

SELF-STUDY SERIES

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Glutaraldehyde: The High-Level Disinfectant of Choice

Learning Objectives:

1. Explain the purpose of high-level disinfection.
2. Describe steps involved in the high-level disinfection process.
3. Review seven advantages to the use of glutaraldehyde.
4. Discuss three areas within the healthcare facility where glutaraldehyde is most frequently used.
5. Describe the personal protective apparel which should be worn when handling contaminated equipment and when working with glutaraldehyde.
6. Review safety precautions which should be used when working with glutaraldehyde.
7. State procedures to follow when cleaning up splashes and spills.
8. Explain procedures to test glutaraldehyde for minimum effective concentration (MEC).
9. Review procedures for correctly disposing of glutaraldehyde.

Glutaraldehyde is a colorless, unstable liquid. Its history as a high-level disinfectant for use in disinfecting and sterilizing contaminated medical and surgical devices spans more than 30 years. Sterilization involves the complete destruction of all microorganisms, including spores. While glutaraldehyde can be used to sterilize delicate instruments that are not readily sterilized by steam or with ethylene oxide, it is not frequently used for this purpose. The primary reason is the lengthy soak time that is necessary. Therefore, for all practical purposes, glutaraldehyde is used most frequently for high-level disinfection.¹

Objective 1: Explain the purpose of high-level disinfection.

High-level disinfection destroys all fungi, vegetative bacteria (including microbacterium tuberculosis), viruses (including HIV, the human immunodeficiency virus), and some spores. In addition to glutaraldehyde, hydrogen peroxide and peracetic acid are sterilants that, at appropriate concentrations, can achieve high-level disinfection. Chemicals used for high-level disinfection could also be used as sterilants with extended exposure time. High-level disinfectants and sterilants are regulated by the U.S. Food and Drug Administration.

Objective 2: Describe steps involved in the high-level disinfection process.

Specific steps must be followed in an exact sequence to best assure that disinfection is effective. These steps are:

- **Cleaning:** Surfaces of medical devices covered with organic material cannot be high-level disinfected if the disinfectant does not come in contact with the surface of the medical

device. Therefore, instruments must be pre-cleaned to remove as much of the organic material as possible. Selecting the proper detergent is critical. Those containing selective enzymes are often used because they can effectively dissolve protein, which reduces the need for manual cleaning.

- **Rinsing and drying:** Rinsing devices after cleaning with large volumes of fresh water will remove residual detergents. Removing moisture after rinsing helps prevent water on wet devices from diluting the glutaraldehyde.
- **Activating the chemical:** Instructions of the manufacturer should be followed when using a glutaraldehyde solution. Alkaline glutaraldehyde is activated by adding the contents of an activator vial to the container's solution. Done properly, the glutaraldehyde will change color to indicate activation and readiness for use. After activating, record activation and expiration dates. This data can be recorded on the storage bottle label or on a label placed on the disinfectant tray and in a log book. Glutaraldehyde should never be used after the suggested reuse date.
- **Preparing the soaking tray:** Once activated, glutaraldehyde should be poured into a plastic tray. (If these are unavailable, stainless steel trays can be used if a plastic mat is used to line the bottom of the tray to prevent metal-to-metal contact.)
- **Soaking:** Clean and dry devices should be immersed completely in the glutaraldehyde. All lumens should be filled, and the soaking tray should be covered with a secure lid. Glutaraldehyde solutions *without* surfactants (surface-active agents) are more appropriate

for use with rigid and flexible endoscopes. However, glutaraldehyde *with* surfactants may be used for flexible endoscopes if a validated protocol developed by the manufacturer is used for rinsing and leak testing. Devices must be soaked for the time stated on the manufacturer's label to destroy vegetative organisms.

- Rinsing and drying: After soaking for the required time, semi-critical devices (those which contact mucous membranes or non-intact skin) or noncritical instruments (those which only come in contact with intact skin) should be rinsed thoroughly with large amounts of water which is the proper quality for the item's use. Semi-critical items may require rinsing with sterile water or sterile water with alcohol prior to use or storage to prevent recontamination with bacteria normally found in water. If critical items (those that contact sterile tissue or the vascular system) have been *sterilized* in glutaraldehyde, the instruments must be removed from the solution using a sterile technique. They must then be rinsed with large amounts of fresh, sterile water and used immediately for the procedure.²

Objective 3: Review seven advantages to the use of glutaraldehyde.

