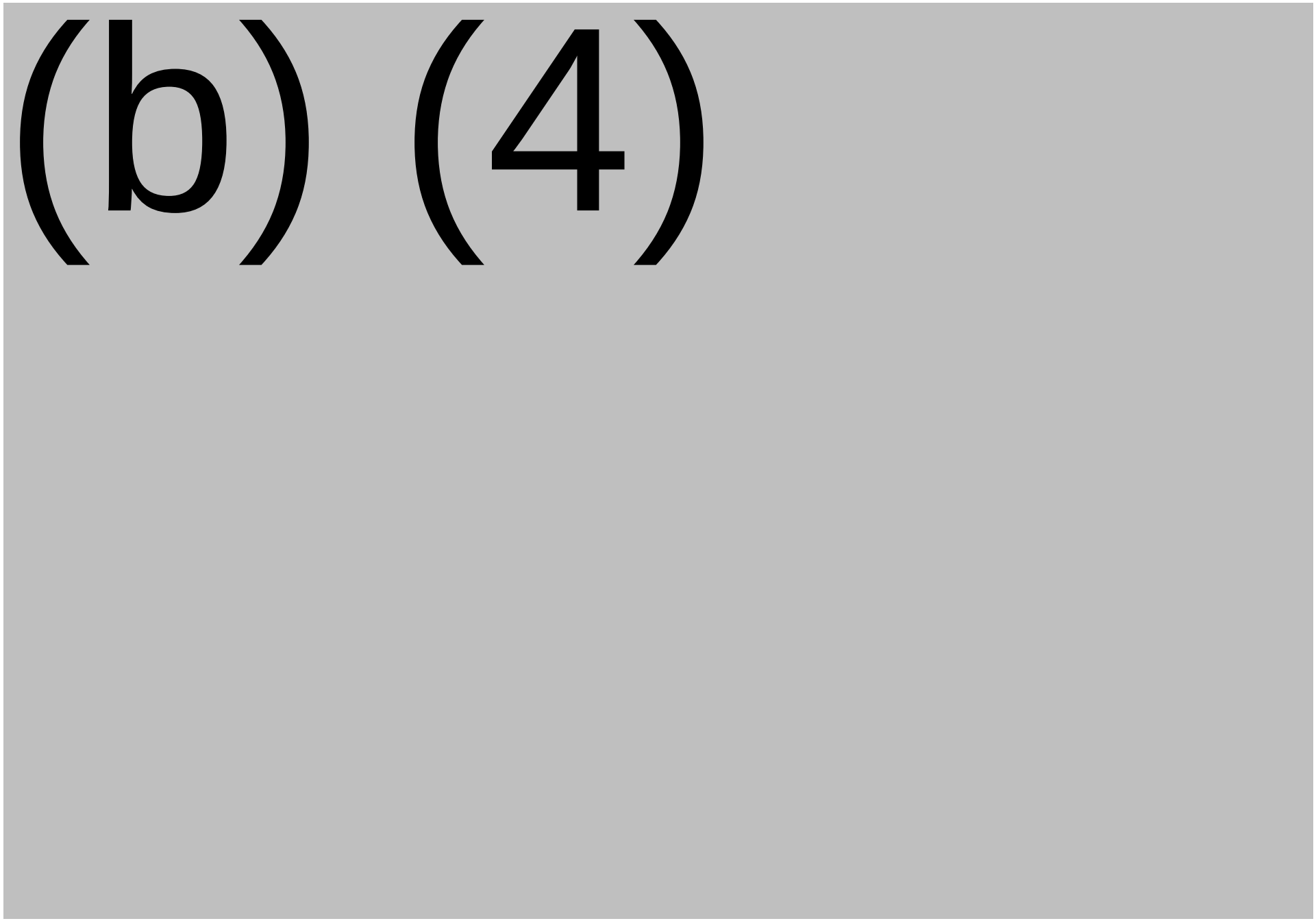
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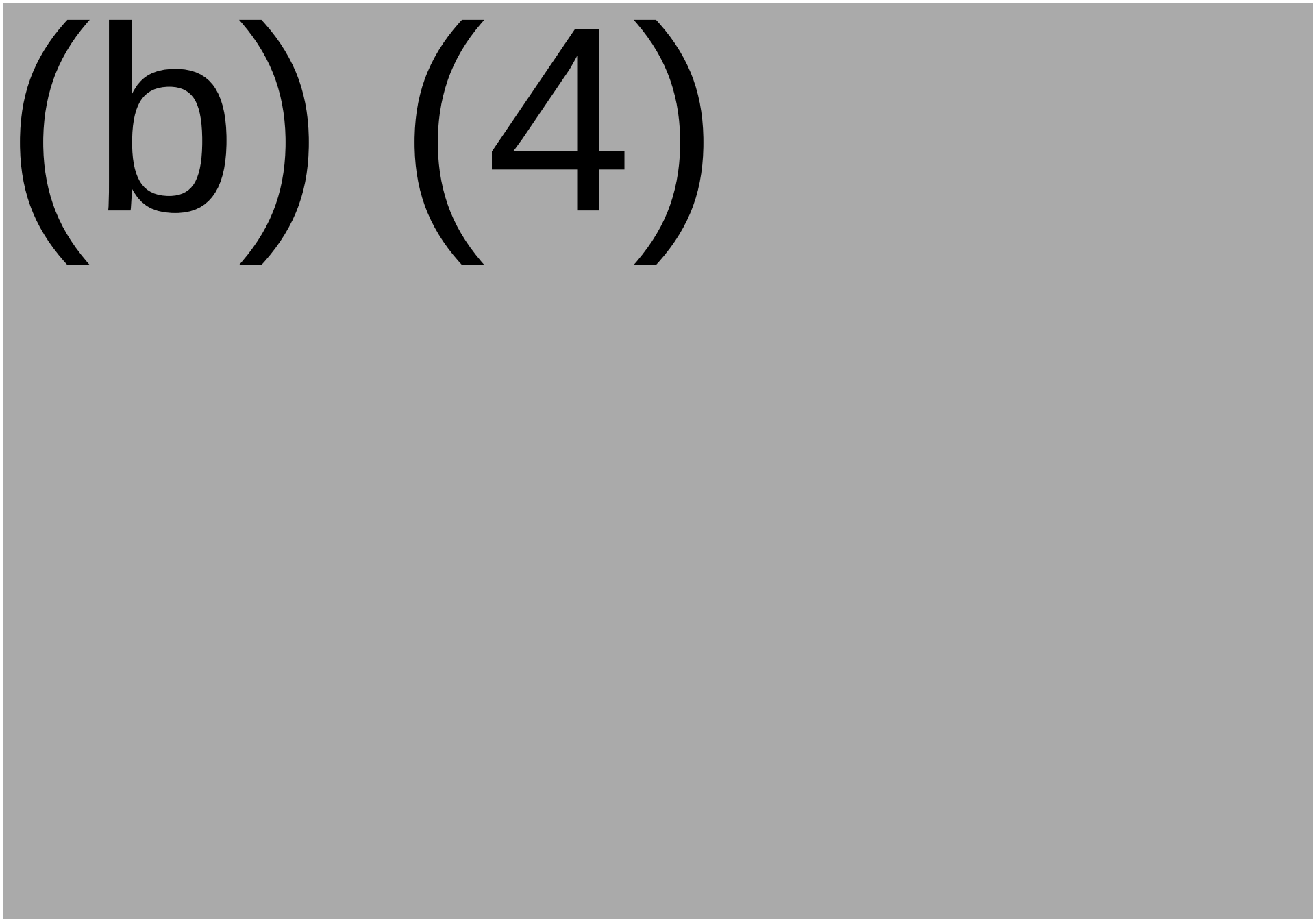
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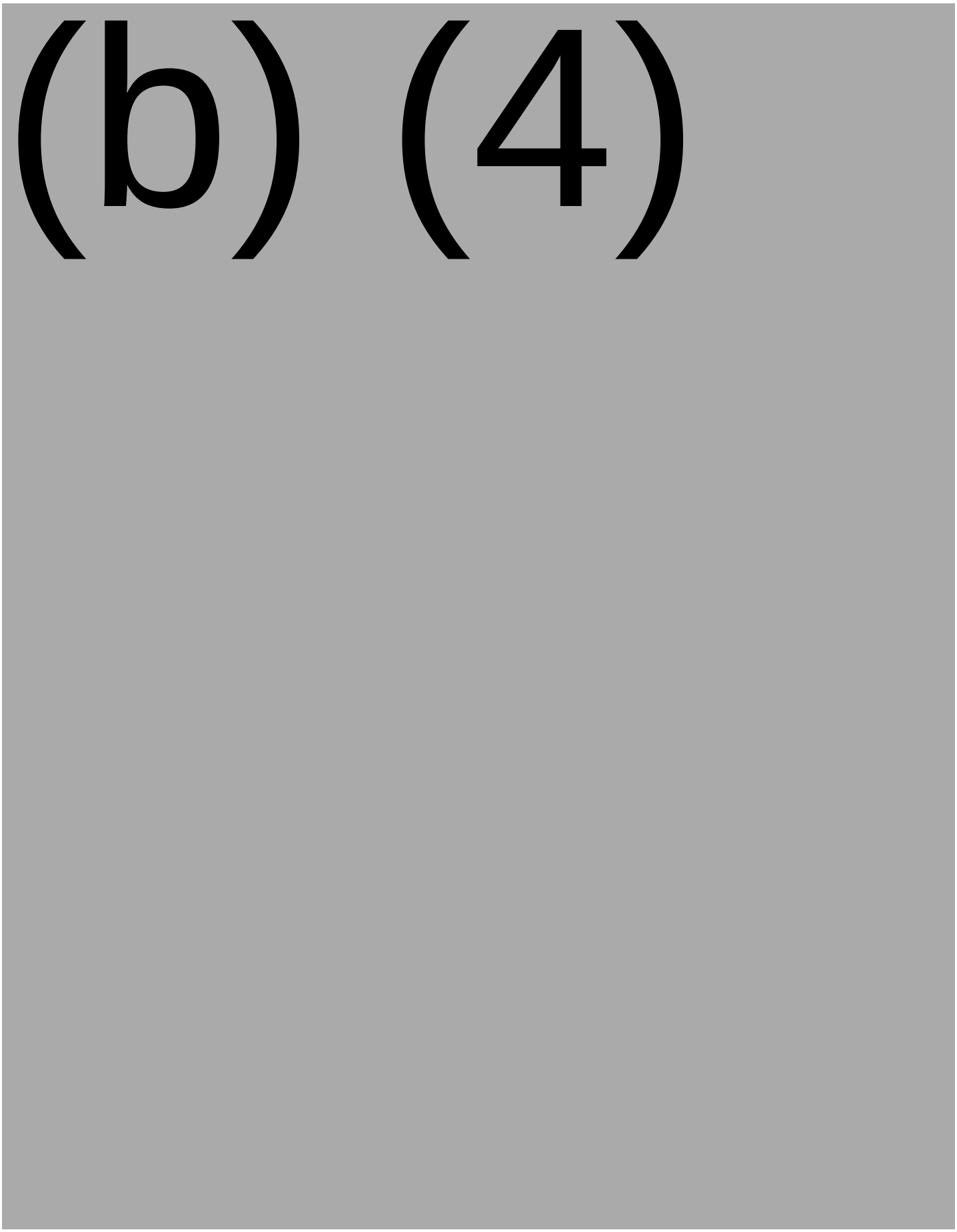
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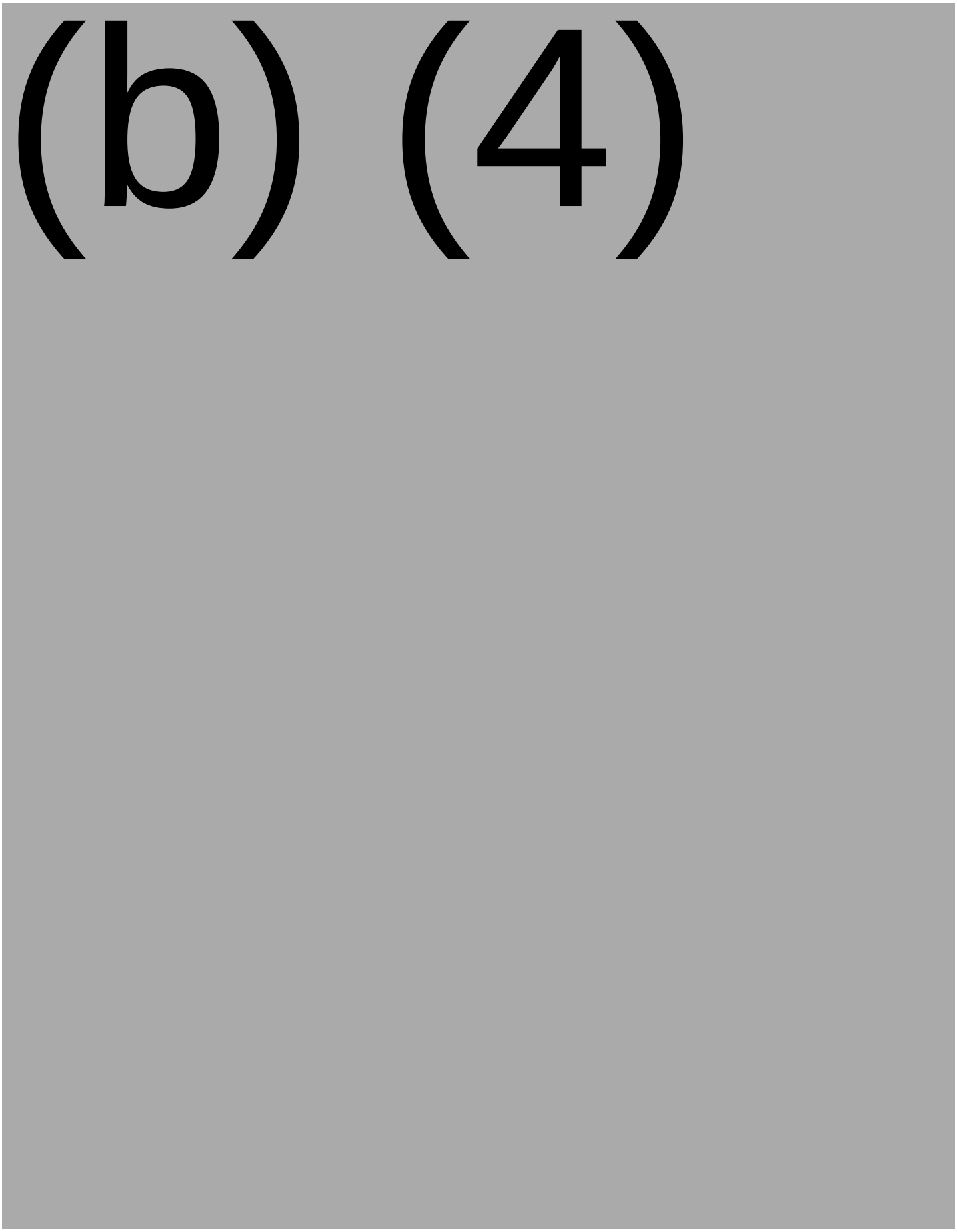
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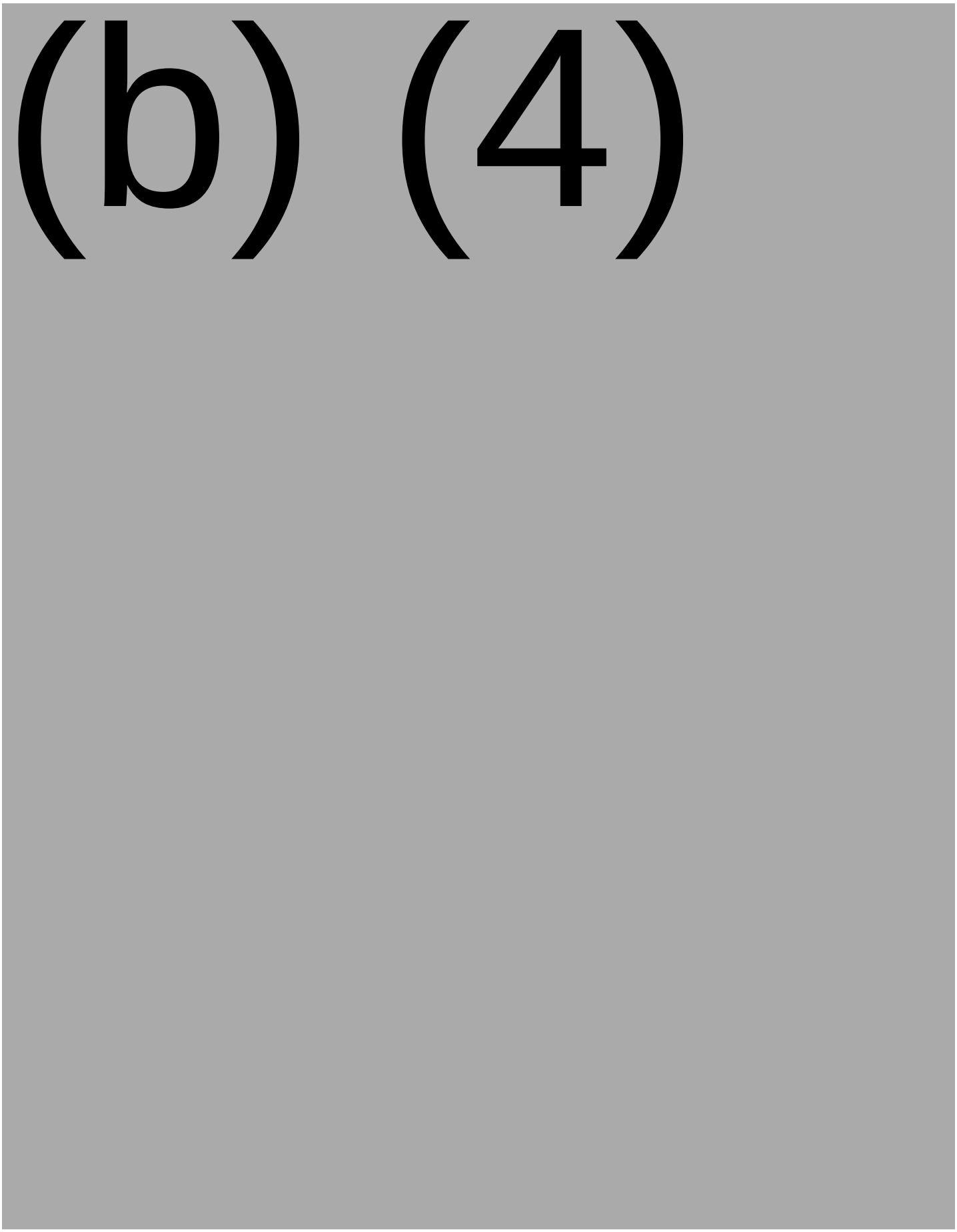
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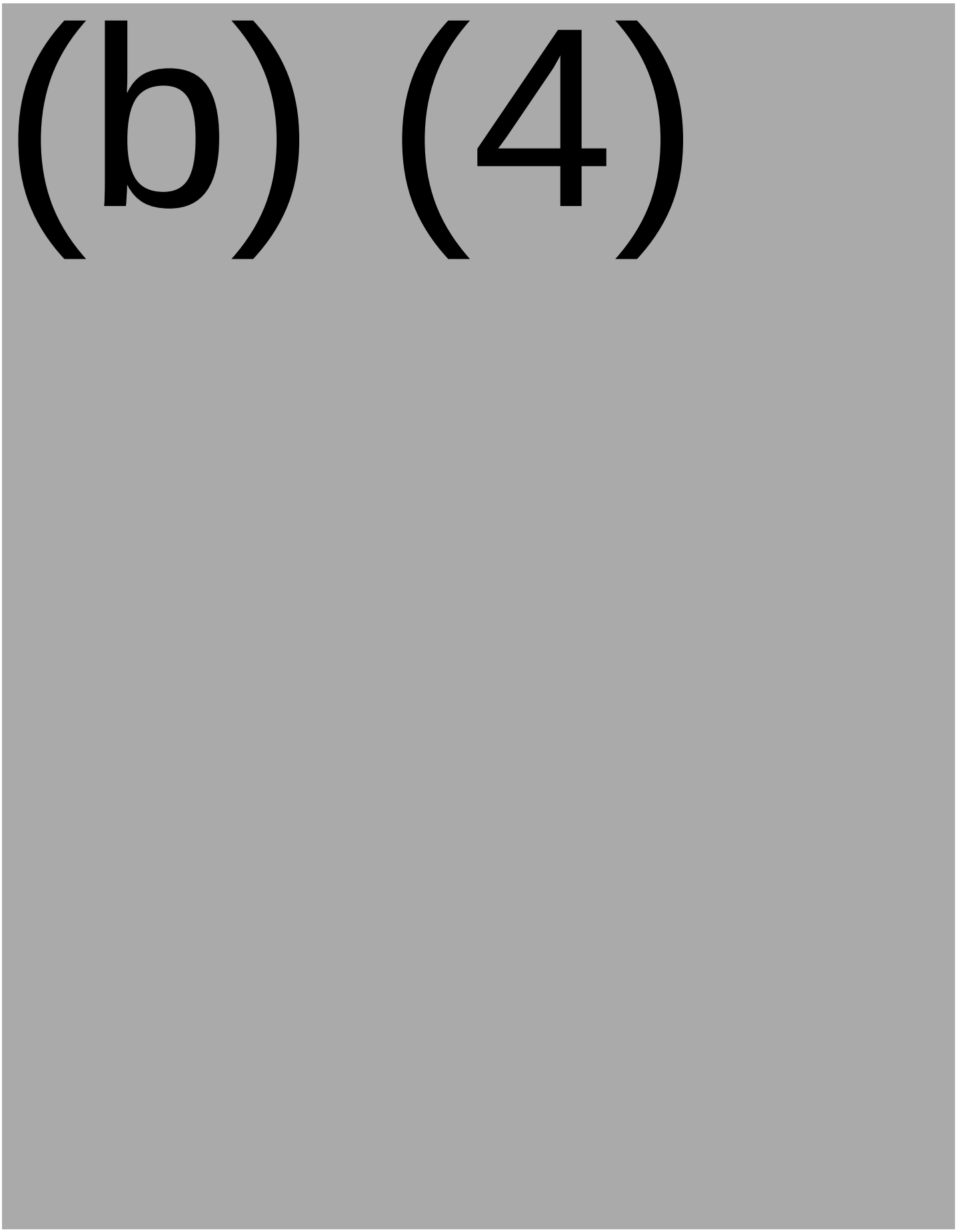
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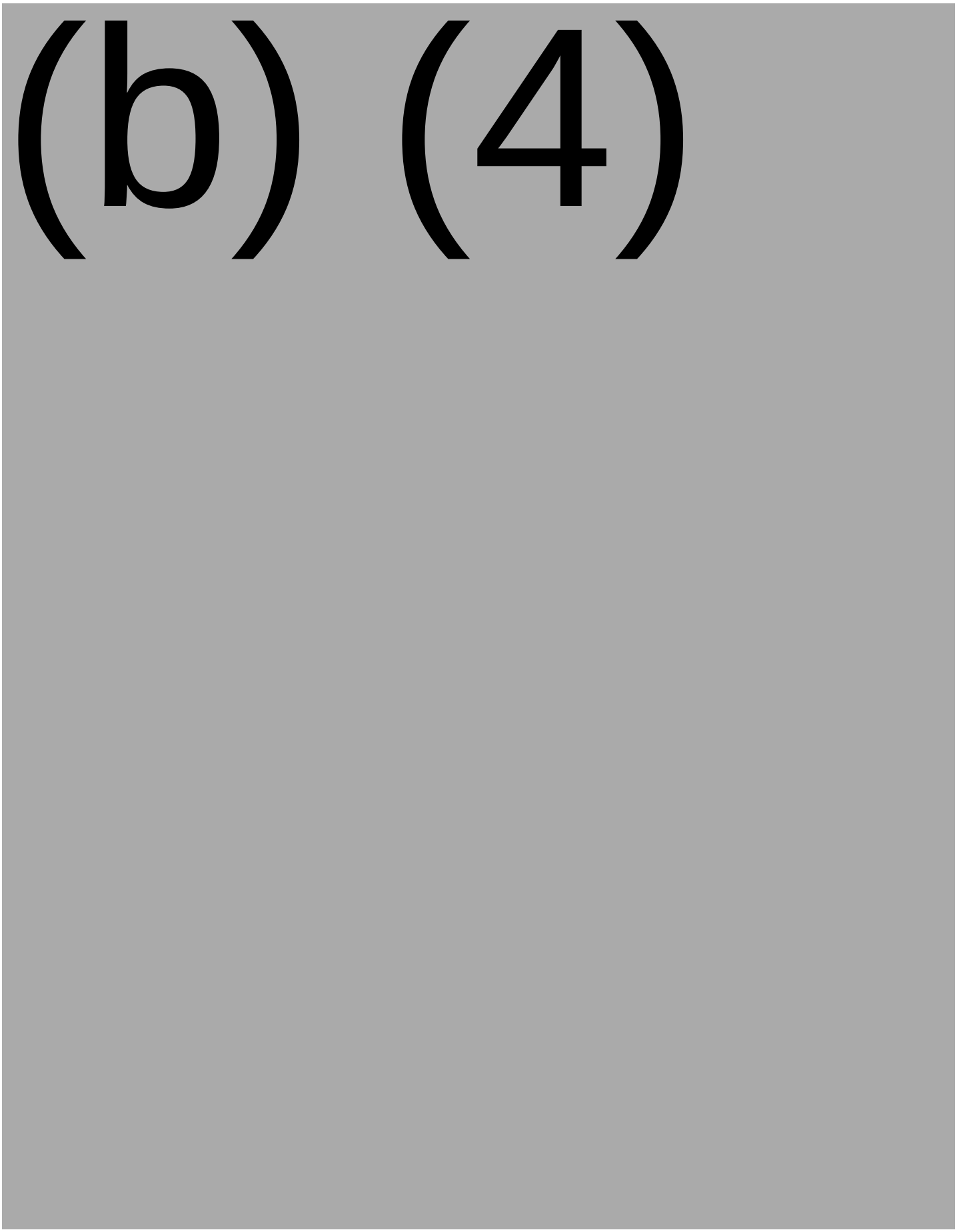
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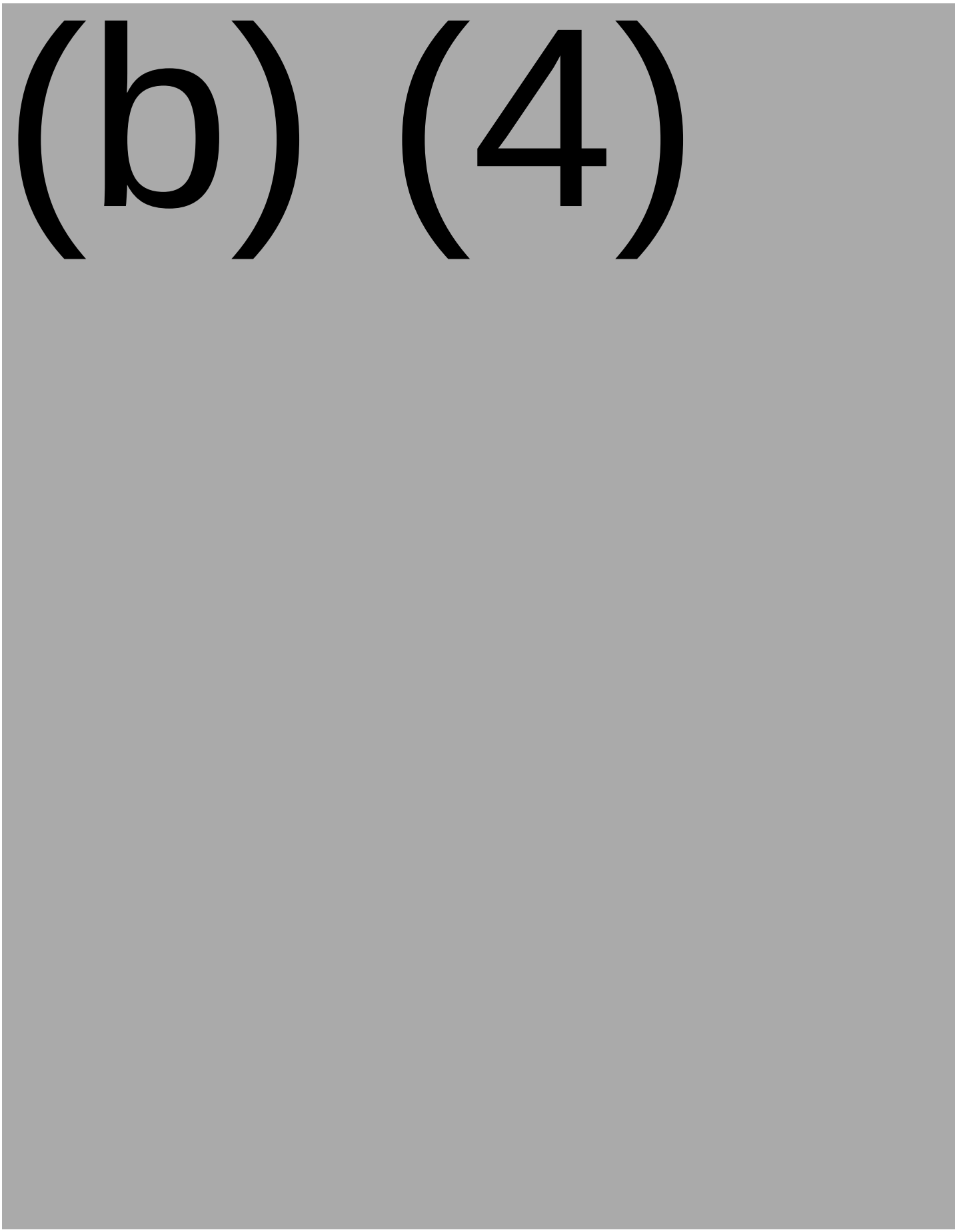
