

## 6. POTENTIAL FOR HUMAN EXPOSURE

### 6.1 OVERVIEW

Glutaraldehyde is used as a biocide in medical, industrial, agricultural, oil and natural gas industry, and laboratory settings (Ballantyne and Jordan 2001; EPA 2007). It can be released to the environment through various means. It may enter indoor air from its uses as a disinfectant, in x-ray development, and from paints and laundry detergents that used it as a slimicide (EPA 2007; Rietz 1985; Sekine et al. 2005). Glutaraldehyde can also enter the atmosphere from oil and gas operations, industrial water treatment processes, poultry house fogging, and vehicle emissions (Arntz et al. 2012; EPA 2007; IPCS 1998; Kohlpaintner et al. 2013).

Releases to water generally occur as a result of waste water disposal from hospitals, textile and paper industries, industrial water treatment processes, cooling water systems, leather tanning, and oil and gas operations (Arntz et al. 2012; EPA 2007; IPCS 1998; Kohlpaintner et al. 2013). Glutaraldehyde solutions are often disposed of as sewage, from which residues can be released to water following sewage treatment processes (IPCS 1998). Disposal of cold disinfectant solutions from hospitals is the major source of glutaraldehyde to surface waters (Emmanuel et al. 2005; IPCS 1998; Jolibois et al. 2002).

When in the environment, glutaraldehyde is generally in the aquatic phase. Glutaraldehyde degrades rapidly under both aerobic and anaerobic conditions in water and under aerobic conditions in soil (EPA 2007; Leung 2001). It is considered to be rather mobile in soils (Leung 2001). Glutaraldehyde does not bioaccumulate in aquatic organisms. Although glutaraldehyde formulations containing ionic and non-ionic surfactants were shown to be toxic to *Vibrio fisheri* and *Daphnia* (Emmanuel et al. 2005), it is not thought to present a significant risk to aquatic or terrestrial compartments when diluted (IPCS 1998). Glutaraldehyde solutions are most stable under acidic to neutral conditions (Ballantyne and Jordan 2001; EPA 2007; IPCS 1998; Smith and Wang 2006; Uhr et al. 2013). Higher pH levels can cause it to polymerize over time (Smith and Wang 2006).

Glutaraldehyde has been identified in both indoor and outdoor air samples (Ban-Weiss et al. 2008; NICNAS 1994; Rietz 1985; Sekine et al. 2005). The majority of the atmospheric monitoring has been done in hospitals and dental clinics where glutaraldehyde is used for sterilization and/or high-level disinfection. The highest airborne concentrations generally occur near the source of sterilization equipment, although the effects are often mitigated by proper ventilation and handling techniques (Rietz 1985). Concentrations of glutaraldehyde in wastewater have been measured, primarily for waste streams

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originating from hospitals where glutaraldehyde solutions are regularly disposed of as sewage (Jolibois et al. 2002).

Exposure to glutaraldehyde is primarily through inhalation (Smith and Wang 2006), although dermal contact and ingestion may also occur (NIOSH 2000, 2011). The general public is generally not exposed to glutaraldehyde, as it is primarily used in industrial or medical applications (EPA 2007; IPCS 1998). People may be exposed in medical facilities or other areas where glutaraldehyde solutions are used for cleaning, and from paint and laundry detergents that contain glutaraldehyde or as a preservative in non-aerosol cosmetics (EPA 2007; IPCS 1998). There is a slight potential for glutaraldehyde residues to contaminate food sources due to its use as a disinfectant in animal housing (EPA 2007). The primary occupational exposure to glutaraldehyde occurs when products are used in medical and dental applications for disinfecting purposes or x-ray processing (EPA 2007; IPCS 1998; NICNAS 1994; Smith and Wang 2006). Operating room nurses, dental professionals, radiographers, x-ray technicians, and cleaning staff have the highest potential for glutaraldehyde exposure (Smith and Wang 2006). However, occupational exposure may also occur as a result of paper manufacturing, oil and gas operations, animal house fogging and cleaning, metalworking, and other industrial processes where glutaraldehyde is used or produced (EPA 2007; IPCS 1998).

## 6.2 RELEASES TO THE ENVIRONMENT

The Toxics Release Inventory (TRI) data should be used with caution because only certain types of facilities are required to report (EPA 2005). This is not an exhaustive list. Manufacturing and processing facilities are required to report information to the TRI only if they employ 10 or more full-time employees; if their facility is included in Standard Industrial Classification (SIC) Codes 10 (except 1011, 1081, and 1094), 12 (except 1241), 20–39, 4911 (limited to facilities that combust coal and/or oil for the purpose of generating electricity for distribution in commerce), 4931 (limited to facilities that combust coal and/or oil for the purpose of generating electricity for distribution in commerce), 4939 (limited to facilities that combust coal and/or oil for the purpose of generating electricity for distribution in commerce), 4953 (limited to facilities regulated under RCRA Subtitle C, 42 U.S.C. section 6921 et seq.), 5169, 5171, and 7389 (limited S.C. section 6921 et seq.), 5169, 5171, and 7389 (limited to facilities primarily engaged in solvents recovery services on a contract or fee basis); and if their facility produces, imports, or processes  $\geq 25,000$  pounds of any TRI chemical or otherwise uses  $>10,000$  pounds of a TRI chemical in a calendar year (EPA 2005).

