SAFETY DATA SHEET

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

POLI SILICONE-component B

Creation date	21st November 2019		
Revision date	09th March 2023	Version	2.0

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

1.1. Product identifier — POLI SILICONE-component B

Substance / mixture — mixture

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

Mixture's intended use

Moulding diverse objects.

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

Supplier

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 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 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

Mixture of organosiloxanes, additives.

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: 540-97-6 EC: 208-762-8	Dodecamethylcyclohexasiloxane (D6)	0,1-<1	not classified as dangerous	1, 2
CAS: 541-02-6 EC: 208-764-9	Decamethylcyclopentasiloxane (D5)	0,1-<1	not classified as dangerous	1, 2, 3

Notes

1 Substance of very high concern - SVHC.
2 Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative

3 The use of the substance is restricted by Annex XVII of REACH Regulation

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

There are not any particular first aid measures required. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
In case of inhalation: Move person into fresh air and keep at rest. Get medical attention if symptoms occur.

If on skin

Remove contaminated clothes. Wash with plenty of soap and water. 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. Depending on the situation, call medical rescue service or ensure medical treatment.

If swallowed

DO NOT INDUCE VOMITING! 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

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. Silicon oxides.
This product may generate hydrogen gas.

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.
This product may generate hydrogen gas. Fight fire remotely due to the risk of explosion.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8. Danger of slipping on spilled product. Prevent contact with skin and eyes. Provide sufficient ventilation. Do not inhale mist/vapours/spray.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. In the event of substantial pollution, contact respective authorities and wastewater treatment plants.

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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace.

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.
Protect against frost.

7.3. Specific end use(s)

not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains no substances for which occupational exposure limits are set.

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

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

Skin protection

Hand protection: Protective gloves resistant to the product.

Prolonged or repeated contact:
Material: Nitrile.
Glove thickness: 1,25 mm; Guideline: EN374-3.

Short contact:
Material: Nitrile / Neoprene
Glove thickness: 0,198 mm; Guideline: EN374-3.

Other protection: Protective antistatic clothing made of natural fibres (cotton) or synthetic fibres resistant to elevated temperatures.

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 (viscous)
Colour	pink
Odour	without fragrance
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	

bottom	4 % (Hydrogen)
upper	74 % (Hydrogen)
Flash point	>200 °C (ASTM D56)
Auto-ignition temperature	500 °C (Hydrogen)
Decomposition temperature	>200 °C
pH	non-soluble (in water)
Kinematic viscosity	5000 mm²/s at 20 °C
Viscosity	4000 mPas (dynamic)
Solubility in water	insoluble
Solubility Diethylether, chlorinated solvents, aromatic hydrocarbons, aliphatic hydrocarbons	miscible in all proportions
Solubility Acetone, ethanol	very slightly soluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	< 0,1 hPa at 20 °C
Density and/or relative density	
Density	1,05 g/cm³ at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Oxidising properties: The product has no oxidizing properties.

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

This product may generate hydrogen gas.

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

A fire or explosion hazard arises because highly flammable gas (hydrogen) is released when it is in contact with: Strong oxidizing agents. Alkalis and caustic products. Chemical compounds with mobile hydrogen, in the presence of metal salts and complexes.

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. Amorphous silica.
Quantity of hydrogen potentially released (l/kg of product): <7

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 mixture.

Acute toxicity

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	NOAEL	OECD 408	1000 mg/kg		Rat	F/M
Inhalation	NOAEL	OECD 453	2.42 mg/l		Rat	F/M
Dermal	NOAEL	OECD 410	1600 mg/kg		Rat	F/M

Dodecamethylcyclohexasiloxane (D6)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	NOAEL	OECD 422	1000 mg/kg		Rat	F/M

Dodecamethylcyclohexasiloxane (D6)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Inhalation	NOAEL	OECD 413	0.0182 mg/l		Rat	F/M

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Route of exposure	Result	Method	Exposure time	Species
	Not irritating	OECD 404		Rabbit

Dodecamethylcyclohexasiloxane (D6)

Route of exposure	Result	Method	Exposure time	Species
	Not irritating	OECD 404		Rabbit

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Route of exposure	Result	Method	Exposure time	Species
	Not irritating	OECD 405		Rabbit

Dodecamethylcyclohexasiloxane (D6)

Route of exposure	Result	Method	Exposure time	Species
Eye	Not irritating	OECD 405		Rabbit

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Route of exposure	Result	Method	Exposure time	Species	Sex
Dermal	Not sensitizing	OECD 429		Mouse	

Dodecamethylcyclohexasiloxane (D6)

Route of exposure	Result	Method	Exposure time	Species	Sex
Dermal	Not sensitizing	OECD 406		Guinea-pig	