Glutaraldehyde in the proper concentration (2 percent or 3.2 percent solution) offers numerous advantages, including:

- It is rapid-acting to reduce instrument processing time.
- It can sterilize instruments which cannot be processed by steam or ethylene oxide sterilization.
- It is noncorrosive and is compatible with the broadest range of materials of any high-level disinfectant/sterilant.
- It has an alkaline pH. This reduces the kill time and broadens the range of microorganisms that can be killed.
- It is antimicrobial even when organic soil is present; this makes it more effective.
- It is reusable for up to 14 or 28 days if effective concentration can be verified; this makes it cost-effective.
- It can be tested to verify that an effective concentration is present. This is important when excessive dilution is suspected.

Objective 4: Discuss three areas within the healthcare facility where glutaraldehyde is most frequently used.

Glutaraldehyde is widely used in healthcare facilities. Departments with especially frequent use include:

- Gastrointestinal labs and operating rooms (to disinfect endoscopes)
- Central Service Departments (to disinfect numerous reusable medical devices)
- Respiratory Therapy Departments (to disinfect tubing, resuscitators, and nebulizers)

Objective 5: Describe the personal protective apparel which should be worn when handling contaminated equipment and when working with glutaraldehyde.

The Occupational Safety Health Administration (OSHA) requires that personnel working with glutaraldehyde during the disinfection and sterilization processes wear proper garments for their personal protection. Required attire includes:

- Gloves. Impervious gloves which cover hands and arms should be worn when working with glutaraldehyde. Gloves meeting this requirement are made of natural rubber latex, butyl and nitrile rubber, and man-made copolymer materials. Gloves containing polyvinyl chloride and neoprene gloves may retain or absorb glutaraldehyde and are not recommended.
- Eyewear. Fluid-proof shield masks and/or protective eye wear should be worn to guard against splashes. Eyewear is necessary when instruments are being manually cleaned before immersion in glutaraldehyde and when the chemical is being poured.
- Gowns/aprons. A fluid-proof gown and/or apron should be worn to protect clothing from splashes when processing medical instruments.

Objective 6: Review safety precautions that should be used when working with glutaraldehyde.³

Glutaraldehyde is not known to be a carcinogen (which causes cancer) or a teratogen (which causes abnormal fetal development). However, glutaraldehyde vapors can cause skin, eye, and other tissue irritations. Precautions to prevent excessive exposure to vapor include:

- Only persons with specific education/training in the proper handling and use of glutaraldehyde should be allowed to work with the product.
- Always use the chemical in a large, well-ventilated area. Ideally, a disinfecting room will have ten air exchanges per hour with vents at floor level. (Glutaraldehyde vapors are heavier than air and will move to the lowest parts of a room.) Also, commercially available ventilation devices including ductless fume hoods should be considered.
- Wearing protective eyewear is a "must" when working with glutaraldehyde. Also, an eyewash station should be nearby. *Note:* Check with your OSHA regulatory agency regarding specific safety requirements for your facility.
- Keep lids on disinfectant trays at all times except when moving devices in or out of the solution.
- Avoid splashing and spills; clean up the solution immediately if a spill occurs.
- Dispose of any rags or towels soiled with glutaraldehyde by immediately rinsing them in water and placing them in a closed plastic bag.

OSHA regulates occupational exposure to glutaraldehyde. There is a threshold limit value (TLV) of 0.2 part per million (ppm) of glutaraldehyde in the atmosphere of a work environment as the permissible exposure limit (PEL) in the workplace.⁴ State-level OSHA officials should also be contacted to determine whether a more stringent PEL has been established for your state.

