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CAS No. 643-79-8

Ortho-Phthalaldehyde

The nomination and screening process for existing chemicals

Existing chemicals are those industrial chemicals available for use in Australia and listed on the Australian Inventory of Chemical Substances (AICS).

Any person or organisation with a concern about the public health, occupational health and safety, or environmental effects of an industrial chemical may nominate it for assessment. Once nominated the chemical undergoes a screening and information gathering process against set criteria and a list of "candidate" chemicals decided upon in consultation with other government agencies. Chemicals from the candidate list may then be recommended for declaration as a Priority Existing Chemical (PEC) on a priority basis. If declared, the chemical enters the assessment process. Assessments may take into account all aspects of the chemical, or only cover specified issues.

Reasons for Nomination

Ortho-phthalaldehyde was nominated by the public because of concerns about its use as a high level disinfectant (ie one that destroys all microorganisms except bacterial spores).

Import, Manufacture and Use

Ortho-phthalaldehyde is a phenolic dialdehyde. *O*-phthalaldehyde appears to have two broad areas of use. Firstly it is used as a chemical reagent in the analysis of amino acids due to its ability to fluoresce (Lindeberg and Gunnar, 1976). Secondly, *o*-phthalaldehyde has antimicrobial activity (Rutala and Weber, 2001) and is used in a 0.55% solution as a high level disinfectant for surgical instruments such as endoscopes. It has been conditionally registered by the United States Environmental Protection Agency as a pesticide (Federal Register, 1996). Other uses noted in literature are in water treatment, paper manufacture, hair colourings, wood treatment and antifouling paints. The only Australian use known to NICNAS is as a surgical instrument disinfectant.

Databases Searched

Following nomination, screening included the following searches:

- TOMES CPS database which is a compilation of a number of chemical, occupational and health databases (available by subscription),
- Exichem which details activities underway in OECD member states on chemicals under the OECD High Production Volume Chemicals Program (accessed via www.olis.oecd.org/exichem.nsf),
- OECD databases (which are not available to the general public),
- MEDLINE which is maintained by the United States National Library of Medicine and indexes articles from a large number of medical and scientific journals (accessed via www.ncbi.nlm.nih.gov/entrez/query.fcgi) and
- SciFinder® (also available by subscription).

Existing Chemicals Information Sheet

In general, the primary sources of information during screening are the TOMES, SciFinder® and OECD databases, the other information sources are searched if no information is found in the primary sources or if a substantive review has been published by an overseas agency. Except in unusual circumstances, only abstracts of published papers are read.

For this particular product little published data were found in the searches and the bulk of the information evaluated consisted of unpublished, some published, and other data such as the Material Safety Data Sheet (MSDS), from the supplier of the disinfecting solution.

Current National Occupational Health and Safety Regulations

O-phthalaldehyde is not listed in the National Occupational Health and Safety Commission's (NOHSC) List of Designated Hazardous Substances (1999).

Information on the Chemical

O-phthalaldehyde showed moderate acute oral toxicity in the rat (LD₅₀ 121mg/kg to 170mg/kg) and low dermal toxicity in rabbits (LD₅₀ > 2000mg/kg using a 0.55% solution), it is a skin and eye irritant in rabbits. No skin sensitization data was available but as related chemical sterilants (glutaraldehyde and formaldehyde) are both skin sensitisers it is likely *o*-phthalaldehyde will display skin sensitization properties. The MSDS for the 0.55% product states that *o*-phthalaldehyde is a potential skin and respiratory sensitiser. Reports of adverse incidents from users of the sterilant include symptoms which may be related to skin or respiratory sensitization, such as skin irritation and rash, pruritis, flushing, eye irritation, cough, dry mouth, rhinitis, facial oedema. Oral (gavage) repeat exposure studies in rats using doses between 5mg/kg bw/day to 50mg/kg bw/day showed direct irritant effects on the stomach lining and on the lungs and some minor effects on blood biochemistry, with no effects seen at the 5mg/kg bw/day dose level. The chemical has not been shown to cause birth defects but did delay foetal development in the rat in an oral (gavage) study at a dose of 40 mg/kg bw/day given to the dams. Doses ranging from 10mg/kg bw/day to 40mg/kg bw/day were used and produced maternal toxicity at all doses including the lowest dose of 10mg/kg bw/day. No effect on foetal development was seen at 20mg/kg bw/day. In a chromosome aberration study in CHO cells *o*-phthalaldehyde was found to be clastogenic, it was positive in a sister chromatid exchange assay and negative in a forward mutation study in the same cell line. An Ames test, an in vitro UDS study and an in vivo chromosome aberration study in rats returned negative results. It is considered unlikely to have any genotoxic effects. No data was found regarding carcinogenicity potential.

Outcome of the screening

As the only use of the chemical in Australia known to NICNAS is as a surgical instrument disinfectant, its regulation comes within the scope of the Therapeutic Goods Administration and the concern was referred to that agency.

References

Lidberg, E and Gunnar, G (1976). Use of *o*-phthalaldehyde for detection of amino acids and peptides on thin-layer chromatograms. J. Chromatogr. 117(2), 439-441

Rutala, W.A and Weber, D.J. (2001). New Disinfection and Sterilization Methods. Emerging Infectious Diseases 7(2), 348-353

Federal Register (1996) Volume 61 Number 208, Notices, page 55296. Office of the Federal Register, National Archives and Records Administration

MEDLINE – US National Library of Medicine

SciFinder® – American Chemical Society

TOMES CPS – Thomson Micromedex