This guidance material provides health care facilities with practical advice on how to safely use glutaraldehyde for cold disinfection, where it is not practicable to eliminate its use. The hazards and risks associated with the use of glutaraldehyde are also outlined.

GLUTARALDEHYDE

Glutaraldehyde is normally used as a 1–2% solution for the cold disinfection of various types of endoscopes and probes used in medical procedures in the health care industry.

Some common products that contain glutaraldehyde include:
- Soluscope D (10–25%)
- Aidel Plus (2%).

Aqueous solutions containing greater than or equal to 0.5% glutaraldehyde are classified as hazardous in accordance with the Approved Criteria for Classifying Hazardous Substances and the List of Designated Hazardous Substances published by the Australian Safety and Compensation Council (ASCC).

EXPOSURE STANDARD FOR GLUTARALDEHYDE

The current occupational exposure standard in Australia for glutaraldehyde is a peak level of 0.1 parts per million (ppm) with a skin sensitisation (‘sen’) notation. Peak exposure standard refers to the maximum airborne level that is not to be exceeded at any time. The skin sensitisation notation relates to the potential of glutaraldehyde to cause allergic contact dermatitis.

Glutaraldehyde has a pungent odour that can be detected by smell at a concentration of 0.04ppm.

HEALTH EFFECTS (HAZARDS) OF EXPOSURE TO GLUTARALDEHYDE

Inhalation of, and exposure to, glutaraldehyde aerosols and vapours can cause:
- respiratory system irritation
- headaches
- nausea
- eye irritation.

Respiratory irritation has been reported at airborne concentrations below 0.2ppm. Eye irritation has also been reported in hospital workers using 2% glutaraldehyde solutions or at concentrations of 0.5ppm. It is possible to exceed the atmospheric occupational exposure standard when using glutaraldehyde solutions (usually 2% or higher) without adequate controls or safety measures.

There have been a number of reports of asthma associated with exposure to glutaraldehyde, but there has been difficulty in determining whether this response was due to an irritant effect or an allergic type response. However, the risk phrase ‘R42’ (may cause sensitisation by inhalation) has been assigned to products containing greater than or equal to 1% glutaraldehyde. This classification is based on the European system used for classifying hazardous substances.

Skin contact with glutaraldehyde solutions may also cause skin irritation and sensitisation leading to allergic contact dermatitis. Skin irritation and sensitisation has been reported to occur usually with glutaraldehyde solutions of 2% or higher.

Complaints about eye and respiratory irritation and a strong odour of glutaraldehyde are an indication that exposure is likely to exceed the peak occupational exposure standard of 0.1ppm and that the current system of work is not providing adequate protection.
LEGAL REQUIREMENTS

The legal requirements are set out in Part 2.1 (General Duties) and Part 4.1 (Hazardous Substances) of the Occupational Health and Safety Regulations 2007. These apply to the use of purchased products containing 0.5% or more of glutaraldehyde and any subsequent dilutions of the original products.

The main duties (as per the OHS regulations) for employers that apply to the use of hazardous substances are summarised below:

- Obtain the manufacturer’s or importer’s material safety data sheet (MSDS).
- Ensure relevant employees have access to the MSDS.
- Establish a hazardous substances register.
- Ensure that containers of supplied hazardous substances are labelled with the manufacturer’s or importer’s label.
- Label decanted substances with at least the product name.
- Control risks to health, according to the specified hierarchy of controls, namely elimination, substitution, isolation, engineering controls, administrative controls and personal protective equipment (PPE).
- Maintain control measures and ensure that they are used.
- Conduct atmospheric monitoring where there is uncertainty about level of exposure.
- Provide information, instruction and training on the hazards, risks and controls.
- Consult with employees and health and safety representatives (HSRs).

ATMOSPHERIC MONITORING FOR GLUTARALDEHYDE

Under the OHS regulations, atmospheric monitoring is required where there is uncertainty about whether the exposure standard is or may be exceeded, or it is necessary to determine whether there is a risk to health. This means that atmospheric monitoring would not be required where exposure is effectively controlled and there is no likelihood that the exposure standard could be exceeded.

