

5. PRODUCTION, IMPORT/EXPORT, USE, AND DISPOSAL

5.1 PRODUCTION

No information is available in the TRI database on facilities that manufacture or process glutaraldehyde because this chemical is not required to be reported under Section 313 of the Emergency Planning and Community Right-to-Know Act (Title III of the Superfund Amendments and Reauthorization Act of 1986) (EPA 2005).

Glutaraldehyde, one of the most important commercial dialdehydes (Kohlpaintner et al. 2013), is produced by either the gas-phase oxidation of cyclopentene or by a Diels-Alder reaction. In the Diels-Alder reaction, the reaction of acrolein and methyl vinyl ether in a 1:1 ratio results in 3,4-dihydro-2-methoxy-2*H*-pyran (CAS No. 4454-05-1), which undergoes acidic hydrolysis to yield glutaraldehyde and alkanol (Kohlpaintner et al. 2013). Both reactions utilize a multistage extraction with water to recover the glutaraldehyde (Kohlpaintner et al. 2013).

Glutaraldehyde is supplied as a 50% biological solution as well as 4, 15, 25, and 45% solutions (EPA 2007; Lewis 2007). It is also available as its bis(sodium bisulfate) adduct (Kohlpaintner et al. 2013). The anhydrous form of glutaraldehyde is unstable and therefore not commercially available (Arntz et al. 2012; EPA 2007).

5.2 IMPORT/EXPORT

Although glutaraldehyde may be imported to the United States from Germany (IPCS 1998), actual import volumes were not available. However, it is classified as a High Production Volume (HPV) chemical; HPV chemicals are those chemicals produced or imported to the United States in volumes >1 million pounds. Historically, international import volumes of glutaraldehyde are as follows: Australia, over 100 tons/year; Sweden, approximately 165 tons/year; Denmark, approximately 50 tons/year; France, greater than 1,000 tons/year; United Kingdom, several hundred tons/year; and Canada, between 33 and 333 tons/year. Additionally, Norway imports approximately 12,700 tons/year of glutaraldehyde-containing products (IPCS 1998). More recent data were not located.

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5.3 USE

Glutaraldehyde is often used in industrial, laboratory, agricultural, and medical settings (Ballantyne and Jordan 2001; EPA 2007). It has numerous uses, including: disinfection and sterilization; leather tanning; chemical intermediate; industrial antimicrobial agent and pesticide (algacide, bactericide, and fungicide); biological tissue fixative; protein and polyhydroxy material cross-linked; x-ray processing; embalming fluid; printing industry preservative; poultry house fogging and other agricultural sanitization; as a materials preservative; intermediate for adhesives, sealants, and pharmaceuticals; and in the paper and textile industries (Borchers 2012; EPA 2007; IPCS 1998; Kohlpaintner et al. 2013; Lewis 2007). In 2015, the Food and Drug Administration (FDA) provided a list of chemical sterilants, including 21 glutaraldehyde-containing products that are cleared for high-level medical disinfection (FDA 2015) (see Table 5-1).

Glutaraldehyde is often used as a disinfectant for hospital, medical, and dental facilities (EPA 2007). One of the primary uses is for the cold sterilization of medical and dental equipment that cannot be heat sterilized, such as endoscopes or bronchoscopes (Ballantyne and Jordan 2001; Borchers 2012; IPCS 1998; Uhr et al. 2013). Glutaraldehyde can be used to sterilize instruments against a wide spectrum of biocidal activity (both Gram-positive and Gram-negative bacteria, spores, and viruses). Glutaraldehyde is most effective for sterilization around pH 8; however, at this pH, it tends to polymerize. Therefore, it is supplied as a stable, acidic solution (pH 3.0–4.5) and activated by an alkaline buffer (i.e., sodium bicarbonate) to pH 7.8–8.0 (Ballantyne and Jordan 2001; IPCS 1998; Uhr et al. 2013). Typically, a 1–3.5% glutaraldehyde solution is utilized for these applications (Ballantyne and Jordan 2001; FDA 2015; IPCS 1998). Glutaraldehyde is also used in x-ray developing solutions as a cross-linking agent to minimize drying time (IPCS 1998).