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**6.2.1 Air**

There is no information on releases of glutaraldehyde to the atmosphere from manufacturing and processing facilities because these releases are not required to be reported (EPA 2005).

Glutaraldehyde may be released to indoor air from its use as a disinfectant (EPA 2007; Rietz 1985). Glutaraldehyde is used in hospitals and dental clinics as a disinfectant as well as in the process of developing x-rays, where it has been identified in air samples (Rietz 1985; Sekine et al. 2005). Releases to air can also occur from the use of paints and detergents that contain glutaraldehyde as a slimeicide (EPA 2007). Levels of glutaraldehyde in indoor air can typically be controlled with proper use and ventilation practices (Rietz 1985).

Releases of glutaraldehyde to outdoor air can occur from its use as a biocide in oil and gas recovery and pipeline operations, as well as industrial water treatment (Arntz et al. 2012; IPCS 1998; Kohlpaintner et al. 2013). Poultry house fogging can also release glutaraldehyde to the air (EPA 2007; IPCS 1998). Glutaraldehyde can also be released to air from vehicle emissions (Ban-Weiss et al. 2008). As might be expected, medium and heavy duty diesel trucks were found to contribute more glutaraldehyde to the atmosphere than light-duty vehicles (Ban-Weiss et al. 2008).

**6.2.2 Water**

There is no information on releases of glutaraldehyde to the water from manufacturing and processing facilities because these releases are not required to be reported (EPA 2005).

Glutaraldehyde may be released to water as a result of its many commercial and industrial uses, including applications as a biocide in industrial water treatment processes, textile and paper industries, cooling and process water systems, oil and gas operations (including hydrofracturing processes), x-ray processing, and leather tanning (API 2015; Arntz et al. 2012; EPA 2007; IPCS 1998; Kohlpaintner et al. 2013; McCurdy 2011). Waste solutions of glutaraldehyde are typically poured down the drain and thus enter sewage treatment facilities. Treated sewage effluent is then released to surface waters, allowing glutaraldehyde residues to enter the aquatic environment (IPCS 1998).

The use of glutaraldehyde in disinfectants can result in significant release of glutaraldehyde to surface waters (Emmanuel et al. 2005; EPA 2007; IPCS 1998; Jolibois et al. 2002; Sano et al. 2005). In particular, disinfectants from facilities such as hospitals are discharged to waste water, often in large

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quantities, which can then enter water resources where they may present a risk to aquatic organisms (Emmanuel et al. 2005; Jolibois et al. 2002). Its use as a cold disinfectant in hospitals, particularly in metropolitan areas, results in large quantities of glutaraldehyde being released to sewage, and it was found that these solutions may retain at least 50% of their biocidal activity (IPCS 1998). Australian data indicate that the primary release of glutaraldehyde to the environment arises from its use as a cold sterilant, which is released to sewage. Assuming that 75% of the 50 tonnes per year of glutaraldehyde used for cold sterilization is disposed of in sewage in a worst-case scenario, the average daily Australian discharge of glutaraldehyde would be 100 kg, resulting in a wastewater concentration of approximately 40 µg/L (IPCS 1998).

Jolibois et al. (2002) predicted that the glutaraldehyde concentration in hospital waste water is 0.50 mg/L, due to disinfecting solutions being released to aquatic environments after use. However, upon measurement of glutaraldehyde concentrations at Rouen University Hospital, it was discovered that peak glutaraldehyde concentrations in waste water were around 8 times higher than predicted. The hospital uses approximately 10 m<sup>3</sup> (10,000 L) of glutaraldehyde-containing solutions per year, containing approximately 365 kg of glutaraldehyde. Measured glutaraldehyde concentrations in the hospital waste water were typically around or below the predicted concentration of 0.5 mg/L, with the exception of one sample, where the glutaraldehyde concentration was 3.72 mg/L. This sample was found to correlate to the timing of disinfectant solution replacements within the hospital, when the remaining solution from the previous week was discarded (Jolibois et al. 2002).