Similarly, atmospheric monitoring would not be required where it is obvious that the exposure standard is likely to be exceeded. For example, if employees detect a strong glutaraldehyde odour or they are experiencing eye and nose irritation, then their exposure is likely to be above the required exposure standard, and action needs to be taken to control the exposure to as low a level as reasonably practicable rather than do atmospheric monitoring.

Atmospheric monitoring may be useful to check the effectiveness of any control measures implemented. For example, monitoring may be necessary to test that a fully enclosed unit is operating properly and that there are no leaks.

Monitoring is also useful for assessing the effectiveness of filters in air recirculating (i.e. semi-enclosed, filtered and non-ducted) systems. The carbon filters should be maintained and replaced according to the manufacturer’s instructions, and monitoring should take place upon commissioning and at regular intervals thereafter.

Atmospheric monitoring is not considered necessary if all the work is performed within ducted fume cupboards that comply with the smoke and face velocity requirements of Australian Standard: Safety in laboratories – fume cupboards (AS/NZS 2243.8:2006), and which are properly maintained.

It needs to be kept in mind that atmospheric monitoring only considers exposure through inhalation. When working with glutaraldehyde, skin contact also needs to be taken into account when determining whether there is a risk to employees.

CONTROLLING THE RISKS TO HEALTH

The best way of eliminating the risk to health is not to use glutaraldehyde at all for cold disinfection. Where this is not reasonably practicable, employers need to reduce the risk to employees’ health to the lowest level by applying the hierarchy of controls (i.e. substitution, isolation, engineering controls, administrative controls and personal protective equipment) specified in the Occupational Health and Safety Regulations 2007. Effective risk control often involves a combination of these control measures.

The current use of glutaraldehyde-substitute chemicals and automated enclosed systems provides a strong indication of their practicability in hospitals. For further information on the application and availability of alternative chemicals and systems, reference can be made to the table on the following page. This is an extract from the table titled ‘Appendix 1 – Summary of products reviewed, environmental controls and applications’. This has been taken from the Victorian Advisory Committee on Infection Control Review Sub-Committee Report 1998 Infection Control Taskforce Glutaraldehyde Recommendation Number 11, dated February 2002.
## SUMMARY OF PRODUCTS REVIEWED AND THEIR APPLICATIONS

<table>
<thead>
<tr>
<th>Product/System</th>
<th>Outcome</th>
<th>Agent</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Disinfection</td>
<td>Sterilisation</td>
<td>Glutaraldehyde</td>
</tr>
<tr>
<td>Automated glutaraldehyde system – reuse (e.g. Medivator system)</td>
<td>✓</td>
<td>–</td>
<td>✓</td>
</tr>
<tr>
<td>Automated glutaraldehyde system – single use (e.g. Soluscope system)</td>
<td>✓</td>
<td>–</td>
<td>✓</td>
</tr>
<tr>
<td>Glutaraldehyde User Station (GUS system) – ductless fume soak station</td>
<td>✓</td>
<td>–</td>
<td>✓</td>
</tr>
<tr>
<td>Peracetic acid (Steris system)</td>
<td>–</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Low temperature hydrogen peroxide plasma system – Sterrad</td>
<td>–</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Ethylene Oxide Gas 100% Steriliser (ETO)</td>
<td>–</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Steam sterilisation</td>
<td>–</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Ortho Phthalaldehyde (OPA)</td>
<td>✓</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Glutaraldehyde – open system (manual)</td>
<td>✓</td>
<td>–</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ Required
– Not required

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**Required**: Automated system using fresh glutaraldehyde each cycle

**Not required**: Sterilisation is preferable
PRACTICAL GUIDANCE ON THE SAFE USE OF GLUTARALDEHYDE

The following section provides some practical guidance on the safe use of glutaraldehyde (for cold disinfection) where it is not reasonably practicable to substitute or eliminate its use.

The hierarchy of controls must be applied to control the risks associated with glutaraldehyde. If high level controls such as elimination, substitution, isolation and engineering controls (e.g., fume cupboards) have been applied as far as reasonably practicable and there is still a risk to health, then controls such as recirculating units and PPE (i.e., respirators, eye/face protection, gloves, apron) may need to be used to control the risk. These types of controls may require higher levels of maintenance, training and supervision to ensure they are effective.

