

SAFETY DATA SHEET



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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

Emergency telephone number : (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

Skin sensitisation : Category 1

Acute aquatic toxicity : Category 1

GHS Label element

Medicinal devices are not subject to GHS labeling.

Hazard pictograms :



Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H400 Very toxic to aquatic life.

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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): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P333 + P313 If skin irritation or rash occurs: 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 for extinction.
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

Substance / Mixture : Mixture
Chemical nature : Liquid

Hazardous components

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Chemical Name	CAS-No.	Concentration (%)
ethanol	64-17-5	≥ 20 - < 30
phthalaldehyde	643-79-8	≥ 5 - < 10

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.

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
- Specific hazards during fire-fighting : Heating can release hazardous gases.
- Hazardous combustion products : No hazardous combustion products are known

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| 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. |

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 | : 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". |

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.
For personal protection see section 8.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Use only with adequate ventilation. |
| 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. |



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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

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

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.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: clear
Colour	: clear, dark blue
Odour	: alcohol-like
Odour Threshold	: No data available
pH	: 7.2 - 7.8
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	
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.
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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
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Components:

ethanol

Acute oral toxicity	: LD50 (Rat): 6,200 mg/kg Symptoms: nausea Assessment: The substance or mixture has no acute oral toxicity
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Acute inhalation toxicity	: LC50 (Rat): 95.6 mg/l Exposure time: 4 h Assessment: The substance or mixture has no acute inhalation toxicity
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phthalaldehyde

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

Product:

Species: Rabbit
Result: Corrosive after 3 minutes to 1 hour of exposure

Components:

ethanol

Method: OECD Test Guideline 404
Result: No skin irritation

phthalaldehyde

Result: Corrosive after 3 minutes to 1 hour of exposure

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Serious eye damage/eye irritation**Product:**

Result: irritating

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
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Components:**ethanol**

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

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

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

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	: Species: Rat, female
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development

Application Route: Oral
Dose: < 10 mg/kg/day
Remarks: Did not show teratogenic effects in animal experiments.

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

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

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

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

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 regulations.

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

SECTION 14. TRANSPORT INFORMATION

International transport regulations

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DOT

UN number	: 3082
Description of the goods	: Environmentally hazardous substance, liquid, n.o.s. (phthalaldehyde)
Class	: 9
Packing group	: III
Labels	: 9
Emergency Response	: 171
Guidebook Number	
Environmentally hazardous	: no

IATA

UN number	: 3082
Description of the goods	: Environmentally hazardous substance, liquid, n.o.s. (phthalaldehyde)
Class	: 9
Packing group	: III
Labels	: 9
Packing instruction (CAO)	: 964
Packing instruction (PAX and CAO)	: 964
Packing instruction (LQ)	: Y964
Packing instruction (EQ)	: E1
Environmentally hazardous	: no

IMDG

UN number	: 3082
Description of the goods	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (phthalaldehyde)
Class	: 9
Packing group	: III
Labels	: 9
EmS Number 1	: F-A
EmS Number 2	: S-F
Marine pollutant	: yes

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

Pollution category	:
Ship type	:

SECTION 15. REGULATORY INFORMATION

Clean Air Act

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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 12 (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

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

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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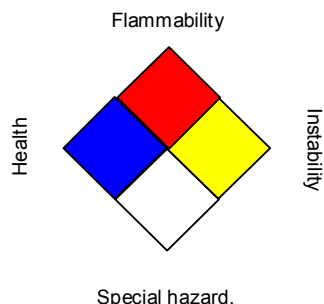


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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

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

Revision Date : 2015/04/21

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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