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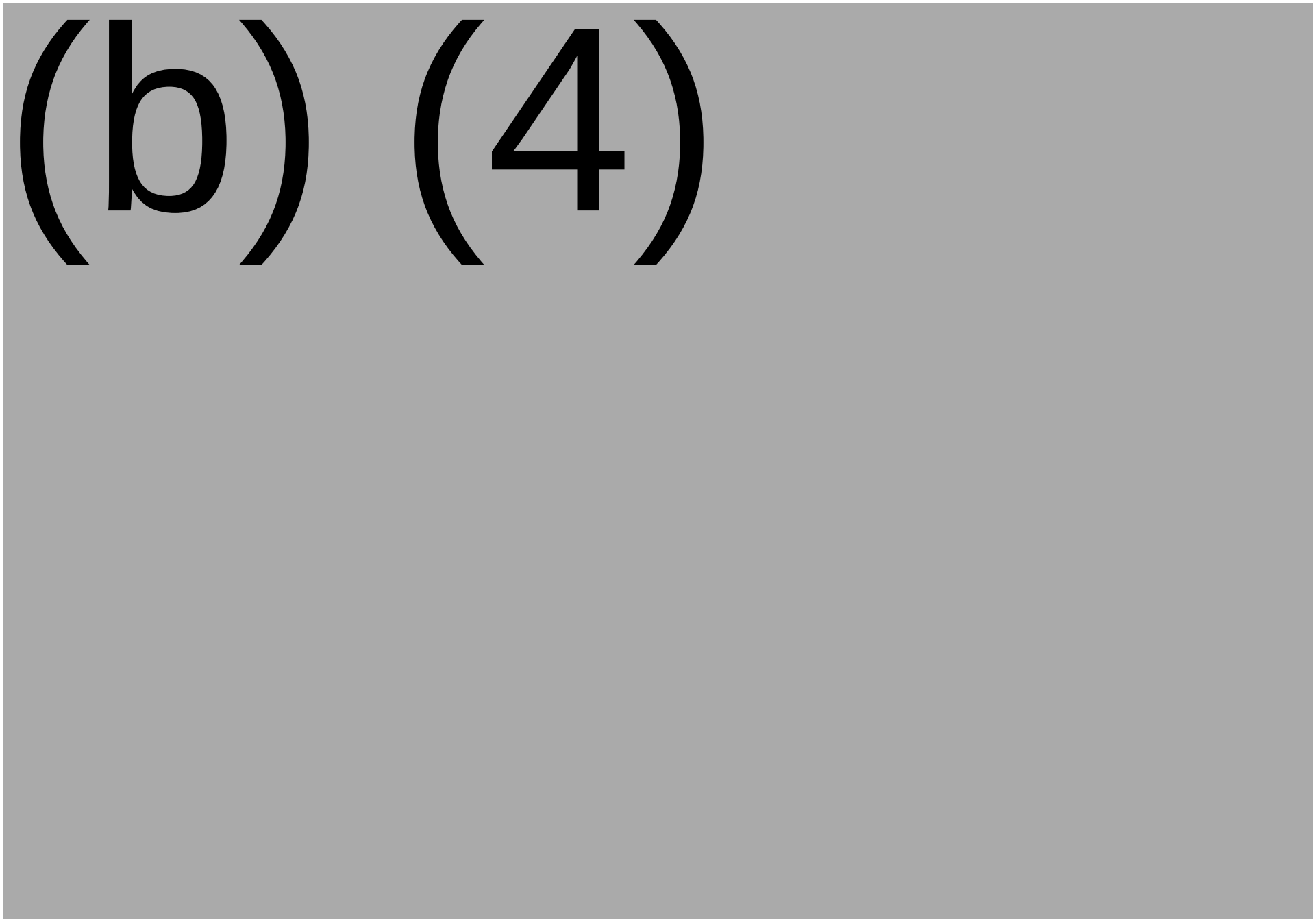
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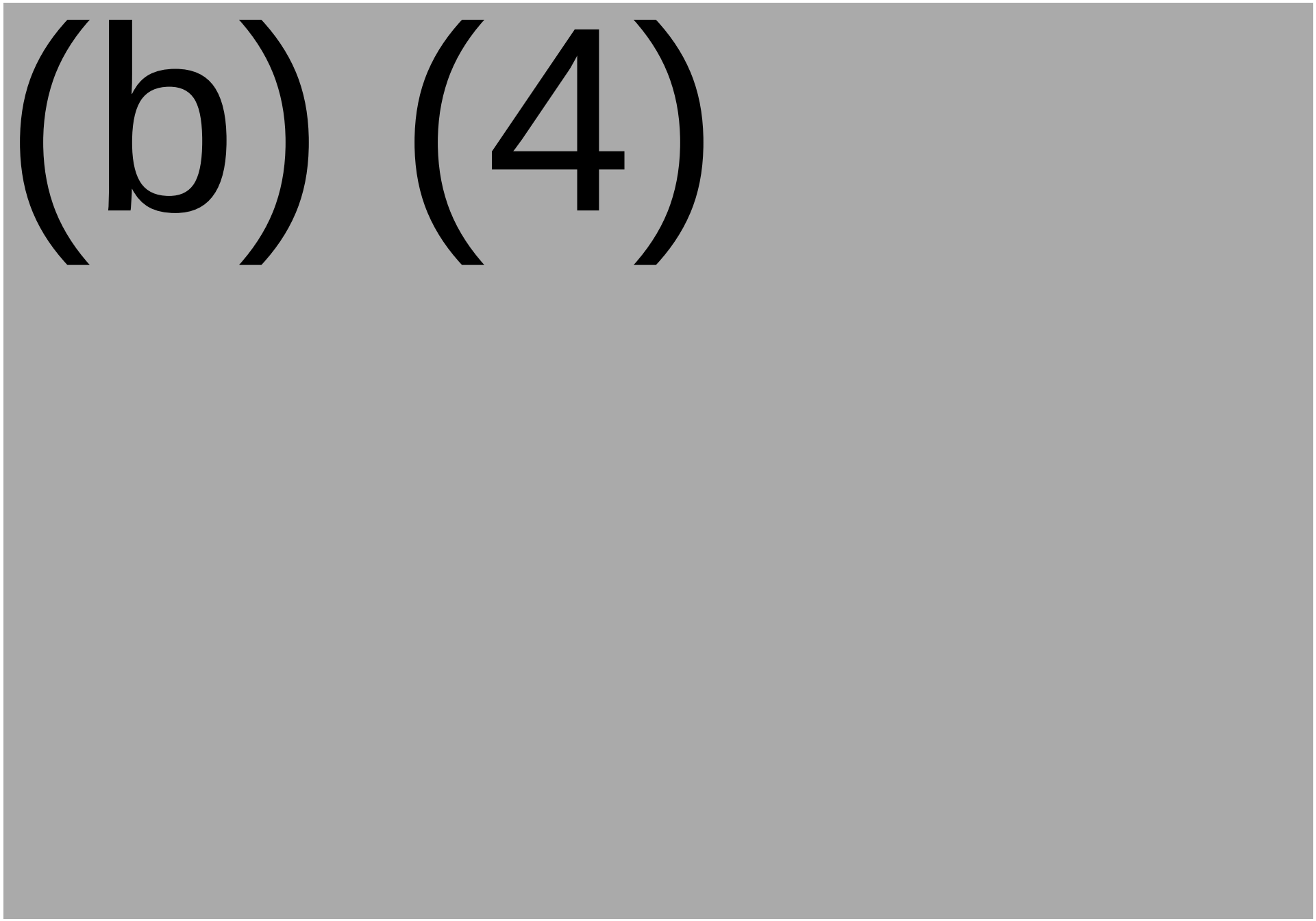
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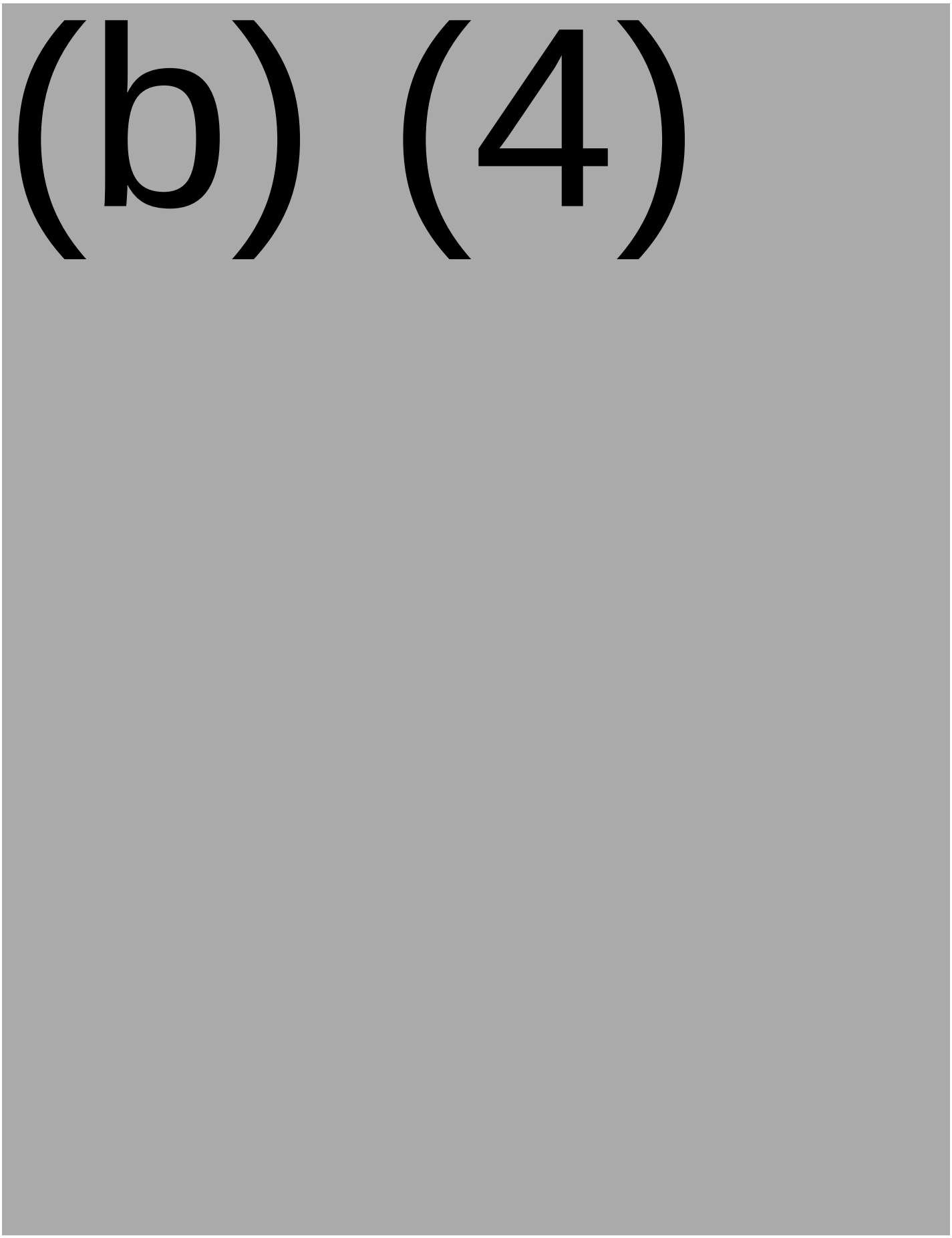
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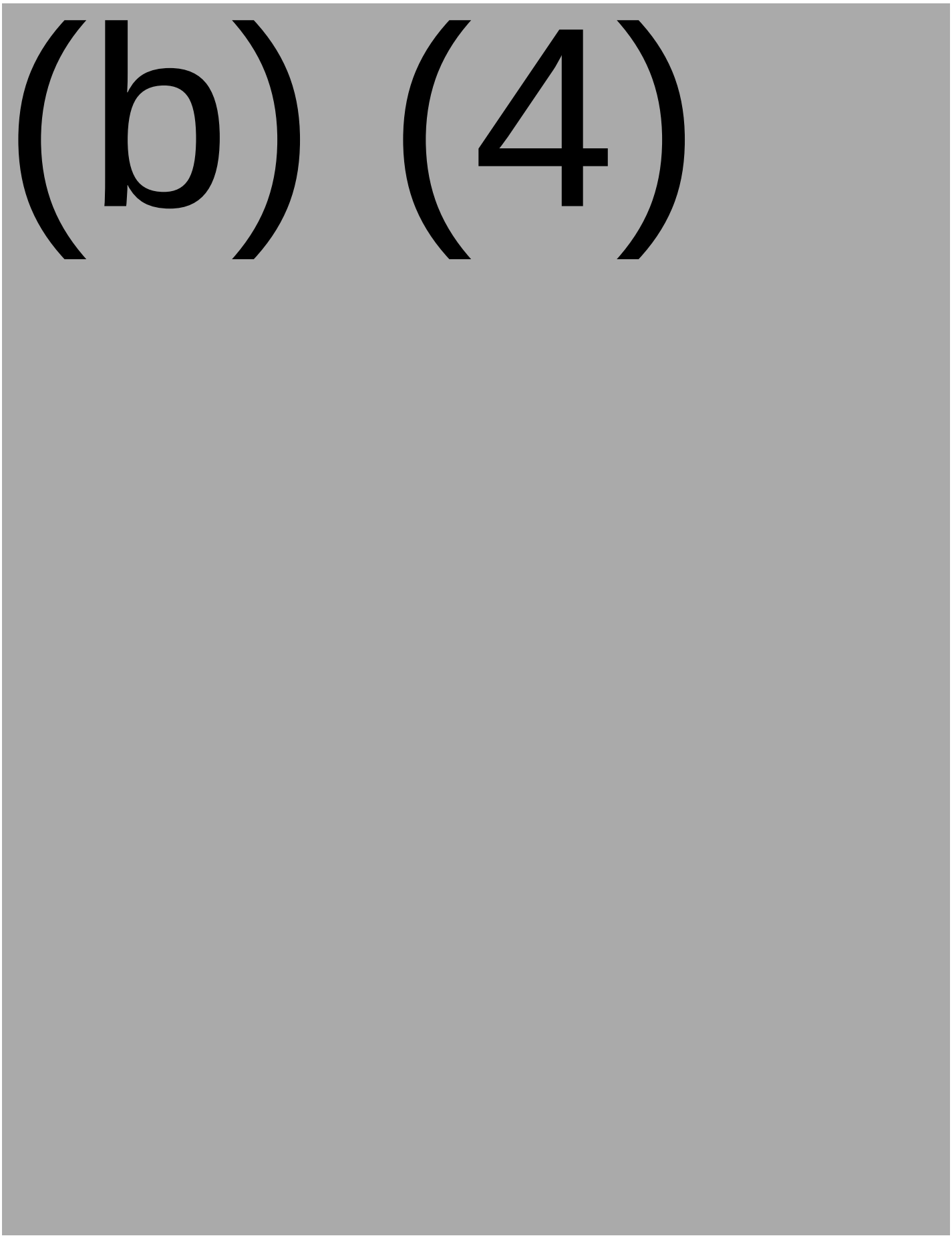
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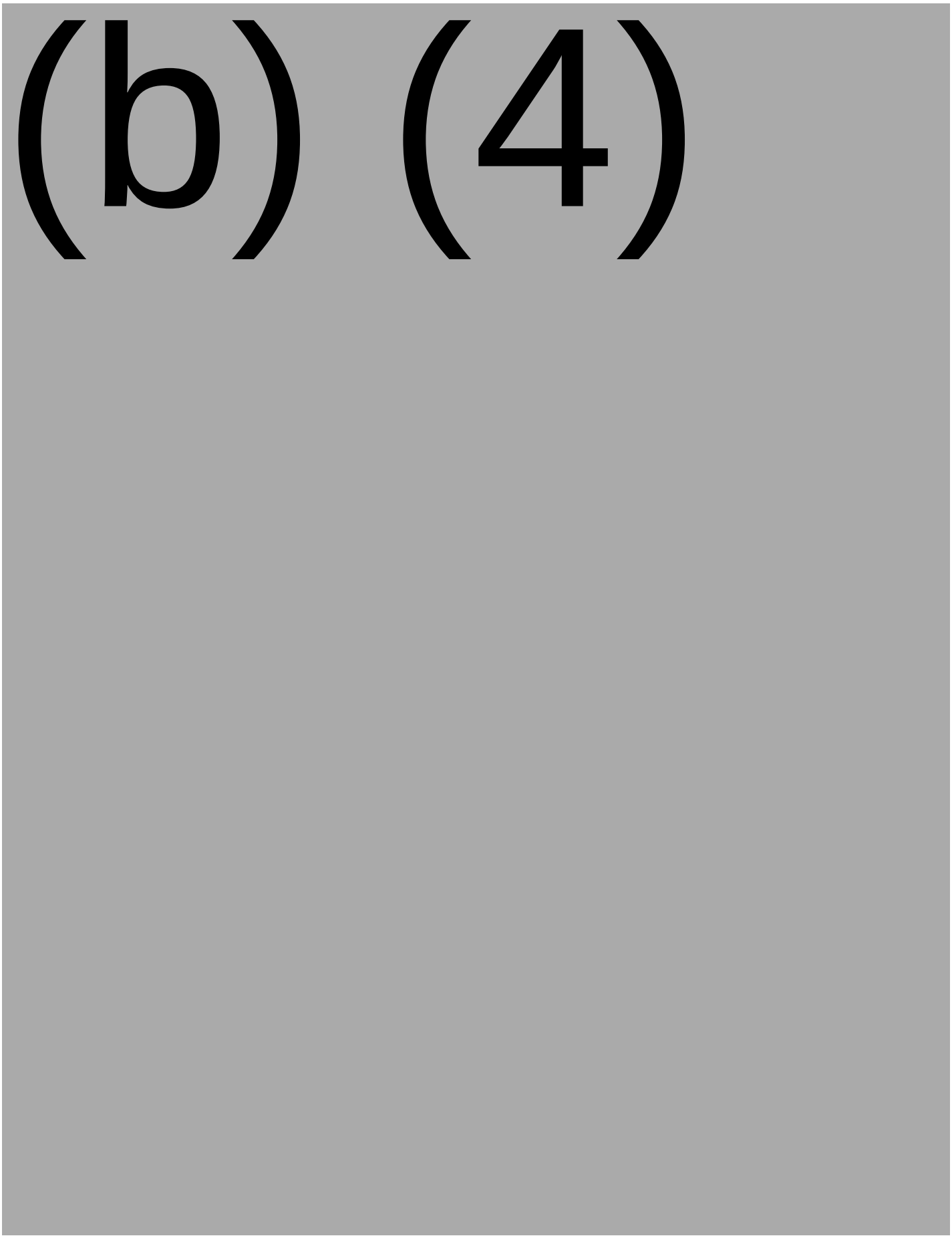
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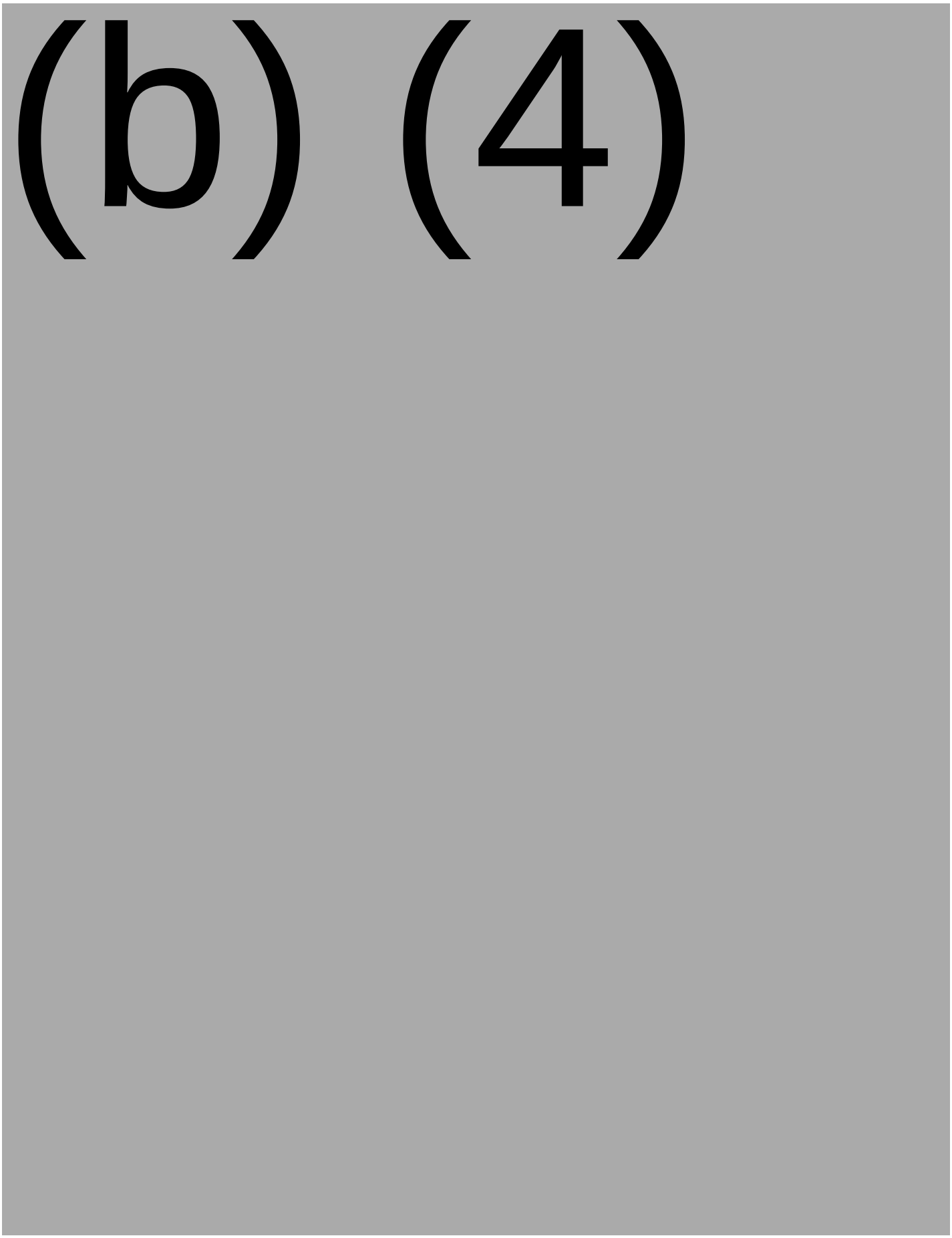
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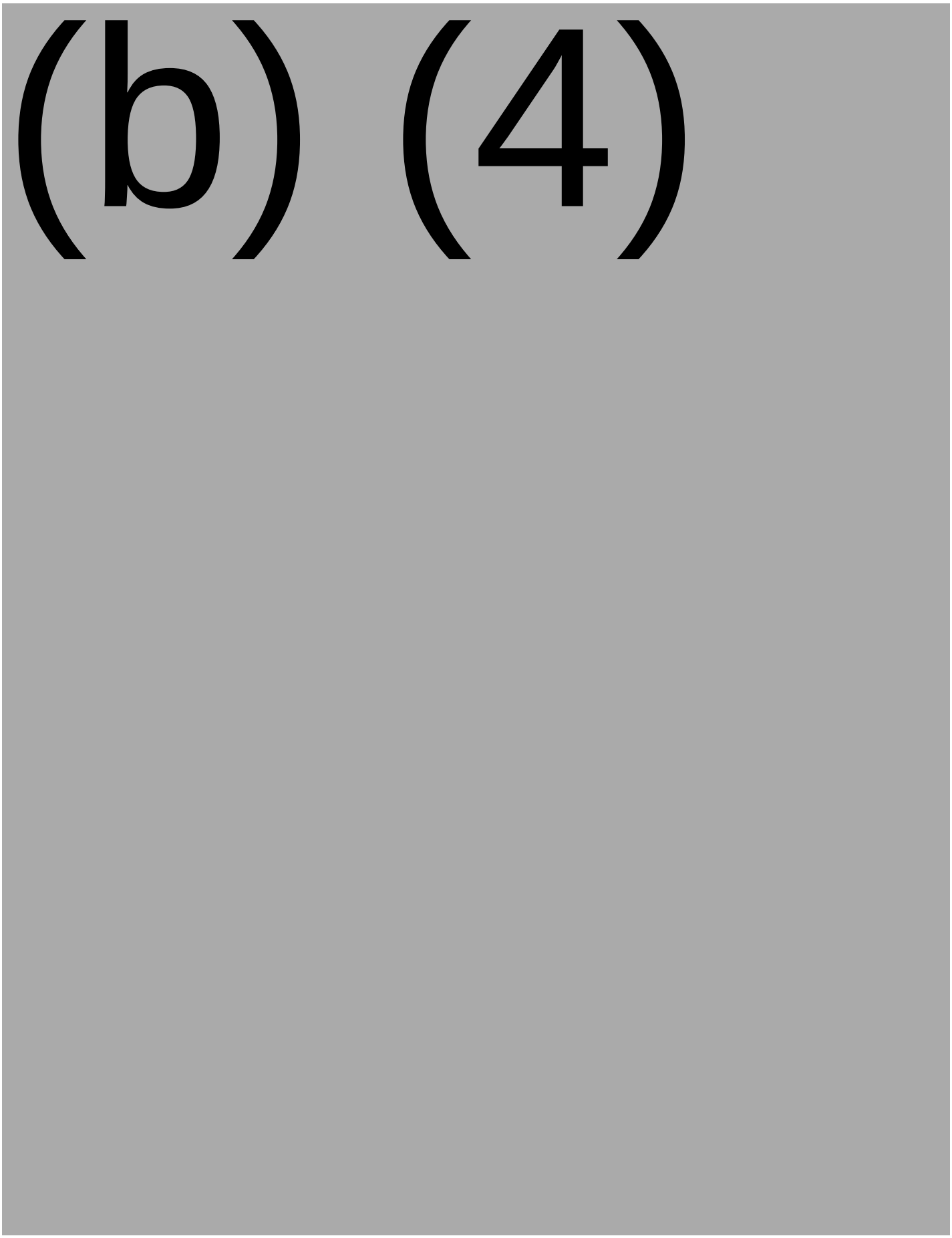
