

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

To: File for Glutaraldehyde (CAS# 111-30-8)

From: George Eurich

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Subject: Screening level for Glutaraldehyde (CAS# 111-30-8)

There are two Initial Threshold Screening Levels* (ITSLs) for glutaraldehyde:

- 0.08 ug/m³ with annual averaging time for chronic exposures
- 2 ug/m³ with 1-hour averaging time for acute exposures

The following references or databases were searched to identify data to determine the screening level: U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS), National Institute for Occupational Safety and Health (NIOSH) Registry for Toxic Effects of Chemical Substances (RTECS), American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), Michigan Department of Environmental Quality (MDEQ) library, International Agency for Research on Cancer (IARC) Monographs, Chemical Abstract Service (CAS) online, National Library of Medicine (NLM) - Toxline, National Toxicology Program (NTP) Status Report, and California Office of Environmental Health Hazard Assessment (CAL-OEHHA) Reference Exposure Levels (RELs). The EPA has not derived a reference concentration (RfC) nor any Acute Exposure Guidance Levels (AEGs) for glutaraldehyde. The Agency for Toxic Substance and Disease Registry (ATSDR) has not derived Minimal Risk Levels (MRLs) for the compound.

Physical Data:

- * Colorless to pale yellow liquid with a pungent odor
- * MW = 100.11
- * Readily soluble in water, alcohol, ether, and similar organic solvents

Glutaraldehyde is a commonly used biocide. The Air Quality Division (AQD) established an Interim ITSL of 8.2 ug/m³ for glutaraldehyde in 1993, based on a Ceiling-TLV (c-TLV) of 0.2 ppm. ACGIH (1998) cited that glutaraldehyde has the potential for skin sensitization. Occupational Safety and Health Administration (OSHA) and NIOSH evaluations of glutaraldehyde concluded that human evidence clearly demonstrated a significant risk of irritation to the eyes, nose, and throat associated with short-term exposures at concentrations of 0.3 ppm and above. The ACGIH c-TLV was revised to 0.05 ppm (0.2 mg/m³) in 1998. This value is intended to minimize the potential for nose, throat, skin, and eye irritation, and headache. A SEN notation was also assigned to the c-TLV, based on the documented reports of skin sensitization in exposed workers. While rodent studies have identified a spectrum of upper respiratory tract lesions, no clear dose-response relationships in humans have been established for airborne glutaraldehyde exposure.

In 1999, NTP performed a chronic study on the toxicology and carcinogenesis of glutaraldehyde in rats and mice. This study identified a LOAEL of 62.5 ppb in female mice

with the critical effect being squamous metaplasia of the respiratory epithelium. A No Observable Adverse Effect Level (NOAEL) was not identified from this study. Using this study, CAL-OEHHA estimated a threshold for effects using EPA's Benchmark Dose software (Version 1.20). However, CAL-OEHHA uses a 5% benchmark response BMR_{05} (at 95% lower bound confidence level) to estimate a point of departure, whereas EPA suggests using 10% (BMR_{10}).

Derivation of Screening Levels

Rule 336.1229 enables AQD to use the most scientifically appropriate risk assessment to determine screening levels. The CAL-OEHHA chronic REL and the ACGIH c-TLV for glutaraldehyde were deemed the most appropriate health based benchmarks to use to derive AQD-specific screening levels.

As noted in the CAL-OEHHA chronic REL derivation, with the benchmark approach no LOAEL UF is needed. The study was a lifetime study so the subchronic UF was 1. An interspecies UF of 3 rather than 10 was used since the Regional Gas Dose Ratio (RGDR) adjustment had been made. Finally, the default intraspecies UF of 10 was used producing a total UF of 30. The resulting inhalation reference exposure level was determined to be 0.08 ug/m^3 based on an annual average time. The AQD is adopting this chronic REL as an ITSL with annual averaging time since CAL-OEHHA uses EPA methodology along with peer review to derive their screening levels. Annual averaging time was applied to the ITSL since CAL-OEHHA specifies that their chronic RELs use annual averaging.

Data was evaluated in order to derive an acute ITSL. A review of the ACGIH documentation for glutaraldehyde revealed that the c-TLV of 0.2 mg/m^3 was appropriately based on health data specific to glutaraldehyde and provided adequate protection of adverse health effects from exposure. Therefore, pursuant to Rule 336.1232(1)(c), an ITSL was calculated based on the c-TLV as follows:

$$\text{ITSL} = \text{OEL}/100$$

Where OEL is an appropriate occupation exposure limit (OEL).

$$\text{ITSL} = (0.2 \text{ mg/m}^3)/100$$

$$\text{ITSL} = 0.002 \text{ mg/m}^3$$

$$\text{ITSL} = 2 \text{ } \mu\text{g/m}^3$$

Based on Rule 336.1232(2)(a), the averaging time for an ITSL based on a c-TLV shall be 1-hour..

Conclusion

There are two Initial Threshold Screening Levels* (ITSLs) for glutaraldehyde:

- 0.08 ug/m^3 with annual averaging time for chronic exposures
- 2 ug/m^3 with 1-hour averaging time for acute exposures

*Footnote: This chemical has two ITSLs with different averaging times. Ambient air impacts cannot exceed either ITSL. Both ITSLs also apply for determinations of permit to install exemptions under R 336.1290 (Rule 290).

References

ACGIH. 1998. TLVs and BEIs based on the documentation of the threshold limit values for chemical substances and physical agents & biological exposure indices. ACGIH. Cincinnati, OH.

National Toxicology Program (NTP). 1999. Toxicology and Carcinogenesis Studies of Glutaraldehyde (CAS NO. 111-30-8) in F344/N Rats and B6C3F1 Mice (Inhalation Studies). TR-490. September 1999. NIH Publication No. 99-3980. Available online at <http://ntp-server.niehs.nih.gov/htdocs/LT-studies/tr490.html>

CAL-OEHHA. 2000. California Office of Environmental Health Hazard Assessment - OEHHA Acute, 8-hour and Chronic Reference Exposure Levels (chRELs). Determination of Noncancer Chronic Reference Exposure Levels. Appendix D3. p286. December 2000. http://www.oehha.ca.gov/air/hot_spots/2008/AppendixD3_final.pdf#page=286
<January 31, 2012> Summary Table available online at <http://oehha.ca.gov/air/allrels.html>