

## **Material Safety Data Sheet**

MSDS-09588-0-001

Rev.: G

**Product:** CIDEX ® OPA Solution

**Issue Date:** 9/27/2010

# 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.

Components	CAS Number	Weight %	ASP- OEL Data (TWA - 8 hr)	ASP - OEL Data (STEL):	ASP - OEL Data (Ceiling Limit Value):	
ortho-Phthalaldehyde (1,2 – benzenedicarboxaldehyde)	643-79-8	<1	19 μg/m³	148 μg/m <sup>3</sup>	Not Determined	

## 3. HAZARDS IDENTIFICATION

Emergency overview: 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 toxic by oral route. Not anticipated to be a significant route of exposure.

**Eye contact:** May cause eye irritation and redness.

**Skin contact:** Not toxic by dermal route. 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

Product code: ASPOPA

tissues of the digestive tract.

**Company:** ADVANCED STERLIZATION PRODUCTS

Product name: CIDEX® OPA Solution CO-1003686

Page 1 of 7

**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:** This material is not reported to cause reproductive effects in humans.

**Mutagenic effects:** Not mutagenic in the Ames assay.

**Sensitization:** May cause sensitization.

Carcinogenicity rating:

Components	CAS Number	ASP	NTP:	IARC:	California Proposition 65 List:
ortho-Phthalaldehyde	643-79-8	Not Determined	Not Determined	Not Determined	Not Listed
(1,2 – benzenedicarboxaldehyde)					

Signs and symptoms: None.

**Medical conditions**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.

Company: ADVANCED STERLIZATION PRODUCTS

Product name: CIDEX® OPA Solution

Product code: ASPOPA CO-1003686

## 5. FIRE-FIGHTING MEASURES

Flash point (°F):

Flash point (°C):

Autoignition temperature:

Flammable limits in air - lower (%):

Not applicable

Not applicable

NFPA rating: 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: 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.

Responders should wear chemical resistant gloves and suitable body protection. Where there is a risk of product contact with shoe, chemical resistant shoe coverings

are recommended.

**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:

**Company: ADVANCED STERLIZATION PRODUCTS** 

Product name: CIDEX® OPA Solution

Product code: ASPOPA

CO-1003686

**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 required.

**Hand protection:** Chemical resistant gloves required.

**Skin and body protection**Wear suitable protective clothing.

Respiratory protection: None required.

Other/general protection: None required.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear
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.

Materials to avoid: Strong acids and strong bases.

Stay away from strong oxidizing agents.

Product code: ASPOPA

CO-1003686

**Conditions to avoid:** Extremes of temperature and direct sunlight.

**Company: ADVANCED STERLIZATION PRODUCTS** 

Product name: CIDEX® OPA Solution

Page 4 of 7

## 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 Skin irritation:**May cause eye irritation.

May cause skin irritation.

Unknown on product.

**Chronic toxicity** 

Oral: Unknown on product. Unknown on product.

**Dermal:** Unknown on product.

**Subchronic toxicity** 

Oral administration of o-phthalaldehyde (active ingredient) 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 (active ingredient) 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.

Company: ADVANCED STERLIZATION PRODUCTS

## 13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: Waste disposal must be in accordance with appropriate US,

Federal, State, Local and International regulations.

Product code: ASPOPA

**Contaminated packaging:**Do not re-use empty containers

Product name: CIDEX® OPA Solution CO-1003686

Page 5 of 7

#### 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:

DOT shipping name:

Hazard class:

Subsidiary risk (hazard class):

Packing group:

DOT reportable quantity (lbs):

Not applicable

Not applicable

Not applicable

### IMO/IMDG:

Hazard class:

IMDG page:

Not applicable

IMDG-labels:

Not applicable

Packing group:

Not applicable

Not regulated

UN/Id No.:

Not applicable

#### ADR/RID:

Hazard class/packing group:

Not applicable
Not applicable
ADR/RID-labels:
Not applicable
UN/ld No.:
Not applicable
Proper shipping name:
Not regulated
TREM-card:
Not applicable

## IATA/ICAO:

Hazard class:Not applicablePacking group:Not applicableProper shipping name:Not regulatedID/UN No.:Not applicableIATA - label:Not applicableERG #Not applicable

## TDG (Canada):

Status: Not applicable Packing group: Not applicable

## 15. REGULATORY INFORMATION

## SARA (311, 312) hazard class:

Immediate health:NoneDelayed health:NoneFire:NoneSudden Release ofNone

**Pressure Hazard:** 

**Company: ADVANCED STERLIZATION PRODUCTS** 

Product name: CIDEX® OPA Solution

Product code: ASPOPA

CO-1003686

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.
- 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.

#### Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, Johnson and Johnson does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage maybe required. Johnson and Johnson assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

**End of Safety Data Sheet** 

**Company:** ADVANCED STERLIZATION PRODUCTS

Product name: CIDEX® OPA Solution

Page 7 of 7

Product code: ASPOPA

CO-1003686