

Attachment 1

High Level Disinfection Procedure: Equipment and *Ortho*-phthalaldehyde 0.55% (OPA) Solution Handling and Usage

Purpose: All high-level disinfectants are utilized in a safe and effective manner to promote employee safety and provide safe instruments for patient care.

Note: **Contact with OPA Solution may stain skin or clothing.** If the solution contacts skin, wash with soap and water for a few minutes. The stain should disappear within 1 – 2 days. **Solution may also stain equipment, and environmental surfaces such as walls, floors and countertops.** Whitening toothpaste may be used to remove environmental staining.

Equipment

OPA solution	Fluid resistant gown
OPA test strips	Mask with eye shield
Test Strip Log	Timer
Whitening toothpaste	Soaking tray
Enzymatic detergent	

PROCEDURE STEPS	KEY POINTS
Each staff member who uses OPA will complete the OPA Solution Competency Skill Checklist and training prior to OPA usage	See attached OPA Competency Skills Checklist
1. Put on personal protective equipment (PPE) - fluid resistant gown, face protection, gloves	PPE must be worn when working with this chemical, including when cleaning, disinfecting instruments.
2. Clean all instruments thoroughly	Clean instruments thoroughly with enzymatic detergent or foam before disinfection <i>OPA stains instruments that are not adequately cleaned</i>
3. Rinse instruments well	Residual detergent must be removed prior to disinfection
4. Remove excess moisture from instruments by drying gently	Wiping reduces the dilution of OPA solution left by residual rinse water
5. Pour OPA Solution into a clean solution tray <i>If not using entire gallon, date the original container with date opened and date expires</i>	Read manufacturer's instructions. <i>Opened gallons of OPA solution may be stored for up to 75 days</i>
6. Record the date the solution was poured from the original container and the expire date for the newly mixed solution <i>Newly mixed solution can NOT be used after 14 days</i>	Document on OPA Test Strip Log See Log for procedure Perform test strip
7. Immerse cleaned, dry instrument completely in the OPA solution	Make sure instrument completely submerged and in the open position.

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PROCEDURE STEPS (cont.)	KEY POINTS (cont.)
8. Cover solution tray securely and soak instruments for 12 minutes at 20 degrees C (room temperature).	High-level disinfection is accomplished in 12 minutes. <i>Set timer for 12 minutes</i>
9. After appropriate soak time, put on clean gloves (also clean fluid-resistant gown and face shield) to remove disinfected instrument from solution.	Prevents recontamination of disinfected instrument.
10. Rinse instrument thoroughly using copious amounts of tap water.	Three (3) minute tap or filtered water rinse recommended.
11. Rinse with ethyl or isopropyl alcohol to remove water borne organisms. Dry item thoroughly and store in a clean manner, preferably covered, to minimize recontamination	Refer to manufacturer's instructions. Perform hand hygiene, put on clean gloves before handling unwrapped disinfected equipment that touches mucous membranes or non-intact skin.
12. Test OPA Solution daily prior to use with OPA Solution Test Strips. Document on Test Strip log.	Verify that the Minimum Effective Concentration (MEC) of OPA (ortho-phthalaldehyde) is present.
DISCARDING OPA-refer to Neutralizing Procedure (Attachment 6)	
13. Neutralize OPA with glycine <i>Follow manufacturer's instructions</i>	
14. Discard OPA Solution down sewer after 14 days, even if the Test Strips indicate a concentration above the MEC.	Discard solution sooner if test strips indicate solution is below MEC. <i>Flush down sewer with copious amounts of water after neutralizing.</i>
15. Soaking containers must be cleaned thoroughly when solution is changed. <i>After cleaning, wipe down with 1:10 solution of bleach and water. Let air dry.</i>	
ADDITIONAL INFORMATION	
16. Whitening toothpaste may be used to clean stains caused by OPA.	Apply small amount of toothpaste to stain, rub gently till stain disappears, rinse thoroughly.
17. Secure soaking container lid when in use to prevent chemical vaporization and to prevent solution contamination.	