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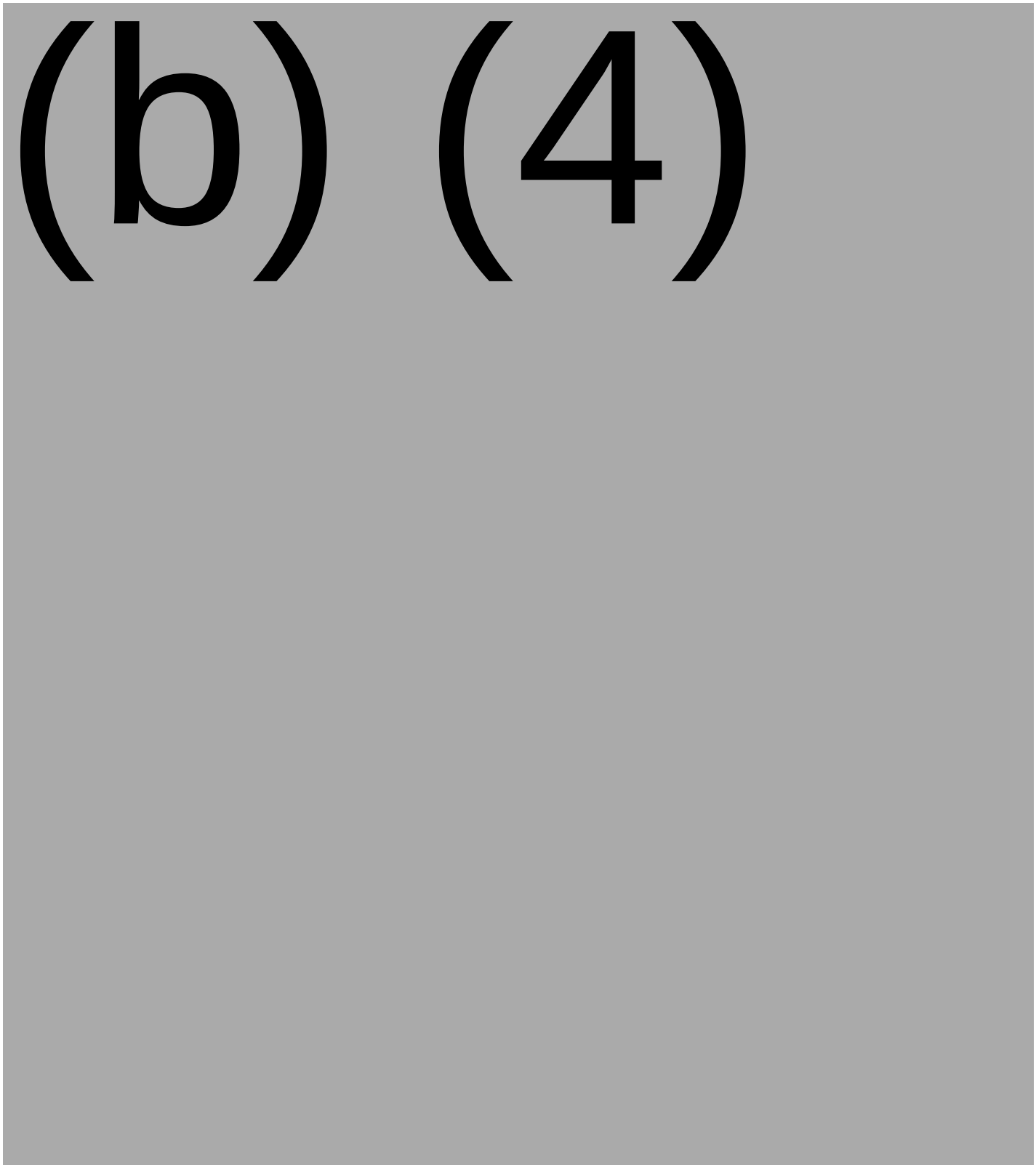
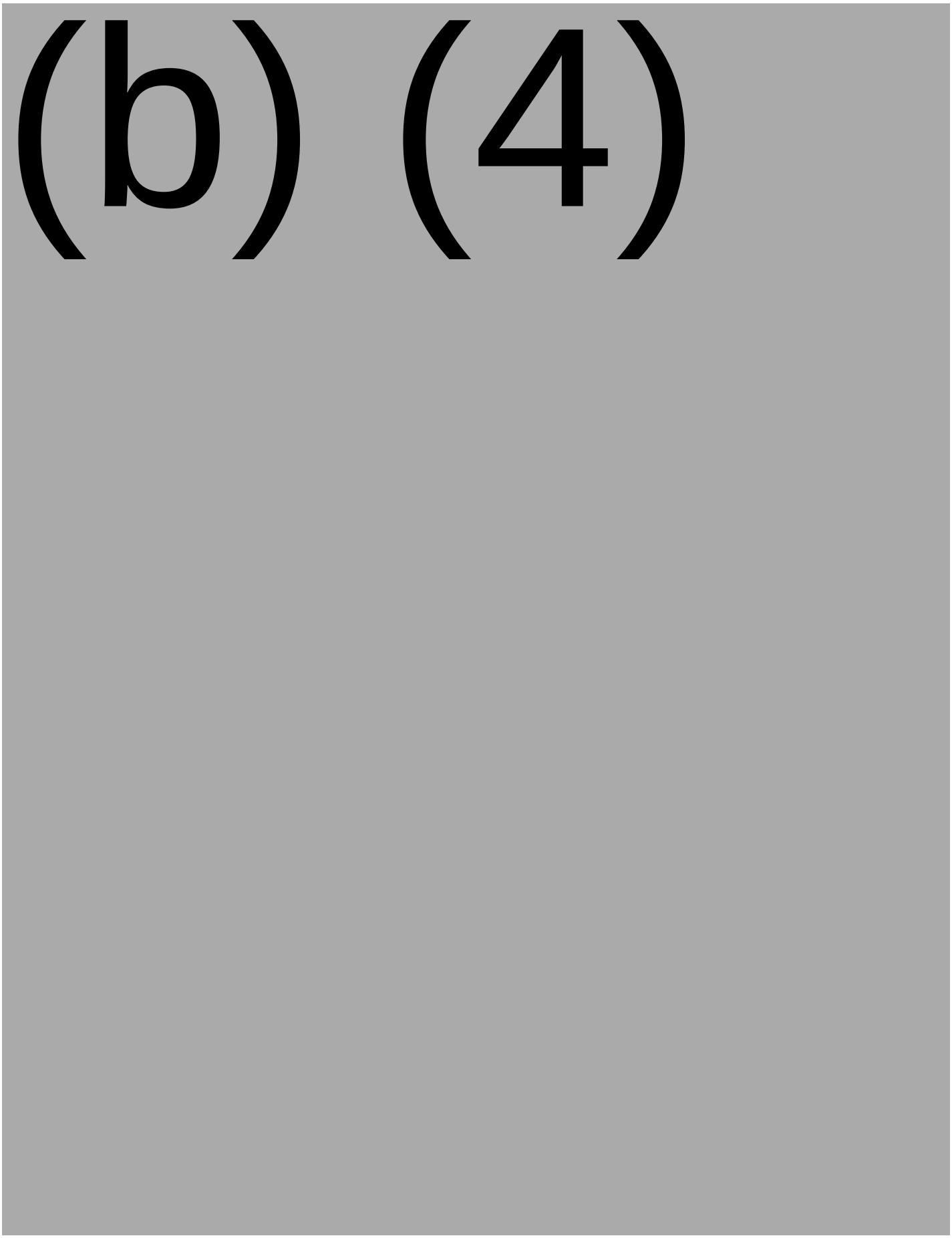
6.3 WAVE 4 RESULTS FOR SECONDARY OBJECTIVES

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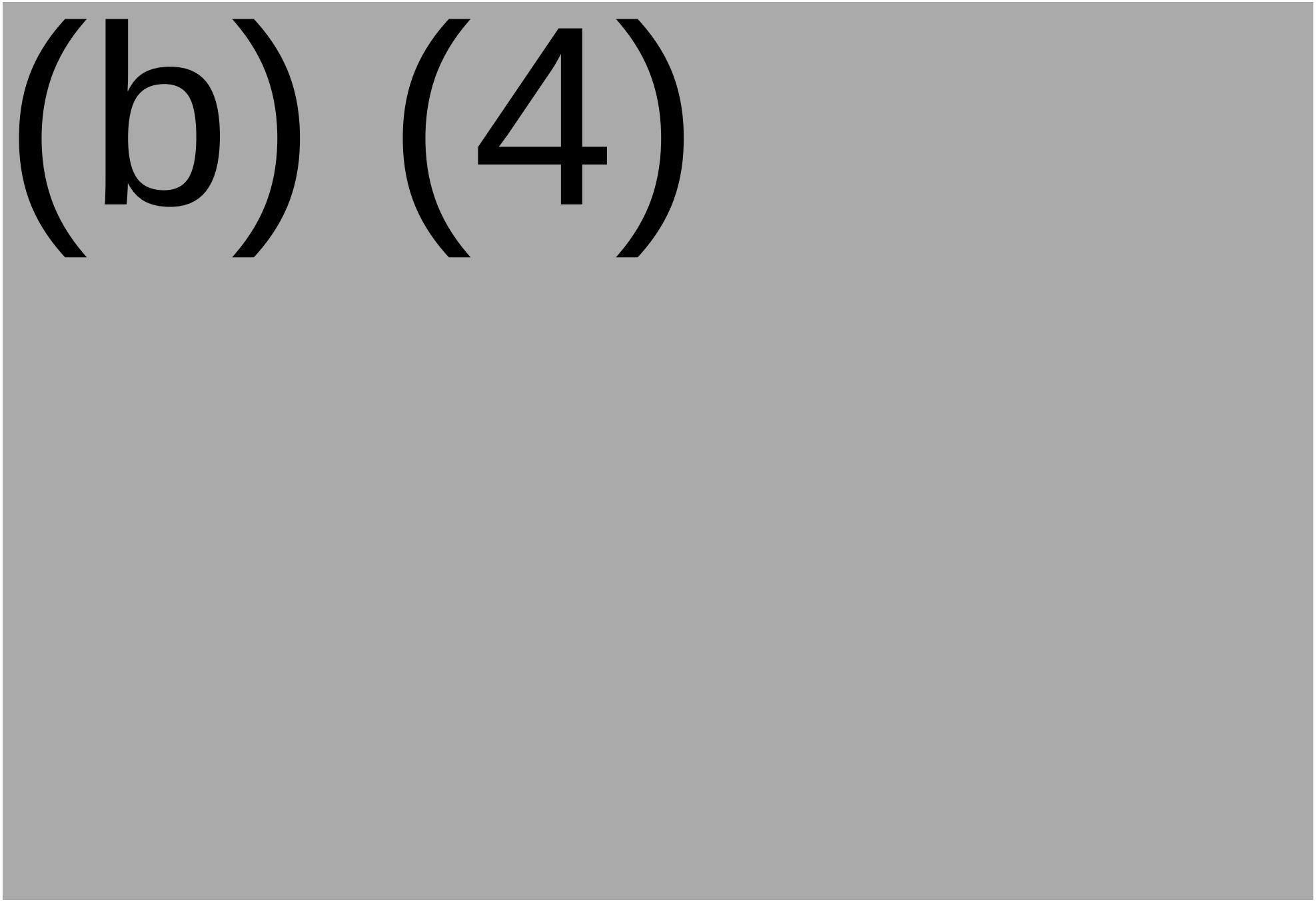
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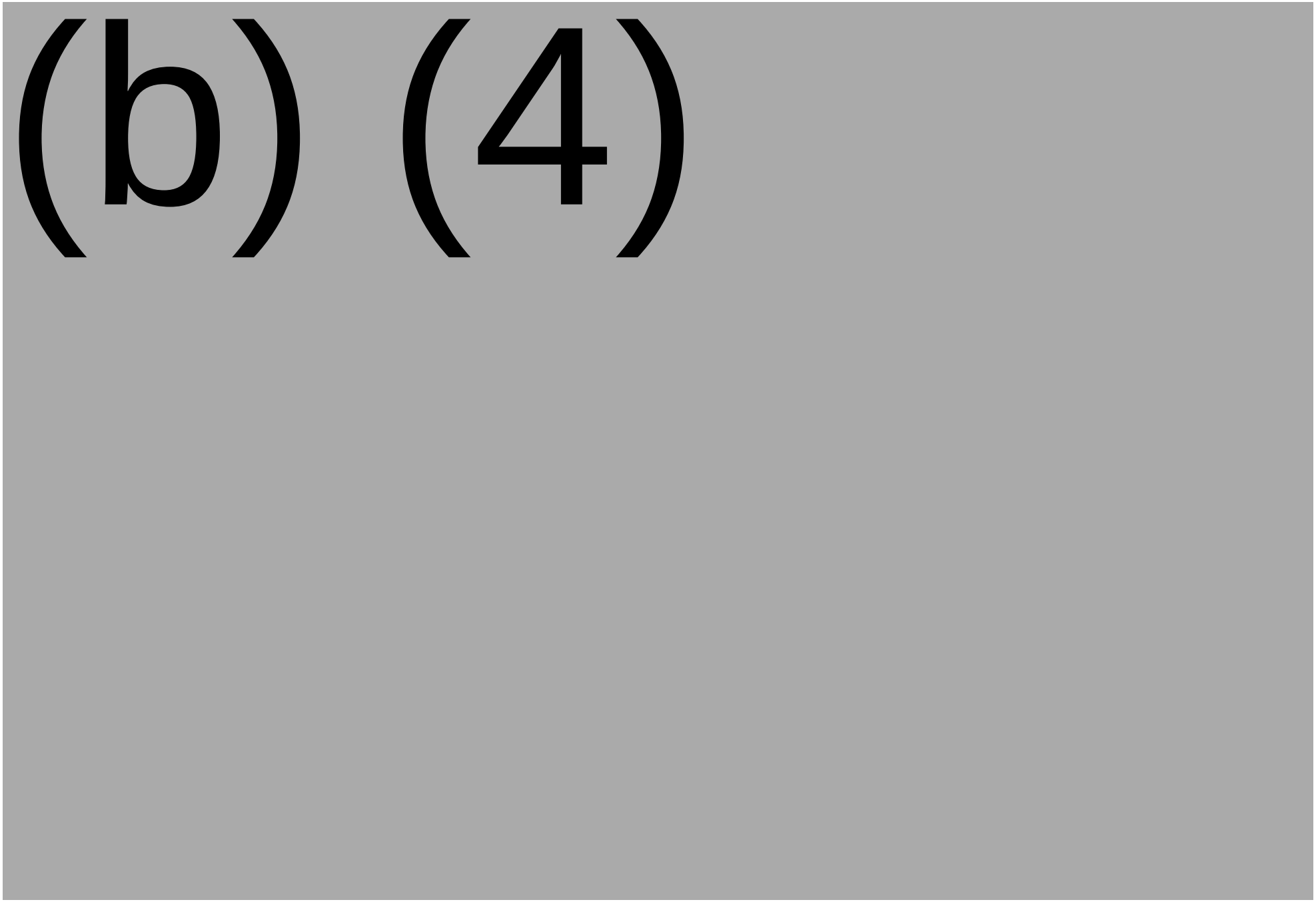
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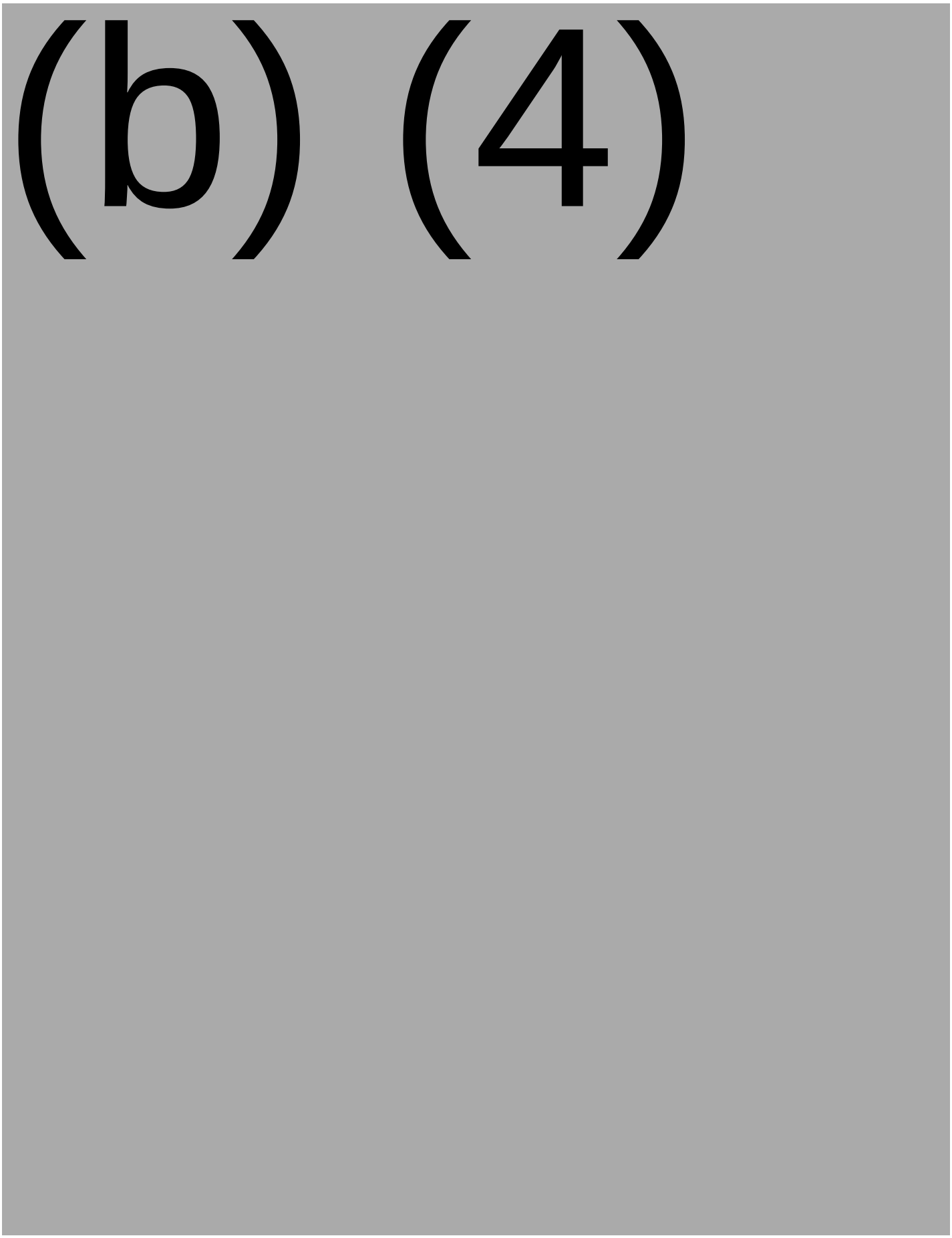
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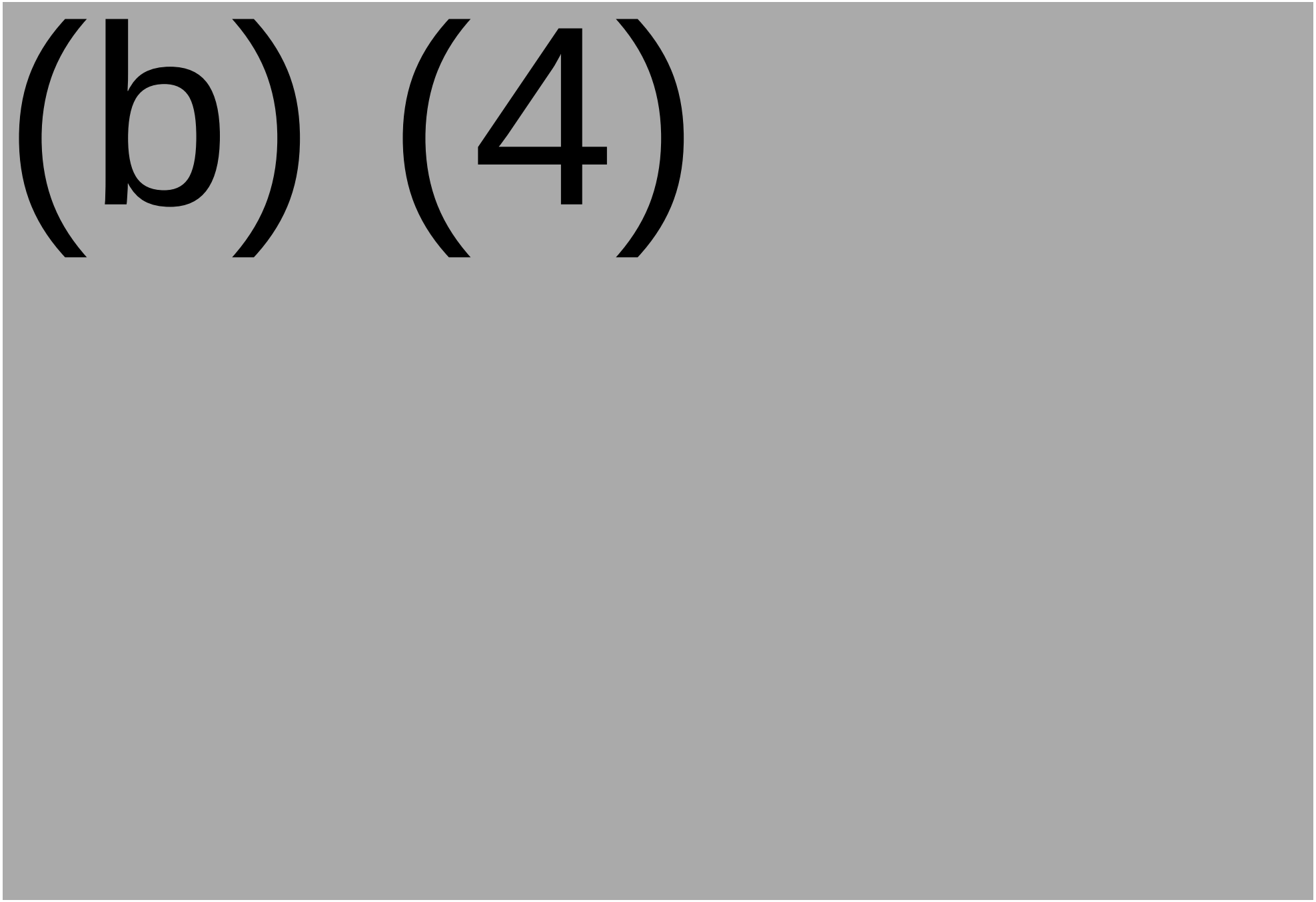
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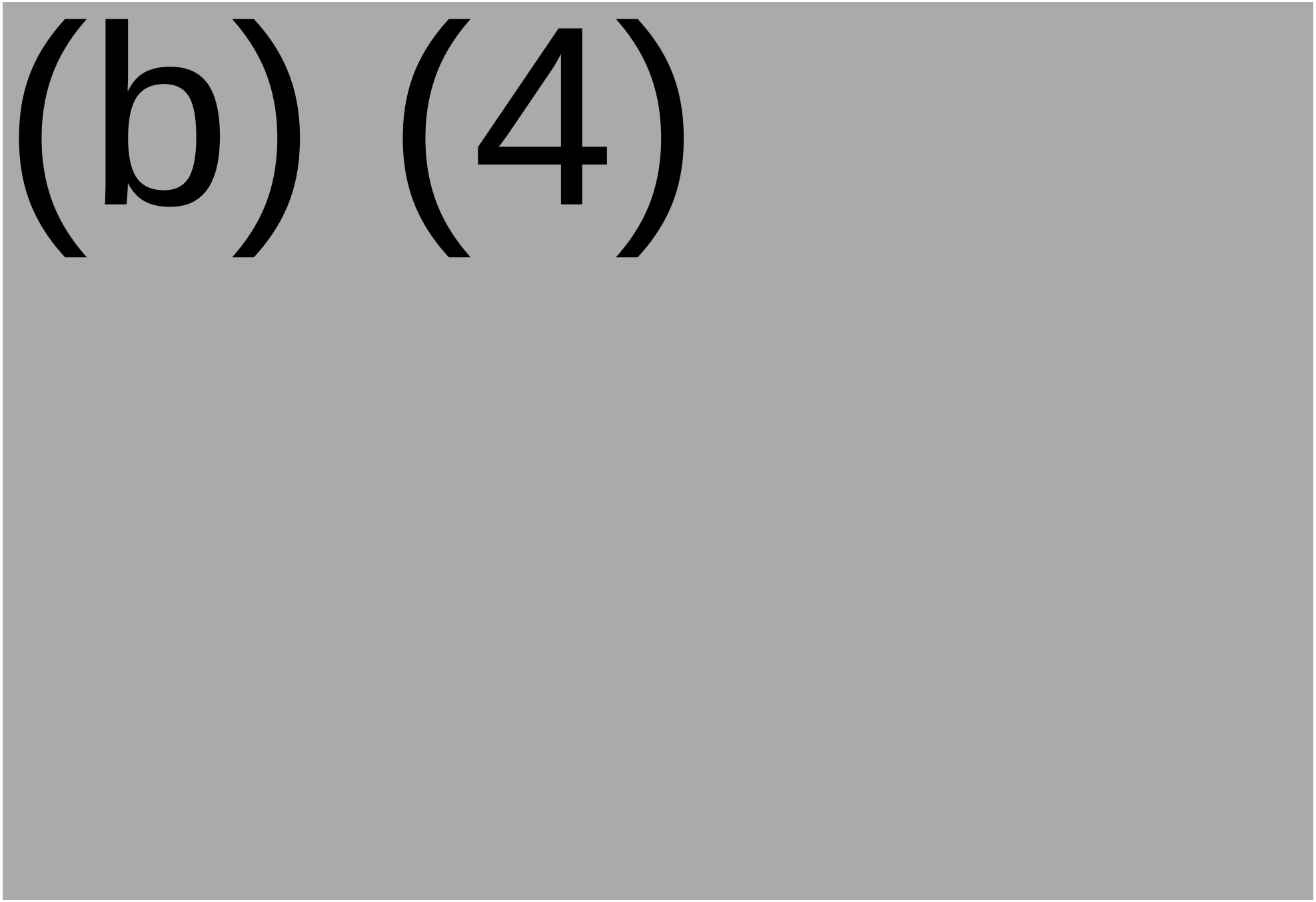
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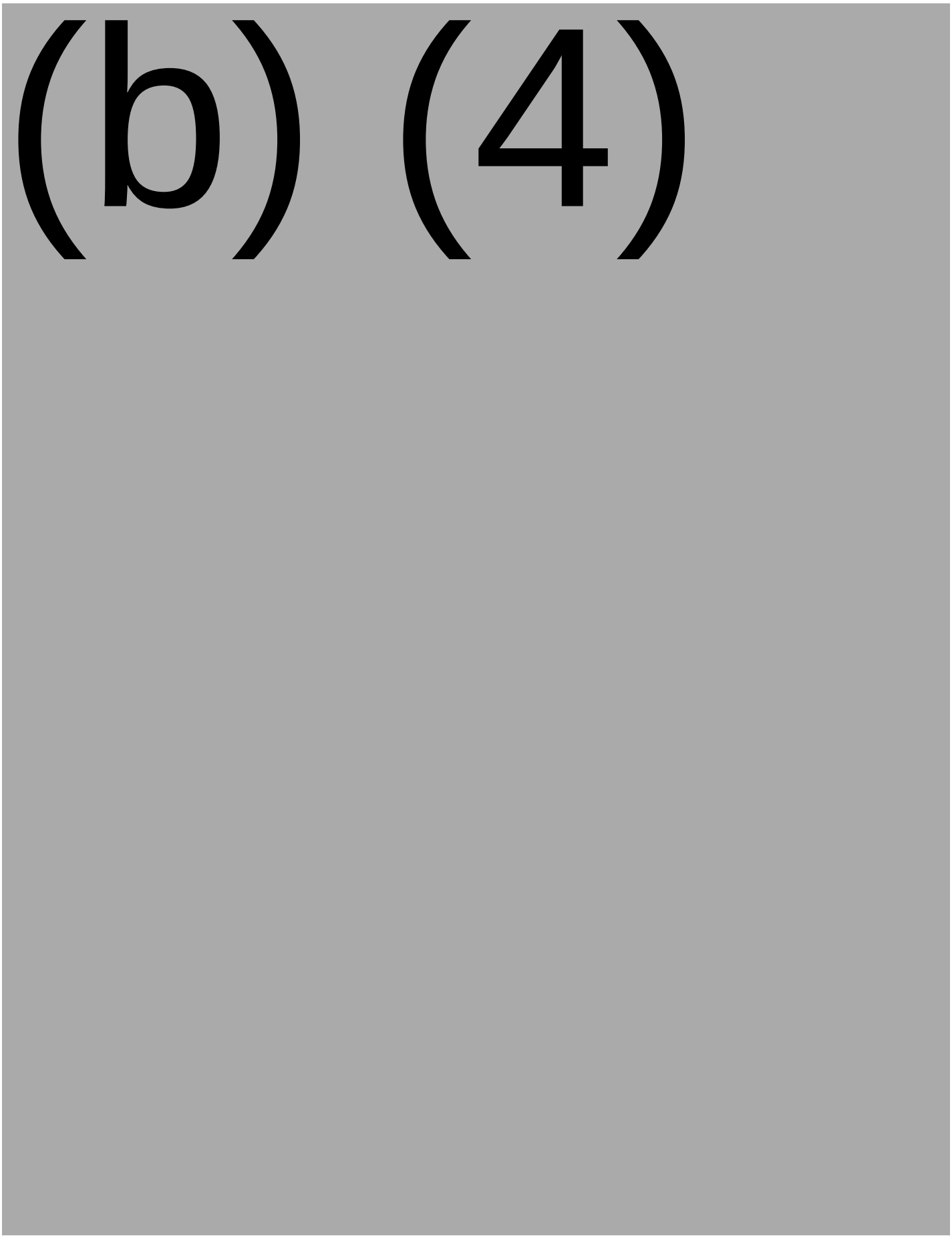
