

SAFETY DATA SHEET

PoliDent

according to Commission Regulation (EU) 2020/878 as amended



POLISOL LIQUID, POLIPRESS LIQUID

Creation date 21st November 2019
Revision date 06th March 2023 Version 2.0

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

- 1.1. Product identifier** POLISOL LIQUID, POLIPRESS LIQUID
Substance / mixture mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
Auxiliary material for dental technology.
Mixture 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 Industry
E-mail polident@polident.si
- 1.4. Emergency telephone number**
00386 5 3304840 - Polident d.o.o. - Available from Mon to Fri 7 a.m. to 3 p.m.
112 - Information center - available 0-24

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.
Full text of all classifications and hazard statements is given in the section 16.
- 2.2. Label elements**
none
- 2.3. Other hazards**
The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization
Amorphous silica, aqueous colloidal solution.
Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 7631-86-9 EC: 231-545-4 Registration number: 01-2119379499-16	Silica, amorphous	30-<40	not classified as dangerous	1

Notes

1 A substance for which exposure limits are set.

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

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SECTION 4: First aid measures

4.1. Description of first aid measures

There are not any particular first aid measures required.

If inhaled

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. Rinse skin with water or shower.

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. Depending on the situation, call medical rescue service or ensure medical treatment.

If swallowed

Rinse out the mouth with water and provide 2-5 dL of water. Never give anything by mouth to an unconscious person. In the event of issues, find medical help.

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

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

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

Symptomatic treatment.

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

not available

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.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing. 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

Follow the instructions in the Sections 7 and 8.

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

Small amount of the product can be wiped out with dry cloth. 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. After removal of the product, wash the contaminated site with plenty of water.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. 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.
Do not expose to sunlight. Avoid freezing.

Storage temperature min 5 °C, max 50 °C

7.3. Specific end use(s)

Expiry date: Considering the instructions for safety storage and handling the expiry date is two years.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
Silica, amorphous (CAS: 7631-86-9)	8 hours	4 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker, Substances representing no risk to the foetus with reference to the limit values.

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

In case of splash use safety glasses. Protective glasses with side shields. EN166 - Personal Eye Protection Standard.

Skin protection

When handling in long-term or repeatedly, use protective gloves. EN ISO 374-1. Material: PVC, rubber. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer.

Respiratory protection

Under regular circumstances it is not necessary.

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	white
Odour	without fragrance
Melting point/freezing point	0 °C
Boiling point or initial boiling point and boiling range	100 °C
Flammability	non-flammable
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	9-10 (undiluted)
Kinematic viscosity	data not available
Viscosity	<20 mPas (dynamic)

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Solubility in water dispersible
Partition coefficient n-octanol/water (log value) data not available
Vapour pressure 23 hPa at 20 °C
Density and/or relative density
Density data not available
Relative density 1,10 - 1,30
Relative vapour density data not available
Particle characteristics data not available

9.2. Other information

Explosive properties The product does not have explosive properties.
Oxidising properties The product has no oxidizing properties.
Particle size: 1 - 100 nm (Method: ISO 22412)
Particle distribution: D50 = 13 nm +- 4 nm (Method ISO 22412)

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Do not dry the solution as this may cause dust to accumulate.

10.5. Incompatible materials

Copper, mild steel and aluminum.

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

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

LD50 (rat): > 5000 mg/kg - The value was estimated based on tests on similar products.

Acute toxicity

Based on available data the classification criteria are not met.

Silica, amorphous

Route of exposure	Parameter	Value	Exposure time	Species	Sex
	LD ₅₀	>10000 mg/kg		Rat	

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

RESPIRATORY SENSITIVITY:

Method: Magnusson-Kligman Result: Does not cause sensitization in laboratory animals. The value was estimated based on tests on similar products.

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Germ cell mutagenicity

Based on available data the classification criteria are not met.

GENOTOXICITY IN VITRO:

Type of test: Ames test (OECD 471) Result: negative. The value was estimated based on tests on similar products.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

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.

Aspiration hazard

Based on available data the classification criteria are not met.

11.2. Information on other hazards

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

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

FISH TOXICITY:

LC50 (Danio rerio): > 5000 mg/l (96 h)

The value was estimated based on tests on similar products.

TOXICITY TO WATER FLEA AND OTHER AQUATIC INVERTEBRATES:

EC50 (Ceriodaphnia dubia): 7600 mg/l (48 h)

TOXICITY TO ALGAE / AQUATIC PLANTS:

NOEC (Selenastrum capricornutum): 60 mg/l (48 h)

EC50 (Selenastrum capricornutum): 120 mg/l (48 h)

EC10 (Selenastrum capricornutum): 140 mg/l (48 h)

Values were estimated based on tests on similar products.

12.2. Persistence and degradability

not available

12.3. Bioaccumulative potential

Does not contain bioaccumulating components.

12.4. Mobility in soil

Under exceptional conditions, transfer from soil to water can occur. Airborne transmission is not expected.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of the product and packaging in accordance with national regulations.

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.

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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

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

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
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
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

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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
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative 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

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.

The changes (which information has been added, deleted or modified)

The version 2.0 replaces the SDS from 21.11.2019.

Changes were made in sections:

- 2.3 Other hazards,
- 11.2 Information on other hazards,
- 12.6 Endocrine disrupting properties and
- 16 Other information

More information

Classification procedure - calculation method.

Safety Data Sheet created by CHEM CONSULTING s.p.(www.chem-consulting.si)

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.