References: OPA Solution Manufacturer's Instruction

Attachment 2 OPA Competency Skill Checklist

NAME _____ DATE _____

ACTION	Comments/Evaluation Acceptable/Needs Improvement Reviewer Signature/Initials
<p>1. Demonstrates knowledge of guidelines for high-level disinfection</p> <ul style="list-style-type: none"> • Utilizes Spaulding classification system for selection of medical devices for high-level disinfection; critical, semi-critical, and non-critical devices. 	
<p>2. Identifies advantages of CIDEX® OPA use</p> <ul style="list-style-type: none"> • <i>Ortho</i>-phthalaldehyde 0.55% - non-glutaraldehyde • Near neutral pH of 7.4 • Light blue solution, low scent • Rapid high-level disinfection – 12 minutes • No surfactant • Easy to use, requires no activation or mixing • Excellent material compatibility • Non-corrosive to metals, including carbon steel, aluminum, copper, and brass • Non-toxic and non-sensitizing composition 	
<p>3. Demonstrates effective use of OPA</p> <ul style="list-style-type: none"> • Understands importance of pre-cleaning devices • Understands compatibility with enzymatic detergents which are near neutral (6-8) in pH • Utilizes appropriate personal protective equipment • Rinses and rough dries all surfaces and lumens before immersion • Immerses devices completely, filling all lumens and eliminating air pockets • Rinses devices following immersion according to manufacturer's guidelines 	
<p>4. Identifies the following guidelines for use/reuse</p> <ul style="list-style-type: none"> • Reusable for up to 14 days, providing MEC is verified • Once opened, unused portion may be stored in original container for no longer than 75 days • 2 year shelf-life for unopened containers • Storage should be in the original sealed container at room temperature in a well-ventilated low traffic area 	
<p>5. Understands the importance of record keeping and monitoring</p> <ul style="list-style-type: none"> • Records the date the container was opened • Tests solution with OPA Solution Test Strip daily and records results for MEC. Dates Test Strip bottle with opened and expired dates. 	
<p>6. Understands limitations for use</p> <ul style="list-style-type: none"> • Identifies solution cannot be used for sterilization • Understands staining can occur on skin, clothing, instruments, equipment, and environmental surfaces on contact • Knows that vapors may cause irritation to eyes, nose and throat 	

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Attachment 3

OPA Solution Fact Sheet

Solution Facts

- Safe to use on most any item that can be soaked in glutaraldehyde. If in doubt contact instrument manufacturer.
- High-level disinfection occurs in 12 minutes at room temperature.
- 14 day reuse life
- Unopened containers –2 year shelf life
- Open containers-75 day shelf life
- Glutaraldehyde-free
- Safe to use in basin with lid
- No activation or mixing required.
- Soaking container with HLD must be *covered to prevent chemical appearance change* (film forms on OPA solution) or *air contamination of solution*. If solution appearance changes, stir solution, use test strip to check MEC level, and cover.
- Accurate, easy to use (must use OPA Test Strips)
- Disposal - down sewer with copious amount water.
- Neutral pH - range of 7.2 to 7.8
- NOT a carcinogenic

Initial Switch Out to OPA

- Thoroughly wash and rinse trays with enzymatic cleaner. If unable to be autoclaved, wipe down with a 1:10 bleach water solution, let air dry, before using Cidex OPA.
- For automated scope washers, run system through one complete cycle with plain water before using Cidex OPA.

Cleaning Instruments Prior to Immersing in OPA

- Must be cleaned with an enzymatic cleaner, then rinsed thoroughly with water.
- If inadequate cleaning has occurred and protein residue remains on surface, staining from the OPA will occur. The gray color of the stained protein means inadequate cleaning has occurred.

Rinsing Instructions

- Following immersion in OPA solution, thoroughly rinse the device three times.
- Immerse or flush the device completely in a large volume of water of water.
- Repeat this procedure at least twice more.
- If OPA is not thoroughly removed through rinsing, the instrument residue can stain the mucosa and skin during next patient procedure.
- After rinsing with water, wipe outer part of scope with alcohol, rinse all lumens, then flush lumens with air to dry.

