Acetol

Toxicity monograph

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Prepared by:

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INTRODUCTION

(b) (4) was asked to produce a toxicity monograph of acetol (CAS RN[1] 116-09-6), 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) (4) 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

As instructed by the client, searches for toxicity data were restricted to the (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) names identified below, as appropriate.

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

[1] Chemical Abstracts Service Registry Number.

[2] (b) (4)

IDENTIFICATION, REACH STATUS AND EU CLASSIFICATION

Identifier / status	
Name	Acetol
Synonym(s)	Hydroxyacetone 1-Hydroxy-2-propanone 1-Hydroxypropan-2-one 2-Oxopropanol
CAS RN	116-09-6
REACH registration number	Not REACH registered
Classification, according to EU CLP (EC 1272/2008)	**Harmonised classification:** None available

TOXICOLOGY

LOCAL EFFECTS

No substance-specific data were identified.

SENSITISATION AND INTOLERANCE

Respiratory tract sensitisation

No substance-specific data were identified.

Skin sensitisation

Human

No substance-specific data were identified.

Non-human

1-Hydroxy-2-propanone was not sensitising when tested on a group of 18 guinea pigs [no further details provided] (Rao *et al.*, 1981).

Oral allergy/intolerance

No substance-specific data were identified.

INHALATION TOXICITY STUDIES

No substance-specific data were identified.

TOXICITY STUDIES – OTHER EXPOSURE ROUTES

Single dose toxicity

Human

No substance-specific data were identified.

Non-human

An oral LD_{50} value[3] of 2200 mg/kg bw has been reported for rats [no further details in the citing source] (Smyth and Carpenter, 1948).

Repeated dose toxicity

No substance-specific data were identified.

GENOTOXICITY

Expert-group opinion

In its opinion on aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones, the EFSA CEF Panel[4] concluded that "despite limitations in study design and reporting… 1-hydroxypropan-2-one should be considered an *in vitro* mutagen in bacteria" (EFSA, 2012). [See also Genotoxicity – Micro-organisms section.]

Mammals (*in vivo*)

No substance-specific data were identified.

Mammalian cells (*in vitro*)

No substance-specific data were identified.

Micro-organisms

Acetol was mutagenic in four limited bacterial reverse mutation (Ames) assays, each using a single *Salmonella typhimurium* strain, when tested at concentrations up to 500 µg/plate with and without S9[5] (strain TA100), or 5 mg/plate[6] (the "maximum non-toxic limit") without S9 (strain TA104) (cited in EFSA, 2012). [Modern guidelines recommend testing in at least five bacterial strains.]

Other

No substance-specific data were identified.

CARCINOGENICITY

No substance-specific data were identified.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

No substance-specific data were identified.

[3] Lethal Dose 50, i.e. the dose that is lethal to 50% of the exposed group.
[4] EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids.
[5] Induced mammalian liver post-mitochondrial fraction used for metabolic activation.
[6] The "concentration/dose" was given in EFSA as "68 µmoles (5 µg/ml)". Based on a molecular weight of 74.1, 68 µmoles equates to 5 mg. Presumably this was the amount tested per plate.

CARDIOPULMONARY EFFECTS[7]

No substance-specific data were identified.

REFERENCES

EFSA (2012). European Food Safety Authority. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). Scientific Opinion on Flavouring Group Evaluation 10, Revision 3 (FGE.10Rev3): Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30. EFSA Journal 10(3), 2563. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2563/epdf

Rao KS, Betso JE and Olson KJ (1981). A collection of guinea pig sensitization test results - grouped by chemical class. Drug and Chemical Toxicology 4, 331-351.

Smyth HF Jr and Carpenter CP (1948). Further experience with the range-finding test in the industrial toxicology laboratory. Journal of Industrial Hygiene and Toxicology 30, 63-68 [cited in EFSA, 2012].

[7] Potential effects on the heart, blood vessels and/or respiratory tract.

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

(b) (4)

(b) 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