

SAFETY DATA SHEET

PoliDent

according to Regulation (EC) No 1907/2006 (REACH) as amended -
COMMISSION REGULATION (EU) 2020/878



Poli3Dent Cleaner

Creation date	12th November 2024	Version	1.0
Revision date			

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

1.1. Product identifier

Substance / mixture	Poli3Dent Cleaner
Chemical name	substance
CAS number	propylene carbonate
Index number	108-32-7
EC (EINECS) number	607-194-00-1
Registration number	203-572-1
	01-2119537232-48

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

Substance's intended use

Cleaning concentrate for 3D printed devices.

Substance uses advised against

The product should not be used in ways other than those referred in Section 1.

1.3. Details of the supplier of the safety data sheet

Manufacturer

Name or trade name	Polident d.o.o., Dental Products Industry
Address	Volčja Draga 42, Volčja Draga, 5293 Slovenia
VAT Reg No	SI31319297
Phone	00386 5 3304840, Fax: 00386 5 3304870
E-mail	polident@polident.si

Competent person responsible for the safety data sheet

Name	Polident d.o.o., Dental Products Industry
E-mail	polident@polident.si

1.4. Emergency telephone number

European emergency number: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification of the substance in accordance with Regulation (EC) No 1272/2008

The substance is classified as dangerous.

Eye Irrit. 2, H319

Most serious adverse effects on human health and the environment

Causes serious eye irritation.

2.2. Label elements

Hazard pictogram



Signal word

Warning

Dangerous substance

propylene carbonate
(Index: 607-194-00-1; CAS: 108-32-7)

Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear eye protection.

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P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501

Dispose of contents/container to in accordance with national regulations.

2.3. Other hazards

The substance does not have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Substance does not meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

Does not contain any PMT or vPvM components.

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical characterization

The substance specified below.

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 607-194-00-1 CAS: 108-32-7 EC: 203-572-1 Registration number: 01-2119537232-48	substance main component propylene carbonate	90-100	Eye Irrit. 2, H319	

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

There are not any particular first aid measures required. Terminate the exposure immediately; move the affected person to fresh air. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

If swallowed

Rinse out the mouth with water and provide 2-5 dL of water. Provide medical treatment if the person has any health problems.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Causes serious eye irritation. Irritation, lacrimation, pain.

If swallowed

Irritation, nausea.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Do not inhale smoke/gases produced by fire or heating. Do not intervene if it endangers your health or if you are not properly trained. Full protective clothing (EN 469:2020), helmet (EN 443:2008), protective boots (EN 15090:2012), gloves (EN 659:2003+A1:2008/AC:2009), and self-contained breathing apparatus (EN 137:2006). Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8.
Prevent contact with skin and eyes.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

Small amount of the product can be wiped out with dry cloth. Prevent other leakage.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent contact with skin and eyes. Wash hands and exposed parts of the body thoroughly after handling.
Use personal protective equipment as per Section 8.
Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

7.3. Specific end use(s)

not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL

propylene carbonate				
Workers / consumers	Route of exposure	Value	Effect	Source
Workers	Inhalation	70.53 mg/m ³	Chronic effects systemic	ECHA REACH
Workers	Inhalation	20 mg/m ³	Chronic effects local	ECHA REACH
Workers	Dermal	20 mg/kg bw/day	Chronic effects local	ECHA REACH
Workers	Dermal	10 mg/m ³	Chronic effects local	ECHA REACH
Consumers	Inhalation	17.4 mg/m ³	Chronic effects systemic	ECHA REACH
Consumers	Inhalation	10 mg/m ³	Chronic effects local	ECHA REACH
Consumers	Dermal	10 mg/kg bw/day	Chronic effects local	ECHA REACH

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propylene carbonate				
Workers / consumers	Route of exposure	Value	Effect	Source
Consumers	Dermal	10 mg/m ³	Chronic effects local	ECHA REACH

PNEC

propylene carbonate		
Route of exposure	Value	Source
Water (regular leak)	0.9 mg/l	ECHA REACH
Water (intermittent release)	9 mg/l	ECHA REACH
Marine water	0.09 mg/l	ECHA REACH
Seawater (intermittent release)	0.9 mg/l	ECHA REACH
Microorganisms in sewage treatment	7400 mg/l	ECHA REACH
Soil (agricultural)	0.81 mg/kg of dry substance of soil	ECHA REACH

8.2. Exposure controls

Do not eat, drink and smoke during work.

Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

If there is a risk of splashing into the eyes, use safety glasses with side protection (EN ISO 16321-1:2022).

Skin protection

Hand protection: Protective gloves resistant to the product. EN ISO 374-1:2017/A1:2018. Protective gloves against chemical risks (Material: consult manufacturer; Penetration time: > 480 min; Thickness: 0.062 mm).

Respiratory protection

It is not needed.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
propylene carbonate (CAS: 108-32-7)	7 (undiluted)
Kinematic viscosity	data not available
propylene carbonate (CAS: 108-32-7)	1.6 mm ² /s
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available

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Particle characteristics

data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

The substance is non-flammable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use.
Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Unknown.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the substance.

Acute toxicity

Based on available data the classification criteria are not met.

propylene carbonate						
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	LD ₅₀	OECD 401	33520 mg/kg bw		Rat	
Dermal	LD ₅₀	OECD 402	>2050 mg/kg bw		Rabbit	

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

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Reproductive toxicity

Based on available data the classification criteria are not met.

propylene carbonate					
Effect	Parameter	Value	Result	Species	Sex
	NOAEL	>1000 mg/kg bw			F

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

propylene carbonate							
Route of exposure	Parameter	Method	Value	Exposure time	Result	Species	Sex
Oral	NOAEL	OECD 408	>5000 mg/kg bw	90 days		Rat	

Aspiration hazard

Based on available data the classification criteria are not met.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data the classification criteria are not met.

Does not contain any components that may cause endocrine disruption for humans.

Other information

not available

SECTION 12: Ecological information

12.1. Toxicity

Based on available data the classification criteria are not met.

Acute toxicity

propylene carbonate					
Parameter	Method	Value	Exposure time	Species	Environment
LC ₅₀		>1000 mg/l		Fish (Cyprinus carpio)	
EC ₅₀		>1000 mg/l		Daphnia (Daphnia magna)	
ErC ₅₀		>929 mg/l		Algae (Pseudokirchneriella subcapitata)	
ErC ₅₀	OECD 201	>900 mg/l	72 hours	Algae and other aquatic plants (Desmodesmus subspicatus)	

12.2. Persistence and degradability

The following data are available.

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Biodegradability

propylene carbonate					
Parameter	Method	Value	Exposure time	Environment	Result
	OECD 301B	83.5 %	29 days		

12.3. Bioaccumulative potential

The following data are available.

propylene carbonate					
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Pow	-0.5				20°C

12.4. Mobility in soil

Based on available data the classification criteria are not met.
Does not contain any PMT or vPvM components.

12.5. Results of PBT and vPvB assessment

Based on available data the classification criteria are not met.
Does not contain any PBT or vPvB components.

12.6. Endocrine disrupting properties

Based on available data the classification criteria are not met.
Does not contain any components that may cause endocrine disruption in the environment.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of the waste in accordance with the local and/or national regulations. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity.
Do not empty unused product in drainage systems.
The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.
Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

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SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

H319 Causes serious eye irritation.

Guidelines for safe handling used in the safety data sheet

P264 Wash hands and exposed parts of the body thoroughly after handling.

P280 Wear eye protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container to in accordance with national regulations.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC ₅₀	Concentration of a substance when it is affected 50 % of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
Eye Irrit.	Eye irritation
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient
NOAEL	No observed adverse effect level

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OEL	Occupational Exposure Limits
PBT	Persistent, bioaccumulative and toxic
PMT	Persistent, mobile and toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.

Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.