Staining

- OPA solution stains organic matter when device is improperly cleaned.
- OPA solution can also stain skin, clothing, and environmental surfaces.
- Avoid staining and chemical exposure by:
 - ❖ Wearing gown, gloves, face protection (face shield) during cleaning disinfection procedures.
 - ❖ Wearing only latex or nitrile gloves-change latex gloves every 10-15 minutes. Do not wear vinyl.
 - ❖ Covering surfaces with potential exposure with waterproof barrier (incontinent pad).
 - ❖ Rinsing the exposed surface with water *immediately*.
 - ❖ Rubbing (gently) the exposed surface with enzymatic cleaner or toothpaste.

Test Strip Use

- Immerse strip in solution for 1 full second
- Read test strip 90 seconds after immersion
- Test strips expire 90 days after opening container

Spills

- *For spill neutralization*, sprinkle approximately 25 grams of glycine (free base) powder per gallon of estimated OPA solution spill. With a mop or other tool, thoroughly blend the glycine into the spill. Allow 5 minutes for deactivation of OPA. Discard down sewer with copious water to prevent clogging. Rinse area and tools used with soap and water solution and follow with a water rinse. Wear PPE.

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3E COMPANY

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Material Safety Data Sheet Transmittal Form Attachment 4

November 16, 2006

Request #: **65314**
 Processed By: **Joel Hawthorne**

Recipient:**GWEN FELIZARDO****Email: FELIZARDO.G@GHC.ORG****Requester:****GWEN FELIZARDO****Email: FELIZARDO.G@GHC.ORG****Phone: 253-383-6374**

Thank you for using 3E's MSDS Paperless Compliance™ service. This service may eliminate the requirement to maintain MSDS on site. Below is a list of the MSDS you requested. Please verify that the MSDS sheet(s) enclosed/attached match what you have ordered.

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PID	Manufacturer ORDERED/Actual	Product Name ORDERED/Actual	UPC	Item
1162411	ADVANCED STERILIZATION/Advanced Sterilization Products	CIDEX OPA/Cidex OPA Solution		
END OF ORDER DETAIL - Request# 65314				



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Material Safety Data Sheet

MSDS-09588-0-001

Rev.: E

Product: CIDEX® OPA Solution

Issue Date: 6-28-05

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Supplier:

Advanced Sterilization Products
 33 Technology Drive
 Irvine, CA 92618

Customer service telephone: 1-800-755-5900

Emergency telephone number: 1-877-208-6653 24 hrs

Product name: CIDEX OPA Solution

Synonyms: None

2. COMPOSITION/INFORMATION ON INGREDIENTS

The ingredients at their given percentages in this product are not considered hazardous to your health.

Components	CAS Number	Weight %	J&J - OEL Data (TWA - 8 hr)	J&J - OEL Data (STEL):	J&J - OEL Data (Ceiling Limit Value):	J&J - PBOEL
ortho-Phthalaldehyde (1,2 - benzenedicarboxaldehyde)	643-79-8	<1	Not Determined	Not Determined	Not Determined	Not Determined

3. HAZARDS IDENTIFICATION

Emergency overview: May cause eye, skin and respiratory irritation.
 May elicit an allergic reaction.
 CIDEX OPA Solution has been reported to cause anaphylactic-like reactions in bladder cancer patients undergoing repeated cystoscopy.
 CIDEX OPA Solution should not be used to reprocess instruments for patients that have shown previous sensitivity to this solution or any of its ingredients.

Properties affecting health: May cause sensitization by repeated skin contact.

Principle routes of exposure:

Oral: Not anticipated to be a significant route of occupational exposure.
Eye contact: May cause eye irritation and redness.
Skin contact: May cause skin irritation. Repeated exposure may cause skin dryness or cracking. Exposure to skin may cause temporary staining.
Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Exposure can irritate and discolor the tissues of the mouth, esophagus and other tissues of the digestive tract.

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Product code: ASPOPA

CO-12305-2

Inhalation: May cause irritation, including but not limited to discharge, coughing, wheezing tightness of chest and throat, difficulty breathing and stinging sensation in nose and throat, tingling of mouth and lips, headache, lose of smell and dry mouth. Symptoms are temporary and reversible.

Hazard information:

Target organ effects: None
Reproductive effects: Not a reproductive effector.
Mutagenic effects: Not mutagenic in the Ames assay.
Sensitization: May cause sensitization.

