



Inhalation of Glutaraldehyde

Summary

Glutaraldehyde solutions should only be used in properly ventilated areas with atmospheric glutaraldehyde below the Threshold Limit Value (TLV)⁽¹⁾ or the recommended or stipulated Occupational Exposure Limit (OEL)⁽¹⁾. Exposure to glutaraldehyde vapor above 0.3 ppmv will cause irritation to the respiratory tract. These symptoms are temporary. However, there have been some reports of respiratory hyper-reactivity in a small number of people. There is no evidence of systemic toxicity, and there is no mechanistic evidence in humans that glutaraldehyde causes respiratory sensitization.

Respiratory Irritation

Acute exposure to glutaraldehyde vapor generated at ambient temperature does not produce systemic toxicity, but may cause irritation of the respiratory tract. With such acute exposures in humans, effects due to peripheral sensory irritation⁽²⁾ start to appear at 0.3 ppmv and become more marked as the vapor concentration increases.

Vapor Concentration, ppmv	Effects
0.04	Odor Threshold
0.05	Threshold Limit Value (TLV) ⁽¹⁾
0.05-0.2	Occupational Exposure Limits (OEL) ⁽¹⁾
0.3	Irritation Threshold MAY INCLUDE STINGING IN EYES; EXCESS TEAR PRODUCTION AND BLINKING; DISCOMFORT IN NOSE, THROAT, AND CHEST; RUNNY NOSE; COUGHING AND SNEEZING; CHEST DISCOMFORT; AND RARELY, NOSEBLEEDS. Note: These effects occur under conditions of overexposure, i.e., where appropriate protective and precautionary measures are not followed, including adherence to the recommended workplace vapor exposure guideline.
1.0	Marked Sensory Irritation to the Eye and Respiratory Tract CAUSES OVEREXPOSED INDIVIDUALS TO VACATE AREA, THUS PRODUCING VOLUNTARY LIMITATION OF EXPOSURE.



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Respiratory Irritation (continued)

By repeated exposure of rats to vapor concentrations in the range of 0.125–0.3 ppmv, there were signs of peripheral sensory irritation and mild inflammatory effects. By repeated exposure to vapor above 0.5 ppmv, there was a steep slope on the concentration-response curve with effects on the respiratory tract being related to its known irritant effects, but with no evidence of systemic toxicity. Studies in the rat have shown that there is a potential for cumulative respiratory tract irritation at concentrations above about 0.125 ppmv. Subchronic exposures to low concentrations, in the range of 49–250 ppbv, produced signs of sensory irritation, but no evidence for specific target organ systemic toxicity.

Studies conducted at elevated temperatures, 60°C (140°F), showed that the high concentrations produced by elevating the generation temperature may be harmful⁽³⁾ by a sustained single exposure.

Other Effects

A few reports describing “asthmatic-like” symptoms by overexposure to high vapor concentrations have been published. Only a few of these have had investigations appropriate for a diagnosis of occupational asthma. Most reports probably represent cases of nonspecific bronchial hyper-reactivity. To date, only a very small number of cases have been diagnosed as asthma on the basis of both clinical features and appropriate investigational procedures. No cases have demonstrated an immunological basis for the asthmatic reaction. That respiratory sensitization is unlikely to be significant is supported by the results from recent laboratory studies⁽⁴⁾ which demonstrated no respiratory hypersensitivity in guinea pigs challenged with glutaraldehyde vapor.

Precautions

- Use glutaraldehyde solutions in properly ventilated areas so that atmospheric glutaraldehyde is below the TLV or the recommended or stipulated OEL.
- Keep containers of glutaraldehyde covered/closed.
- Avoid splashes and spills; clean up immediately (and appropriately) if they occur.