Objective 7: State procedures to follow when cleaning up splashes and spills.⁵

If a small spill (less than one gallon) occurs, appropriate cleanup procedures include:

- Collect safety glasses, appropriate gloves, mop and bucket, sponges and towels, squeegee, plastic trash bag (for disposal) and household ammonia.
- Mix eight ounces of household ammonia with an equal amount of water.
- Mop, sponge, or squeegee the diluted ammonia solution into the spilled glutaraldehyde for one to two minutes.
- Collect the neutralized liquid with a mop, sponge, towel, squeegee or dustpan and flush it down the drain with large amounts of fresh water.

Note: Existing conditions, such as the type of ventilation, air turnover rate, and the room size and temperature, affect the amount of glutaraldehyde that can safely be cleaned up by an employee. If discomfort (including the tearing of eyes or nasal/respiratory irritation) occurs when cleaning up a “small” spill, the room’s ventilation is inadequate to handle the spill. The room should be vacated immediately, and a team equipped to handle a larger spill should be used.

To clean up a large spill (generally over one gallon of glutaraldehyde):

- Collect items required for a small spill and, in addition, the following: breathing mask equipped with an organic vapor filter, rubber boots (or shoe protectors), plastic dustpan, plastic scoop, and ammonium carbonate powder (technical grade).
- Use the plastic scoop to sprinkle a sufficient amount of ammonium carbonate powder to cover most of the surface covered by the spilled glutaraldehyde.
- Allow about five minutes for the ammonium carbonate powder to begin to dissolve and “neutralize” the glutaraldehyde.
- Use a mop or squeegee to mix the ammonium carbonate into the spilled glutaraldehyde for one to two minutes.
- Collect the liquid slurry with a mop or squeegee and plastic dustpan; flush it down the drain with large amounts of water.
- Rinse the cleaning utensils with large amounts of water; discard the rinse water down the drain with large amounts of water.

- Thoroughly rinse any sponges or towels used for final cleanup with water; place them in a tightly closed plastic trash bag for disposal.

Objective 8: Explain procedures to test glutaraldehyde for minimum effective concentration (MEC).

Sometimes the Central Service technician knows that a solution is contaminated. At other times, mixed solutions cannot be properly stored. In both of these instances, the solution must be discarded. Sometimes, however, a glutaraldehyde solution that has been used for sterilization or high-level disinfection purposes must be tested to verify that its concentration is above the MEC. Microbacterium tuberculosis provides the most severe challenge to a glutaraldehyde solution of any vegetative organism. Therefore, the MEC for glutaraldehyde is established based upon the effectiveness of its activity against this microorganism.

The test method recommended by the manufacturer of the glutaraldehyde must be used. Frequency of testing depends upon the extent of the glutaraldehyde’s use and the manufacturer’s recommendations. However, solutions should be tested at least daily and whenever excessive dilution or heavy contamination is suspected. A log book should be used to record the results of the MEC test and temperature of the solution, as included in the manufacturer’s instructions.

Objective 9: Review procedures for correctly disposing of glutaraldehyde.

Glutaraldehyde can normally be disposed of as an ordinary domestic waste; it is not considered to be hazardous waste. (Confirm this with applicable state and local environmental protection agencies; follow required procedures if they differ from those suggested in this lesson.) At the end of its useful life, glutaraldehyde can be combined with large amounts of water to dilute the solution’s concentration while it is flushed down normal water drains of the facility.

References

¹ Except where otherwise indicated, this Self-Study Lesson is based upon: Johnson & Johnson Medical, Inc. *Professional Education: The Use of Glutaraldehyde in the Healthcare Environment*. Study Guide. Arlington, TX. 1994.

² The classification of medical instruments based upon infection risk was developed by E.H. Spaulding.

³ Details about the safe use and handling of glutaraldehyde-based products in healthcare facilities can be found in: *ANSI/AAMI ST 58*. 1996.

⁴ *AAMI Standards and Recommended Policies, Vol 1.1, Sterilization, Part 1*. Sterilization in Health Care Facilities.

⁵ See reference 3.

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Objective 1: Explain the purpose of high-level disinfection.

