Know your chemicals

A FACTSHEET ON

GLUTARALDEHYDE/ CIDEX

Anu Goel

This factsheet is an attempt to unveil glutaraldehyde, a widely used disinfectant. We expect the readers to take due precautions while dealing with this chemical and spread the message across, so that ignorance does not cause harm to the people using it. The factsheet is divided into the following sections:

- WHAT IS GLUTARALDEHYDE?
- WHERE IS THIS CHEMICAL USED?
- WHAT ARE THE HEALTH EFFECTS OF GLUTARALDEHYDE?
- SAFETY ACTION PROGRAM TO REDUCE EXPOSURE LEVELS
- PRECAUTIONS AND FIRST AID

WHAT IS GLUTARALDEHYDE?

Glutaraldehyde is a colourless, oily liquid, which is also commonly available as a clear, colourless, aqueous solution. It is a powerful, cold disinfectant, used widely in the health services for high-level disinfection of medical instruments and supplies and available with trade names such as: Cidex, Totacide, and Asep.

Glutaraldehyde is toxic and harmful if inhaled or swallowed, irritating to the eyes and respiratory tract, also corrosive to the eyes and skin, and may cause permanent eye injury. Glutaraldehyde is a skin sensitizer and may cause a severe allergic skin reaction, dermatitis and skin irritation, nasal/throat irritation, headaches, cough, and asthma.

KNOW YOUR CHEMICALS: SOME FACTS ABOUT GLUTARALDEHYDE

FACT 1: Glutaraldehyde is a fixative, (particularly with nitrogen, ammonia, amines, proteins) thus making it a powerful disinfectant. It attacks proteins in the nucleus of microorganisms, DNA and protein sacks of viruses, so microorganisms do not build up resistance to it. It is active optimally at a neutral pH to alkaline pH.

FACT 2: Factors which influence the activity of glutaraldehyde, are:
- Contact times- times are longer for killing spores as compared to those required for vegetative bacteria.
- Concentration- 0.2% for Staph. E Coli & Pseud.
- 0.5% for fungicidal, 2% for spores
- Temperature- increase in temperature between 25o C - 40o C increases reactivity time and killing efficiency.
- pH is a very important factor affecting the killing ability of glutaraldehyde

FACT 3: Surfactants used with glutaraldehyde enhance glutaraldehyde’s killing efficiency, increase its stability and reduce its volatility.

FACT 4: Exposure Limits
NIOSH, Occupational Safety and Health Act, and the American Conference of Governmental Industrial Hygienists has set the exposure limit for glutaraldehyde at 0.20 ppm as a Ceiling Value Limit which must not be exceeded, even for an instant, at any time during the work day. It has been found that short-term exposure to glutaraldehyde in concentrations of 0.3 ppm or higher, results in significant risk of irritation to the eyes, nose, and throat. Even at low concentrations (below 0.2 ppm), studies have found that glutaraldehyde causes symptoms of irritation.
Glutaraldehyde is classified in the hazardous substance list – OSHACT – which sets an occupational exposure limit for ‘airborne glutaraldehyde’ at 0.2 ppm.

Glutaraldehyde, aqueous solution meets the Canadian WHMIS criteria for class(es):
- **D1B** Poisonous and infectious material – Immediate and serious effects – Toxic
- **D2B** Poisonous and infectious material – Other – Toxic
- **E** Corrosive material

**FACT 5:** EU Comments on various concentration: (see box)

Our country still does not have any standards and regulations for the use of this chemical.

WHERE IS THIS CHEMICAL USED?

Glutaraldehyde is a widely used disinfectant and a sterilizing agent (commonly available in 1 percent and 2 percent solutions) in medical and dental settings. It is used in embalming (25% solution), as an intermediate and fixative for tissue-fixing in electron microscopy (20 percent, 50 percent and 99 percent solutions) and in X-ray films.

Places in medical sets up where glutaraldehyde is used:
- Endoscopy units
- Theatres
- ICUs
- Labour wards
- For infection control
- Dental units

**WHAT ARE THE HEALTH EFFECTS OF GLUTARALDEHYDE?**

- Irritates skin, eyes, throat and lungs, causes sensitization of skin and respiratory tract.
- Once sensitized to glutaraldehyde, further exposure to even very small amounts of the substance can lead to: Dermatitis, Rhinitis and Conjunctivitis ⇒ you may never be able to work near glutaraldehyde ever again.