The odor threshold for glutaraldehyde, 0.04 ppmv, is below the TLV or the stipulated or recommended OEL. Detection of a glutaraldehyde odor is the first indication that ventilation or work practices may not be adequate, and that corrective action should be taken. **If respiratory discomfort is experienced, or if there are other reasons to suspect the ventilation may be inadequate to keep glutaraldehyde vapors below the TLV or the recommended or stipulated OEL, vapor monitoring of the work area should be done.**

Inhalation of vapor may aggravate asthma and inflammatory or fibrotic pulmonary disease. Thus, workers who suffer from such conditions and must work in an area with glutaraldehyde should wear a self-contained breathing apparatus, or if not available, an officially approved or certified air-purifying respirator equipped with an organic vapor cartridge.

Footnotes

1. The Threshold Limit Value (TLV) refers to the airborne concentration of substances and represents conditions that the American Conference of Governmental Industrial Hygienists (ACGIH) believes will not cause adverse health effects by repeated exposure, day after day. The TLV established for glutaraldehyde is 0.05 ppmv, based on irritancy.

The Occupational Exposure Limit (OEL) refers to the airborne concentration of a substance that should not be exceeded. OELs for glutaraldehyde vary among countries, but are generally in the 0.05 to 0.2 ppmv range. OELs are sometimes expressed in mg/litre. For glutaraldehyde, the value in mg/litre divided by 4 gives the value in ppmv.

For many substances, the TLV or OEL is expressed as a time-weighted average over an eight-hour working day (TWA_8). For others, it is expressed as a TWA_8 qualified by a Short-Term Exposure Limit (STEL), which is a 15-minute TWA that should not be exceeded at any time. Exposures above the TWA_8 up to the STEL should be no longer than 15 minutes, should not occur more than four times a day, and there should be at least 60 minutes between successive exposures in this range. For glutaraldehyde, the TLV or OEL is expressed as a Ceiling (C) value, which is the concentration that should not be exceeded during any part of the working exposure. The TLV-C value for glutaraldehyde is 0.05 ppmv. There is no associated qualifying TWA_8 , but sampling may be over a 15-minute period.

When a workplace exposure guideline (TLV or OEL) has not been established, or if it is believed that the recommended guideline is inappropriate, then Union Carbide has a formal review process to establish a value to be applied to its workplaces; this is referred to as an Internal Exposure Limit (IEL). This is a compliance limit, applicable worldwide within Union Carbide. IELs are reviewed periodically to ensure that they provide adequate protection. IELs are expressed as a TWA_8 sometimes qualified by a STEL, or as a Ceiling value. Union Carbide has established an Internal Workplace Exposure Limit (IEL) of 0.1 ppmv as a Ceiling value for glutaraldehyde.

2. Materials having peripheral sensory irritant effects are capable of reversibly interacting with sensory nerve-endings in exposed body surfaces, such as the skin or covering/lining membranes of the eye and respiratory tract. As a result, there is a feeling of discomfort where the site of contamination occurs together with the development of certain reflex effects. For example, exposure of the eye to an airborne sensory irritant causes a stinging sensation in the eye accompanied by excess tearing and blinking. This is an entirely normal biological response to sensory irritant materials and gives warning of exposure to such materials together with some degree of protection, e.g., on the eye, both blinking and excess tearing will limit exposure. Furthermore, such effects are generally experienced at concentrations below those producing any inflammation or injury. For glutaraldehyde, a study with a volunteer panel has shown that the threshold for sensory irritation by vapor exposure is 0.3 ppmv for humans. Since this value is above all current exposure guidelines, the appearance of sensory irritant effects will indicate that there is overexposure to glutaraldehyde vapor. At 1.0 ppmv, there is marked sensory irritation to the eye causing the overexposed individual to vacate the area, and thus producing a voluntary limitation of exposure.
3. Harmful, in this instance, refers to injury to the respiratory tract and possibly death (with sufficiently long and high-concentration exposure).
4. Bushy Run Research Center (1994), Report No. 92U1193: "Glutaraldehyde and Formaldehyde Vapor Pulmonary Hypersensitivity Study in Guinea Pigs." BRRC, Export, PA.



Union Carbide Corporation

• 39 Old Ridgebury Road •

Danbury, CT 06817-0001

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