(b) (4)

1-Hydroxy-2-butanone

Toxicity monograph

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INTRODUCTION

(b) (4) was asked to produce a toxicity monograph of 1-hydroxy-2-butanone (CAS RN[1] 5077-67-8), focussing on the inhalation route of exposure. Data on the inhalation of tobacco smoke containing the ingredient (if available) have not been included in this monograph.

EXPERTISE

(b) was founded[2] in 1961 to provide independent, high-quality research, information and advice on chemical toxicology to industry and governmental departments. Its risk assessors have been working together for many years (more than 40 years in some instances) and have a record of objectivity and scientific excellence. All the senior and principal scientists in the current team are accredited and listed in the European (Eurotox) and UK Royal Society of Biology/British Toxicology Society Registers of Toxicologists and are thus bound by their specific codes of conduct.

TOXICITY DATA SEARCH CRITERIA

Searches for toxicity data were restricted to (b) (4) databank (see the Appendix for details) and the TOXNET system of databases and databanks (which includes Toxline (the toxicity subset of Medline), HSDB, GENETOX, DART, CCRIS, IRIS, ITER and CPDB). Since these searches could not necessarily be relied upon specifically to identify cardiopulmonary data, additional searches were conducted in PubMed tailored to identify such information.

All searches were conducted in October 2016 using the CAS RN and (in PubMed only) name identified below, as appropriate.

The data summarised in this report refers to the unheated form unless otherwise stated.

[1] Chemical Abstracts Service Registry Number.

[2] as the (b) (4)

IDENTIFICATION, REACH STATUS AND EU CLASSIFICATION

Identifier / status	
Name	1-Hydroxy-2-butanone
Synonym(s)	1-Hydroxybutan-2-one 2-Oxobutanol Ethyl hydroxymethyl ketone
CAS RN	5077-67-8
REACH registration number	Not REACH registered
Classification, according to EU CLP (EC 1272/2008)	**Harmonised classification:** None available

TOXICOLOGY

No substance-specific data were identified.

CARDIOPULMONARY EFFECTS[3]

No substance-specific data were identified.

OTHER CONSIDERATIONS

In its scientific opinion on aliphatic acyclic diols, triols and related substances, the EFSA CEF Panel[4] concluded that there was "no safety concern" from the use of 1-hydroxy-2-butanone as a food flavouring agent at a current estimated intake of 0.012 µg/day in Europe (EFSA, 2010).

REFERENCES

EFSA (2010). European Food Safety Authority. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). Scientific Opinion on Flavouring Group Evaluation 92 (FGE.92): Consideration of aliphatic acyclic diols, triols, and related substances evaluated by JECFA (68th meeting) structurally related to aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones evaluated by EFSA in FGE.10Rev1 (2009). EFSA Journal 8(9), 1453. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1453/abstract

[3] Potential effects on the heart, blood vessels and/or respiratory tract.
[4] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids.

APPENDIX: The ((b) (4) database and databank

(b) (4)

(b) (4) includes information from peer-reviewed toxicology and nutrition journals as well as secondary sources and websites. In addition to primary literature on the health effects of chemicals, (b) (4) covers official publications and evaluations issued by authoritative groups including:

- WHO/IPCS reports and evaluations (including CICADs and EHCs, and IARC, JECFA and JMPR monographs), and the WHO Air Quality and Drinking-Water Quality Guidelines
- OECD SIDS dossiers/SIARS
- IUCLID data sets
- EU Risk Assessment Reports
- EU expert committee opinions (including EU scientific committees, and EFSA scientific panels) and other reports from EU agencies and institutes etc (including ECHA, ECVAM, EMA and CPS&Q)
- ECETOC, HERA, Council of Europe and other pan-European programmes
- UK government agency (including Defra, EA, FSA, DoH, HSE, HPA, PSD and VMD) and advisory committee (e.g. COT, COM, COC, ACNFP, SACN, ACP, ACAF, VPC, VRC and ACRE) reports and evaluations
- Opinions from other UK organisations such as the Royal Society
- US agency reports and evaluations (EPA, ATSDR, FDA, NTP, OSHA, NCEA, CFSAN, CERHR, NIEHS, CDC, OEHHA and ACGIH)
- Health Canada evaluations
- BUA, DFG, BG Chemie and BfR reports and monographs
- Gezondheidsraad opinions, including those from its various committees such as DECOS
- RIVM reports
- Danish EPA reviews
- Reports and other information provided by Swedish governmental organisations, including the National Food Administration and the Swedish Chemicals Agency
- Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals
- Australian agency reviews including NICNAS Priority Existing Chemical Assessments, APMVA reports and (jointly with New Zealand) FSANZ assessments
- Japanese Chemical Industry Ecology-Toxicology & Information Center reports
- CIR, RIFM and other specialist industry groups
- (b) **Toxicity Profiles**