- 1. High-level disinfectants destroy:
a. all fungi
b. all vegetative bacteria
c. all viruses
d. all of the above
2. High-level disinfectants ___ be used as sterilants with sufficient exposure time.
a. can b. cannot

Objective 2: Describe steps involved in the high-level disinfection process.

- 3. Which is the proper sequence of steps for high-level disinfection?
a. cleaning, activating chemicals, preparing soak tray, soaking, rinsing/drying
b. cleaning, rinsing/drying, activating chemicals, preparing soak tray, soaking, rinsing/drying
c. cleaning, rinsing/drying, soaking, activating chemicals, preparing soak tray, rinsing/drying
4. Why is it not possible to high-level disinfect surfaces of medical devices covered with organic material?
a. the device cannot be adequately immersed in solution
b. the disinfectant cannot come in contact with the device's surface
c. padding on the bottom of the tray interferes with disinfection
5. Where can activation and expiration date data for glutaraldehyde be placed?
a. on the bottle label
b. on a label on the disinfectant tray
c. in a log book
d. all of the above
6. Glutaraldehyde solutions _____ surfactants are more appropriate for use with rigid and flexible endoscopes.
a. with
b. without
7. Fresh, sterile water must be used to rinse:
a. non-critical devices
b. semi-critical devices
c. critical devices
d. all of the above

Objective 3: Review seven advantages to the use of glutaraldehyde.

- 8. Which of the following is the proper concentration of glutaraldehyde?
a. 2%
b. 2.3%
c. 3.2%
d. a and c above
9. An advantage of the alkaline pH of glutaraldehyde is it:
a. reduces the kill time
b. makes verification of concentration possible
c. can be used to sterilize instruments which cannot be processed with steam
d. all of the above are true

Objective 4: Discuss three areas within the healthcare facility where glutaraldehyde is most frequently used.

- 10. The Respiratory Therapy Department generally uses glutaraldehyde to disinfect colonoscopes.
a. True
b. False

Objective 5: Describe the personal protective apparel which should be worn when handling contaminated equipment and when working with glutaraldehyde.

- 11. Gloves made of which materials can be used when working with glutaraldehyde?
a. polyvinyl chloride
b. neoprene
c. butyl and nitrile rubber
d. all of the above are acceptable

12. Eyewear to guard against glutaraldehyde splashes is necessary when:

- a. manually cleaning instruments
b. glutaraldehyde is being poured
c. both of the above
d. neither of the above

Objective 6: Review safety precautions which should be used when working with glutaraldehyde.

- 13. The ideal number of air exchanges per hour for a disinfecting room is:
a. 8 exchanges
b. 10 exchanges
c. 12 exchanges
d. 14 exchanges

- 14. Occupational exposure to glutaraldehyde is regulated by:
a. OSHA
b. FDA
c. CDC

Objective 7: State procedures to follow when cleaning up splashes and spills.

- 15. Household ammonia should be mixed with water to clean up:
a. a small spill (less than one gallon)
b. a large spill (more than one gallon)
c. any spill, if ventilation is adequate

16. Ammonium carbonate powder (technical grade) should be used to clean up what type of glutaraldehyde spill?

- a. a small spill (less than one gallon)
b. a large spill (more than one gallon)
c. any spill, if ventilation is adequate

Objective 8: Explain procedures to test glutaraldehyde for minimum effective concentration (MEC).

17. The minimum effective concentration (MEC) of glutaraldehyde is tested with which of the following?

- a. data in the log book
b. manufacturers' information
c. microbacterium tuberculosis
d. any of the above

18. Frequency of testing for glutaraldehyde concentration depends upon:

- a. manufacturer's recommendations
b. frequency of use
c. suspected heavy contamination
d. all of the above

Objective 9: Review procedures for correctly disposing of glutaraldehyde.

19. Glutaraldehyde is a _____ waste.
a. domestic
b. hazardous

20. Disposing of glutaraldehyde that has reached the end of its useful life involves:

- a. pouring it into a plastic trash bag
b. flushing down normal waste drains along with large amounts of water
c. combining with household ammonia before pouring into a plastic bag
d. combining with ammonium carbonate powder before pouring down drains of the facility

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