

<b>Johns Hopkins Safety Manual</b>	<i>Guidance Number</i>	<b>HSE G03</b>
<i>Subject:</i> Guidance for Employees Using Ortho-phthalaldehyde (Cidex® OPA) to Disinfect Equipment	<i>Last Review Date</i>	09/23/08
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To: Employees who perform high level disinfection on medical equipment and/or work in the area where Cidex® OPA is used

**Rationale:**

Ortho-phthalaldehyde (Cidex® OPA) is a chemical which must be used according to manufacturer's directions in order to protect employees, visitors and patients.

**References:**

29 CFR 1910.1030 Blood Borne Pathogen

29 CFR 1910.1200 Chemical Right to Know

29 CFR 1910 subpart K section (29 CFR 1910.151 (c) medical services and first aid.

ANSI/AIHA Z9.5-1992, 5.8

Baltimore Code Article 25 Sewers § 2-5 (h) Limitations on Discharges into Sanitary Sewers & § 6-5 Program to Reduce Volume and Toxicity.

Department of the Environment (COMAR 16.13.02) Identification and Listing of Hazardous Waste.

Department of the Environment (COMAR 26.13.03) Standards Applicable to the Generators of Hazardous Waste.

HSE policy # 004 Incident and Injury Reporting

HSE policy # 005 Occupational Injury Management

HSE policy # 501 Blood Borne Pathogen Annual Exposure Plan

HSE policy # 703 Management of Hazardous Chemicals

Miller, Kristine M., MFA. (Ed) *Protecting Those Who Serve: Health Care Worker Safety*. Oakbrook Terrace: Joint Commission Resources, Inc, 2005

NFPA 45, Chapter 6-8.7.1

1. **Any site which decides to use Ortho-phthalaldehyde needs to report this to Hospital Epidemiology and Infection control (Ext. 5-8384) and Health, Safety and Environment (Ext. 5-5918).**
2. Reference material (listed in Appendix A) and all logs (eyewash log, Johns Hopkins Cidex® OPA Daily Log and Johns Hopkins Cidex® OPA Strips Weekly QA Log) must be kept in a notebook near the area where Ortho-phthalaldehyde is in use.
3. Rooms where Ortho-phthalaldehyde is in use must have ten (10) air exchanges per hour OR local exhaust approved by HSE.
  - A. For disinfecting equipment in a container with a very small diameter contact John Schaefer for permission. (Ext. 5-5918).
4. A visual indicator must be used to assess proper fume hood operation. The assessment of the visual indicator will be documented on the Johns Hopkins Cidex® OPA Daily Log.
5. The container used to soak the equipment in Cidex® OPA must be covered at all times except when the employee is manipulating the equipment,
6. Rooms where Ortho-phthalaldehyde is in use must be clearly marked (on door or next to entrance if door is usually open) with a yellow caution sign. (See caution signs requirements in HSE # 501 Blood Borne Pathogen Exposure Control Plan.)
  - A. Blood Borne Pathogen Symbol
  - B. Ortho-phthalaldehyde (Cidex® OPA) in use
  - C. Contact information

