

Division of Ethicon, Inc.

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
o <i>rtho</i> -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.

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.

None
Not a reproductive effector.
Not mutagenic in the Ames assay.
May cause sensitization.

None.

Carcinogenicity rating:

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

Signs and symptoms:

Medical conditions	Inhalation of vapor may cause asthma-like symptoms (chest discomfort and
aggravated by exposure:	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): Flash point (°C): Autoignition temperature: Flammable limits in air - lower (%): NFPA rating: HMIS/ NFPA rating and classification:	Not applicable Not applicable Not applicable Health: 1 flammability: 0 reactivity: 0
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: upper:	None 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

Technical measures/precautions: Safe handling advice:	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. Wear appropriate personal protection. Avoid contact with skin, eyes and clothing. Remove contaminated clothing and launder 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

10. STABILITY AND REACTIVITY

Chemical stability:

Hazardous polymerization:

Hazardous decomposition products:

Stable under recommended storage conditions.

Hazardous polymerization does not occur.

Unknown on product.

Company: ADVANCED STERLIZATION PRODUCTS Product name: CIDEX® OPA Solution Product code: ASPOPA CO-12305-2

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

Conditions to avoid:

Extremes of temperature and direct sunlight.

11. TOXICOLOGICAL	INFORMATION
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<u>Acute toxicity</u> LD50/oral/rat (mg/kg) = LD50 Dermal Rabbit (mg/kg):	>5000 mg/kg >2000 mg/kg
<u>Local effects</u> Oral: Eye irritation Skin irritation: Inhalation:	Non-toxic May cause eye irritation. May cause skin irritation. Unknown on product.
<u>Chronic toxicity</u> Oral: Inhalation:	Unknown on product. Unknown on product.
Dermal:	Unknown on product.
<u>Subchronic toxicity</u> Oral: Dermal:	Oral administration of o-phthalaldehyde to rats for 90 days resulted in a NOEL of 5mg/kg/day. Unknown on product.
Specific effects	
Corrosive effects: Sensitization: Target organ effects: Mutagenic effects:	Not corrosive. May elicit an allergic reaction. None Not mutagenic in Ames test.
Reproductive effects: Developmental effects:	Unknown on product. 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

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 If required, neutralize by sprinkling approximately 25 grams Methods for cleaning up: of alycine (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: DOT shipping name: Hazard class: Subsidiary risk (hazard class): Packing group: DOT reportable quantity (Ibs):	Not applicable Not regulated Not applicable Not applicable Not applicable Not applicable
IMO/IMDG:	
Hazard class: IMDG page: IMDG-labels: Packing group: MFAG table No.: Proper shipping name: UN/Id No.:	Not applicable Not applicable Not applicable Not applicable Not applicable Not regulated Not applicable
ADR/RID:	
Hazard class/packing group: Item: ADR/RID-labels: UN/Id No.: Proper shipping name: TREM-card:	Not applicable Not applicable Not applicable Not applicable Not regulated Not applicable
IATA/ICAO:	
Hazard class: Packing group: Proper shipping name: ID/UN No.: IATA - label: ERG #	Not applicable Not applicable Not regulated Not applicable Not applicable Not applicable
TDG (Canada): Status: Packing group:	Not applicable Not applicable

Company: ADVANCED STERLIZATION PRODUCTS Product name: CIDEX® OPA Solution Product code: ASPOPA CO-12305-2

15. REGULATORY INFORMATION

SARA (311, 312) hazard class:	
Immediate health:	None
Delayed health:	None
Fire:	None
Sudden Release of	None
Pressure Hazard:	
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