



Version 3.4 Revision Date: 2018/06/09 SDS Number: 100000011340 Date of last issue: 2018/01/27
Date of first issue: 2015/03/27

SECTION 1. IDENTIFICATION

Substance name : CIDEX OPA Concentrate

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

Flammable liquids : Category 3

Skin corrosion : Category 1B

Eye irritation : Category 2A

Skin sensitisation : Category 1

Acute aquatic toxicity : Category 1

Chronic aquatic toxicity : Category 1

GHS label elements

Medicinal devices are not subject to GHS labeling.

Hazard pictograms :



Signal word :
Danger



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Hazard statements :
H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
P391 Collect spillage.
Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS



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Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
ethanol	64-17-5	<= 20
phthalaldehyde	643-79-8	<= 5.75

SECTION 4. FIRST AID MEASURES

- If inhaled : If breathed in, move person into fresh air.
Artificial respiration and/or oxygen may be necessary.
Consult a physician.
Victim to lie down in the recovery position, cover and keep him warm.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with plenty of water.
Call a physician immediately.
Wash contaminated clothing before re-use.
Keep warm and in a quiet place.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.
- If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Do NOT induce vomiting.
Call a physician immediately.
Drink plenty of water.
- Most important symptoms and effects, both acute and delayed : Sensitisation
Causes burns.
Nausea
Vomiting
- Notes to physician : Treat symptomatically.
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry powder
Water spray jet
- Unsuitable extinguishing media : High volume water jet
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- Specific hazards during fire-fighting : Heating can release hazardous gases.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Remove undamaged containers from fire area if it is safe to do so.
- Further information : In the event of fire, cool tanks with water spray. Prevent fire extinguishing water from contaminating surface water or the ground water system.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Evacuate personnel to safe areas. 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.
- Environmental precautions : Prevent further leakage or spillage if safe to do so. 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".
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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : Do not remove screw cap until immediately ready for use. To avoid thermal decomposition, do not overheat. Keep away from heat and sources of ignition. Avoid inhalation, ingestion and contact with skin and eyes. Use only with adequate ventilation. 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.
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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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ethanol	64-17-5	TWA	1,000 ppm	ACGIH
		STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m ³	OSHA Z-1
		TWA	1,000 ppm 1,900 mg/m ³	OSHA P0
		PEL	1,000 ppm 1,900 mg/m ³	CAL PEL

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.
 In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.
 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.

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 Neoprene gloves

Eye protection : Face-shield



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Skin and body protection	: chemical resistant apron, coat or coverall Boots
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. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: clear
Colour	: clear, dark blue
Odour	: alcohol-like
Odour Threshold	: No data available
pH	: 7.5
Melting point/range	: < 0 °C
Boiling point/boiling range	: 87.8 °C
Flash point	: 32.2 °C
Evaporation rate	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: 0.9896 g/cm ³ (20 °C)
Solubility(ies)	
Water solubility	: soluble
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: log Pow: 0.677
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	



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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. Hazardous polymerisation does not occur.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat.
Incompatible materials	:	Acids Alkali metals Reducing agents Oxidizing agents
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate: 3,096 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

ethanol

Acute oral toxicity	:	LD50 (Rat): 7,060 mg/kg Symptoms: nausea Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	LC50 (Rat): 2,000 mg/l Exposure time: 4 h Assessment: The substance or mixture has no acute inhalation toxicity
	:	LC50 (Mouse): > 20 mg/l Exposure time: 4 h



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Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

phthalaldehyde

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

Skin corrosion/irritation

Components:

ethanol

Method: OECD Test Guideline 404

Result: No skin irritation

phthalaldehyde

Result: Corrosive after 3 minutes to 1 hour of exposure

Serious eye damage/eye irritation

Product:

Result: irritating

Components:

ethanol

Result: Eye irritation

Respiratory or skin sensitisation

Product:

Result: May cause sensitisation by skin contact.