Carcinogenicity rating:

Components	CAS Number	J & J:	NTP:	IARC:	California Proposition 65 List:
<i>ortho</i> -Phthalaldehyde (1,2 – benzenedicarboxaldehyde)	643-79-8	Not Determined	Not Determined	Not Determined	Not Determined

Signs and symptoms: None.

Medical conditions aggravated by exposure: Inhalation of vapor may cause asthma-like symptoms (chest discomfort and tightness, difficulty with breathing) as well as aggravate pre-existing asthma.

4. FIRST AID MEASURES

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Ingestion: Do not induce vomiting. Rinse mouth followed by drinking a large quantity of water

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

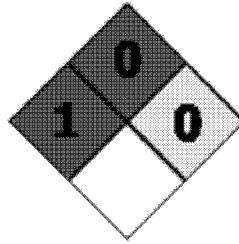
Skin contact: Wash contaminated areas thoroughly with soap and water. Remove contaminated clothing and wash before re-use. Seek medical attention if irritation develops or persists.

Protection of first-aiders: None.

Notes to physician: Probable damage to the mucosa from oral exposure may contraindicate the use of gastric lavage.

5. FIRE-FIGHTING MEASURES

Flash point (°F):	Not applicable
Flash point (°C):	Not applicable
Autoignition temperature:	Not applicable
Flammable limits in air - lower (%):	Not applicable
NFPA rating:	Health: 1 flammability: 0 reactivity: 0
HMIS/ NFPA rating and classification:	



Fire fighting information:

Suitable extinguishing media:	Use any extinguishing agent which is suitable for the surrounding fire
Extinguishing media which must not be used for safety reasons:	None
Specific methods:	None
Special protective equipment for firefighters:	Wear self-contained breathing apparatus for fire fighting if necessary.
Hazardous combustion products:	None
Explosivity:	None
Explosion limits:	
lower:	None
upper:	None

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Wear eye and skin protection while handling material for clean-up. Avoid breathing vapors and/or mists.
Environmental precautions:	Do not wash down sewers or waterways.
Methods for cleaning up:	If required, neutralize by sprinkling approximately 25 grams of glycine (CAS# 56-40-6) powder per gallon of CIDEX OPA Solution spill. Thoroughly blend the glycine into the spill using mop or other tools. Allow 5 minutes contact for neutralization. Pick up and transfer to properly labeled containers. Allow neutralization to continue for 1 hour and then dispose of in accordance with all applicable federal, state, and local regulations. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions:

Use in well ventilated area and use with appropriate exhaust ventilation, for example a minimum of 10 air exchanges per hour or as defined by state and local regulations.

Safe handling advice:

Wear appropriate personal protection. Avoid contact with skin, eyes and clothing. Remove contaminated clothing and laundry before reuse.

Storage:

Technical measures/storage conditions:

This product should be stored between 59°F (15°C) and 86°F (30°C)

Incompatible products:

Keep containers tightly closed.

Avoid contact with strong acids and bases. Keep from contact with oxidizing materials.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls:

Ensure adequate ventilation.

Eye protection:

Eye protection recommended.

Hand protection:

Chemical resistant gloves recommended.

Skin and body protection

Wear suitable protective clothing.

Respiratory protection:

None required.

Other/general protection:

None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Clear liquid

Physical state:

Liquid

Color:

Light blue

pH:

7.2-7.8

Odor:

Slight Odor

Boiling temperature (°F):

212

Boiling temperature (°C):

100

Freezing point/range (°C):

0

Freezing point/range (°F):

32

Specific gravity:

1.0003g/cc

Evaporation rate:

similar to water

Water solubility:

soluble

10. STABILITY AND REACTIVITY

Chemical stability:

Stable under recommended storage conditions.

Hazardous polymerization:

Hazardous polymerization does not occur.

Hazardous decomposition products:

Unknown on product.

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Materials to avoid:

Strong acids and strong bases.
Stay away from strong oxidizing agents.

Conditions to avoid:

Extremes of temperature and direct sunlight.