Glutaraldehyde is often used in industrial settings. In oil and gas recovery and pipeline activities, as well as industrial water treatment, glutaraldehyde may be used as a biocide (API 2015; Arntz et al. 2012; IPCS 1998; Kohlpaintner et al. 2013; McCurdy 2011). Glutaraldehyde is used in a variety of applications for the oil industry, such as in oil storage tanks, water floods, drilling and packer fluids, gas pipe and well systems, and hydrofracturing equipment to prevent growth of sulfate reducing bacteria that contributes to metal corrosion. Glutaraldehyde can also be found in water-based lubricants for conveyors, air washer and industrial scrubbing systems, cooling and process water systems, and sugar beet mills and water systems. In the paper industry, it may be used as a biocide in process water systems, pigments, fillers, and coatings (EPA 2007; IPCS 1998). It is also used in both the paper and textile industries to improve

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Table 5-1. FDA-Cleared Glutaraldehyde-Containing Disinfectants for Medical Devices

Manufacturer	Active ingredient	Sterilant contact conditions	High-level disinfectant contact conditions
Healthpoint, Ltd.	3.4% glutaraldehyde 20.1% isopropanol	Indication for device sterilization For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C: 6 hours at 25°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes	For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C: 5 minutes at 25°C; 14 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes
Sporicidin International	1.12% glutaraldehyde 1.93% phenol/phenate	Indication for device sterilization; 12 hours at 25°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	20 minutes at 25°C; 14 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes
MediVators, Inc.	2.5% glutaraldehyde	Indication for device sterilization; 7 hours 40 minutes at 35°C; 28 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes and additional supporting information	Automated Endoscope Reprocessor 5.0 minutes at 35°C; 28 days Maximum Reuse (for processing in an Automated Endoscope Reprocessor only with FDA-cleared capability to maintain the solution temperature at 35°C); contact conditions established by simulated use testing with endoscopes
Cetylite Industries, Inc.	3.2% glutaraldehyde	Indication for device sterilization; 10 hours at 20°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	40 minutes at 20°C; 28 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes
MedSci, Inc.	3% glutaraldehyde	Indication for device sterilization; 10 hours at 25°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	25 minutes at 25°C; 28 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes

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Cottrell Limited	2.4% glutaraldehyde	Indication for device sterilization; 10 hours at 20°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	45 minutes at 20°C; 14 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes
Cottrell Limited	3.4% glutaraldehyde	Indication for device sterilization; 10 hours at 20°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	45 minutes at 20°C; 28 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes
Metrex Research, Inc.	3.4% glutaraldehyde	Indication for device sterilization; 10 hours at 25°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only. FDA accepted Metricide Plus as identical to Cidex Plus	90 minutes at 25°C; 28 days Maximum Reuse; FDA accepted Metricide Plus as identical to Cidex Plus
Metrex Research, Inc.	2.5% glutaraldehyde	Indication for device sterilization; 10 hours at 25°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only; FDA accepted Metricide 28 as identical to Cidex Formula 7	90 minutes at 25°C; 28 days Maximum Reuse; FDA accepted Metricide 28 as identical to Cidex Formula 7
Metrex Research, Inc.	2.6% glutaraldehyde	Indication for device sterilization; 10 hours at 25°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only; FDA accepted Metricide as identical to Cidex	45 minutes at 25°C; 14 days Maximum Reuse; FDA accepted Metricide as identical to Cidex
Johnson & Johnson Medical Products	2.4% glutaraldehyde	Indication for device sterilization; 10 hours at 25°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	45 minutes at 25°C; 14 days Maximum Reuse; contact conditions based on literature references
Johnson & Johnson Medical Products	2.5% glutaraldehyde	Indication for device sterilization; 10 hours at 20–25°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	90 minutes at 25°C; 28 days Maximum Reuse; contact conditions based on literature references