- What are the main health hazards associated with breathing in glutaraldehyde?
  - Glutaraldehyde is a moderate to strong irritant. Vapour levels below 0.2 ppm (0.8 mg/m³) have been reported to cause nose and throat irritation, nausea and headaches. Chest discomfort, tightness and difficulty in breathing may also occur. There are a few reports of glutaraldehyde causing a late

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**Concentration**

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<thead>
<tr>
<th>Concentration</th>
<th>Effects</th>
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<tbody>
<tr>
<td>greater than or equal to 50%</td>
<td>Toxic; toxic by inhalation and if swallowed. Causes burns. May cause sensitization by inhalation and skin contact.</td>
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<tr>
<td>greater than or equal to 25%</td>
<td>Toxic; harmful if swallowed; toxic by inhalation, causes burns, may cause sensitization by inhalation and skin contact.</td>
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<td>and less than 50%</td>
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<tr>
<td>greater than or equal to 2%</td>
<td>Corrosive; harmful by inhalation and if swallowed; causes burns, may cause sensitization by inhalation and skin contact.</td>
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<td>and less than 10%</td>
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<tr>
<td>greater than or equal to 1%</td>
<td>Harmful; harmful by inhalation and if swallowed irritating to respiratory system and skin; risk of serious damage to eyes; may cause sensitization by inhalation and skin contact.</td>
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<td>and less than 2%</td>
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<tr>
<td>greater than or equal to 0.5%</td>
<td>Harmful; irritating to eyes, respiratory system and skin; may cause sensitization by inhalation and skin contact.</td>
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allergic reaction, like asthma, when inhaled. However, there is insufficient information to conclude it is a respiratory sensitizer.

■ What happens when glutaraldehyde aqueous solution comes in contact with the skin?

Solutions may cause mild to severe irritation, depending on the concentration of the solution and the duration of contact. There is one report of severe irritation seen in a study with volunteers. Corrosive effects (necrosis) were seen when rabbits were skin tested with solutions containing 25 percent or more glutaraldehyde. Glutaraldehyde may cause an allergic skin reaction in sensitised individuals. No skin absorption has been reported in humans. However, in rabbit studies, glutaraldehyde was absorbed in amounts great enough to cause death.

■ Can glutaraldehyde aqueous solution hurt the eyes?

The vapour is irritating to the eyes. Depending on the concentration, solutions may be very irritating and may cause serious, irreversible injury. This evaluation is based on the observation of severe burns in animal studies.

■ What happens if glutaraldehyde aqueous solution is accidentally swallowed (enters the digestive system)?

No human information is available. Ingestion in an occupational setting is unlikely due to the pungent odour and irritating qualities of glutaraldehyde. If ingested, it will cause irritation. This evaluation is based on animal information and information available for other aldehydes. Ingestion of a large amount of glutaraldehyde may cause toxic effects similar to alcohol poisoning with symptoms of central nervous system depression (drowsiness, dizziness), nausea and vomiting.

■ What are the long-term health effects of exposure to glutaraldehyde aqueous solution?

SKIN CONTACT: Repeated or prolonged contact may cause drying and cracking of skin (dermatitis).

ALLERGIC CONTACT DERMATITIS: Contact with solutions or the vapours have resulted in skin sensitization. Symptoms of skin sensitization include rashes and itching, reddening and scaling (eczema) of the skin (hands, wrists, arms, face). An aqueous solution containing 0.5 percent glutaraldehyde was found to produce a sensitization reaction in volunteers in a challenge study. However, concentrations of 0.1 or 0.2 percent glutaraldehyde did not produce a reaction.

RESPIRATORY SENSITIZATION: There is limited evidence that glutaraldehyde causes respiratory sensitization. In particular, one study found that two workers with pre-existing respiratory problems (asthma) developed a late respiratory allergic reaction when exposed to glutaraldehyde vapour. Symptoms of respiratory sensitization resemble asthma and include sneezing, wheezing, chest tightness and difficulty in breathing.