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Result	Method	Exposure time	Specific target organ	Species	Sex	Source
Negative	OECD 476					In vitro; gene mutations test
Negative	OECD 473					In vitro; Chromosomal aberration
Negative	OECD 486			Rat (mammalian liver cells)	F/M	In vivo; Unscheduled DNA Synthesis (UDS)

Dodecamethylcyclohexasiloxane (D6)

Result	Method	Exposure time	Specific target organ	Species	Sex	Source
Negative	OECD 474			Mouse		in vivo; Mammalian erythrocyte micronucleus test
Negative	OECD 471					in vitro; Bacterial reverse mutation test
Negative	OECD 471					in vitro; Bacterial reverse mutation test
Negative	OECD 476					in vitro; Bacterial reverse mutation test

Carcinogenicity

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Route of exposure	Parameter	Method	Value	Result	Species	Sex
Inhalation	NOAEC	OECD 453	≥2.42 mg/l	Negative	Rat	F/M

Reproductive toxicity

Based on available data the classification criteria are not met.

Decamethylcyclopentasiloxane (D5)

Effect	Parameter	Method	Value	Result	Species	Sex	Source
		OECD 471		Negative	Bacteria (Salmonella typhimurium, Escherichia coli)		In vitro; Bacterial reverse mutation test
		OECD 474		Negative	Rat	F/M	In vivo; Mammalian erythrocyte micronucleus test
Effects on fertility	NOAEL	OECD 416	>2.496 mg/l	Negative	Rat	F/M	

Dodecamethylcyclohexasiloxane (D6)

Effect	Parameter	Method	Value	Result	Species	Sex	Source
	NOAEL	OECD 422	≥1000 mg/kg	Negative	Rat	F/M	Fertility
	NOAEL	OECD 414	≥1000 mg/kg	Negative	Rabbit	F	Teratogenicity

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

Mixture does contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

Decamethylcyclopentasiloxane (D5)

Parameter	Method	Value	Exposure time	Species	Environment
LC_{50}	OECD 204	>0.016 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
NOEC	OECD 204	≥0.016 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC_{50}	OECD 202	>0.0029 mg/l	48 hours	Daphnia (Daphnia magna)	
NOEC	OECD 202	≥0.0029 mg/l	48 hours	Daphnia (Daphnia magna)	
EC_{50}	OECD 201	>0.012 mg/l	96 hours	Algae (Pseudokirchneriella subcapitata)	
NOEC	OECD 201	≥0.012 mg/l	96 hours	Algae (Pseudokirchneriella subcapitata)	
NOEC	OECD 210	≥0.014 mg/l	90 days	Fish (Oncorhynchus mykiss)	
NOEC	OECD 211	≥0.015 mg/l	21 days	Daphnia (Daphnia magna)	

Dodecamethylcyclohexasiloxane (D6)

Parameter	Method	Value	Exposure time	Species	Environment
LC_{50}	OECD 204	>0.016 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC_{50}	OECD 202	>0.0029 mg/l	48 hours	Daphnia (Daphnia magna)	
NOEC	OECD 201	>0.002 mg/l	72 hours	Algae (Pseudokirchneriella subcapitata)	
ErC_{50}	OECD 201	>0.002 mg/l	72 hours	Algae (Pseudokirchneriella subcapitata)	

Chronic toxicity

Dodecamethylcyclohexasiloxane (D6)

Parameter	Method	Value	Exposure time	Species	Environment
NOEC	OECD 210	≥0.014 mg/l	90 days	Fish (Oncorhynchus mykiss)	

12.2. Persistence and degradability

Biodegradability

Decamethylcyclopentasiloxane (D5)

Parameter	Method	Value	Exposure time	Environment	Result
		0.14 %			Hardly biodegradable

Dodecamethylcyclohexasiloxane (D6)

Parameter	Method	Value	Exposure time	Environment	Result
	OECD 310	4.5 %	28 days		Bioaccumulative, Hardly biodegradable

not available

12.3. Bioaccumulative potential

Decamethylcyclopentasiloxane (D5)

Parameter	Method	Value	Exposure time	Species	Environment	Temperature [°C]
BCF		16200		Bacteria (Pimephales promelas)		
Log Kow	OECD 123	8.02				25,3°C

Dodecamethylcyclohexasiloxane (D6)

Parameter	Method	Value	Exposure time	Species	Environment	Temperature [°C]
BCF	OECD 305	2860	49 days			
Log Kow		8.87				23°C

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Mixture does contain any substance meet the criteria for PBT or vPvB in accordance with 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 waste in accordance with the local and/or national 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. 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.

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

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).

National regulations (Germany)

WGK Water hazard class: WGK 1 - slightly hazardous to water

Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

Decamethylcyclopentasiloxane (D5)

Restriction	Conditions of restriction
70	1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020. 2. For the purposes of this entry, "wash-off cosmetic products" means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.

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
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
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
log Kow	Octanol-water partition coefficient
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
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.