Waste water originating in hospitals can contain hundreds of hazardous chemicals (Emmanuel et al. 2005). Interactions between these chemicals can have additional consequences in the environment, such as the combination of glutaraldehyde from disinfectants with surfactants, chemicals commonly contained in detergents (Emmanuel et al. 2005). A study of the release of glutaraldehyde from waste water to water resources determined that it is acutely toxic to aquatic organisms (Emmanuel et al. 2005). It may be considered moderately toxic to aquatic organisms and highly toxic to algae (Jolibois et al. 2002), although it appears that in many situations, dilution mitigates the risk to the aquatic environment (IPCS 1998). The risk to the aquatic environment, particularly algae, may be higher during periods of drought (IPCS 1998). Additionally, biodegradation and reaction with proteinaceous constituents of raw sewage may help to mitigate glutaraldehyde concentrations in waste water (IPCS 1998).

Smaller volumes and concentrations of glutaraldehyde are typically used in applications other than cold sterilization. X-ray film processing may not present a significant hazard to the aquatic environment as

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glutaraldehyde reacts with sulfites in the process. For cooling water discharge, Australian data indicate that glutaraldehyde is released to sewage at maximum concentrations of 250 mg/L. Leather tanning is expected to result in discharge of 1–3% of the original amount of glutaraldehyde, which may then react with dissolved proteins in the effluent from the tannery. As animal housing typically results in release to the atmosphere through spraying, it is not expected to contribute significantly to aquatic glutaraldehyde contamination. In Sweden, waste water emanating from paper mills can contain glutaraldehyde at concentrations of 6 mg/L (IPCS 1998).

Glutaraldehyde has been investigated for use as a biocide in ballast water treatment for both marine and freshwater systems (U.S. Coast Guard 2004). In this capacity, there is a significant likelihood of release to water (Sano et al. 2005). A study of biocides for ballast water noted that after treatment, some residual glutaraldehyde could remain in water (U.S. Coast Guard 2004). Despite its release potential, glutaraldehyde appears to be an effective biocidal treatment against a wide range of organisms for this application (U.S. Coast Guard 2004). It was noted that glutaraldehyde is a Class D substance under the Merchant Shipping Regulations (Control of Pollution by Noxious Liquid Substances in Bulk), Schedule I (1987) for Great Britain, under which discharge into the sea is prohibited and discharge of residual mixtures is subject to restrictions. Glutaraldehyde is also regulated under OSHA (U.S. Coast Guard 2004). However, since it was found to have a relatively quick half-life in water (<2 days) and has limited regulatory concerns, the study found that glutaraldehyde has a potential for use in ballast water treatment for marine water and freshwater use (U.S. Coast Guard 2004).

### 6.2.3 Soil

There is no information on releases of glutaraldehyde to the soil from manufacturing and processing facilities because these releases are not required to be reported (EPA 2005).

Glutaraldehyde use in disinfectants could result in release to soils and sediments (EPA 2007; IPCS 1998) through release of waste water that may leach into surrounding soils. Likewise, glutaraldehyde could potentially be released to soil as a result of industrial uses, including industrial water treatment processes, paper and textile industries, cooling and process water systems, and oil and gas recovery operations (Arntz et al. 2012; EPA 2007; IPCS 1998; Kohlpaintner et al. 2013). However, as glutaraldehyde is a hydrophilic compound, biodegrades in soil, and does not bioaccumulate, it does not appear to present a risk to the terrestrial environment (IPCS 1998).

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**6.3 ENVIRONMENTAL FATE****6.3.1 Transport and Partitioning**

In the environment, glutaraldehyde is expected to partition to water, due to small air/water and soil/water partition coefficients. It degrades under both aerobic and anaerobic conditions in water and under aerobic conditions in soil (EPA 2007). Due to the limited persistence in air, soil, and water, significant transport of glutaraldehyde is not expected (IPCS 1998). If glutaraldehyde is present in soil and sediments, however, it is not expected to significantly adsorb (Emmanuel et al. 2005), but could potentially be mobile. A study was performed to determine the adsorption and desorption potential of glutaraldehyde in various soil types. Aqueous solutions of glutaraldehyde in 0.01 M calcium chloride at concentrations of 0.51, 1.0, 2.5, 5.0, and 10.3 g/L were used to determine measured  $K_{oc}$  values in different soil types.  $K_{oc}$  values of glutaraldehyde in sandy loam, silty clay loam, silt loam, loamy sand, and sediment were determined to be 210, 500, 340, 460, and 120, respectively. These results indicate that glutaraldehyde has a moderate to high mobility in soil, and will therefore not adsorb strongly (Leung 2001). In particular, glutaraldehyde has a high mobility in sandy soil, but a more moderate mobility in sandy loam, silt loam, silty clay loam, and loamy sandy soils (EPA 2007). Based on an estimated Henry's Law constant of  $2.4 \times 10^{-8}$  atm-m<sup>3</sup>/mole, glutaraldehyde is not expected to volatilize from water surfaces (Leung 2001). It also has a low likelihood of volatilizing from either moist or dry soil (Leung 2001).

