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SECTION 1. IDENTIFICATION

Substance name : CIDEX OPA Solution

Manufacturer or supplier's details

Company name of supplier : Advanced Sterilization Products

Address : 33 Technology Drive
Irvine, CA 92618
US

Telephone : (800) 755-5900
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-527-3887

Recommended use of the chemical and restrictions on use

Recommended use : High level disinfection

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitisation : Category 1

GHS label elements

Medicinal devices are not subject to GHS labeling.

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
Response:



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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste dis-
posal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
phthalaldehyde	643-79-8	>= 0.1 - < 1

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
If symptoms persist, call a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with plenty of water.
If symptoms persist, call a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is con-
scious).
Call a physician immediately.

Most important symptoms and effects, both acute and delayed : Allergic reactions

Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-
cumstances and the surrounding environment.



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Hazardous combustion products : No hazardous combustion products are known

Further information : No information available.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Do not breathe vapours or spray mist.
Evacuate personnel to safe areas.

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No data available

Advice on safe handling : To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.

Recommended storage temperature : 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.



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Hazardous components without workplace control parameters

Components	CAS-No.
phthalaldehyde	643-79-8

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No personal respiratory protective equipment normally required.
In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.

Hand protection

Remarks : Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Impervious gloves

Eye protection : Safety glasses with side-shields

Skin and body protection : No special precautions required.

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : light blue, clear

Odour : No data available

Odour Threshold : No data available

pH : 7.2 - 7.8

Melting point/range : 0 °C



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Boiling point/boiling range	: 100 °C
Flash point	: No data available
Evaporation rate	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Density	: 1.0 g/cm ³ (20 °C)
Solubility(ies)	
Water solubility	: soluble
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: None reasonably foreseeable.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
Conditions to avoid	: To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	: Acids Alkali metals Reducing agents Oxidizing agents Water
Hazardous decomposition products	: None known.



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SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

phthalaldehyde

Acute oral toxicity : LD50 Oral (Rat): 178 mg/kg

Skin corrosion/irritation

Product:

Remarks: slight irritation

Components:

phthalaldehyde

Result: Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Product:

Remarks: slight irritation

Respiratory or skin sensitisation

Product:

Remarks: Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Components:

phthalaldehyde

Result: May cause sensitisation by skin contact.

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

Components:

phthalaldehyde

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: <10 milligram per kilogram



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Result: No teratogenic effects

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity**Components:****phthalaldehyde**

Species: Rat

NOAEL: 5 mg/kg

Application Route: Oral

Exposure time: 90 days

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to algae : Remarks: The active ingredient o-phthalaldehyde is considered toxic to algae. However upon dilution the activity is reduced.

Components:**phthalaldehyde**

Toxicity to fish : (Oncorhynchus mykiss (rainbow trout)): 0.072 mg/l
Exposure time: 96 h
Test Type: LC50

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.087 mg/l
Exposure time: 48 h

Persistence and degradability

No data available

Bioaccumulative potential**Components:****phthalaldehyde**

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available



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Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

Additional ecological
information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
This product has no known ecotoxicological effects.

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regula-
tions.

Contaminated packaging : Empty containers should be taken to an approved waste han-
dling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act**



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SARA 302 : This material does not contain any components with a section 302 EHS TPQ.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations : Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.



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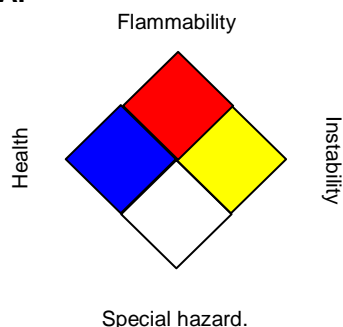
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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012/12/31
Numbers: 123456,78 as 123,456.78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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