■ Will glutaraldehyde aqueous solution cause any problems with the reproductive system?

No human information is available. There was no evidence of reduced fertility in male mice treated with glutaraldehyde.

■ Will glutaraldehyde aqueous solution cause effects on the foetus/unborn baby?

One study found no increase in the number of spontaneous abortions in hospital workers exposed to glutaraldehyde. Teratogenic and fetotoxic effects were seen in an animal study. However, the doses given were great enough to also produce maternal toxicity. According to some other studies, it is a mutagen and teratogen.

■ Is there potential for glutaraldehyde to build-up or accumulate in the body?

Aldehydes are metabolised in the body and there is little potential for accumulation. Glutaraldehyde is largely metabolised to carbon dioxide and excreted in exhaled air.

GLUTARALDEHYDE SAFETY ACTION PLAN

Because of the increased awareness of the potential hazards of exposure to glutaraldehyde, many medical facilities have begun to search for alternative germicides. Automated systems utilising peracetic acid or hydrogen peroxide are examples of new technologies that have been promoted as safer alternatives. New automated equipment technologies require significant initial capital outlays and
can be very expensive to use on a daily basis.

The following seven-step program, if carefully implemented, will eliminate all glutaraldehyde overexposure during routine work procedures, protect workers during emergency spill clean-up procedures, and help the facility comply with safety regulations.

**Identify All Usage Locations**
All departments that use glutaraldehyde must be identified and included in the safety program. Eliminate as many usage locations as possible and centralize usage to minimize the number of employees involved with the handling of glutaraldehyde.

**Monitor Exposure Levels**
Measurement of glutaraldehyde exposure levels must be conducted in all usage locations. Currently, three types of monitoring methods are available for glutaraldehyde: passive diffusion monitors (monitoring badges); sample pumps and cassettes, which require sophisticated lab analysis (OSHA Method #64); and hand-held direct reading meters (sold by several companies as a Glutaraldemeter or Glutameter), which provide a discrete sample of an instantaneous measurement.

**Training**
An in-depth education and training program should be conducted for all employees who work with hazardous chemicals. The training program should include discussion on safe work practices, proper protective clothing, and safe spill clean-up procedures.

**Use Personal Protective Equipment**
All employees who work with glutaraldehyde must be provided appropriate personal protective equipment. This equipment includes proper eye/face protection, chemical protective gloves, and protective clothing. Only splash goggles with side shield protection and fitting snugly all around the eyes are acceptable when working with glutaraldehyde. These goggles should have combination eyeshield/face masks, which are commonly used for splash protection because the liquid could splash on the forehead and drip into the eyes. In addition to splash goggles, OSHA guidelines require face protection when working with glutaraldehyde. Employees should wear face shields that wrap around the face and extend down past the chin for adequate face protection.

**Protective gloves:** Disposable latex surgical or exam gloves do not provide adequate glutaraldehyde protection. These gloves are usually only 5 to 6 millimetres thick and can deteriorate through contact with glutaraldehyde. Most latex gloves are 9 to 10 inches long and extend only to the wrist. Acceptable glutaraldehyde protective gloves should be 11 to 13 inches long so that they extend far enough up the arm to provide protection from drips and splashes. Studies have shown that ‘nitrile and butyl rubber gloves are the materials most impervious to glutaraldehyde, showing no breakthrough after eight hours of exposure. Gloves made of polyethylene and certain man-made copolymers give protection for several hours’. Polyvinyl chloride and neoprene gloves are not recommended because they do not give adequate protection from glutaraldehyde and may actually absorb the chemical.

**Protective clothing:** Isolation gowns, lab coats, or aprons plus sleeve protectors are also necessary when working with glutaraldehyde. All protective clothing must be made of a material that is impervious to glutaraldehyde i.e ‘ Liquid-resistant’ or ‘liquid-impervious’ clothing. One type of material that provides acceptable protection is polyethylene-coated polypropylene.

**Implement Administrative, Work Practice, and Engineering Controls**

**Administrative controls**
Limit employee access to glutaraldehyde usage locations and eliminate as many usage locations as possible by centralizing usage in a few locations. Central Supply is a logical choice for such consolidation. CS Department workers regularly work with other chemicals and are familiar with protective clothing requirements. Also, the CS Department has good general room ventilation, which can help control vapour levels.

