

# GLUTARALDEHYDE

**CAS number:** 111-30-8

**Synonyms:** 1,3-Diformylpropane, glutaral, glutaric dialdehyde, 1,5-pentanedial

**Chemical formula:**  $C_5H_8O_2$

**Structural formula:** —

## Workplace exposure standard (amended)

**TWA:** —

**STEL:** —

**Peak limitation:** 0.05 ppm (0.2 mg/m<sup>3</sup>)

**Notations:** DSEN, RSEN.

**IDLH:** —

**Sampling and analysis:** The recommended value is quantifiable through available sampling and analysis techniques.

## Recommendation and basis for workplace exposure standard

A peak limitation of 0.05 ppm (0.2 mg/m<sup>3</sup>) is recommended to protect for acute eye and respiratory tract irritation and headaches in exposed workers.

Given the limited data available from the primary sources, it is recommended that a review of additional sources be conducted at the next scheduled review.

## Discussion and conclusions

Glutaraldehyde is widely used as cold steriliser aqueous solution in medical clinics and hospitals for cleaning delicate items or electronic materials. Other applications in industrial workplaces include as a tanning agent, a biocide in metalworking fluids, oil and gas pipelines, water treatment systems and preservative in fabric softeners.

Based on the available data in humans and animals, the critical effects of exposure are irritation, leading to respiratory and dermal sensitisation, including the development of occupational asthma.

No clear dose-response relationships in humans are established (ACGIH, 2018). Volunteers reported nose, throat, skin and eye irritation, headaches and several other symptoms associated with exposure at and less than 0.1 ppm; based on short-term (15-minute) personal sampling. Respiratory sensitisation was considered possible at airborne concentrations below 0.2 ppm (STEL) (ACGIH, 2018). DFG (2002) suggested a ceiling limit is warranted due to severe effects reported in volunteers and short-term animal studies where severe effects in animals were observed (DFG, 2002).

The peak limitation of 0.05 ppm (0.2 mg/m<sup>3</sup>) is considered protective of irritant effects and is based on the recommendation by ACGIH (2015) and supported by human evidence from the DFG (2002) and NIOSH (2011). Noting the absence of a clear dose-response relationship in humans, it is recommended that an investigation of additional data sources is undertaken at the next scheduled review.

## **Recommendation for notations**

Not classified as a carcinogen according to the Globally Harmonized System of Classification and Labelling on Chemicals (GHS).

Classified as a skin sensitiser and respiratory sensitiser according to the GHS.

There are insufficient data to assign a skin notation.

DRAFT

## APPENDIX

### Primary sources with reports

Source	Year set	Standard
<b>SWA</b>	<b>1991</b>	<b>Peak limitation: 0.1 ppm (0.41 mg/m<sup>3</sup>)</b>
<b>ACGIH</b>	<b>2015</b>	<b>TLV-Ceiling: 0.05 ppm (0.2 mg/m<sup>3</sup>)</b>
<p>TLV-Ceiling recommended to minimise irritation of nose, throat, skin, and eyes and headaches. DSEN notation assigned based on occupational exposures and animal studies. RSEN notation based on documented occupational asthma in workers and animal studies where Th-2 cytokine profile indicated.</p> <p>Summary of additional data:</p> <p>Not classified as carcinogenic in humans and insufficient evidence to recommend a Skin notation.</p> <p>Human data:</p> <ul style="list-style-type: none"> <li>No clear dose-response relationships in humans established</li> <li>Reports of nose, throat, skin and eye irritation, headaches and several other symptoms associated with exposure <math>\leq 0.1</math> ppm; based on short-term (15-minute) personal sampling</li> <li>Reported symptoms of headaches and tingling of the face at concentrations between 0.077–0.105 ppm (15 min)</li> <li>Numerous studies indicating respiratory sensitisation associated with exposure in medical healthcare industry</li> <li>An investigation of respiratory symptoms consistent with occupational asthma among 24 symptomatic healthcare workers: <ul style="list-style-type: none"> <li>peak expiratory flow rates indicated a work-related effect in 13 workers; bronchial provocation tests at 0.02 ppm were conducted for 8 workers; occupational asthma was confirmed by a positive late reaction in 5 patients and a dual reaction in 3 subjects</li> <li>specific IgE antibodies to glutaraldehyde were positive for 7 of the 24 workers</li> </ul> </li> <li>Occupational asthma identified in workers at levels below 0.2 ppm (15 min STEL).</li> </ul> <p>Animal data:</p> <ul style="list-style-type: none"> <li>LD<sub>50</sub>: 2,560 mg/kg (rabbit, dermal)</li> <li>LD<sub>50</sub>: 5,000 ppm (rat, inhalation 4 h)</li> <li>NOAEL: 0.16 ppm (rats and mice, inhalation) with potential evidence of inflammation at lower levels (0.06 ppm); lowest concentration tested</li> <li>Contact hypersensitivity demonstrated to be dose related in guinea pigs and mice</li> <li>Dermal application initiated a Th-1 cytokine immune response and Th-2 cytokine asthma related response</li> <li>Mouse ear swelling tests conducted indicating concentration dependant response supporting evidence as product causing both contact dermatitis and occupational asthma symptoms</li> <li>No significant genotoxic dose related response in <i>S. typhimurium</i> or other <i>in vivo</i> mice and rat studies.</li> </ul>		