Components:

ethanol

Result: Does not cause skin sensitisation.

phthalaldehyde

Result: May cause sensitisation by skin contact.

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Test Type: Ames test
Result: negative
Remarks: In vitro tests did not show mutagenic effects

Components:

ethanol

Genotoxicity in vitro : Test Type: Ames test
Species: Mutagenicity (Salmonella typhimurium - reverse mutation assay)
Result: negative



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Carcinogenicity**IARC**

Group 1: Carcinogenic to humans

ethanol

64-17-5

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity**Components:****phthalaldehyde**

Effects on foetal development

: Species: Rat, female
Application Route: Oral
Dose: <10 milligram per kilogram
Result: No teratogenic effects**STOT - single exposure****Components:****ethanol**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure**Components:****ethanol**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Components:****phthalaldehyde**Species: Rat
NOAEL: 5 mg/kg
Application Route: Oral
Exposure time: 90 days**Aspiration toxicity****Components:****ethanol**

No aspiration toxicity classification



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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:

ethanol

Toxicity to fish : (Leuciscus idus (Golden orfe)): 8,140 mg/l
Exposure time: 48 h
Test Type: LC50

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,268 - 14,221 mg/l
Exposure time: 48 h

Toxicity to algae : EC50 (Chlorella pyrenoidosa (aglae)): > 100 mg/l

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

Components:

ethanol

Biodegradability : Biodegradation: > 70 %
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

ethanol

Bioaccumulation : Remarks: Accumulation in aquatic organisms is unlikely.

Partition coefficient: n-octanol/water : log Pow: -0.35 (20 °C)
Method: OECD Test Guideline 117

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.

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**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(phthalaldehyde)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(phthalaldehyde)
Class : 9
Packing group : III
Labels : 9
Packing instruction (cargo
aircraft) : 964
Packing instruction (LQ) : Y964
Packing instruction (EQ) : E1
Packing instruction
(passenger aircraft) : 964



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Packing instruction (LQ) : Y964
Remarks : Special Provision A197: Environmentally hazardous substances, classified under UN 3077 or UN 3082, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of the IATA DGR provided the packagings meet the general provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package \leq 1mL for liquids or \leq 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(phthalaldehyde)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes
Remarks : 2.10.2.7: Environmentally Hazardous Substances/Marine Pollutants, classified under UN 3077 or UN 3082, packaged in single or combination packagings containing a net quantity per single of inner packaging of 5L or less for liquids or having a net mass per single of inner packaging of 5kg or less for solids are not subject to the IMDG provided the packagings meet the general requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.4 to 4.1.1.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package \leq 1mL for liquids or \leq 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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**

UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(phthalaldehyde)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : no
Remarks : 49 CFR 171.4 - Marine Pollutant Exception: Except when transporting aboard a vessel, the requirements of this subchapter do not apply to non-bulk packagings transported



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by motor vehicles, rail cars, and aircraft., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

SECTION 15. REGULATORY INFORMATION

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

ethanol	64-17-5	20 %
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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

ethanol	64-17-5	20 - 30 %
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Pennsylvania Right To Know

ethanol	64-17-5	20 - 30 %
phthalaldehyde	643-79-8	5 - 10 %

New Jersey Right To Know

ethanol	64-17-5	20 - 30 %
phthalaldehyde	643-79-8	5 - 10 %

California Prop 65

ethanol	WARNING! This product contains a chemical known to the State of California to cause cancer.
ethanol	WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Other regulations

: Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export

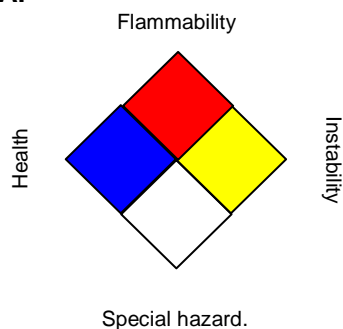
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notification because Food, Drugs and cosmetic products are exempt.

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

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