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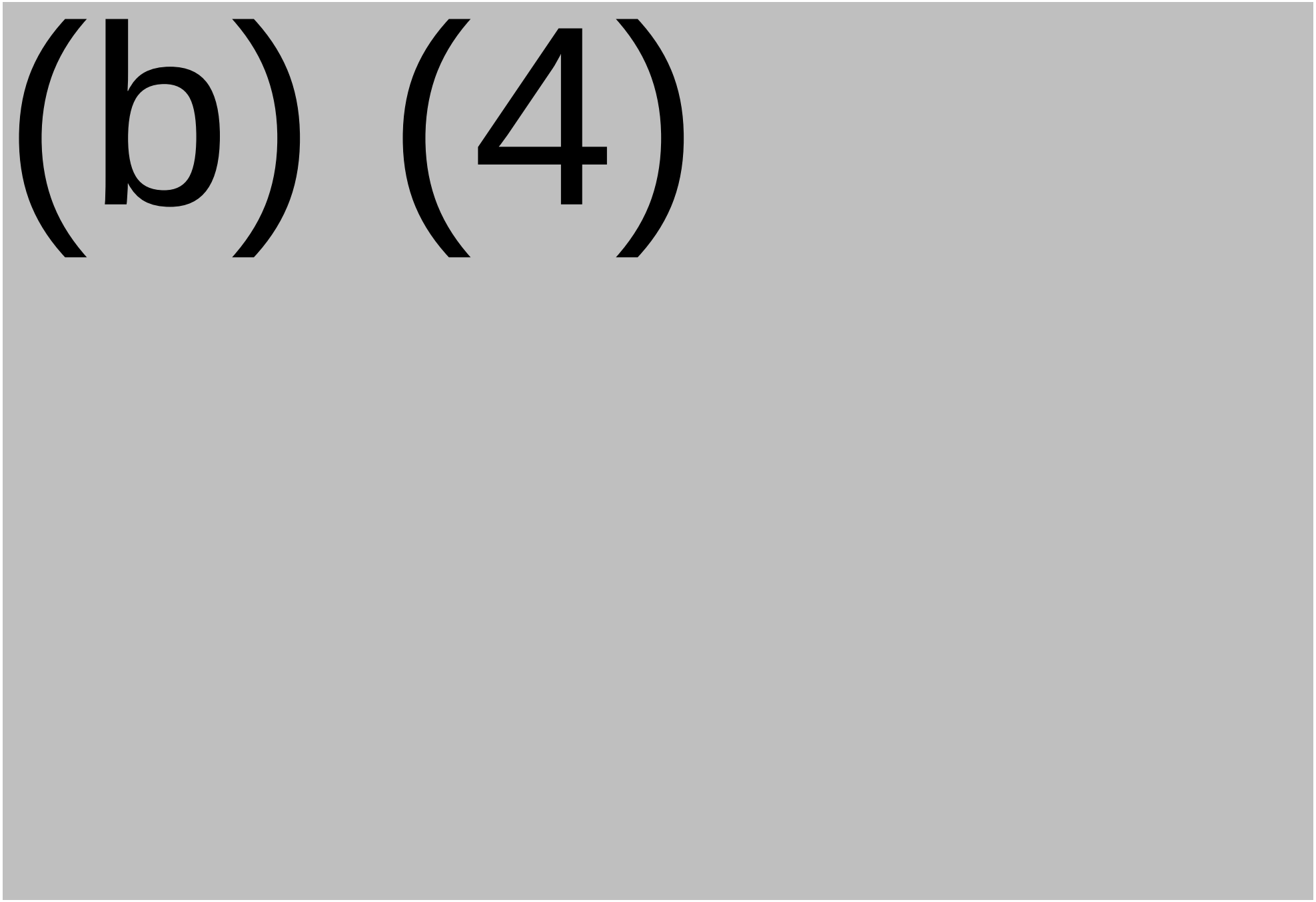
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7. SUMMARY OF WAVE 4 RESULTS

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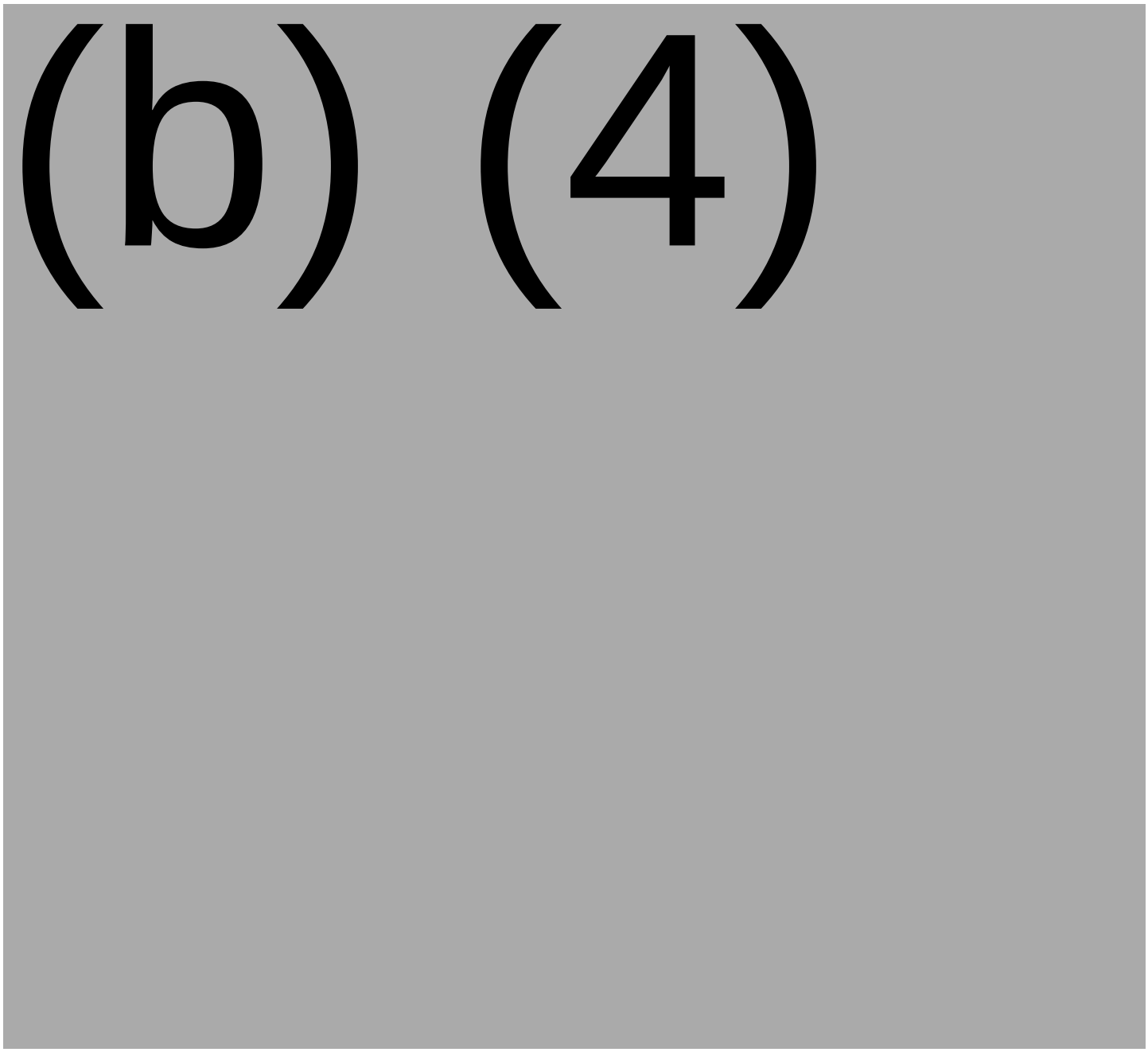
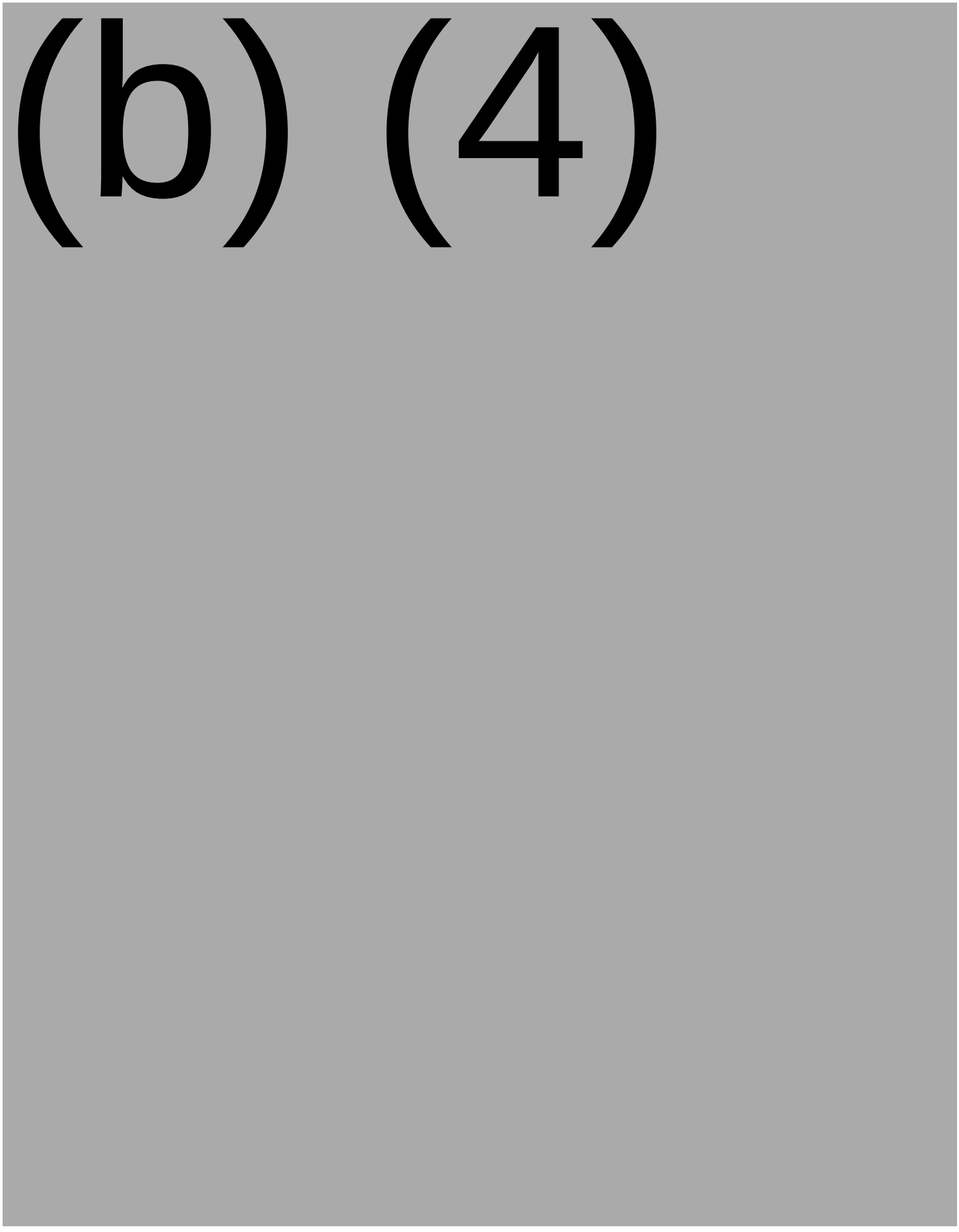
General Snus MRTP Marketing Support Plan

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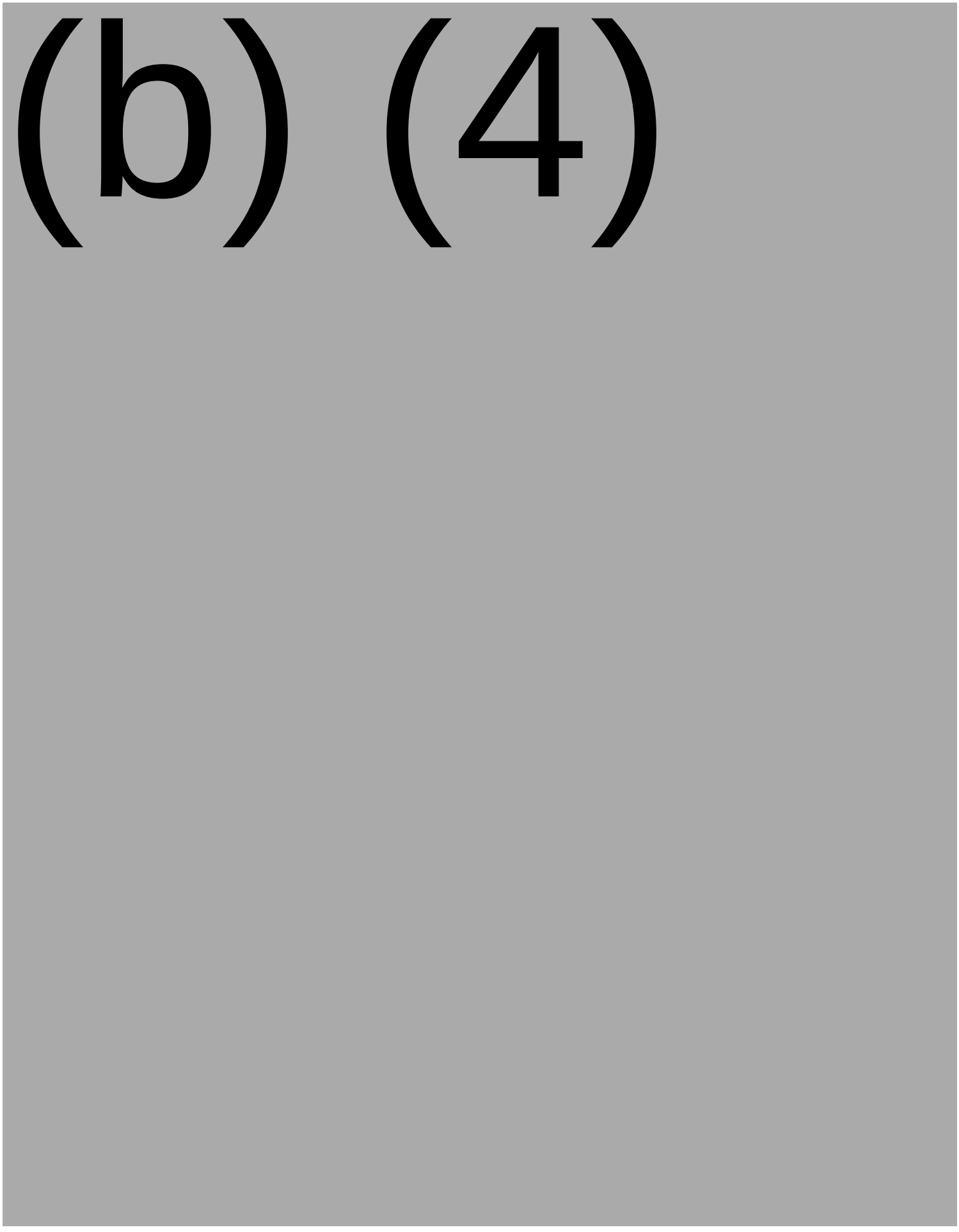
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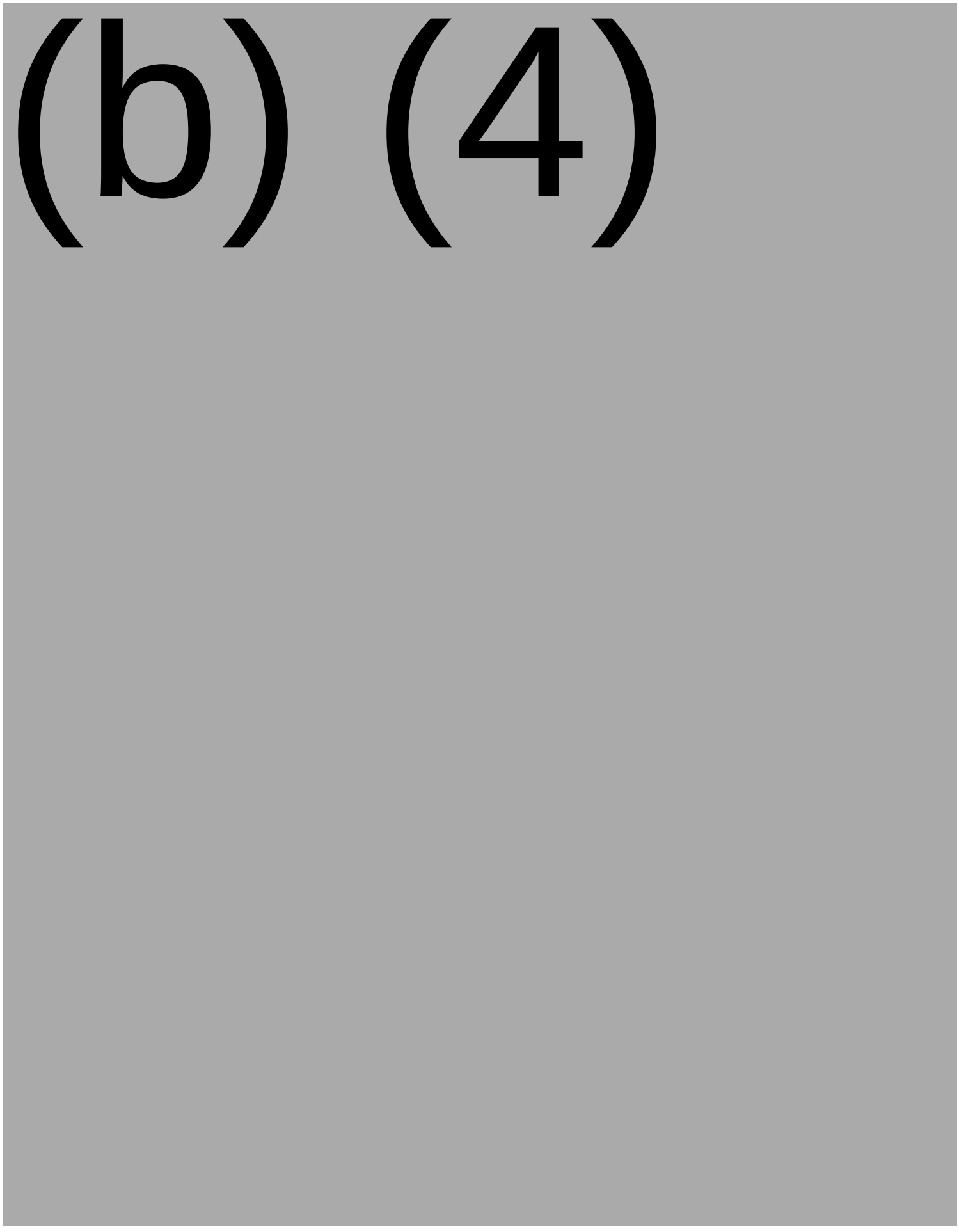
Swedish Match used this age-gated environment as the primary location for MRTP consumer educational information.