Source	Year set	Standard
<b>DFG</b>	<b>2002</b>	<b>MAK: 0.05 ppm (0.21 mg/m<sup>3</sup>); Momentary value: 0.2 ppm (0.83 mg/m<sup>3</sup>)</b>
<p>MAK applied to prevent irritant effects of substance exposures.</p> <p>Summary of additional data:</p> <p>No appreciable increase in human cancer risk expected if the MAK is observed.</p> <p>Human data:</p> <ul style="list-style-type: none"> <li>Studies confirm sensory and irritation effect responses linked to concentrations greater than 0.1 mL/m<sup>3</sup>.</li> </ul> <p>Animal data:</p> <ul style="list-style-type: none"> <li>Inconsistent results in <i>in vitro</i> tests with bacteria.</li> </ul>		
<b>SCOEL</b>	<b>NA</b>	<b>NA</b>
No report.		
<b>OARS/AIHA</b>	<b>NA</b>	<b>NA</b>
No report.		
<b>HCOTN</b>	<b>2005</b>	<b>Ceiling limit: 1 ppm (0.25 mg/m<sup>3</sup>)</b>
<p>Critical effect of short-term exposures determined to be sensory irritation of the eyes, nose and throat. Health based OEL for exposure in air recommended at 0.4 mg/m<sup>3</sup>.</p> <p>Summary of additional data:</p> <p>Ceiling limit warranted due to steep dose-response curves in volunteer and short-term animal studies, and with severe effects (respiratory damage and death) in animals.</p> <p>Human data:</p> <ul style="list-style-type: none"> <li>NOAEL: 0.4 mg/m<sup>3</sup> for sensory irritation.</li> </ul> <p>Animal data:</p> <ul style="list-style-type: none"> <li>LD<sub>50</sub>: 2,500 mg/kg (rat, dermal)</li> <li>LD<sub>50</sub>: 94–177 mg/m<sup>3</sup> (23.5–44.3 ppm) (rats, inhalation); vapour generated at 60–65°C.</li> </ul>		

## Secondary source reports relied upon

Source	Year	Additional information
NICNAS	✓ 1994	<ul style="list-style-type: none"> <li>Priority Existing Chemical No. 3 (Full Public Report)</li> <li>0.5% solution noted as skin irritant in humans, and a skin sensitizer in 1–2% of the test population</li> <li>Sufficient evidence to conclude occupational asthma and rhinitis can result from exposure in the workplace.</li> </ul>
OECD	✓ 1995	<ul style="list-style-type: none"> <li>Health concerns may arise where available control measures such as ventilation have not been implemented.</li> </ul>



Source	Year	Additional information
US NIOSH	✓ 2011	<ul style="list-style-type: none"> <li>No specific human data identified that reported the degree of skin absorption</li> <li>Considered to have low acute toxicity following exposure by the dermal route</li> <li>Repeated-insult patch tests in humans and predictive tests in animals demonstrate support skin sensitiser notation in both humans and animals.</li> </ul>

## Carcinogenicity — non-threshold based genotoxic carcinogens

Is the chemical mutagenic?

No

**The chemical is not a non-threshold based genotoxic carcinogen.**

## Notations

Source	Notations
SWA	Sen
HCIS	Respiratory sensitisation – category 1, Skin sensitisation – category 1A
NICNAS	NA
EU Annex	NA
ECHA	Resp. Sens. 1, Skin Sens. 1A
ACGIH	Carcinogenicity – A4, DSEN, RSEN
DFG	Carcinogenicity – 4, Sa (respiratory sensitiser), Sh (dermal sensitiser)
SCOEL	NA
HCOTN	—
IARC	NA
US NIOSH	SK:SEN

NA = not applicable (a recommendation has not been made by this Agency); — = the Agency has assessed available data for this chemical but has not recommended any notations

## Skin notation assessment

### Calculation

Insufficient data to assign a skin notation.

## IDLH

Is there a suitable IDLH value available?

No

## Additional information

Molecular weight:	100.11
Conversion factors at 25°C and 101.3 kPa:	1 ppm = 4.1 mg/m <sup>3</sup> ; 1 mg/m <sup>3</sup> = 0.24 ppm
This chemical is used as a pesticide:	<input type="checkbox"/>
This chemical is a biological product:	<input type="checkbox"/>
This chemical is a by-product of a process:	<input type="checkbox"/>
A biological exposure index has been recommended by these agencies:	<input type="checkbox"/> ACGIH <input type="checkbox"/> DFG <input type="checkbox"/> SCOEL

## Workplace exposure standard history

Year	Standard
Click here to enter year	

## References

American Conference of Industrial Hygienists (ACGIH®) (2018) TLVs® and BEIs® with 7<sup>th</sup> Edition Documentation, CD-ROM, Single User Version. Copyright 2018. Reprinted with permission. See the [TLVs® and BEIs® Guidelines section](#) on the ACGIH website.

Deutsche Forschungsgemeinschaft (DFG) (2006) Glutaraldehyde – MAK value documentation.

European Chemicals Agency (ECHA) (2019) Glutaraldehyde – REACH assessment.

Health Council of the Netherlands (HCOTN) (2005) Glutaraldehyde. Health-based calculated occupational cancer risk values. The Hague: Health Council of the Netherlands; publication no. 2005/05OSH.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (1994) Glutaraldehyde: Priority Existing Chemical No.3. Full Public Report.

Organisation for Economic Cooperation and Development (OECD) (1995) SIDS initial assessment profile – Glutaraldehyde.

US National Institute for Occupational Safety and Health (NIOSH) (2011) NIOSH Skin Notation Profiles: Glutaraldehyde.