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Manufacturer	Active ingredient	Sterilant contact conditions	High-level disinfectant contact conditions
Johnson & Johnson Medical Products	3.4% glutaraldehyde	Indication for device sterilization; 10 hours at 20–25°C; 28 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	20 minutes at 25°C; 28 days Maximum Reuse; contact conditions based on literature references
Wave Energy Systems	2.5% glutaraldehyde	Indication for device sterilization; 10 hours at 22°C; 30 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test only	45 minutes at 22°C; 30 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes.
Advanced Sterilization Products	2.4% glutaraldehyde	10 hours at 25°C; 14 days Maximum Reuse; contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes	45 minutes at 25°C; 14 days Maximum Reuse; contact conditions established by simulated use testing with endoscopes

AOAC = Association of Official Analytical Chemists; FDE = U.S. Food and Drug Administration

Source: FDA 2015

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the wet strength as well as the stability of fibers (Kohlpaintner et al. 2013). Metalworking fluids may also contain glutaraldehyde as an antimicrobial agent (McEntee 2000). In the leather tanning industry, 0.5–2% solutions of glutaraldehyde may be used for leather softening and to help resist mold, water, and alkalis (IPCS 1998).

Agriculturally, glutaraldehyde is used in poultry houses for egg sanitation, cleaning of hatcheries and processing facilities, in animal housing, and for sanitizing farm equipment and other hard surfaces (EPA 2007; IPCS 1998). Typical cleaning solutions contain 0.1–0.3% glutaraldehyde and are sprayed, washed, or foamed onto surfaces. A 400 ppm solution of glutaraldehyde can be used with automated equipment for fogging. Egg shells are sanitized with 750 ppm glutaraldehyde solutions. In aquaculture, glutaraldehyde may be used to help control viruses (IPCS 1998).

In the laboratory, glutaraldehyde is used to cross-link with proteins (Chotani et al. 2012; IPCS 1998). In aqueous solutions, it will partially polymerize, resulting in oligomers (IPCS 1998). It is also used as a bifunctional coupling reagent to bind antibodies to enzymes (Wulff and Henniger 2012) and as a biological tissue fixative (IPCS 1998; Winslow 2003), as well as for the polymerization of pyridoxylated human hemoglobin (Winslow 2003).

The distribution of glutaraldehyde in end-use products for Australia includes: 55% for cold disinfectant for health care settings; 20% for x-ray film processing; 10% for water treatment; 5% for animal housing disinfecting; 5% for tanning of leather; and 5% other (i.e., toilet disinfection, microscopy, aquaculture, and air duct disinfection). In France, the distribution is as follows: 50% for disinfection, 40% for photographic uses, 5% for the leather industry, and 5% for the paper industry. Norwegian usage of glutaraldehyde is primarily for industrial cleaning agents (80%), followed by 14% in photocopying developers. The United Kingdom primarily uses glutaraldehyde for cold disinfectant applications and as a biocide in off-shore oil processes (IPCS 1998). Distribution of use was not available for the United States.

There are limited direct consumer uses of glutaraldehyde, although it may be present in paints and laundry detergents as a slimicide (EPA 2007). It is used to sanitize hard surfaces in areas that the general population may encounter (EPA 2007). It may also be present as a preservative in non-aerosol cosmetics in the European market at concentrations <0.1% (IPCS 1998; McEntee 2000). Use of glutaraldehyde as a pesticide for food use is prohibited (EPA 2013g). Glutaraldehyde may have been used for the topical treatment of warts (i.e., plantar warts), although it is generally not used on skin (Siebert and Harke 2012).

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Counterfeit products advertised as glutaraldehyde, but containing substitutes such as formaldehyde and/or other aldehydes, may be found in some markets (McGinley 2012). Toxicity profiles of such products may be significantly different from that of genuine glutaraldehyde; counterfeit products may also be difficult to distinguish from genuine glutaraldehyde without the assistance of sophisticated analytical procedures.

5.4 DISPOSAL

Glutaraldehyde is considered toxic to fish, aquatic invertebrates, oysters, and shrimp and should not be discharged to water bodies (EPA 2007; IPCS 2000; NIOSH 2000). It is subject to requirements under the National Pollution Discharge Elimination System (NPDES) (EPA 2007).