Worksafe Australia Completes Glutaraldehyde Assessment

Summary

From an assessment of information about the health and environmental effects of glutaraldehyde, hazards during its use, exposure data, and control measures currently available, Worksafe Australia[1] has concluded that glutaraldehyde can be used safely if the proper control measures are in place. Risks may be satisfactorily controlled in a cost-effective manner by a judicious combination of training, ventilation, good work practices, and personal protection.

Purpose and Scope of the Assessment

The glutaraldehyde assessment was made under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the principal aim of which is to help protect people and the environment from the harmful effects of industrial chemicals by ensuring that the risks to occupational health and safety, to public health, and to the environment are known and understood. It is the first major public international review of glutaraldehyde to have been conducted.

Worksafe's 176-page report on glutaraldehyde is an in-depth look at the chemical, including its uses, occupational and environmental exposure, and public health assessment. It deals with chemistry, methods of detection and analysis, kinetics, and metabolism. The effects of glutaraldehyde on *in vitro* and *in vivo* test systems are reviewed, addressing acute toxicity, irritation, sensitization, repeated-dose toxicity, reproductive toxicity, teratogenicity, and genotoxicity. Under human health effects, the potential for irritation, sensitization, and other effects is discussed, and medical case histories are reviewed.

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Worksafe's Conclusions and Recommendations

- The main health hazards of glutaraldehyde are irritation of the skin, eyes, and respiratory system. Adverse health effects have been observed principally in the health care industry, due to the high number of workers in this industry and the poor controls in many workplaces.
- For the uses of glutaraldehyde described in this report, it is unlikely that glutaraldehyde will pose a significant health and safety risk to the general public or a significant risk to the environment.
- Occupational exposure to glutaraldehyde can be reduced simply by the adoption of safer work practices.
- Based on information about its human health effects and the results of animal and *in vitro* testing, glutaraldehyde is classified as a hazardous substance[2] at concentrations >0.1% w/w, according to the Approved Criteria for Australia[3]. It is recommended that suppliers incorporate health hazard information consistent with the classification of glutaraldehyde in their MSDSs and labels.
- The evidence for the respiratory sensitizing effect of glutaraldehyde is not sufficient to recommend classification under the Approved Criteria[3], but it is recommended that the position be further reviewed. Similarly, the acute inhalational toxicity classification should be reviewed when more data are available.
- It is recommended that labels and MSDS of glutaraldehyde-containing products be up to standard, and that the following statements be included on MSDS for glutaraldehyde products:
  - –"Occupational asthma and/or rhinitis have been indicated in a number of workers exposed to glutaraldehyde."
  - –"The results of more recent assays have generally shown that glutaraldehyde is mutagenic *in vitro*. *In vivo* tests to date have been negative. Consequently, glutaraldehyde does not meet the criteria for classification as a mutagen."
- For the health care industry, it is recommended that safe use guidelines be provided for health care and dentistry workplaces.
- Workers potentially exposed to glutaraldehyde need to be trained in the safe work practices which are appropriate to their particular workplace, and that a record of training be kept.
- The implementation of effective control measures recommended–e.g., enclosures, engineering controls, safe work practice, personal protective equipment, in accordance with the hierarchy of control measures detailed in the National Model Regulations and Code of Practice for the Control of Workplace Hazardous Substances[4].
- In general, any proposed alternative to glutaraldehyde should be carefully considered to ensure that the risks to health and safety are not increased.
- The environmental persistence of glutaraldehyde is extremely limited. It reacts with proteins and is rapidly biodegraded at aqueous concentrations below about 10 mg/L. Glutaraldehyde is moderately toxic to aquatic fauna and moderately-to-highly toxic to algae. However, its lack of persistence confers adequate aquatic safety margins, and it has not been associated with any incidents of environmental damage in the years in which it has been used in Australia.
- Worksafe concluded that glutaraldehyde can be used safely, provided proper control measures to protect workers and the environment are put in place by employers.

Comments

To obtain a copy of the full Workplace Australia study, formally titled, "Priority Existing Chemical No. 3: Glutaraldehyde – Full Public Report," send a check or money order for your country's equivalent of $25 (Australian) to:

Manager, AGPS Press
Australian Government Publishing Service
GPO Box 84
Canberra, ACT 2601, Australia

Union Carbide is in general agreement with the conclusions and recommendations of Worksafe Australia.

Footnotes

(1) Worksafe Australia is the equivalent of the Occupational Safety and Health Administration, an agency of the U.S Department of Labor. The assessment of glutaraldehyde was made under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This Scheme was established by the Commonwealth Industrial Chemicals (Notification and Assessment) Act 1989, which came into operation on July 17, 1990. NICNAS is administered by Worksafe Australia. Assessments under NICNAS are done in conjunction with the Commonwealth Environmental Protection Agency and the Department of Human Services and Health.

(2) It should be noted that the definition of a hazardous substance is not universal. It may differ by country.

(3) National Occupational Health and Safety Commission: Approved Criteria for Classifying Hazardous Substances [NOHSC:0006 (1993)], AGPS, Canberra, 1993.

(4) National Occupational Health and Safety Commission: Control of Workplace Hazardous Substances: National Code of Practice for the Control of Workplace Hazardous Substances [NOHSC:0003 (1993)], and National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC:0002 (1993)], Australian Government Publishing Service, Canberra, 1993.

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