SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	CIDEX™ OPA Solution
Registration number	-
Synonyms	None.
Issue date	13-May-2021
Version number	3.2
Revision date	27-May-2021
Supersedes date	-

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	High level disinfection.
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

Local Entity

Address	Advanced Sterilization Products (UK) Limited The Capitol Building Oldbury, Bracknell, RG12 8FZ
Country	United Kingdom
E-mail	ASP-SDS@asp.com

1.4. Emergency telephone number

CHEMTREC GB: +44 20 3807 3798

+(44)-870-8200418

CHEMTREC International: +1 703-741-5970

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 2	H411 - Toxic to aquatic life with long lasting effects.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms

Signal word None.

Hazard statements

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

P273 Avoid release to the environment.

Response

P391 Collect spillage.

Storage Not assigned.

Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental information on the label EUH208 - Contains Phthalaldehyde. May produce an allergic reaction.

2.3. Other hazards This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII. The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
Phthalaldehyde	0.55	643-79-8 211-402-2	-	-	

Classification: Acute Tox. 3;H301;(ATE: 178 mg/kg), Skin Corr. 1B;H314, Eye Dam. 1;H318, Skin Sens. 1;H317, Aquatic Acute 1;H400(M=10), Aquatic Chronic 1;H410(M=10)

List of abbreviations and symbols that may be used above

M: M-factor

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all H-statements is displayed in section 16. Components not listed are either non-hazardous or are below reportable limits.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. Get medical attention if any discomfort continues.

Skin contact Wash off with plenty of water. Get medical attention if irritation develops and persists.

Eye contact Rinse immediately with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist. Remove contact lenses, if present.

Ingestion Call a physician immediately. If swallowed, rinse mouth with water (only if the person is conscious).

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed. The product has been reported to cause anaphylactic-like reactions.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Use extinguishing agent suitable for type of surrounding fire.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Avoid breathing mist/vapours. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment.
For emergency responders	Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
6.2. Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so.
6.3. Methods and material for containment and cleaning up	This product is miscible in water. Prevent product from entering drains. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	To avoid thermal decomposition, do not overheat. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash thoroughly after handling. Avoid inhalation of vapours/mist and contact with skin and eyes. Avoid ingestion. Avoid release to the environment.
7.2. Conditions for safe storage, including any incompatibilities	To maintain product quality, do not store in heat or direct sunlight. Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see section 10 of the SDS). Store in original container. Recommended storage temperature: 15 - 30 °C.
7.3. Specific end use(s)	High level disinfection.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no effect levels (DNELs)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information	Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear safety glasses with side shields (or googles) in accordance with EN 166. Wear safety glasses with side shields (or goggles).
Skin protection	

- Hand protection	Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Nitrile or butyl rubber gloves are recommended. Be aware that the liquid may penetrate the gloves. Frequent change is advisable. Suitable gloves can be recommended by the glove supplier.
- Other	Wear suitable protective clothing. Use of an impervious apron is recommended.
Respiratory protection	No protection is ordinarily required with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Wash thoroughly after handling.
Environmental exposure controls	Inform appropriate managerial or supervisory personnel of all environmental releases. Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Form	Liquid.
Colour	Light blue. Clear.
Odour	Characteristic.
Melting point/freezing point	0 °C (32 °F) ~Water
Boiling point or initial boiling point and boiling range	100 °C (212 °F)
Flammability	This material will not burn.
Lower and upper explosion limit	
Explosive limit - lower (%)	Not flammable.
Explosive limit – upper (%)	Not flammable.
Flash point	Not flammable.
Auto-ignition temperature	Not flammable.
Decomposition temperature	> 100 °C (> 212 °F) (Ethyl Alcohol) estimated
pH	7.2 - 7.8
Kinematic viscosity	1 mm2/s ~Water estimated
Solubility	
Solubility (water)	Soluble in water.
Partition coefficient n-octanol/water (log value)	0.677
Vapour pressure	~Water
Density and/or relative density	
Density	1 estimated
Relative density	1.0 g/cm³ ~Water
Relative density temperature	20 °C (68 °F)
Vapour density	> 1 ~Water estimated
Particle characteristics	Not applicable, material is a liquid.