1) **Mirror of Modified Risk Webpage:** "The Choice Is Clear"

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."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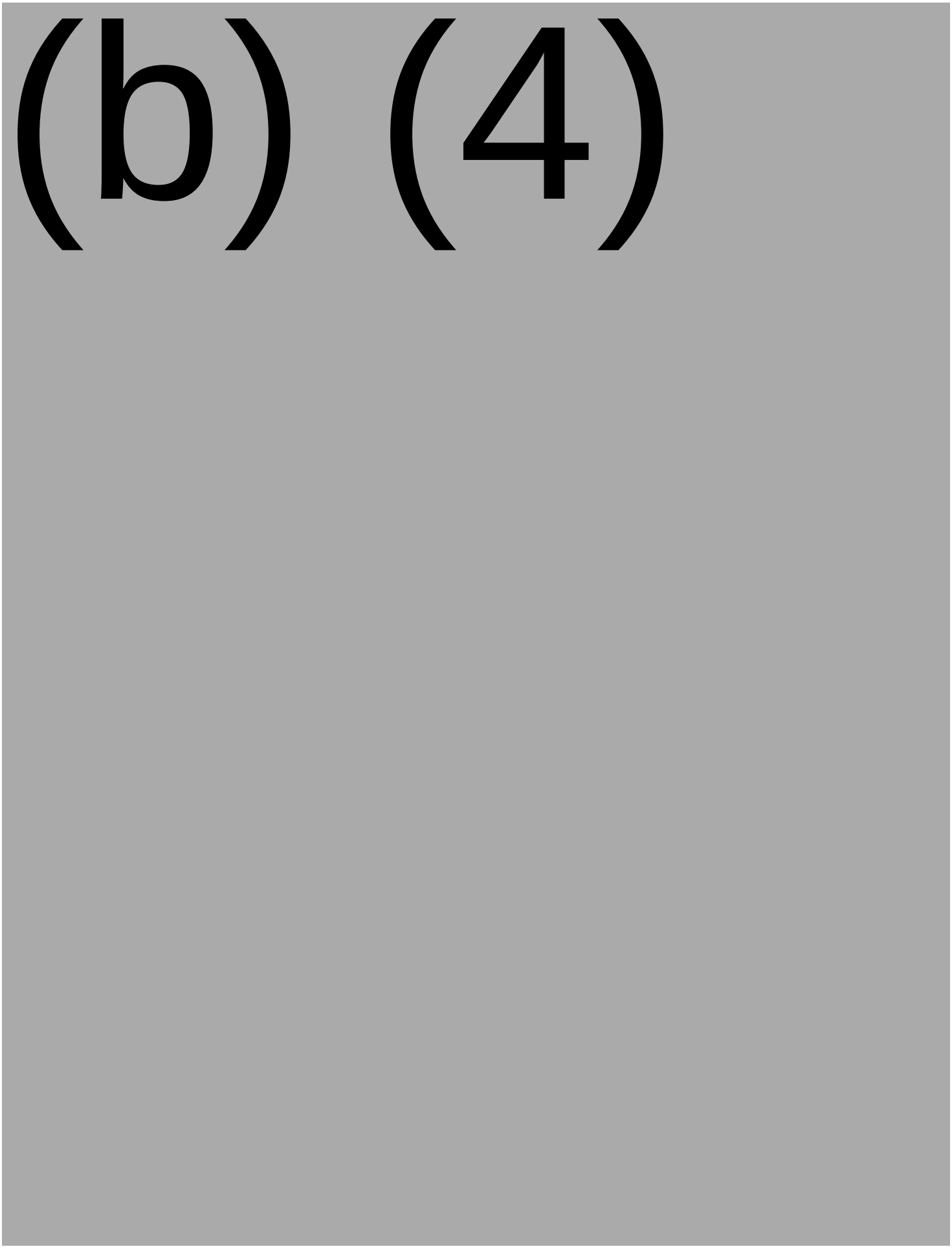
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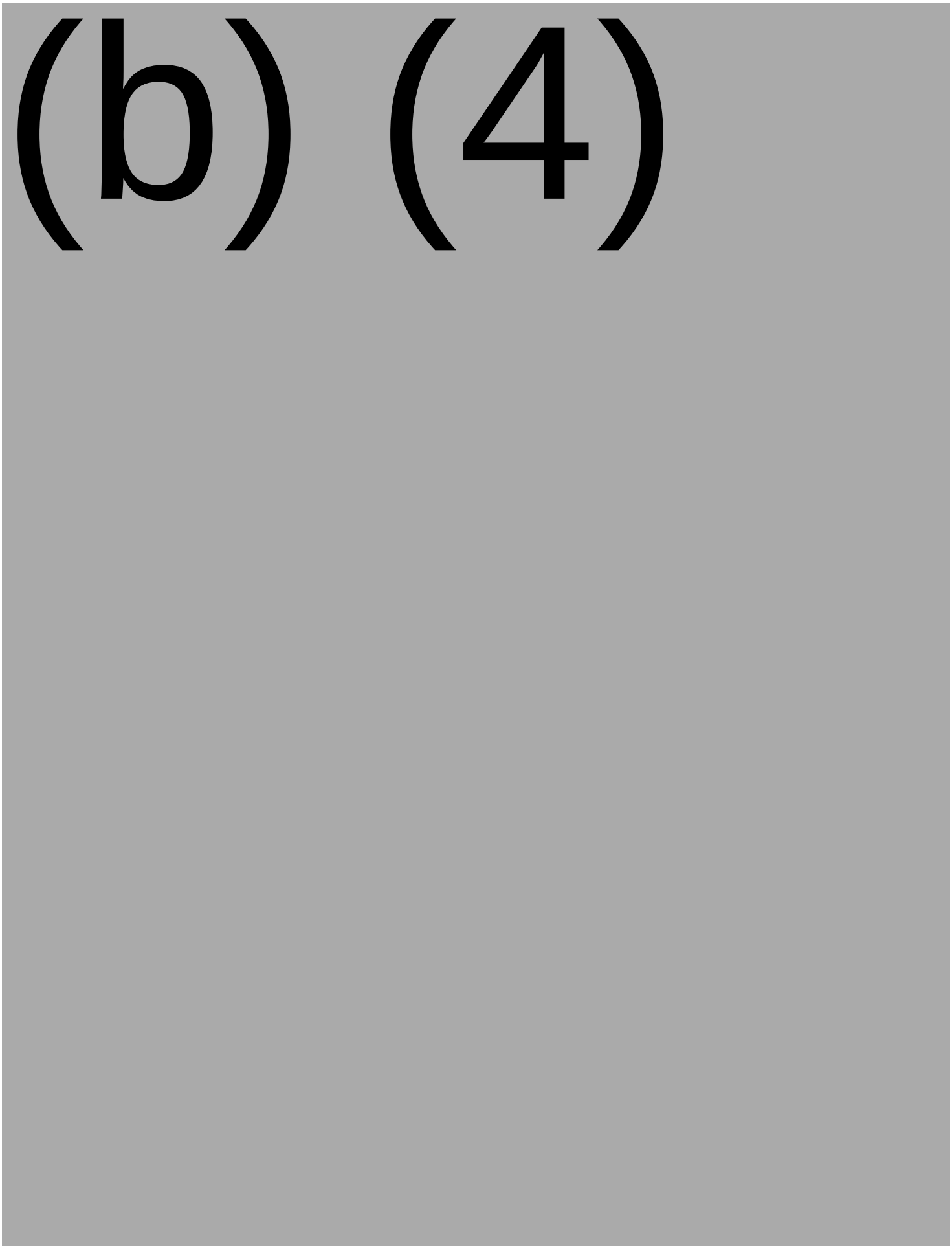
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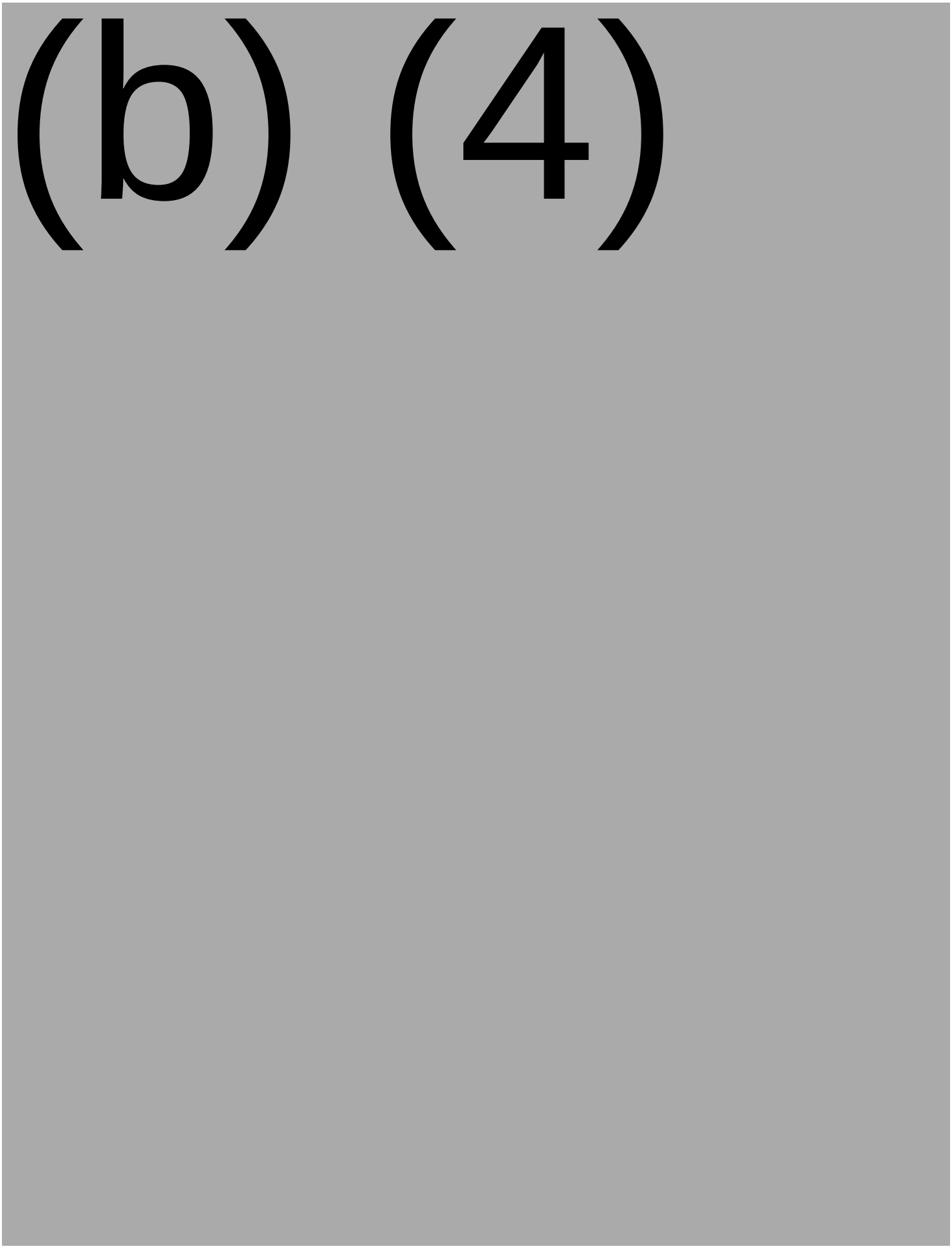
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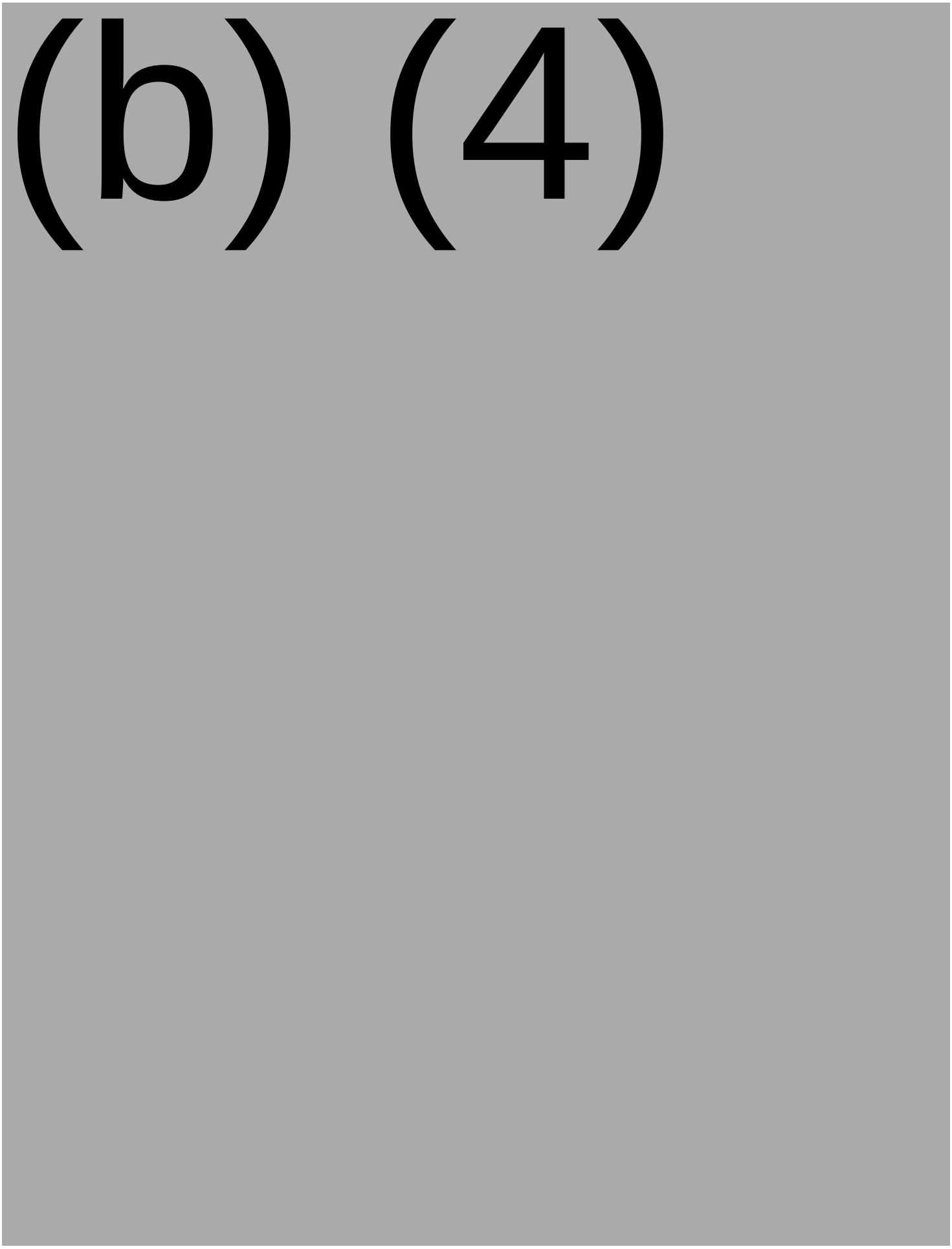
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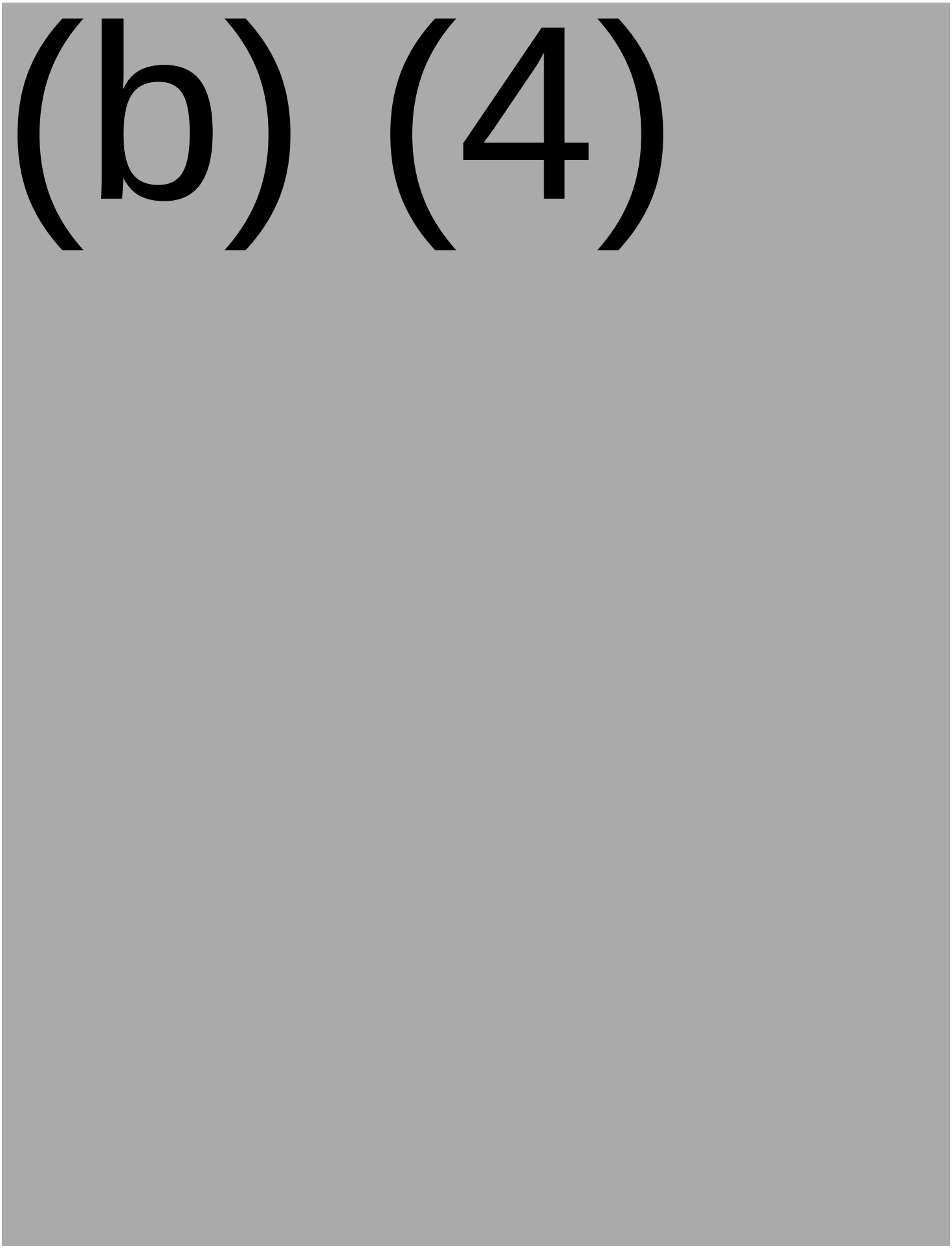
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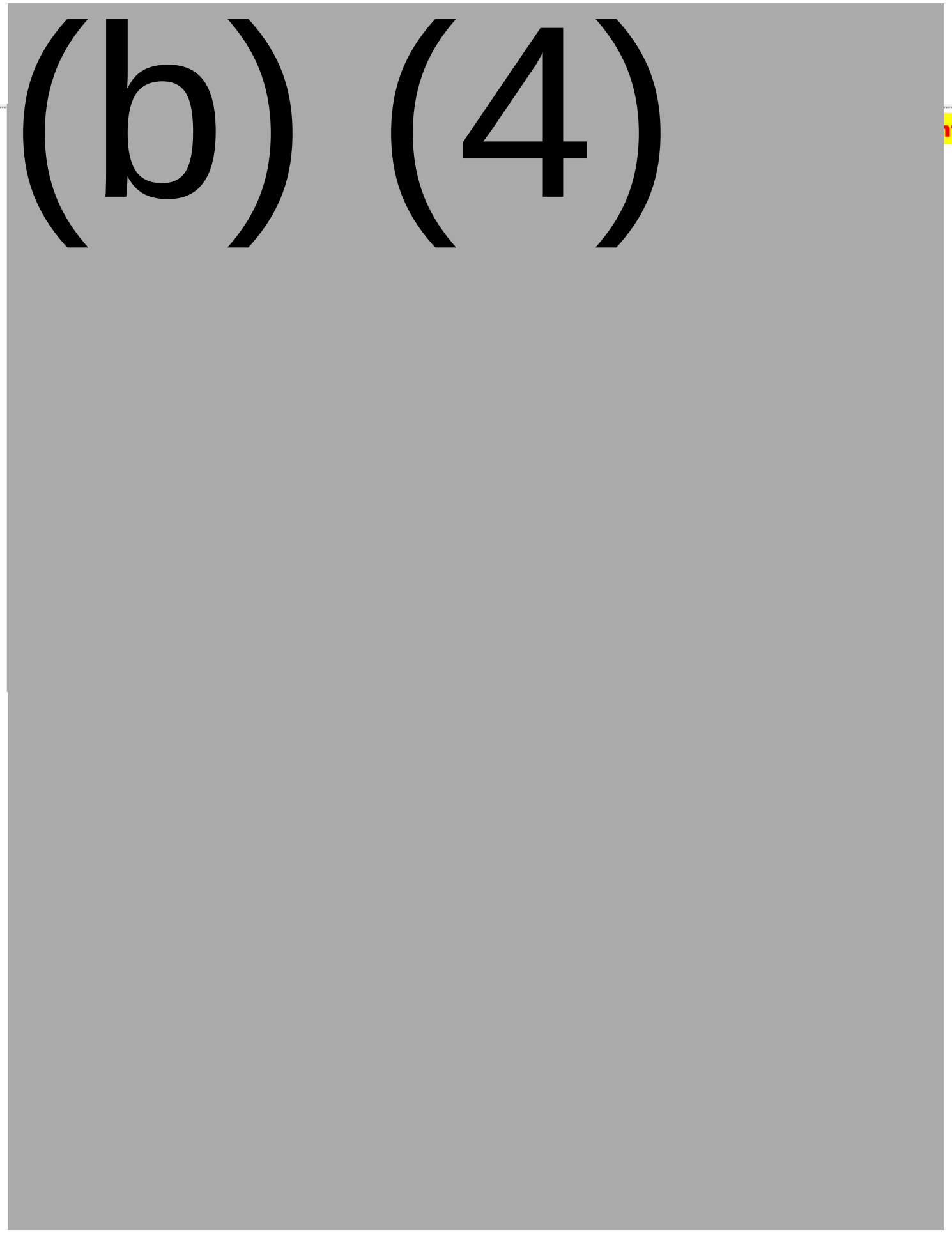
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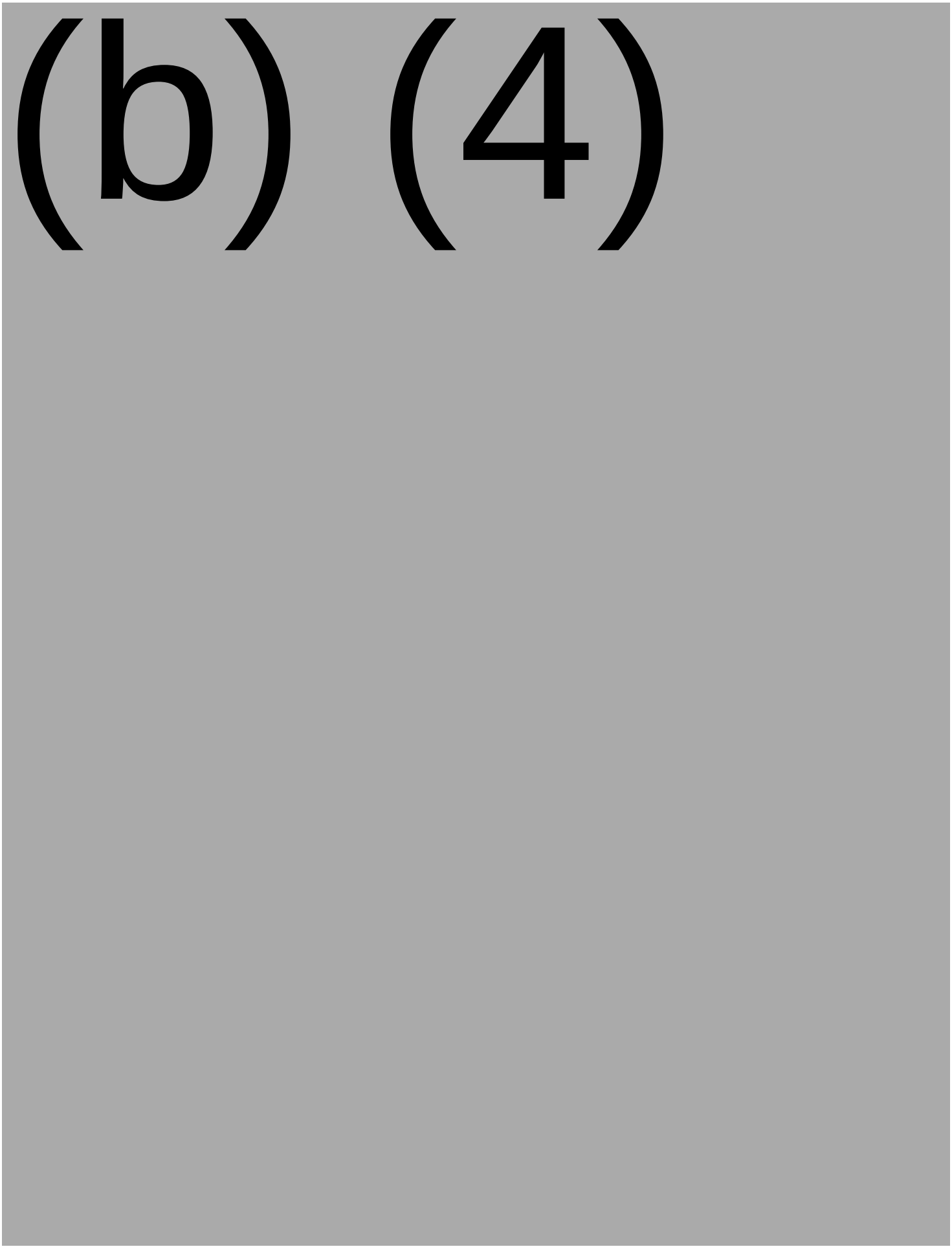
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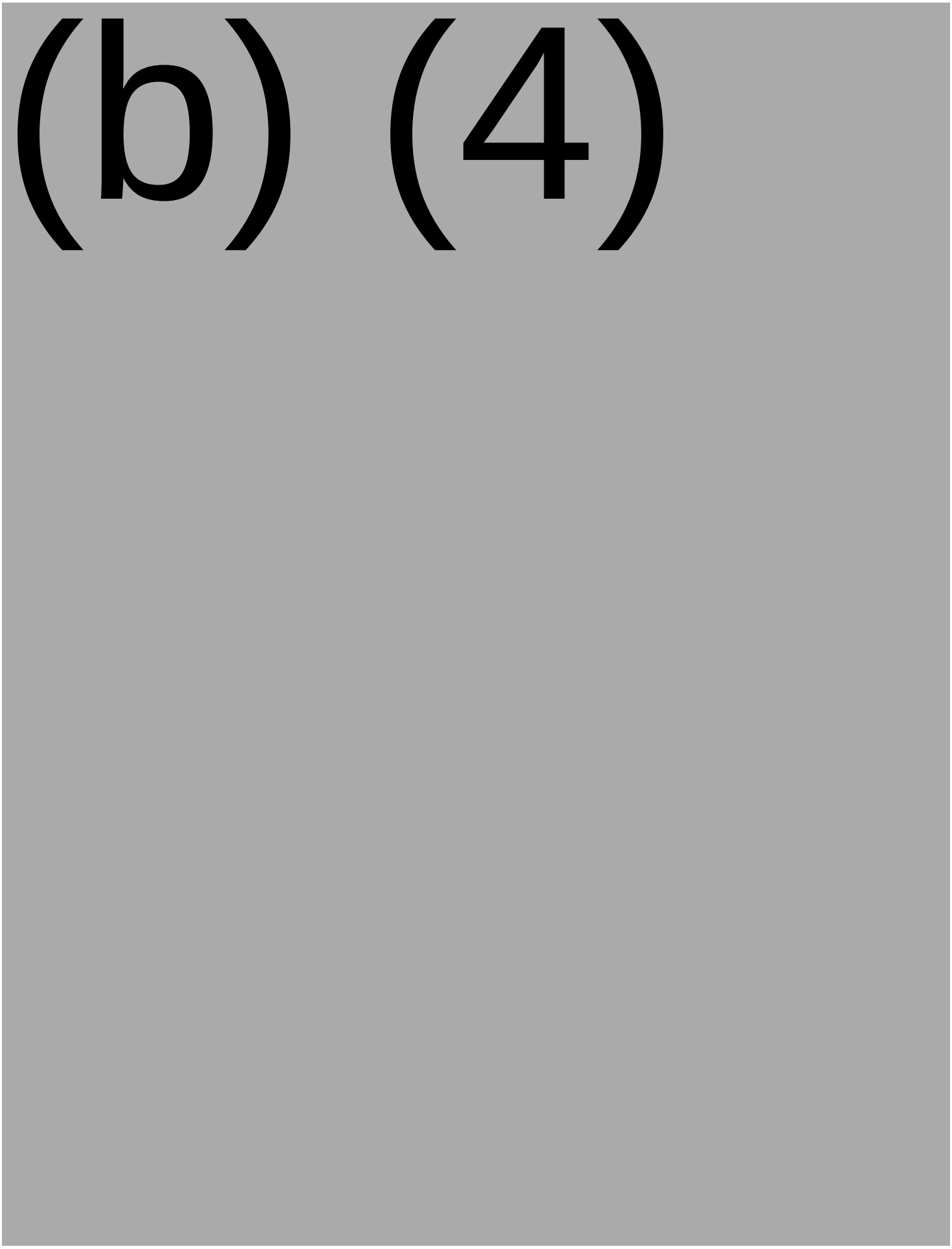
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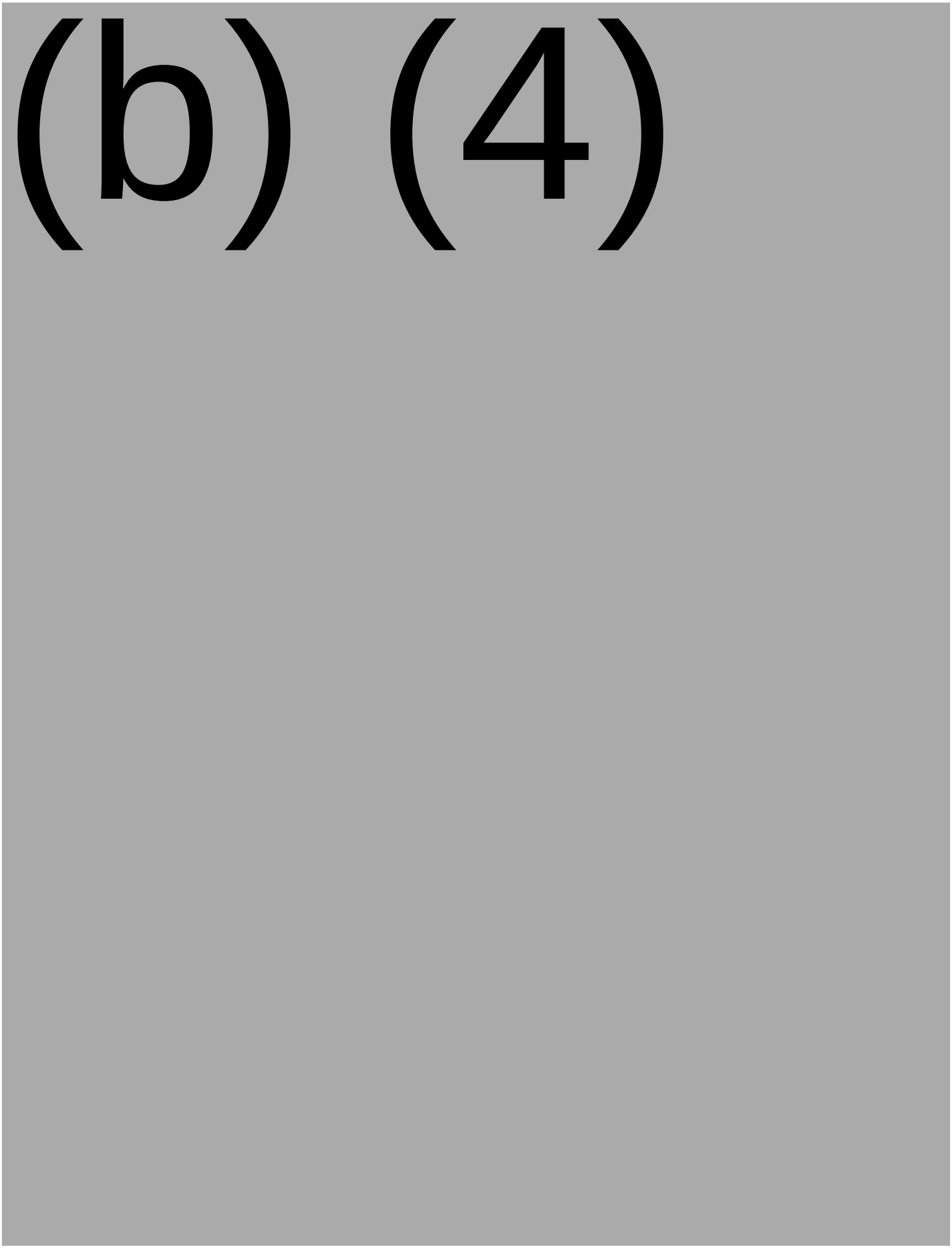