**6.3.2 Transformation and Degradation**

Glutaraldehyde is a hydrophilic compound and is considered to be readily biodegradable in both water and soil (EPA 2007; IPCS 1998; Jolibois et al. 2002; Leung 2001). It is not expected to bioaccumulate in aquatic organisms at an appreciable rate (IPCS 1998), based on an estimate bioconcentration factor (BCF) value of 3.2 calculated from its log  $K_{ow}$  of -0.18 (EPA 2007). Glutaraldehyde is considered toxic to fish, aquatic invertebrates, oysters, and shrimp (EPA 2007; IPCS 2000; NIOSH 2000); however, dilution mitigates the risk to the aquatic environment. The risk to aquatic organisms is thought to be low under typical, non-drought conditions and there are no appreciable risks to the terrestrial environment from release of glutaraldehyde (IPCS 1998).

Glutaraldehyde is stable under acidic to neutral conditions (EPA 2007). The anhydrous form of glutaraldehyde is unstable, and therefore, it is only available commercially as a solution (Arntz et al. 2012; EPA 2007; Lewis 2007). While glutaraldehyde is stable in light, it oxidizes in the presence of air (Smith and Wang 2006). Additionally, increasing temperature and pH results in decreased stability for

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aqueous glutaraldehyde solutions (Smith and Wang 2006). Glutaraldehyde tends to polymerize around pH 8–9, which coincides with the pH where it is most effective as a disinfectant. It is, therefore, supplied as a stable, acidic solution of pH 3.0–4.5 and must be activated by an alkaline buffer such as sodium bicarbonate to pH 7.8–8.9 before use (Ballantyne and Jordan 2001; IPCS 1998; Smith and Wang 2006; Uhr et al. 2013). Dilute glutaraldehyde solutions (1–3.5%) are typically used for disinfecting, but they tend to polymerize with time, resulting in a solution containing limited aldehyde radicals and consequently reduced antibacterial function. Glutaraldehyde solutions must, therefore, be prepared fresh on a regular basis (Smith and Wang 2006).

**6.3.2.1 Air**

Small amounts of glutaraldehyde that volatilize to air (for example, from water cooling tower drift due to its use as a biocide in cooling systems) will not likely persist in the atmosphere. It is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals. For this reaction, it has an estimated half-life in air of 16 hours. Glutaraldehyde had a photolysis half-life of 196 days in an aqueous buffered solution (Leung 2001), suggesting that direct photolysis is possible. Additionally, glutaraldehyde is hydrophilic and will be removed from the atmosphere by wet deposition (IPCS 1998).

**6.3.2.2 Water**

Glutaraldehyde is expected to quickly decompose in water (Emmanuel et al. 2005; EPA 2007; IPCS 1998; Leung 2001; U.S. Coast Guard 2004), and has been classified as readily biodegradable in freshwater, as determined by the Organization for Economic Cooperation and Development (OECD) 301D (Closed Bottle) method, with the potential for degradation in marine environments.

A study performed using a river water-sediment system found that glutaraldehyde degraded rapidly under both aerobic and anaerobic conditions. In this system, glutaraldehyde was found to partition primarily to the water phase, with a pseudo-first-order half-life of 10.6 hours under aerobic conditions and 7.7 hours under anaerobic conditions (Leung 2001). Glutaraldehyde was stable in sterilized control samples maintained at pH 5 and 7 for 31 days; however, at pH 9, 30% was degraded, primarily to a cyclicized dimer of glutaraldehyde, 3-formyl-6-hydroxy-2-cyclohexene-1-propanal. Extrapolated half-lives for abiotic degradation of 508, 102, and 46 days at pH 5, 7, and 9, respectively were calculated. Under aerobic conditions, glutaraldehyde was found to degrade to glutaric acid and subsequently carbon dioxide, whereas under anaerobic conditions, it was degraded into 5-hydroxypentanal followed by 1,5-pentanediol (Leung 2001). A second study from the EPA Registration Eligibility Decision (RED) document for

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glutaraldehyde reported hydrolysis half-lives at 25°C of 628, 394, and 63.8 days at pH 5, 7, and 9, respectively (EPA 2007). At 70°C, hydrolysis of glutaraldehyde proceeds more rapidly with half-lives of 53, 6.5, and 0.23 days at pH levels of 5, 7, and 9, respectively. Glutaraldehyde was also photolytically degraded to a small degree in natural sunlight at 25°C. The half-life was calculated to be 195 days. A buffered, aqueous solution at pH 5 was used in the experiment (EPA 2007).