11. TOXICOLOGICAL INFORMATION**Acute toxicity**

LD50/oral/rat (mg/kg) = >5000 mg/kg

LD50 Dermal Rabbit (mg/kg): >2000 mg/kg

Local effects

Oral: Non-toxic
Eye irritation May cause eye irritation.
Skin irritation: May cause skin irritation.
Inhalation: Unknown on product.

Chronic toxicity

Oral: Unknown on product.

Inhalation: Unknown on product.

Dermal: Unknown on product.

Subchronic toxicity

Oral: Oral administration of o-phthalaldehyde to rats for 90 days resulted in a NOEL of 5mg/kg/day.

Dermal: Unknown on product.

Specific effects

Corrosive effects: Not corrosive.
Sensitization: May elicit an allergic reaction.
Target organ effects: None
Mutagenic effects: Not mutagenic in Ames test.

Reproductive effects: Unknown on product.
Developmental effects: Oral administration of o-phthalaldehyde to pregnant rats indicated that at maternally non-toxic doses (less than 10 mg/kg/day) there was no developmental effect.

Carcinogenic effects: Unknown on product.

12. ECOLOGICAL INFORMATION**Ecotoxicity:**

Ecotoxicity effects: Unknown on this product.
Aquatic toxicity effects: This product is harmful to aquatic organisms.

Mobility: Unknown on product.
Persistence / degradability: Unknown on product.
Bioaccumulation: Unknown on product.
Degradation: Unknown on product.

13. DISPOSAL CONSIDERATIONS

Company: ADVANCED STERILIZATION PRODUCTS
Product name: CIDEX® OPA Solution

Product code: ASPOPA
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Waste from residues / unused products:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority.
This product is not a hazardous waste as defined by EPA definitions.

Contaminated packaging:

Do not re-use empty containers

Methods for cleaning up:

If required, neutralize by sprinkling approximately 25 grams of glycine (CAS # 56-40-6) powder per gallon of CIDEX OPA Solution spill. Thoroughly blend the glycine into the spill using mop or other tools. Allow 5 minutes contact for neutralization. Pick up and transfer to properly labeled containers. Allow neutralization to continue for 1 hour and then dispose of in accordance with all applicable federal, state, and local regulations.
Clean contaminated surface thoroughly.

14. TRANSPORT INFORMATION

DOT:

DOT UN-No:	Not applicable
DOT shipping name:	Not regulated
Hazard class:	Not applicable
Subsidiary risk (hazard class):	Not applicable
Packing group:	Not applicable
DOT reportable quantity (lbs):	Not applicable

IMO/IMDG:

Hazard class:	Not applicable
IMDG page:	Not applicable
IMDG-labels:	Not applicable
Packing group:	Not applicable
MFAG table No.:	Not applicable
Proper shipping name:	Not regulated
UN/Id No.:	Not applicable

ADR/RID:

Hazard class/packing group:	Not applicable
Item:	Not applicable
ADR/RID-labels:	Not applicable
UN/Id No.:	Not applicable
Proper shipping name:	Not regulated
TREM-card:	Not applicable

IATA/ICAO:

Hazard class:	Not applicable
Packing group:	Not applicable
Proper shipping name:	Not regulated
ID/UN No.:	Not applicable
IATA - label:	Not applicable
ERG #	Not applicable

TDG (Canada):

Status:	Not applicable
Packing group:	Not applicable

Company: ADVANCED STERILIZATION PRODUCTS
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15. REGULATORY INFORMATION

SARA (311, 312) hazard class:

Immediate health: None
Delayed health: None
Fire: None
Sudden Release of Pressure Hazard: None
Reactivity: None

TSCA inventory list: Listed under TSCA: Yes

WHMIS:

WHMIS trade secret: None
WHMIS hazard class: None

Canada DSL inventory list: Listed on DSL: Yes

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensations and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act
4. TSCA = Toxic Substance Control Act
5. WHMIS = Canadian Workplace Hazardous Materials Information System
6. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

None

Additional advice None

Literary Reference: None

MSDS format: North American Format - U.S. and Canada
This Material Safety Data Sheet was prepared in accordance with OSHA 29 CFR 1910.1200.

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End of Safety Data Sheet

Company: ADVANCED STERLIZATION PRODUCTS
Product name: CIDEX® OPA Solution

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