Suitable eyewash units must be available for immediate emergency use in all glutaraldehyde usage locations.
Work practice controls
Studies have shown that glutaraldehyde vapours increase whenever the solution is agitated. Vapour levels increase when glutaraldehyde is poured into or dumped out of a soaking bin, when instruments are placed into and removed from the solution, and when instruments are rinsed. Employees should be trained to minimize agitation of the solution as much as possible during these work procedures. If exposure monitoring shows that these procedures result in excessive exposure levels, the work process should be enclosed in a glutaraldehyde fume hood system.

Engineering controls
Rooms in which glutaraldehyde is used should have a minimum of 10 air exchange rates per hour. General room ventilation, however, will not effectively control glutaraldehyde exposure levels. As recommended glutaraldehyde exposure limits decrease, installing glutaraldehyde local exhaust fume hoods becomes more important. The manufacturer of the CIDEX brand of glutaraldehyde solutions modified its MSDS to state that a local exhaust fume hood should be used in any room that does not have a minimum of 10 air exchange rates per hour. Placing the glutaraldehyde-soaking bin in a fume hood will eliminate virtually all glutaraldehyde exposure problems. To ensure proper performance, the fume hood should have a minimum face velocity of at least 80 feet per minute.

Neutralize solutions before disposal
Most health care facilities dispose of spent glutaraldehyde solutions by simply pouring them down a drain connected to a sanitary sewer. This practice causes two significant problems. First, the spent solution may adversely affect the operation of the local sewage treatment facility. The local Publicly Owned Treatment Works (POTW) may therefore prohibit disposal into the sewer system. Second, the physical process of pouring several gallons of glutaraldehyde solution into a sink or toilet may cause significant worker exposure to glutaraldehyde vapours.

Spent glutaraldehyde solutions can have residual antimicrobial activity that may affect sewage treatment operations. Increasingly, local sewage treatment facilities have chosen to prohibit the disposal of glutaraldehyde solutions into their sewer systems.

These problems can be avoided by neutralizing the spent Cidex. A neutralizing agent will, over time, chemically inactivate the glutaraldehyde. The chemical reaction transforms glutaraldehyde into a harmless solution that is safe to pour into the sanitary sewer and does not give off vapours when poured.

Glutaraldehyde-neutralizing agents should be chosen carefully, as the performance of products on the market varies greatly. The time required for complete neutralization can range from 10 minutes to 8 to 12 hours or longer. The glutaraldehyde concentration of the solution in the end should be approximately 10 ppm or less, as above this concentration, the solution may retain antimicrobial activity and adversely affect the operation of the sewage treatment facility.

Develop a Spill Clean-up Plan
The last potentially hazardous situation is the clean-up of a glutaraldehyde spill. A ‘response team’ should be created to develop and execute procedures for glutaraldehyde spills. All spills, no matter how small, should be cleaned up immediately.

Response team personnel must be thoroughly trained and required to wear the following protective attire: eye/face protection, impervious gloves, full length, glutaraldehyde-impervious clothing, impervious boots or shoe protection and respirators. Exposure levels should be measured with a direct-reading meter and respirator selection must be based on glutaraldehyde exposure levels in the spill area. Remove contaminated clothing immediately. Keep it in closed containers. Discard or launder before reusing. Inform laundry personnel of contaminant’s hazards. Wash hands thoroughly after handling this material. Maintain good housekeeping.

GLUTARALDEHYDE EXPOSURE
Exposure to glutaraldehyde vapour in the workplace is a significant hazard to employees, which must be addressed in a manner consistent with the Health & Safety in Employment Act 1992.

The Occupational Safety & Health Service of the Department of Labour (OSH) has published a booklet entitled ‘The Safe Occupational Use of Glutaraldehyde in the Health Industries’. The
booklet provides a general overview of the hazards posed by glutaraldehyde in radiographic and high-level disinfection applications, and presents principles for control of the hazards.