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1. For Sterilization questions contact HEIC at Ext. 5-8384.
  2. For Safety questions contact HSE at Ext. 5-5918.
  3. Name of site person to be contacted in an emergency
7. Containers which are used for Ortho-phthalaldehyde must be clearly marked with the complete name (generic or Brand name) and the dates the solution was poured into the container and the date (fourteen (14) days later) that the solution is to be discarded.
8. In order to safely use Ortho-phthalaldehyde, employees need to:
- A. Be trained on its use either by HEIC, HSE, the manufacturer's representative, a Nurse Educator or Health Stream (when it becomes available) yearly. Training logs must be submitted to HSE. (Appendix B)
  - B. **Follow the manufacturer's directions when using Ortho-phthalaldehyde in order to protect themselves, other employees, visitors and patients from adverse events related to the use of Ortho-phthalaldehyde.**
  - C. Be aware that Cidex® OPA will stain organic material. Because it stains organic material grey, it will also stain employee skin, clothing and even the counters that contain organic material.
  - D. **Appropriate PPE (gloves, eye/face protection and gowns) must be used when pouring Ortho-phthalaldehyde, neutralizing Ortho-phthalaldehyde and when handling the device being disinfected.**
  - E. Follow the manufacturer's directions for determining the Minimum Effective Concentration (MEC) of Cidex® OPA every day by using Cidex® OPA Test Strips and record results on log.
  - F. Perform QA on Cidex® OPA Test Strips
    1. Cidex® OPA Test Strips are to be QA tested at the time the bottle of strips is opened for the first time, per manufacturer's directions.
      - a. If a new bottle of test strips fails the QA test and a second new bottle with the same lot number also fails the QA test, save both bottles and packaging for investigation. The entire lot may be defective.
      - b. Contact Clinical Products Specialist (x-2-1900) to report when two new bottles of Cidex® OPA Test Strips with the same lot number fail QA testing. Document this information on the back of the current log. (date/time/name/lot #/etc.)
    2. If you need fresh Ortho-phthalaldehyde® OPA to perform the QA on the Cidex® OPA strips the following week, leave enough Ortho-phthalaldehyde in the original manufacturer's container to perform the test.
      - a. Tightly cap the original manufacturer's container of Cidex® OPA.
      - b. Date the original manufacturer's container to expire in seventy-five (75) days from the date opened.
      - c. If the manufacturer's expiration date is less than seventy-five days from the date the bottle was opened, then you use the manufacturer's expiration date.
      - d. This is considered to be fresh Cidex® OPA if these rules are followed.
    3. Expiration dates:
      - a. Both Cidex® OPA and Cidex® OPA strips have manufacturer's expiration dates.
      - b. Both have new expiration dates based on the date the container was opened.
      - c. The Rule: The earliest expiration date is the one you use when you have two expiration dates.
  - G. Triple rinse the manufacturer's original container with water and then dispose of container in regular trash.
  - H. Lumens of medical equipment must be manually irrigated with detergent solution, Ortho-phthalaldehyde and rinse solutions.
    1. When the syringe is filled with the solution, it must be carefully filled and securely attached to the channel opening or channel irrigator.
    2. The solution must be slowly pushed into the channel.

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3. If too much force is used, the syringe will separate from the channel and spray the employee.
  - a. If this happens and the solution touches the employee's mouth and/or eye(s), follow HSE Policies # 004 and 005. This should not happen if you are wearing the appropriate PPE.
  - b. Employee must be able to report what they were exposed to:
    - i. 1. Detergent/water solution
    - ii. 2. Ortho-phthalaldehyde solution or
    - iii. 3. Type of Rinse Solution and whether it is the 1st, 2nd, or 3rd rinse.
- I. Neutralize all Ortho-phthalaldehyde following the directions for the Glycine. This includes any Ortho-phthalaldehyde which has expired while in the manufacturer's original container.
  1. The neutralization must be documented on the same log where the Cidex® OPA testing is recorded.
    - a. One ounce of Glycine per 1 gallon of Ortho-phthalaldehyde.
    - b. Mix the Glycine and the Ortho-phthalaldehyde thoroughly.
  2. Glycine is available free of charge from HSE (Ext. 5-5918).
  3. Unused Glycine should be returned to HSE.
  4. Neutralized Ortho-phthalaldehyde can be flushed down the sink with copious amounts of water.
9. Spills of Cidex® OPA will be cleaned up utilizing the "Guidelines for Spill Clean-UP of Cidex® OPA Solution" from Advanced Sterilization Products® (attached).

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**Appendix A:**

**Additional References for this Guideline – which must be available to employee working with Cidex® OPA:**

1. Manufacturer’s directions for the following are required for safe use of Cidex® OPA:
  - A. Directions for Cidex® OPA
  - B. Directions for Cidex® OPA Solution Test Strips
  - C. Directions for Glycine (See label of jar)
  - D. Directions for the equipment being disinfected
  - E. Directions for the detergent being used to clean the equipment
  - F. Advanced Sterilization Products® chart entitled “How to Use Cidex® OPA Solution”
  - G. Why you should test your Cidex® OPA
  - H. Cidex® OPA technical information (attached)
  - I. “Guidelines for Spill Clean-Up of Cidex® OPA Solution”
2. MSDS sheets for the following:
  - A. Cidex® OPA
  - B. Glycine
  - C. The detergent being used to clean the equipment
  - D. Cidex OPA Strips – Non MSDS letter
3. Policies
  - A. IFC Policy # 014: Cleaning & Disinfection
  - B. Nursing policies for Endoscopy
  - C. HSE Policy # 037: Emergency Equipment: Eye Wash, Drenching Hose and Shower Equipment