Since glutaraldehyde is a biocide, it is toxic to many aquatic organisms (Emmanuel et al. 2005; NIOSH 2000). Emmanuel et al. (2005) concluded that glutaraldehyde release in hospital waste water at typical concentrations ranging from 0.50 to 3.72 mg/L would not likely pose a threat to beneficial bacteria in waste water treatment processes (Emmanuel et al. 2005).

Contamination of groundwater and surface waters by glutaraldehyde is unlikely due to rapid biodegradation potential and dilution in surface waters (EPA 2007; IPCS 1998). Degradation of glutaraldehyde in sewage treatment plants, where it reacts with proteins in the effluent, is expected to help mitigate release to water (IPCS 1998). Dilution may also have a significant effect on glutaraldehyde concentrations in water. Studies at a Canadian paper mill and a de-inking plant showed rapid reductions in glutaraldehyde concentrations in white water effluent (water that is removed from paper-processing systems during formation of paper sheets, filtered, and reused within several seconds or minutes to reduce the need for fresh water). After 6 hours, the glutaraldehyde concentration in white water effluent from the paper mill was reduced from 51 to 4 mg/L. At the de-inking plant, glutaraldehyde concentrations in effluent was reduced from 56 to 5 mg/L in 7 hours. The study concluded that dilution was a contributing factor in decreasing the glutaraldehyde concentrations (IPCS 1998).

### 6.3.2.3 Sediment and Soil

Glutaraldehyde does not appear to present any appreciable risks when released to the terrestrial environment due to its adsorption coefficients, tendency to partition to water, and biodegradation potential. It is expected to have limited persistence in soil (EPA 2007; IPCS 1998).

When present in soil and sediments, it is not expected to adsorb significantly and will have a moderate to high mobility (Emmanuel et al. 2005; EPA 2007; Leung 2001), based on measured  $K_{oc}$  values ranging from 120 to 500 (Leung 2001). The high mobility indicates that glutaraldehyde may not be present in significant quantities in soil. It has been found to rapidly degrade in soils under aerobic conditions (EPA



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2007). Leung (2001) reported that glutaraldehyde was metabolized rapidly under both aerobic and anaerobic condition in a water-sediment system.

#### 6.3.2.4 Other Media

No information was located regarding the transformation and degradation of glutaraldehyde in other media.

### 6.4 LEVELS MONITORED OR ESTIMATED IN THE ENVIRONMENT

Reliable evaluation of the potential for human exposure to glutaraldehyde depends in part on the reliability of supporting analytical data from environmental samples and biological specimens.

Concentrations of glutaraldehyde in unpolluted atmospheres and in pristine surface waters are often so low as to be near the limits of current analytical methods. In reviewing data on glutaraldehyde levels monitored or estimated in the environment, it should also be noted that the amount of chemical identified analytically is not necessarily equivalent to the amount that is bioavailable. The analytical methods available for monitoring glutaraldehyde in a variety of environmental media are detailed in Chapter 7.

#### 6.4.1 Air

Glutaraldehyde was found to be released to air from vehicle emissions. Measurements taken in a San Francisco Bay area highway tunnel during the summers of 2001 and 2006 found mean emission factors from light-duty vehicles of 0.13 and 0.06 mg glutaraldehyde/kg gasoline, respectively. Glutaraldehyde was not detected in samples from 1999. Medium- and heavy-duty diesel trucks were found to emit more glutaraldehyde to the atmosphere than light-duty vehicles; in 2006, a mean emission factor of 0.55 mg glutaraldehyde/kg diesel was measured in the tunnel (Ban-Weiss et al. 2008). Light-duty vehicles and medium/heavy-duty diesel trucks passed through separate bores of the tunnel.

Sampling was performed at three Danish hospitals and a dental clinic to determine the concentrations of glutaraldehyde in air in facilities where it is used for disinfection of endoscopes and in the development of x-rays. Air samples obtained over 15–25-minute time periods found concentrations of glutaraldehyde ranging from <0.080 to 0.500 mg/m<sup>3</sup> (<0.02–0.12 ppm) of air. Levels in the hospital settings were higher than those in the dental clinic, where glutaraldehyde is primarily used for x-ray development. In the hospital samples, the highest levels of airborne glutaraldehyde were found in the surgical department.

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According to the authors, the low glutaraldehyde concentrations found in these facilities are likely a result of proper handling and ventilation practices (Rietz 1985).

A dental clinic in Kanagawa, Japan that utilizes a glutaraldehyde solution for equipment sterilization was monitored for airborne glutaraldehyde concentrations. Eight-hour samples were collected using a passive sampler when the dental clinic was closed, such that the wind speeds during sampling were constant. Samples were obtained at 1.2 m above the floor, at the typical breathing height of a Japanese adult. Indoor air concentrations ranged from not detectable to 16 ppb. The highest concentrations were located in the examination room, nearest the sterilizer, whereas glutaraldehyde was not detectable in the waiting room (Sekine et al. 2005).