Under the Health & Safety in Employment Act 1992, the employer is obliged to ensure that for all processes using glutaraldehyde, adequate measures are taken to limit exposure to airborne glutaraldehyde vapour. Adequacy of these safety measures should be verified for the process and re-verified if the process is changed in a way that may impact glutaraldehyde exposure. Furthermore, the process should be regularly audited to ensure that the safety measures continue to be effective.

- What are the fire and explosion dangers associated with glutaraldehyde aqueous solution?

Aqueous solution is not flammable. However, after the water evaporates the remaining material will burn. During a fire, toxic decomposition products such as carbon monoxide and carbon dioxide can be generated.

- Is glutaraldehyde aqueous solution stable when exposed to air, moisture, or heat?

Normally stable, but can oxidize in air. Stability decreases as the pH and temperature increase. Commercial solutions are usually stored at an acidic pH (about 3-4) to slow down polymerization and are later activated by raising the pH to a slightly alkaline state.

- Are there any conditions to avoid when using glutaraldehyde aqueous solution?

High temperatures (above 100°C), evaporation of water.

- Does glutaraldehyde aqueous solution have an odour threshold (at what level can I smell it)?

0.04 ppm (recognition); 0.3 ppm (irritation threshold)

- Is the odour of Glutaraldehyde aqueous solution reliable as a warning property?

NOT RELIABLE – odour threshold and irritation level is about the same magnitude as the TLV.

PRECAUTIONS AND FIRST AID

According to the Occupational Safety & Hazardous Act, some basic precautions that should be taken are:

- Use it where there is proper ventilation equipment or at least in a well-ventilated area.
- Avoid skin contact, splashes and exposure to fumes or droplets in the air (wear gloves, masks and goggles)
- Keep lids on troughs, buckets and waste bins.

- How can I work with glutaraldehyde aqueous solution safely?

This material is CORROSIVE and TOXIC. Before handling, it is very important that engineering controls are operating and that protective equipment requirements are being followed. Avoid generating vapours or mists. Wear appropriate personal protective equipment. Inspect containers for damage or leaks before handling. Use the type of containers recommended by the manufacturer. Unprotected persons should avoid all contact with this chemical, including contaminated equipment. Do not use with incompatible materials such as strong acids, strong alkalies and amines. To avoid splashing, cautiously dispense into sturdy containers made of compatible materials. Whenever possible, use self-closing portable containers for dispensing small amounts of this material. Never transfer liquid by pressurizing original container with air or inert gas. Never add water to a corrosive. Always add corrosives to water. When mixing with water, stir small amounts, slowly. Use cold water to prevent excessive heat generation. Never return contaminated material to its original container. Label containers. Avoid damaging containers. Keep containers closed when not in use. Empty containers may contain residues, which are hazardous.

FIRST AID

* If you inhale glutaraldehyde

Remove source of contamination or move victim to fresh air. Obtain medical advice immediately

* If it touches your skin

Avoid direct contact and always wear protective clothing. Flush the contaminated area with lukewarm, gently running water for at least 20-30 minutes. If irritation persists, repeat flushing. Do not interrupt flushing. Under running water, remove
contaminated clothing, shoes, and leather goods (e.g. watchbands, belts). Transport victim to an emergency care facility immediately.

Completely decontaminate clothing, shoes and leather goods before re-use or discard.

**If someone gets glutaraldehyde aqueous solution in their eyes**

Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for at least 20-30 minutes. Neutral saline solution may be used as soon as it is available. Take care not to rinse contaminated water into the unaffected eye. If irritation persists, repeat flushing. Quickly transport victim to an emergency care facility.

**If someone swallows glutaraldehyde aqueous solution**

Never give anything by mouth if victim is rapidly losing consciousness, is unconscious or convulsing. Have victim rinse mouth thoroughly with water. **Do not induce vomiting.** Have victim drink 240 to 300 ml (8 to 10 ozs) of water. If vomiting occurs naturally, rinse mouth and repeat administration of water. Obtain medical attention immediately.

**Is there anything else I need to know about first aid?**

Provide general supportive measures (comfort, warmth, and rest). Consult a doctor and/or the nearest Poison Control Centre for all exposures except minor instances of inhalation or skin contact.

**References**

Booklet on Glutaraldehyde: HSEs Information Centre, Broad Lane, Sheffield S3 7HQ