WHERE IT IS NOT REASONABLY PRACTICABLE TO ELIMINATE THE USE OF GLUTARALDEHYDE OR TO USE A SUBSTITUTE, THEN SUITABLE CONTROLS WOULD INCLUDE THE FOLLOWING:

- Obtain MSDS for glutaraldehyde and make sure it is accessible to employees.
- Purchase the least hazardous (i.e., most dilute) form of glutaraldehyde.
- Purchase in ready to use concentration (e.g., 1–2%) to minimise handling.
- Use the lowest concentration for the job.
- Do not use glutaraldehyde as a general disinfectant for bench tops and general surfaces.
- Do not use glutaraldehyde out in the open on a bench.
- Use fully automated enclosed type units where practicable (see note below).
- Where automated enclosed systems are not practicable, all handling (including activation and disposal) of glutaraldehyde is to be within a ducted fume cupboard fitted with a sink.
- Test and maintain fume cupboard to ensure compliance with the smoke and face velocity (0.5 m/s) requirements of Australian Standard: Safety in laboratories – fume cupboards (AS/NZS 2243.8:2006).
- Minimise the use of glutaraldehyde where possible.
- Use safe method of pouring and mixing to minimise splashing, e.g., purchase smaller containers that are easier to pour from; use safety pouring nozzles; use containers/tubs fitted with taps, bungs, lips or spouts; and use automated mixers or dilution systems where available.
- Use smaller containers or tubs that minimise exposed liquid surface area.
- Label containers (including soaking tubs) to identify the contents.
- Keep lids on soaking containers when not in use (clear lids are preferable so contents are visible).
- Store products near to where they are used.
- Maintain good housekeeping.
- Prohibit eating and drinking around chemicals.
- Use glutaraldehyde in a designated area where there is less pedestrian traffic or bystanders.
- Ensure good general ventilation in work areas where glutaraldehyde is used.
- Ensure appropriate spill containment measures are in place.
- Provide adequate washing, decontamination and emergency facilities for use in the event of spills. These should include running water, emergency eye wash, spill kits containing adsorbent and neutralising material, eye/face protection, gloves, apron and organic vapour respirators.
- Promptly clean up spills.
- Do not place towels under soaking tubs.
- Safely dispose of waste and ‘empty’ containers of glutaraldehyde (i.e., deactivate/flush).
- Use appropriate PPE, including chemical safety goggles/face shields, impervious aprons and gloves (e.g., nitrile, neoprene and butyl rubber gloves), to prevent skin and eye contact when handling glutaraldehyde in a fume cupboard.
- Ensure that PPE is cleaned after use and kept in good working order.
- Ensure gloved hands, instruments and containers are thoroughly rinsed under running water after contact with glutaraldehyde.
- Restrict use and availability of glutaraldehyde to designated and trained employees.
- Safe work procedures for use of glutaraldehyde should be documented to assist with training.
- Provide relevant information, instruction, training and supervision to employees required to use glutaraldehyde.
- Review controls if incidents or near-misses occur or if symptoms of exposure are reported.

NOTES

1. Fully automated, enclosed units should have appropriate spill containment and fail safe features, such as leak/pressure checks, prior to commencement of operation. A back-up plan should also be established in case the unit fails.
2. Recirculating (semi-enclosed, filtered, non-ducted) units should only be used where fume cupboards are not practicable. These units should only be used in areas with low traffic and good general ventilation, and they should preferably be used with less hazardous substitutes. Containers in the units should be covered with lids to extend the life of the filter and prevent significant breakthrough. These type of units need to be very stringently maintained to ensure that they are in good working order. Maintenance should include service contracts and regular inspections and replacement of filters. The filter condition of these units may also be questionable, particularly when they are used infrequently or have not been used for some time. Atmospheric monitoring may be required to demonstrate the effectiveness of the filter. Contact the manufacturer for further information.
3. Do not use disposable paper or surgical type masks for glutaraldehyde vapours.
The information presented in A Guide to Safe Use of Glutaraldehyde is intended for general use only. It should not be viewed as a definitive guide to the law, and should be read in conjunction with the Occupational Health and Safety Act 2004.

Whilst every effort has been made to ensure the accuracy and completeness of A Guide to Safe Use of Glutaraldehyde the advice contained herein may not apply in every circumstance. Accordingly, the Victorian WorkCover Authority cannot be held responsible, and extends no warranties as to:

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