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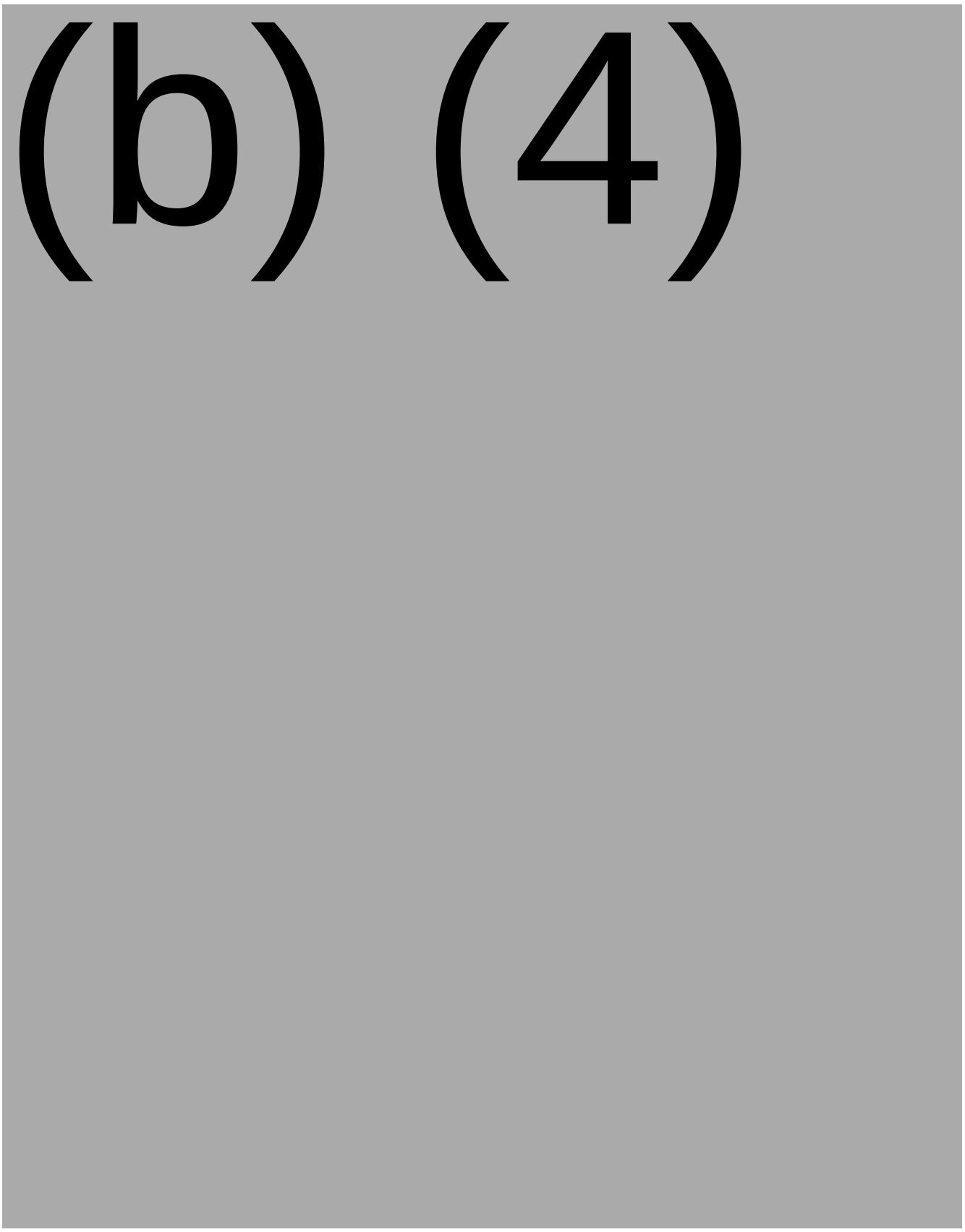
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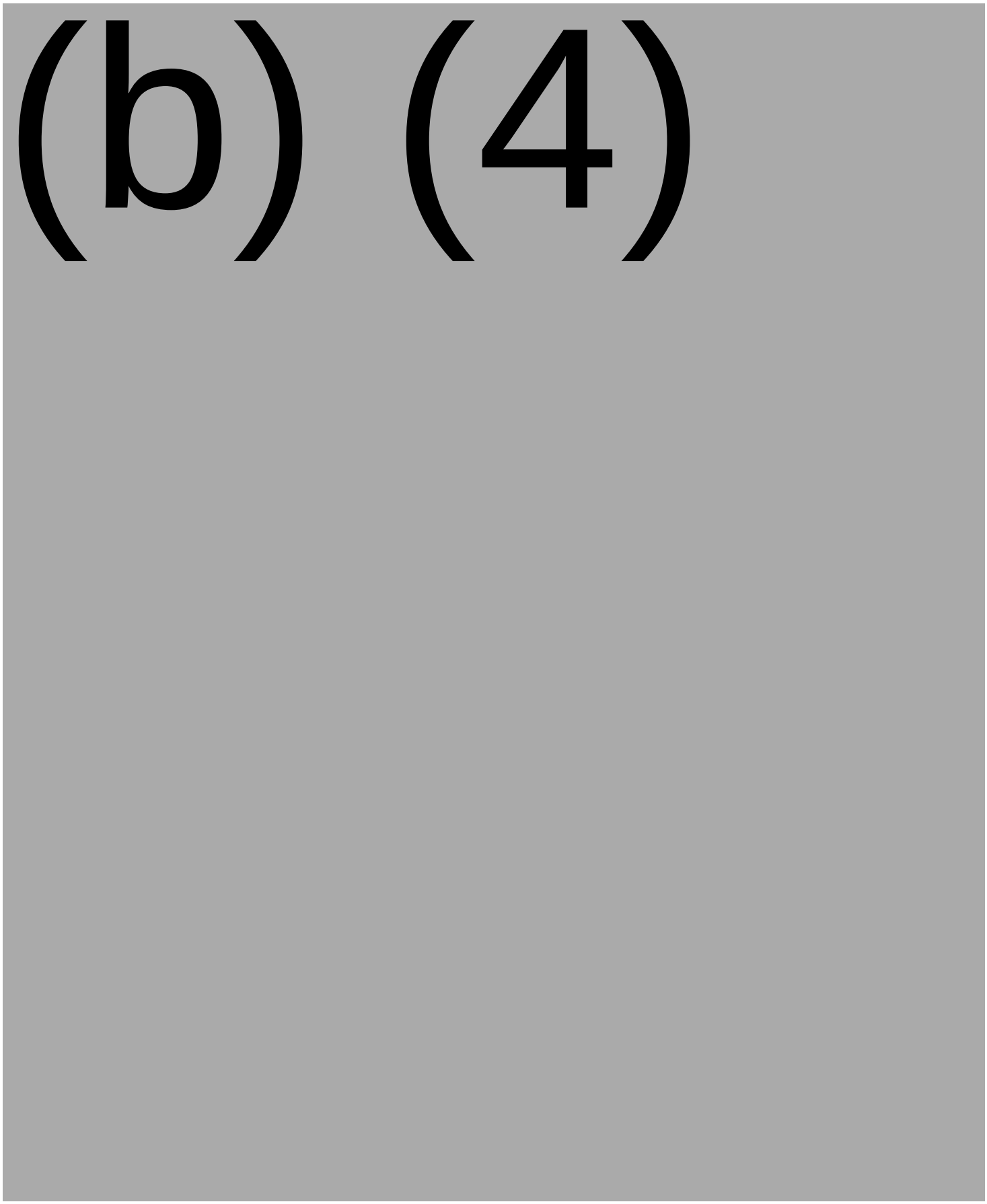
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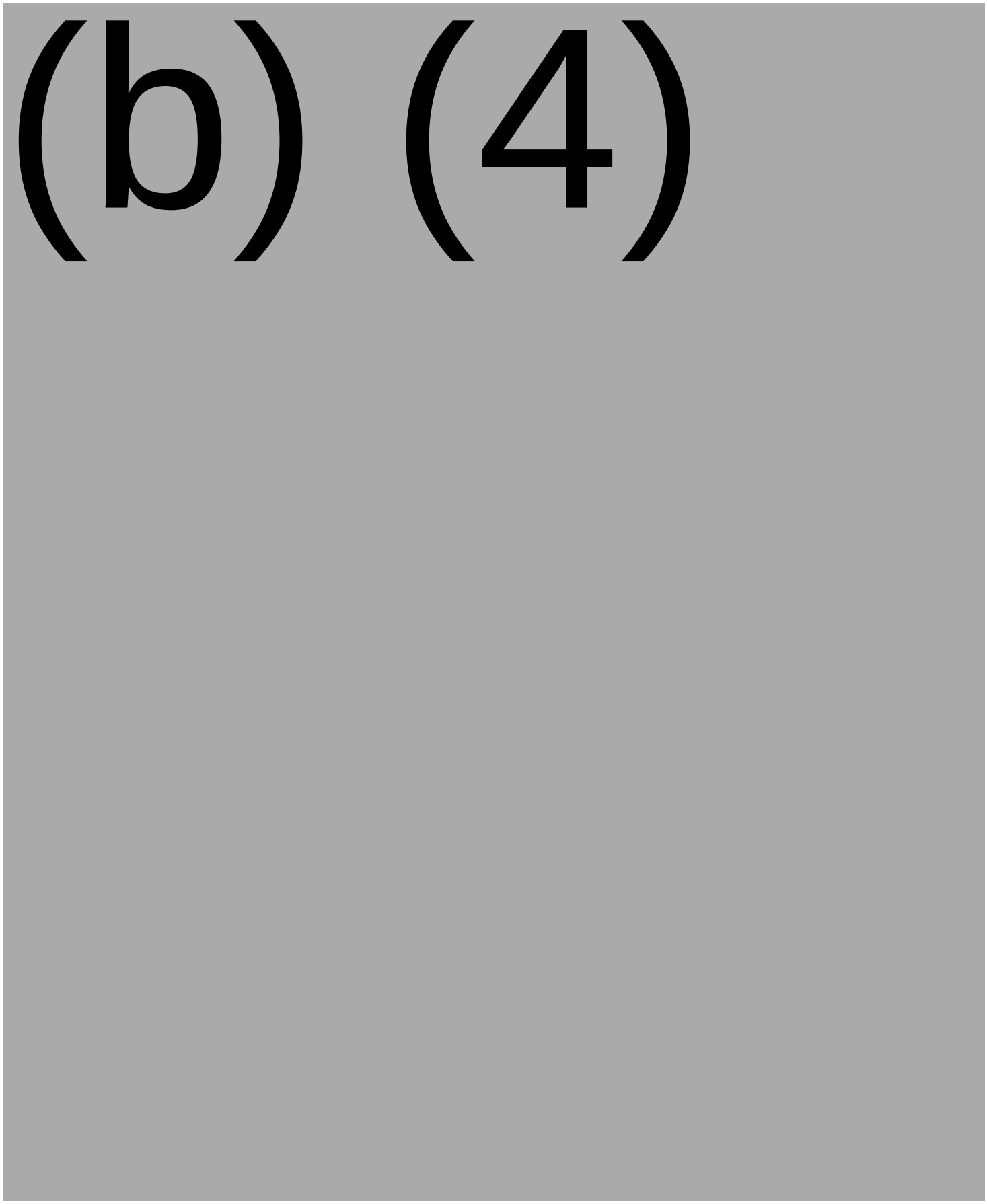
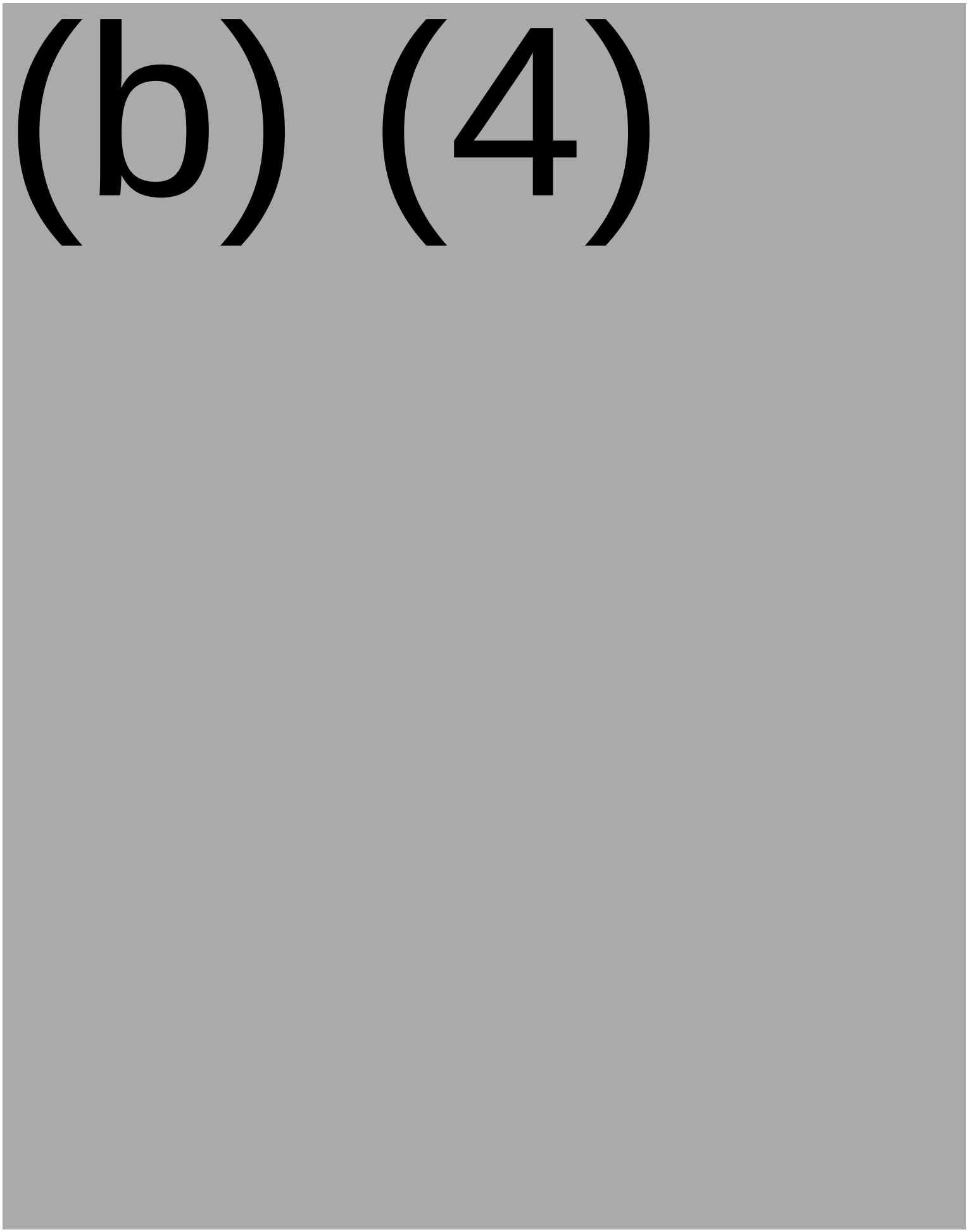
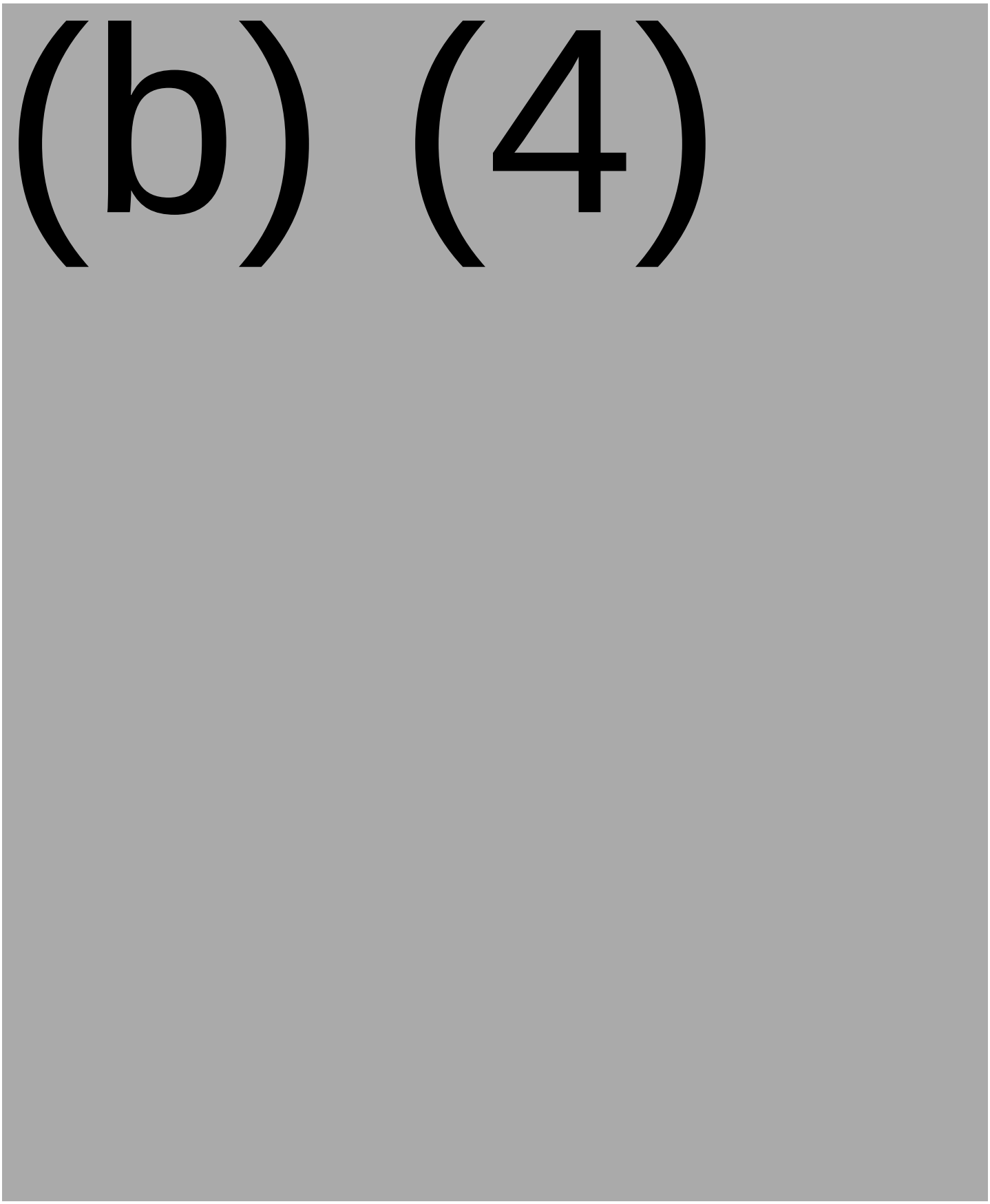

(b) (4)

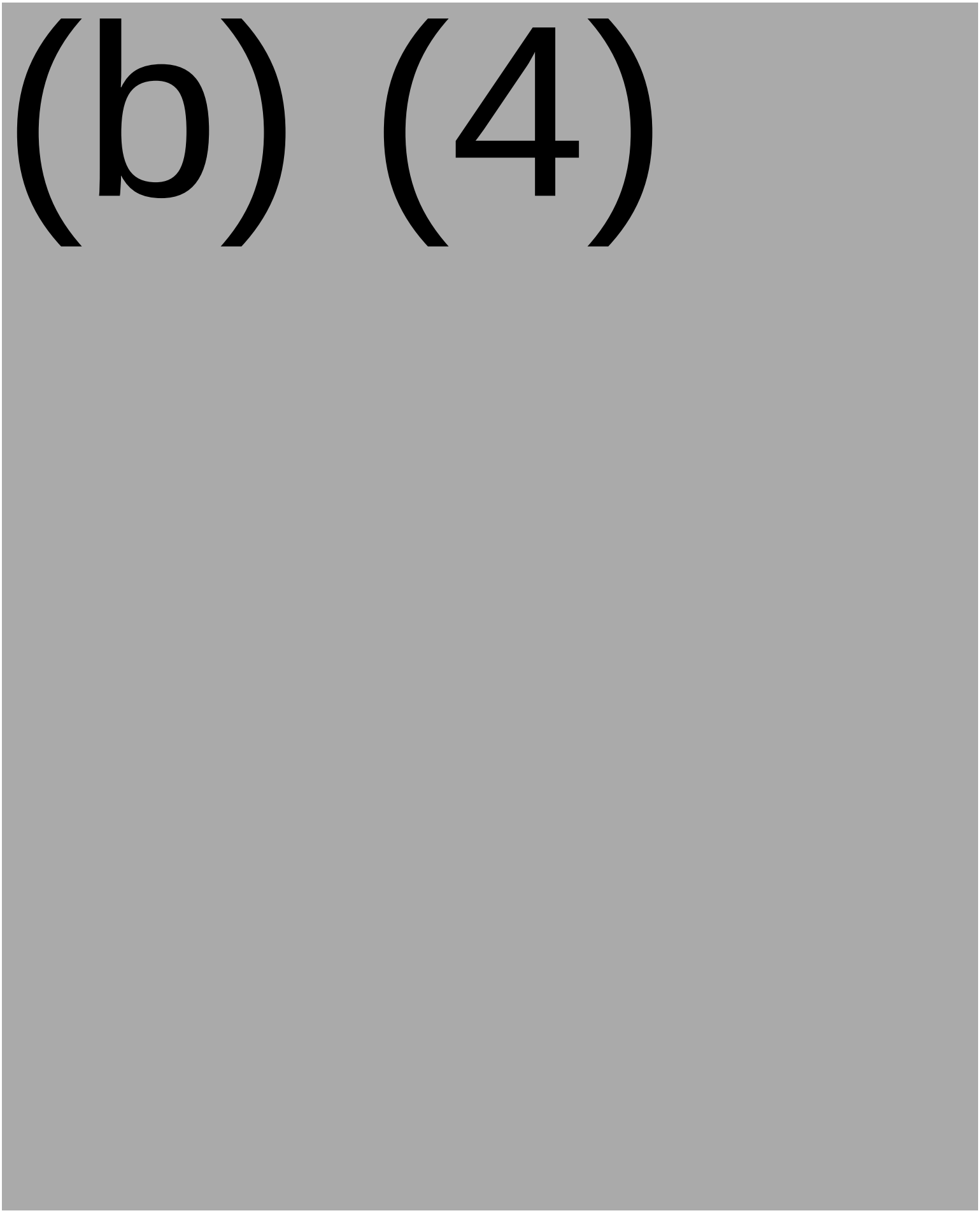
(b) (4)

- **Other General Snus website (Nov. 2021 – current) pages, that do not contain MRTP content:**
    - Landing – see Appendix 2A (1), pg. 3
    - Forgot password – see Appendix 2A (1), pg. 4
    - Password reset on the way – see Appendix 2A (1), pg. 5
    - Registration process, outside age gate – see Appendix 2A (1), pgs. 6-9
    - Registration confirmation page, behind age gate: - see Appendix 2A (1), pg. 10
    - Registration error message, outside age gate: - see Appendix 2A (1), pg. 11
