

Johns Hopkins Safety Manual	<i>Guidance Number</i>	HSE G03
<i>Subject:</i> Guidance for Employees Using Ortho-phthalaldehyde (Cidex® OPA) to Disinfect Equipment	<i>Review Date</i>	10/17/08
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To: Employees who perform high level disinfection on medical equipment and/or work in the area where Ortho-phthalaldehyde (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.

FDA Notice dated 10/31/07 "Public Health Notification from FDA, CDC, EPA and OSHA: Avoiding Hazards Using Cleaners and Disinfectants on Electronic Medical Equipment.

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 a chemical fume hood OR local exhaust approved by HSE.
 - A. For disinfecting equipment in containers with small mouth diameter openings contact HSE 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 Ortho-phthalaldehyde (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

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- B. No food or drink label
 - C. Protective clothing required
 - D. Ortho-phthalaldehyde (Cidex® OPA) in use
 - E. Contact information
 - 1. For Sterilization questions contact HEIC at Ext. 5-8384.
 - 2. For Safety questions contact HSE at Ext. 5-5918.
 - 3. Name of site persons from this site 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 on-line training annually. The on-line training has a twenty-five (25) question test that all employees using Ortho-phthalaldehyde must take and pass annually.
 - 1. Training logs must be submitted to HSE. (Appendix B) when a Nurse Educator, HEIC employee, HSE employee or a manufacturer's representative is doing the training.
 - 2. Training is available on Health Stream and on HSE web site.
 - 3. The Nurse Educator in your department can arrange access for you.
 - 4. If you do not have a Nurse Educator contact HSE at 5-5918 to arrange for access to the Ortho-phthalaldehyde training.
 - 5. Annually means that the training has been taken at the latest by the thirteen (13) month anniversary of previous training.
 - 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 Ortho-phthalaldehyde will stain organic material. It stains organic material (skin, clothing, and counters with organic materials) a grey color.
 - D. **Appropriate PPE (gloves, eye/face protection (face shield #1397 from the Protective Devices List is recommended) and fluid impermeable 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 Ortho-phthalaldehyde (Cidex® OPA) before each use of the solution by using Cidex® OPA Test Strips. Record results on log.
 - F. When you check the MEC, you must also assess the temperature of the Ortho-phthalaldehyde (Cidex® OPA) and record it on the log.
 - 1. Contact time – as it relates to a disinfectant – is the length of time that the disinfectant must remain on the clean instrument or clean surface being disinfected in order to kill the organisms on that surface.
 - 2. The contact time of twelve (12) minutes for Ortho-phthalaldehyde is good ONLY if the solution is at least 20° C (= 68° F).
 - 3. If the temperature is below this level there is no guarantee that high level disinfection of the equipment will take place. DPP400W Cooper Waterproof Digital Thermometer is recommended for measuring the temperature.
 - G. 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,

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- 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. The strips should be tested weekly.
 3. If you need fresh Ortho-phthalaldehyde (Cidex® 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 Ortho-phthalaldehyde (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 Ortho-phthalaldehyde (Cidex® OPA) if these rules are followed.
 4. 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.
- H. Triple rinse the manufacturer's original container with water and then dispose of container in regular trash.
- I. 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.
 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: (See Appendix C for Risk Assessment of Exposure to Chemicals and Blood Borne Pathogens.)
 - i. Enzymatic detergent/water solution
 - ii. Rinse after use of enzymatic detergent
 - iii. Ortho-phthalaldehyde solution or
 - iv. Type of Rinse Solution and whether it is the 1st, 2nd, or 3rd rinse.
- J. 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.
 - c. Let the mixture set for one hour.
 - d. Neutralized Ortho-phthalaldehyde can be flushed down the sink with copious amounts of water.
 2. Glycine is available free of charge from HSE (Ext. 5-5918).
 3. Unused Glycine should be returned to HSE.
9. Spills of Cidex® OPA will be cleaned up utilizing the "Guidelines for Spill Clean-UP of Cidex® OPA Solution" from Advanced Sterilization Products®.

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Appendix A:

Additional References for this Guideline – which must be available to employee working with Cidex® OPA: Most of these references are available on the HSE website just below the link to this Guidance Document with the title “Forms”.

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
 - I. “Guidelines for Spill Clean-Up of Cidex® OPA Solution”
 - J. Directions for the use of the Automatic Endoscope Reprocessor – IF you are using one.
- The Automatic Endoscope Reprocessor must capable of being set to at least 25° C (=77° F) if is being used with Cidex OPA
2. MSDS sheets for the following:
 - A. Cidex® OPA
 - B. Glycine
 - C. The enzymatic detergent being used to clean the equipment. Johns Hopkins currently has two authorized enzymatic detergents: Enzol® and Asepti-zyme.
 - 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
4. FDA notice dated 10/31/07 “Public Health Notification from FDA, CDC, EPA and OSHA: Avoiding Hazards Using Cleaners & Disinfectants on Electronic Medical Equipment.
 1. Some of the equipment being disinfected with Ortho-phthalaldehyde at JH is electrical equipment.
 2. This notice contains other information of interest to anyone working with Ortho-phthalaldehyde.

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CIDEX® OPA TRAINING LOG

Instructor _____ Course Number H16 Date _____

Location

Campus _____ Building _____ From _____ To _____

Information Covered

- MSDS Sheets for Cidex® OPA, enzymatic detergent, Glycine
- Policies on Disinfection & Cleaning & Cidex® OPA
- Directions for equipment being disinfected, Cidex® OPA, Cidex® OPA strips
- Engineering Controls (Ventilation [room, local and fume hood])
- Administrative Controls (Policy (+logs))
- Work Practice Controls (PPE)
- Eyewash requirements **will be covered in local eyewash training**
- Cleaning Process
- Disinfection Process
- Neutralization of Cidex® OPA
- QA on Cidex® OPA Strips
- Clinical Precautions
- Other

Summary Of Demonstrations

- Demonstration of QA on Cidex® OPA Strips

Attendance

Name	Badge Number	Signature
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____


Signature of Person providing training: _____ Date: _____
Title of person providing training
Training Records

Revised: 10/17/08

Fax a copy to the Health, Safety and Environment office at 5-5929

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Appendix C:



Risk Assessment of Exposure to Chemicals & Blood Borne Pathogens

EXPOSED TO	RISK OF CHEMICAL EXPOSURE	RISK OF BLOOD BORNE PATHOGEN EXPOSURE
Enzol® or Asepti-zyme® + water	Medium	High
Rinse after use of Enzymatic detergent	Low	High
Ortho-phthalaldehyde (Cidex® OPA)	High	Varies on how long the instrument has been in the solution
Rinse #1	High	Low
Rinse #2	Medium	Low
Rinse #3	Low	Low