Material Safety Data Sheet

MSDS-09588-0-001
Rev.: E
Product: CIDEX® OPA Solution
Issue Date: 6-28-05

I. 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.

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<tbody>
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<td>ortho-Phthalaldehyde</td>
<td>643-79-8</td>
<td>&lt;1</td>
<td>Not Determined</td>
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<td>(1,2 – benzenedicarboxaldehyde)</td>
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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.
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.

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<tr>
<th>Components</th>
<th>CAS Number</th>
<th>J &amp; J:</th>
<th>NTP:</th>
<th>IARC:</th>
<th>California Proposition 65 List:</th>
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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.

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 launder before reuse.

Storage:

Technical measures/storage conditions: This product should be stored between 59°F (15°C) and 86°F (30°C) Keep containers tightly closed.

Incompatible products: 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.
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
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.

[4. 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
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 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