Australian studies of glutaraldehyde in air during cold disinfection practices found that concentrations rarely exceeded 0.1 ppm when proper ventilation procedures were followed (NICNAS 1994). Monitoring of Australian hospitals near endoscopy areas where glutaraldehyde was used in 1–2% solutions, using both personal and area monitoring equipment, found air concentrations ranging from 0 to 0.49 ppm, while operating room measurements ranged from 0 to 0.9 ppm. Monitoring at dental facilities resulted in air concentrations ranging from 0.007 to 0.022 ppm. Other hospitals were found to have personal glutaraldehyde monitoring air concentrations up to 0.6 ppm and area monitoring concentrations of up to 0.3 ppm (NICNAS 1994). Air concentrations of glutaraldehyde in areas where x-ray film is processed were generally <0.2 ppm in Australia. The air concentrations ranged from 0 to 0.4 ppm (NICNAS 1994). In an Australian chicken farm, air concentrations were found to be 0.007 ppm when an egg collector sprayed 0.1–0.3% glutaraldehyde solutions on eggs (NICNAS 1994).

#### **6.4.2 Water**

Glutaraldehyde has been detected in waste water originating from hospitals. Measurements of glutaraldehyde concentrations in wastewater from Rouen University Hospital were typically around or below 0.5 mg/L, with the exception of a peak concentration of 3.72 mg/L, which coincided with a weekly disposal of disinfecting solutions (Jolibois et al. 2002).

#### **6.4.3 Sediment and Soil**

Monitoring data for glutaraldehyde in soil and sediment were not available.

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**6.4.4 Other Environmental Media**

No information regarding glutaraldehyde concentrations in other environmental media was located.

**6.5 GENERAL POPULATION AND OCCUPATIONAL EXPOSURE**

Primary exposure to glutaraldehyde occurs through inhalation (Smith and Wang 2006), although dermal contact and ingestion may also occur (NIOSH 2000, 2016). Exposure of the general population may be minimal, however, as glutaraldehyde is primarily used in industrial or medical applications (EPA 2007; IPCS 1998). Consumer applications of glutaraldehyde, such as use in cosmetics, are thought to present low concern to the general population. While unlikely, exposure to the general population could occur in health care settings where cleaning agents containing glutaraldehyde are used, primarily in the case of a spill or inadequate rinsing of surfaces; following drift from cooling water towers used in water treatment; from air duct fogging disinfection if proper ventilation procedures are not followed; via household items (i.e., laundry detergents or paints) that use glutaraldehyde as a preservative (e.g., slimicide); or from various sources in the papermaking process (EPA 2007; IPCS 1998). Because glutaraldehyde is used in oil and gas recovery operations (including hydrofracturing processes), there is potential for exposure among workers and among the general population living in areas surrounding such operations. Although glutaraldehyde is used as a disinfectant for poultry/livestock equipment and processing, it degrades so rapidly that the potential for glutaraldehyde residues to contaminate food sources is very slight. People using masking kits containing glutaraldehyde for use as a urinary adulterant (added to urine after collection) to interfere with drug testing may also be exposed from inhalation or dermal routes (Wu et al. 1994). Patients undergoing selected medical procedures may inadvertently be exposed. For example, glutaraldehyde has been widely implicated as the cause of colitis and diarrhea following endoscopy or sigmoidoscopy procedures, the likely result of contact irritation (e.g., Ahishali et al. 2009; Birnbaum et al. 1995; Dolce et al. 1995; Durante et al. 1992; Fukunaga and Khatibi 2000; Hanson et al. 1998; Rozen et al. 1994; Shih et al. 2011; Stein et al. 2001; West et al. 1995).

Occupational exposure may occur during processes which use or produce glutaraldehyde, particularly when proper ventilation is not used or when products are sprayed (IPCS 1998). This may result from the addition of glutaraldehyde to industrial processes; paper manufacture; aluminum rolling; oil and gas drilling; x-ray film processing; fogging and spraying for disinfecting purposes; pesticidal applications such as cleaning of animal and poultry cages; and cleaning of medical and dental facilities and equipment (EPA 2007; IPCS 1998).

