

SAFETY DATA SHEET

PoliDent

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



POLIVEST, POLITERM SPEED , UNIVECAST, POLIPRESS

Creation date	21st November 2019	Version	2.0
Revision date	02nd March 2023		

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

- 1.1. Product identifier**
Substance / mixture POLIVEST, POLITERM SPEED , UNIVECAST, POLIPRESS mixture
UFI XQ00-P00V-F00N-4X7N
- 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
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 classified as dangerous.

STOT RE 1, H372

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

Most serious adverse effects on human health and the environment

Causes damage to organs through prolonged or repeated exposure (inhalation).

- 2.2. Label elements**
Hazard pictogram



Signal word
Danger

Hazardous substances

quartz (SiO₂)
cristobalite

Hazard statements

H372 Causes damage to organs through prolonged or repeated exposure if inhaled.

Precautionary statements

P260 Do not breathe dust.
P284 In case of inadequate ventilation wear respiratory protection.
P501 Dispose of container to in accordance with national regulations.

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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

Powder mixture of quartz and cristobalite on the base of phosphate bond.

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: 14808-60-7 EC: 238-878-4	quartz (SiO ₂)	15-<65	STOT RE 1, H372 (lungs (inhalation))	1
CAS: 14464-46-1 EC: 238-455-4	cristobalite	5-<30	STOT RE 2, H373	

Notes

1 A substance for which exposure limits are set.

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

In case of feeling unwell, move the person to fresh air and leave him in a comfortable position that facilitates breathing. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Rinse skin with water. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids; 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 clean 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

Inhalation of dust may irritate the respiratory tract. May cause silicosis. Harms organs through prolonged or repeated inhalation exposure.

If on skin

Contact with skin and eyes may cause mechanical irritation. Irritation, itching, redness.

If in eyes

Contact with skin and eyes may cause mechanical irritation. Irritation, itching, redness.

If swallowed

Not expected.

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

Water, carbon dioxide. Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

Water - full jet. Avoid extinguishing methods that may create dust clouds.

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

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. 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. Prevent contact with skin and eyes. Do not inhale dust. Slip hazard on bulk product. Avoid dust generation.

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

Pick up the product mechanically. Dispose of the collected material according to the instructions in the section 13. Small amount of the product can be wiped out with dry cloth. Prevent dusting. 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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Only adequate trained persons may deal with product. For use in dentistry only.

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Protect from moisture. Do not inhale dust. Provide adequate ventilation in places where dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment. Handle packaged products with care to prevent accidental release/dusting.

Do not eat, drink or smoke when using this product. Contaminated clothing must be changed before entering the dining room.

7.2. Conditions for safe storage, including any incompatibilities

Store the product only in the original container in a cool and dry place.

Do not store together with food, drink and animal feed. Store in a well-ventilated place.

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. 38

Substance name (component)	Type	Value	Note
quartz (SiO ₂) dust - alveolar fraction (CAS: 14808-60-7)	8 hours	1,25 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar.
	KTV (15 min)	2,5 mg/m ³	

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Slovenia

Uradni list RS, št. 38

Substance name (component)	Type	Value	Note
quartz (SiO ₂) dust - inhalable fraction (CAS: 14808-60-7)	8 hours	10 mg/m ³	Inhalable fraction - the part of the total suspended substance inhaled by the worker.
	KTV (15 min)	20 mg/m ³	

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. 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

Protective glasses with side shields. EN166 - Personal Eye Protection Standard.

Skin protection

Hand protection: Protective gloves resistant to the product. EN ISO 374-1. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer.

Before use, protective gloves must in any case be tested for their specific suitability for the workplace (i.e. mechanical resistance, product compatibility and antistatic properties). Follow the manufacturer's instructions and information regarding the use, storage, care and replacement of protective gloves. Protective gloves must be replaced as soon as they are physically damaged or worn. Plan your work to avoid the constant use of protective gloves.

Respiratory protection

Under regular circumstances it is not necessary. Use a mask with anti-dust filter when the exposition limits of the substances are exceeded or at the place with insufficient ventilation.

Half mask with dust filter FFP2 or FFP3 - EN 405:2002+A1:2010, EN 136:1998/AC:2000, EN 14387:2021. For concentrations of dust/gases/vapours above the usable limit of the filters, for oxygen concentrations below 17% or in unclear conditions, use self-contained breathing apparatus with a closed circuit according to the EN 145:1998, EN 138:1996 standard.

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	solid
Colour	white
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	5-7 (20% solution)
Kinematic viscosity	data not available
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	
Density	1,2-1,5 g/cm ³ at 21 °C
Relative vapour density	data not available
Particle characteristics	data not available

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9.2. Other information

Ta izdelek je higroskopičen. Izdelek se strdi z dodatkom vode.

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 from moisture in the air and water.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

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.

Acute toxicity

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Contact with skin and eyes may cause mechanical irritation.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Contact with skin and eyes may cause mechanical 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.

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

Harms organs through prolonged or repeated inhalation exposure.

Inhalation of dust may irritate the respiratory tract. May cause silicosis.

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

The product is not classified as dangerous for the environment. However, prevent uncontrolled release.

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12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

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 waste in accordance with local and/or state regulations. Proceed in accordance with valid regulations on waste disposal. 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. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification.

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.

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007). 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

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).

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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

H372	Causes damage to organs through prolonged or repeated exposure.
H372	Causes damage to lungs (by inhalation) through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

Guidelines for safe handling used in the safety data sheet

P260	Do not breathe dust.
P284	In case of inadequate ventilation wear respiratory protection.
P501	Dispose of 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
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
log Kow	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

STOT RE Specific target organ toxicity - repeated exposure

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

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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:

- 2.2 Label elements,
- 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.(info@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.