    - Find a Store, outside age gate: - see Appendix 2A (1), pgs. 12-14
    - Contact Us, outside age gate: - see Appendix 2A (1), pg. 15
    - What is Snus & How to Use, behind age gate: – see Appendix 2A (1), pg. 24
    - How it's Made, behind age gate: – see Appendix 2A (1), pg. 25
    - Products, behind age gate: – see Appendix 2A (1), pg. 30
    - Coupons, behind age gate: – see Appendix 2A (1), pgs. 34-35
    - Elevated Stories, behind age gate: – see Appendix 2A (1), pgs. 36-55
    - The Most Chill Giveaway Rules, outside age gate: - see Appendix 2A (1), pgs. 56-59
    - The Most Chill Giveaway sweeps pages, behind age gate: - see Appendix 2A (1), pgs. 60-66
    - Privacy Policy, outside age gate: – see Appendix 2A (1), pgs. 78-92.
    - My Account, behind gate: – see Appendix 2A (1), pgs. 93-96


(b) (4)

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

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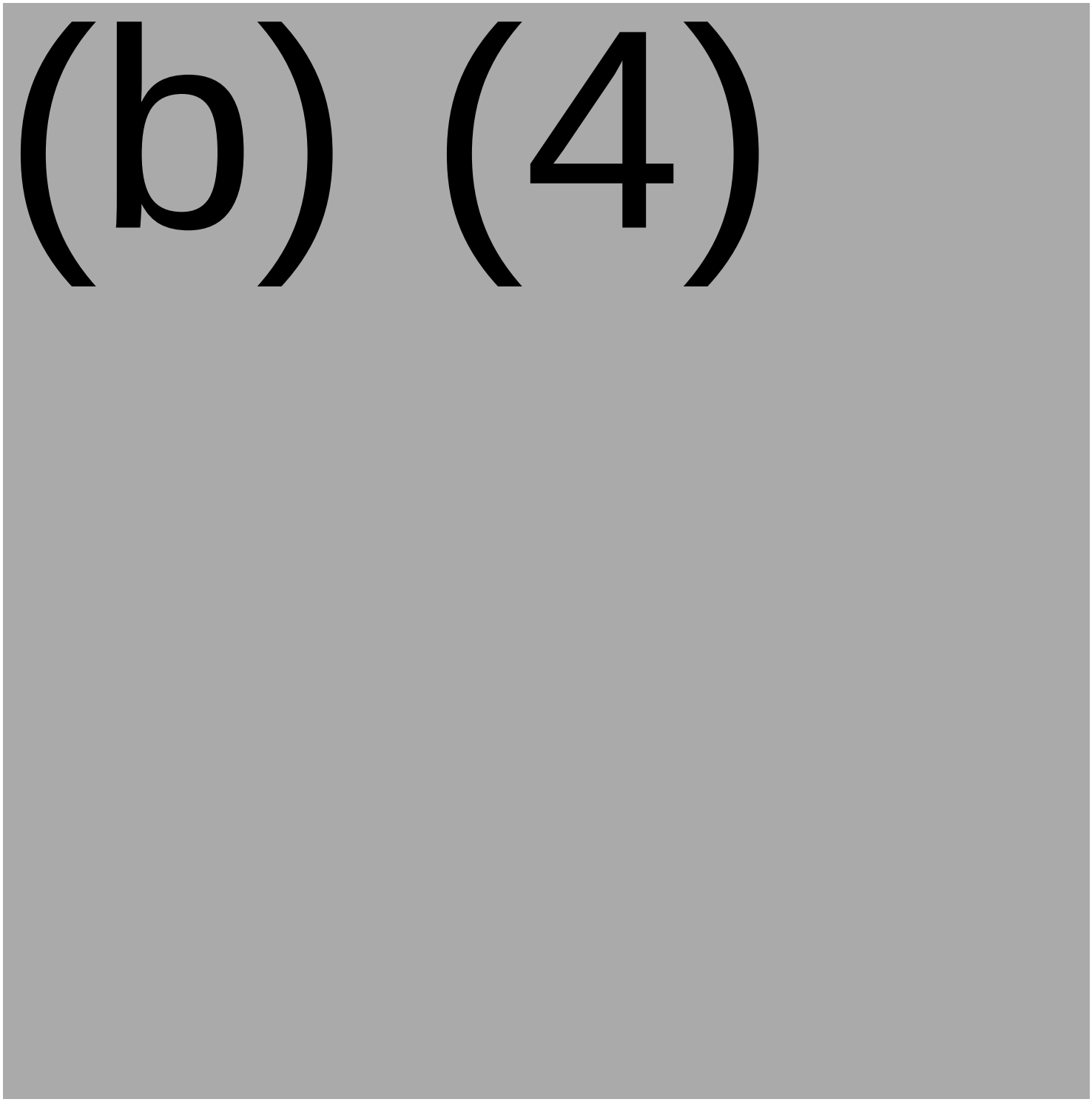
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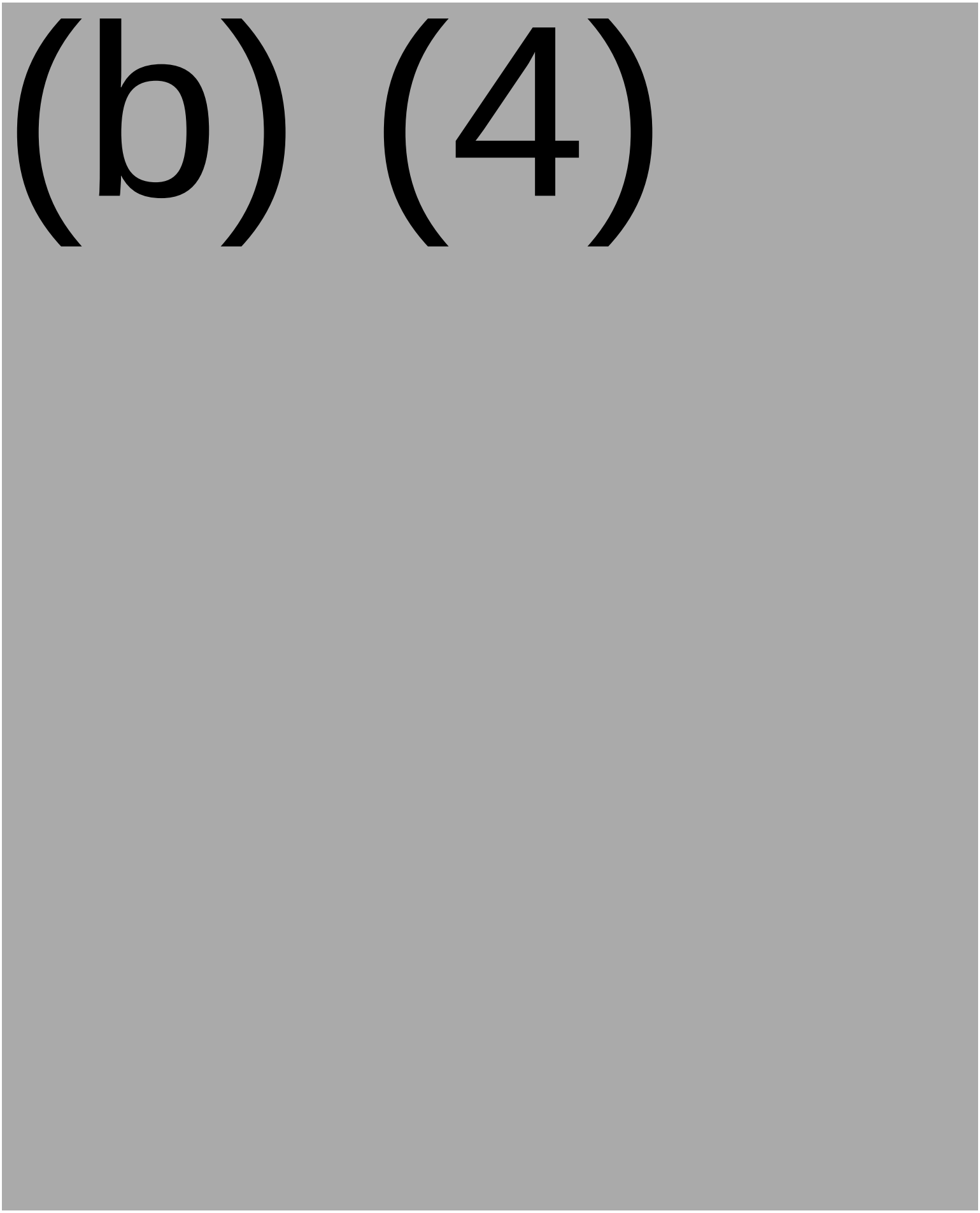
(b) (4)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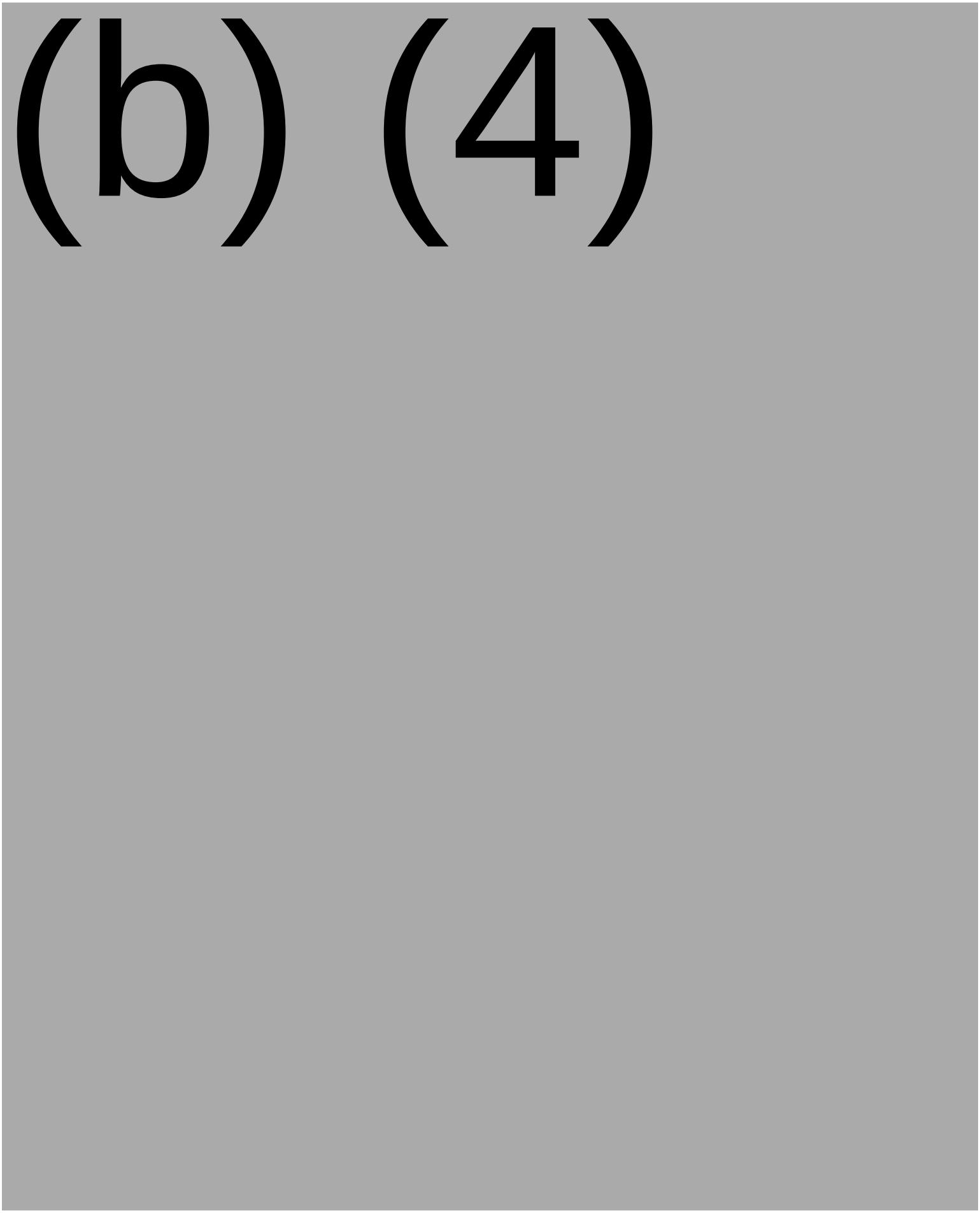
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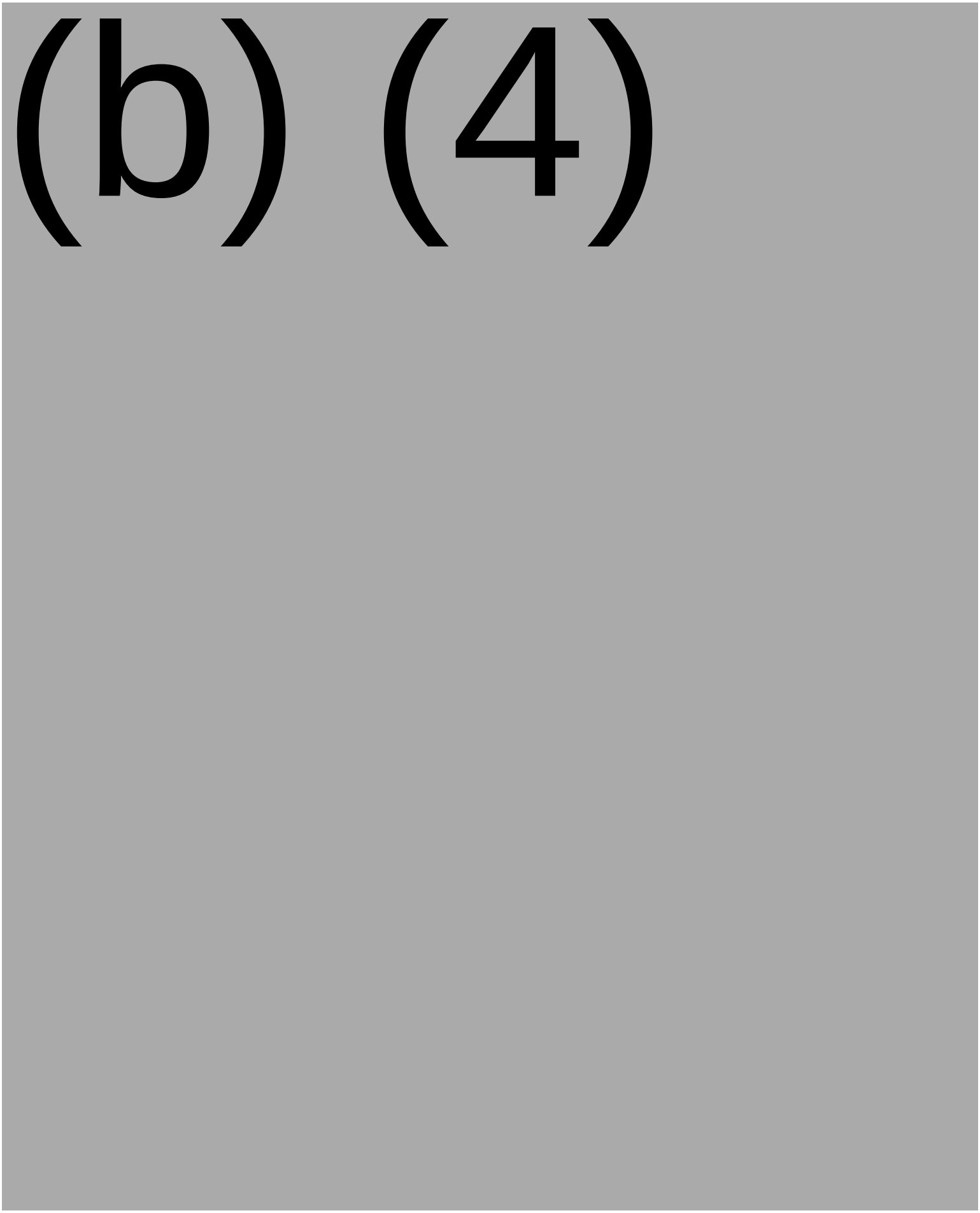
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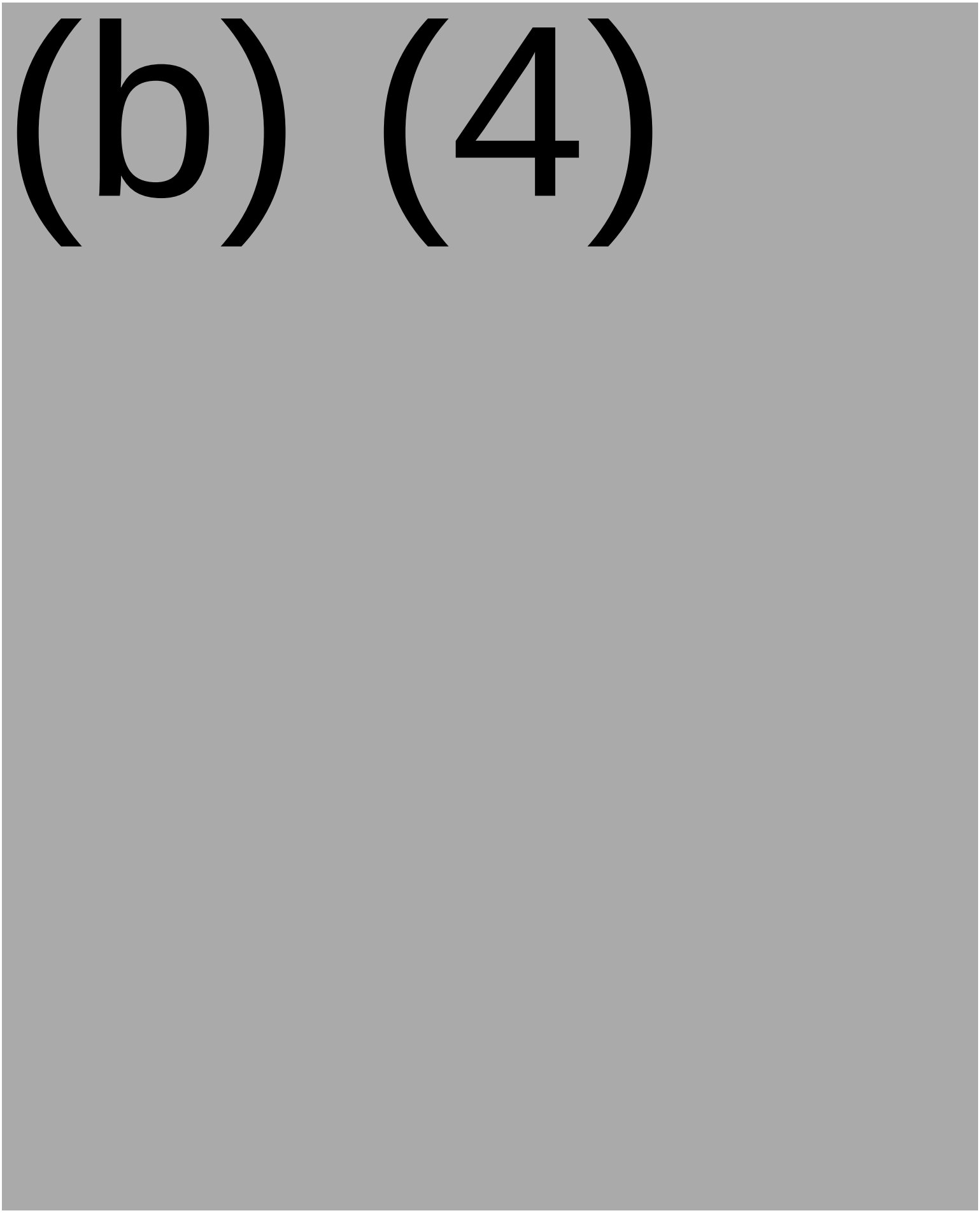
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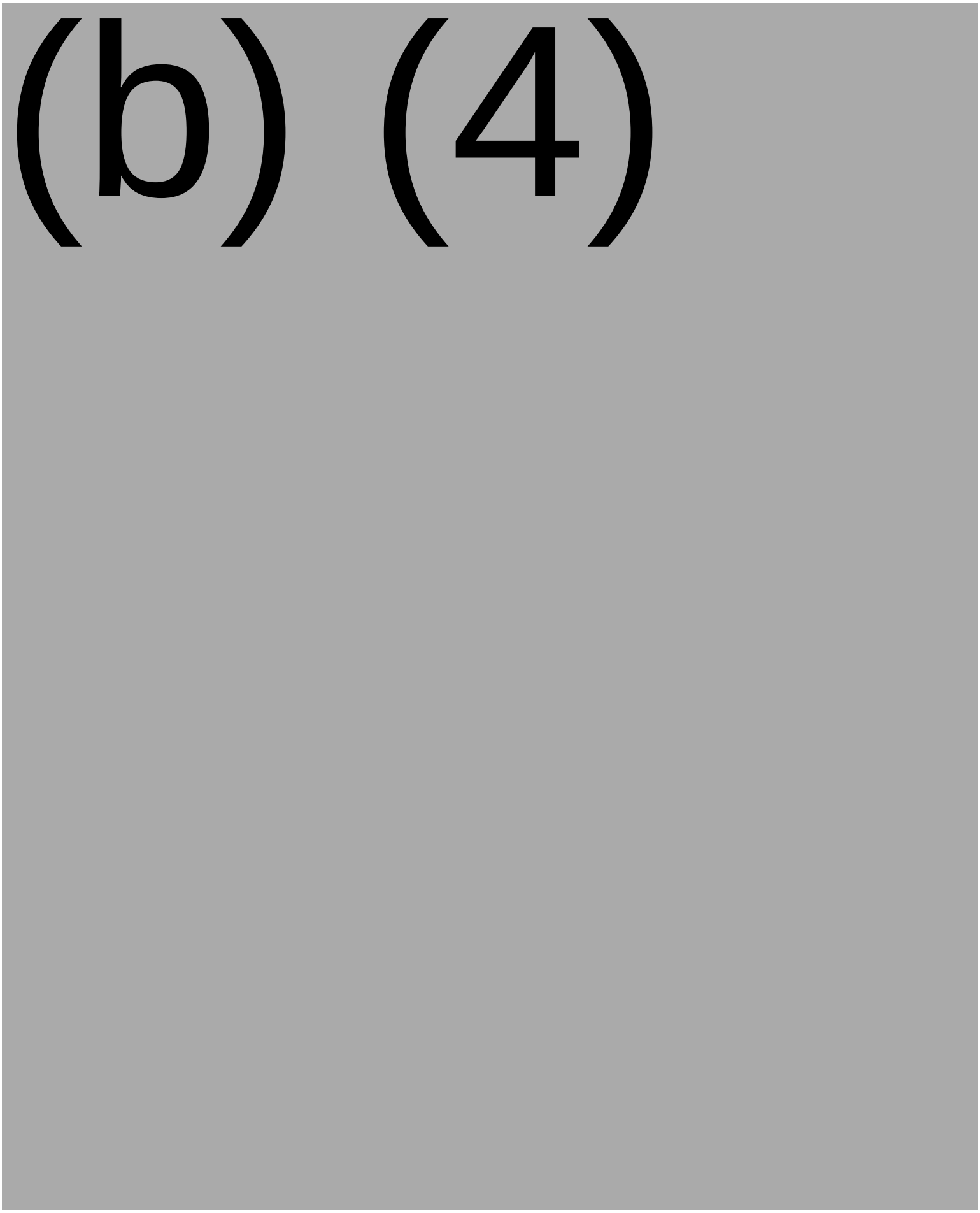
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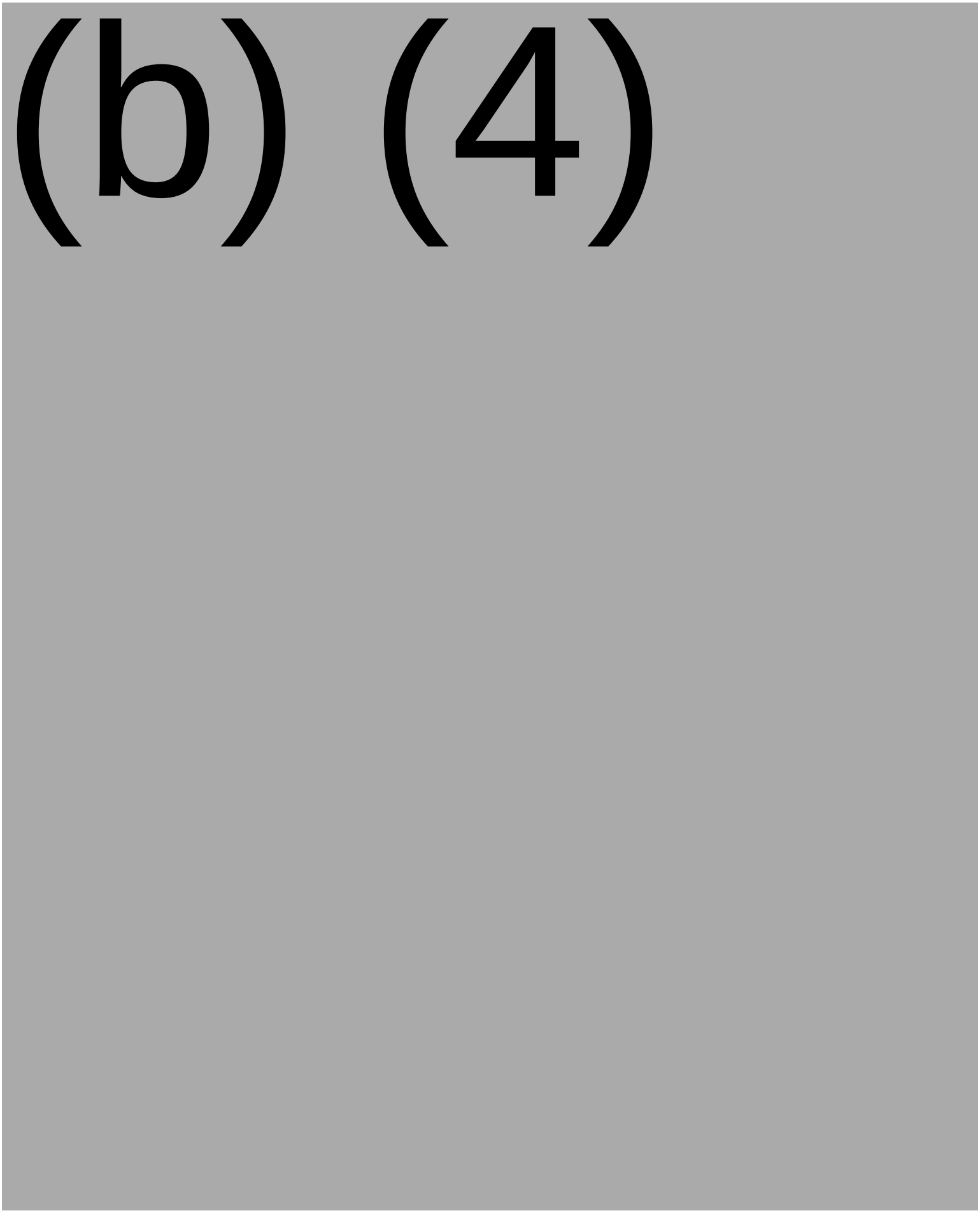
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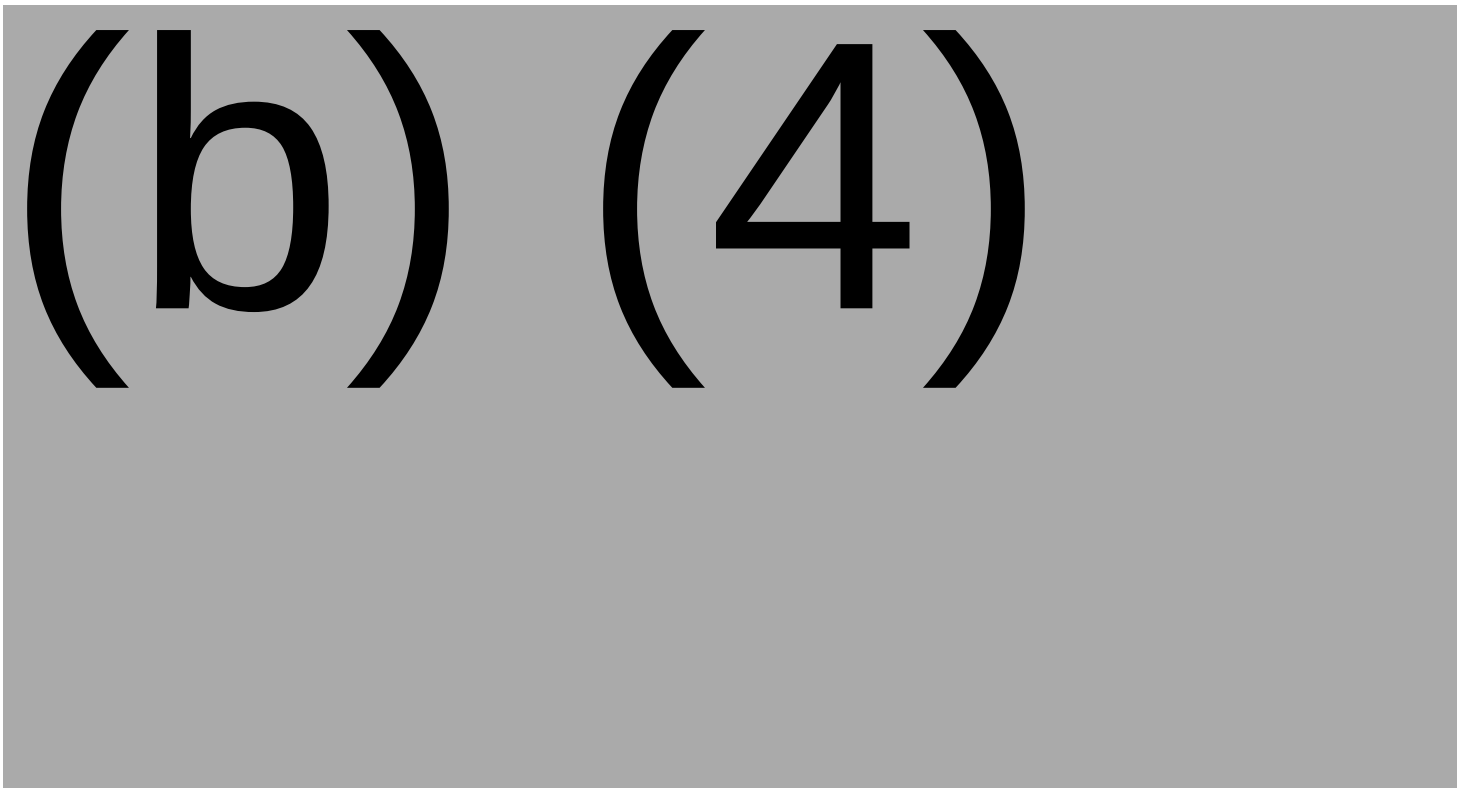
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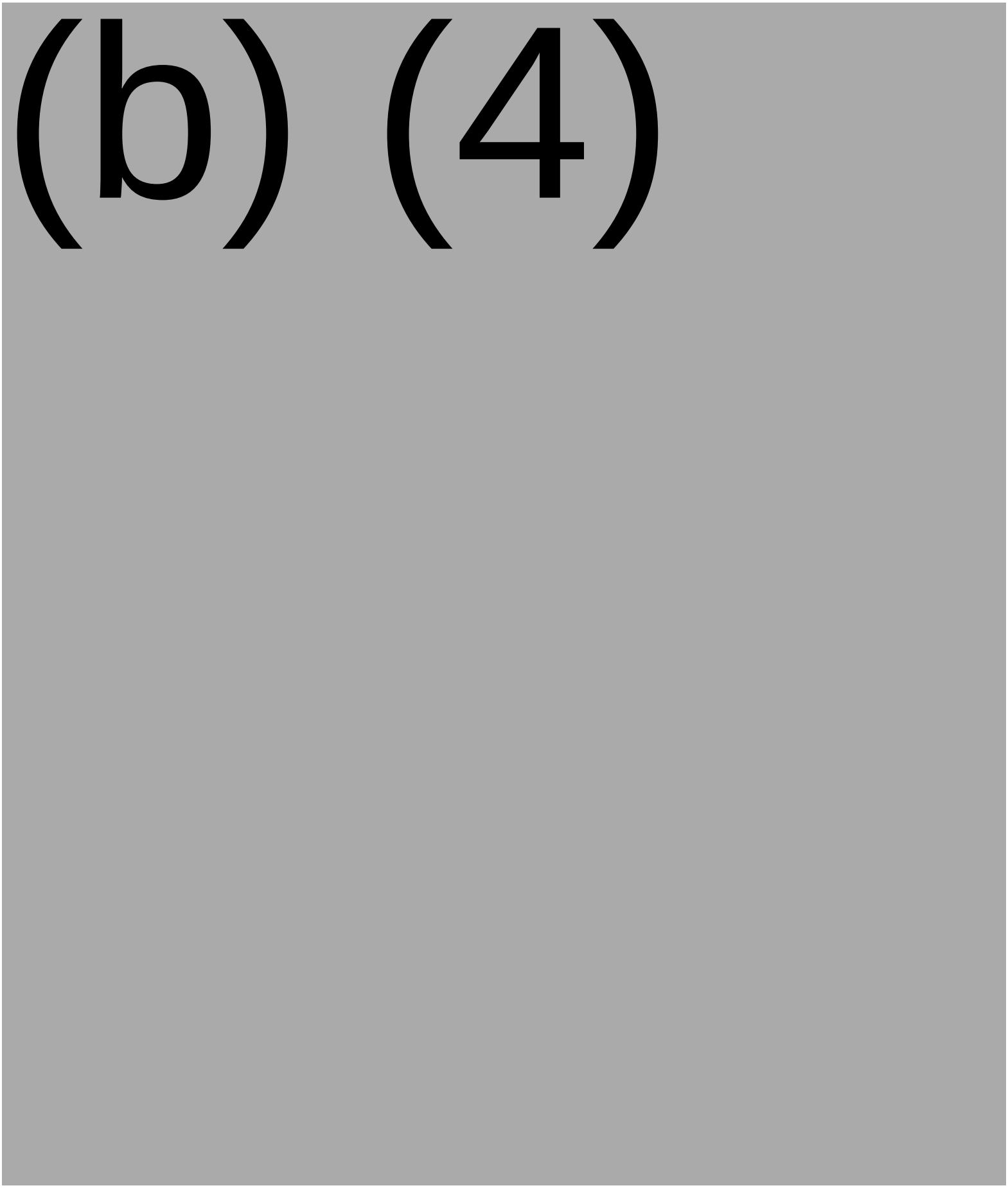
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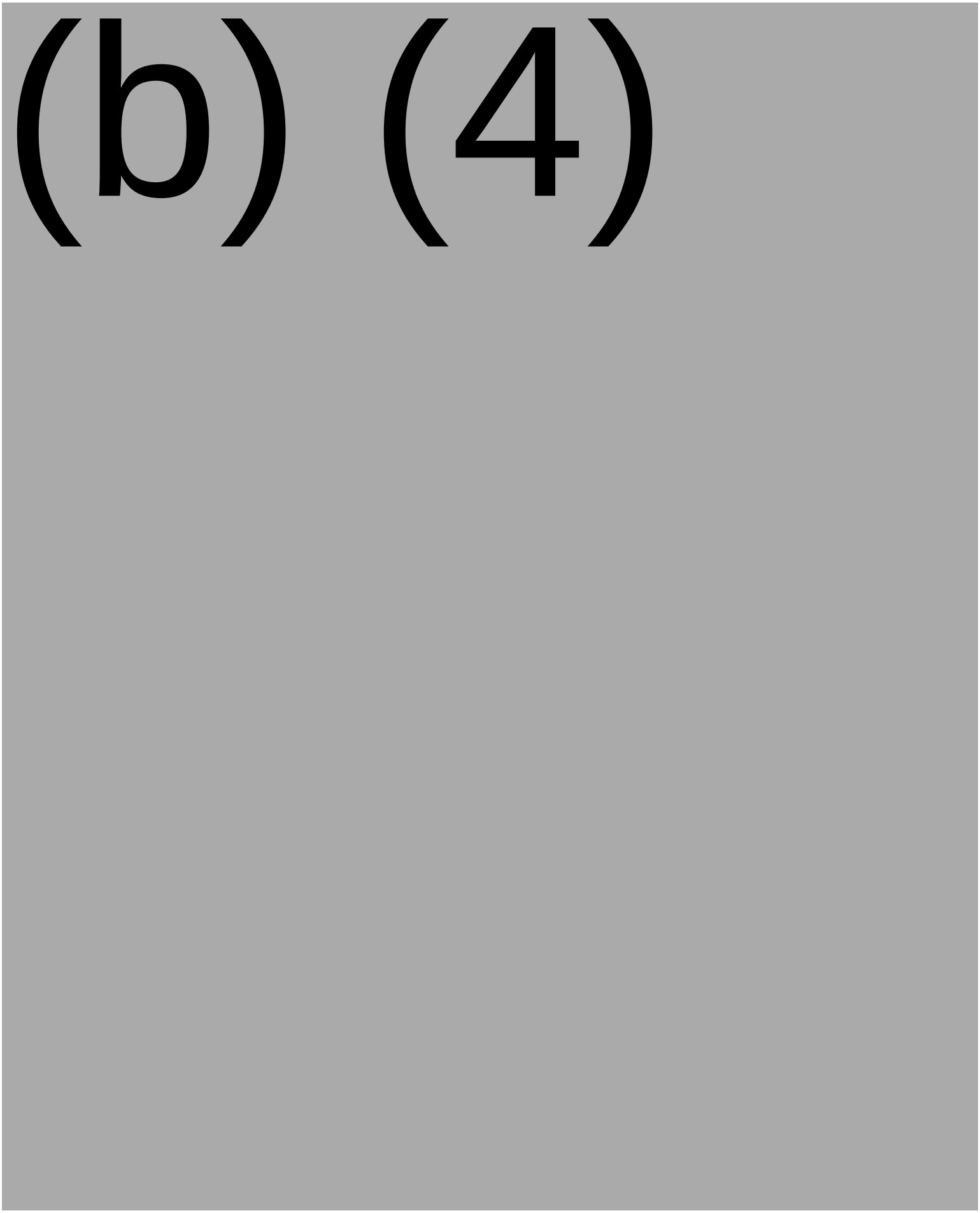
(b) (4)