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The primary occupational exposure to glutaraldehyde appears to be inhalation and dermal contact from use in medical and dental applications (EPA 2007; IPCS 1998; NICNAS 1994; Smith and Wang 2006). Total exposure depends on the frequency and duration of contact as well as environmental glutaraldehyde concentrations and the use of personal protective equipment (Rietz 1985; Smith and Wang 2006). Medical equipment and dental equipment, such as endoscopes and operating room instruments, are often disinfected using glutaraldehyde solutions at higher concentrations (as high as 3.5% active ingredient) than used in pesticidal applications (e.g., 0.25% active ingredient for egg sanitation) (EPA 2007). Between 5 and 10% of health care workers are reported to be exposed to glutaraldehyde (Cohen and Patton 2006). Operating room nurses, radiographers, x-ray technicians, and cleaners tend to have the highest health-care related occupational exposure rates (Smith and Wang 2006). Air concentrations of glutaraldehyde during disinfection of medical equipment were found to range between <0.5 and 570 ppb, depending on the usage, ventilation, and other conditions. Disinfection via manual methods produced higher air concentrations than automated disinfection processes (EPA 2007). Disinfection of dental equipment using a 2% solution over 5 and 6 minutes resulted in glutaraldehyde air concentrations of 540 and <160 ppb, respectively (EPA 2007).

Inhalation is a primary pathway of exposure to personnel in facilities where glutaraldehyde is used or produced. At various glutaraldehyde manufacturing and formulation facilities, glutaraldehyde air concentrations were measured at <10–340 ppb over 15-minute sampling intervals (EPA 2007). Paper manufacturing processes, including application of adhesives, pigments, and fillers, and addition of glutaraldehyde as a slimeicide to paper mill process water, can result in exposure. Paper mills using a 50% solution had glutaraldehyde air concentrations ranging from not detectable to 130 ppb over 30–60 minutes (EPA 2007). In a latex plant where a 45% glutaraldehyde solution was used, air concentrations of 27 ppb were observed over a 15-minute time period (EPA 2007).

During aluminum milling processes, air concentrations were found to range from not detectable to 180 ppb (EPA 2007). At a drilling field utilizing a glutaraldehyde-containing product, Aldacide G, air concentrations of 20–120 ppb were measured (EPA 2007).

Glutaraldehyde can be used for spraying and fogging disinfection at poultry houses. Inhalation exposure can occur when personnel enter the facility following application. At various poultry hatcheries and houses, air concentrations of glutaraldehyde ranged from not detectable to 1,060 ppb for 500 and 1,000 ppm solutions with sampling periods ranging from 10 to 60 minutes (EPA 2007). Air concentrations following manual spraying of a 2% solution in a chicken facility, sampled over

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15 minutes, ranged from 20 to 120 ppb (EPA 2007). Fogging with a 3% glutaraldehyde solution has also been tested for disinfection following SARS outbreaks (EPA 2007).

Glutaraldehyde exposure may also result from the use of metal working fluids, in cooling tower applications, and during painting processes (EPA 2007). Air concentrations measured while 45% glutaraldehyde-containing metal working fluids were transferred between containers were found to range from <71 to <290 ppb over 16- and 22-minute sampling durations, respectively (EPA 2007). Dermal exposure to glutaraldehyde from metalworking fluids could also occur (EPA 2007). Transfer of a 45% solution for a cooling tower application over a 5-minute period resulted in an air concentration of <660 ppb glutaraldehyde (EPA 2007). Around a paint spray booth at an automobile manufacturing plant, a 30-minute sample found air concentrations of glutaraldehyde ranging from not detectable to 158 ppb (EPA 2007).

## 6.6 EXPOSURES OF CHILDREN

This section focuses on exposures from conception to maturity at 18 years in humans. Differences from adults in susceptibility to hazardous substances are discussed in Section 3.8, Children's Susceptibility.

Children are not small adults. A child's exposure may differ from an adult's exposure in many ways. Children drink more fluids, eat more food, breathe more air per kilogram of body weight, and have a larger skin surface in proportion to their body volume than adults. A child's diet often differs from that of adults. The developing human's source of nutrition changes with age: from placental nourishment to breast milk or formula to the diet of older children who eat more of certain types of foods than adults. A child's behavior and lifestyle also influence exposure. Children crawl on the floor, put things in their mouths, sometimes eat inappropriate things (such as dirt or paint chips), and may spend more time outdoors. Children also are generally closer to the ground and have not yet developed the adult capacity to judge and take actions to avoid hazards (NRC 1993).

Exposure of children to glutaraldehyde is expected to be minimal, as glutaraldehyde is primarily used in industrial and medical applications (EPA 2007; IPCS 1998). It may be possible for children to be exposed to glutaraldehyde residues and vapor in medical facilities, particularly those where improper ventilation exists, or by exposure to paint fumes and household products (i.e., laundry detergent) containing glutaraldehyde (EPA 2007; IPCS 1998). Because glutaraldehyde is used in oil and gas recovery operations (including hydrofracturing processes), there is potential for exposure among children

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living in areas surrounding such operations. The potential for exposure to glutaraldehyde through ingestion of dust and soil is expected to be low based on the low potential for soil adsorption and the high rate of degradation. Glutaraldehyde has not been detected in breast milk.