9.2. Other information

9.2.1. Information with regard to physical hazard classes	No relevant additional information available.

9.2.2. Other safety characteristics

Evaporation rate	~Water

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Stable at normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.

10.4. Conditions to avoid Heat, flames and sparks. To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials Acids. Alkali metals. Reducing Agents. Oxidizing agents.

10.6. Hazardous decomposition products Upon decomposition, this product emits carbon monoxide, carbon dioxide and/or low molecular weight hydrocarbons.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.

Skin contact May cause slight skin irritation.

Eye contact May cause slight eye irritation.

Ingestion Under normal conditions of intended use, this material does not pose a risk to health.

Symptoms Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Product	Species	Test Results
CIDEX™ OPA Solution (CAS Mixture)		
Acute		
Oral		
		> 5000 mg/kg (Calculation method)

Components	Species	Test Results
Phthalaldehyde (CAS 643-79-8)		
Acute		
Oral		
LD50	Rat	178 mg/kg

Skin corrosion/irritation Slight irritation.
Phthalaldehyde: Corrosive after 3 minutes to 1 hour of exposure.

Serious eye damage/eye irritation Slight irritation.

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.

Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.

Carcinogenicity Due to partial or complete lack of data the classification is not possible.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information The product is a mixture.

11.2. Information on other hazards

Endocrine disrupting properties The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1. Toxicity Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Phthalaldehyde (CAS 643-79-8)			
Aquatic			
Crustacea	EC50	Daphnia magna	0.087 mg/l, 48 hours
Fish	LC50	Oncorhynchus mykiss	0.072 mg/l, 96 hours

12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	No data available on bioaccumulation.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	This product is water soluble and may disperse in soil.
12.5. Results of PBT and vPvB assessment	This mixture does not contain substances assessed to be vPvB / PBT according to Regulation (EC) No 1907/2006, Annex XIII.
12.6. Endocrine disrupting properties	The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7. Other adverse effects	None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. Waste codes should be assigned by the user based on the application for which the product was used.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Phthalaldehyde)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	90
Tunnel restriction code	E
14.4. Packing group	III
14.5. Environmental hazards	Yes.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

RID

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Phthalaldehyde)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes.
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

ADN

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Phthalaldehyde)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes.

14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.

IATA

14.1. UN number	UN3082
14.2. UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Phthalaldehyde)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	Yes.
ERG Code	9L
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. When transported in packaging with a net capacity of less than 5 L / 5 kg of the material, this material is not subject to these regulations, provided certain general packaging provisions are met. Refer to Special Provision A197 for further requirements.

IMDG

14.1. UN number	UN3082
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Phthalaldehyde)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes.
EmS	F-A, S-F
14.6. Special precautions for user	Read safety instructions, SDS and emergency procedures before handling. Not subject to the provisions of this regulation when appropriately packaged in quantities of 5 litres or less per section 2.10.2.7 (For IMDG).
14.7. Maritime transport in bulk according to IMO instruments	Not established.
General information	Not subject to the provisions of this regulation when appropriately packaged in quantities of 5 litres or less per Special Provision 375 (For ADR, RID and ADN).

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EU) 2019/1021 On persistent organic pollutants (recast), as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations Follow national regulation for work with chemical agents in accordance with Directive 98/24/EC, as amended.

15.2. Chemical safety assessment No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

ADN: European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Chemical Abstract Service.
CEN: European Committee for Standardization.
EC50: Effective Concentration 50%.
IATA: International Air Transport Association.
IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk.
IMDG: International Maritime Dangerous Goods.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
MARPOL: International Convention for the Prevention of Pollution from Ships.
PBT: Persistent, bioaccumulative and toxic.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STEL: Short term exposure limit.
TWA: Time Weighted Average.
vPvB: Very persistent and very bioaccumulative.

References HSDB® - Hazardous Substances Data Bank

Information on evaluation method leading to the classification of mixture The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Training information Follow training instructions when handling this material.

Disclaimer Advanced Sterilization Products, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.