### 6.7 POPULATIONS WITH POTENTIALLY HIGH EXPOSURES

The highest glutaraldehyde exposure rates appear to affect personnel working in medical and dental facilities where glutaraldehyde is used as a disinfecting agent (EPA 2007; IPCS 1998). Significant exposure may also occur among workers involved in oil and gas recovery operations, although limited information is available regarding exposure levels within such operations.

### 6.8 ADEQUACY OF THE DATABASE

Section 104(i)(5) of CERCLA, as amended, directs the Administrator of ATSDR (in consultation with the Administrator of EPA and agencies and programs of the Public Health Service) to assess whether adequate information on the health effects of glutaraldehyde is available. Where adequate information is not available, ATSDR, in conjunction with NTP, is required to assure the initiation of a program of research designed to determine the health effects (and techniques for developing methods to determine such health effects) of glutaraldehyde.

The following categories of possible data needs have been identified by a joint team of scientists from ATSDR, NTP, and EPA. They are defined as substance-specific informational needs that if met would reduce the uncertainties of human health assessment. This definition should not be interpreted to mean that all data needs discussed in this section must be filled. In the future, the identified data needs will be evaluated and prioritized, and a substance-specific research agenda will be proposed.

#### 6.8.1 Identification of Data Needs

**Physical and Chemical Properties.** The physical and chemical properties of glutaraldehyde are general well understood and have been discussed in Chapter 4 (Table 4-2). There are no significant data needs.

**Production, Import/Export, Use, Release, and Disposal.** According to the Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. Section 11023, industries are required to submit substance release and off-site transfer information to the EPA. No information is available in

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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).

Methods of manufacturing and uses of glutaraldehyde are available and have been discussed in Chapter 5. However, import and export volumes were not available. Additional information concerning import and export, release, and disposal of glutaraldehyde is needed.

**Environmental Fate.** Data suggest that glutaraldehyde is rapidly degradable in air, water, and soil (EPA 2007; IPCS 1998; Leung 2001). Additional data do not appear necessary at this time.

**Bioavailability from Environmental Media.** No data exist regarding glutaraldehyde bioavailability from environmental media such as soil or drinking water. However, glutaraldehyde is known to rapidly biodegrade in soil and water (EPA 2007; Leung 2001); thus, it is not expected to be bioavailable from these sources.

**Food Chain Bioaccumulation.** Glutaraldehyde is not expected to bioconcentrate due to its ability to be degraded in the environment (IPCS 1998; Leung 2001). Therefore, bioaccumulation through the food chain is expected to be low (IPCS 1998). No data needs are identified.

**Exposure Levels in Environmental Media.** Reliable monitoring data for the levels of glutaraldehyde in contaminated media at hazardous waste sites are needed so that the information obtained on levels of glutaraldehyde in the environment can be used in combination with the known body burden of glutaraldehyde to assess the potential risk of adverse health effects in populations living in the vicinity of hazardous waste sites.

**Exposure Levels in Humans.** Exposure to glutaraldehyde can occur primarily through inhalation and dermal contact with solutions containing glutaraldehyde, such as disinfectants (EPA 2007; IPCS 1998; Smith and Wang 2006). Inhalation and dermal exposures are fairly well understood. However, there is a possibility of exposure through food sources, especially where animal housing is cleaned with glutaraldehyde solutions. Additional information concerning exposure through ingestion would be useful. Because glutaraldehyde is used in oil and gas recovery operations (including hydrofracturing processes) and pipeline installations, information regarding exposure levels among workers and among the general population in areas surrounding such operations would be useful.

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This information is necessary for assessing the need to conduct health studies on these populations.

**Exposures of Children.** Children may be exposed to glutaraldehyde through the same routes as adults. However, occupationally exposed workers are generally at greater risk of exposure to higher levels of glutaraldehyde than the general U.S. population. Additional information concerning exposure of children to glutaraldehyde is needed.

Child health data needs relating to susceptibility are discussed in Section 3.13.2, Identification of Data Needs: Children's Susceptibility.

**Exposure Registries.** No exposure registries for glutaraldehyde were located. This substance is not currently one of the compounds for which a sub-registry has been established in the National Exposure Registry. The substance will be considered in the future when chemical selection is made for sub-registries to be established. The information that is amassed in the National Exposure Registry facilitates the epidemiological research needed to assess adverse health outcomes that may be related to exposure to this substance.

### 6.8.2 Ongoing Studies

No ongoing environmental fate studies for glutaraldehyde were identified using identified in the NIH Research Portfolio Online Reporting Tools (RePORTER 2014).