SAFETY DATA SHEET

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

PoliDent

Poli3Dent Model

Creation date	20th October 2024		
Revision date		Version	1.0

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

1.1. Product identifier — Poli3Dent Model

Substance / mixture: mixture

UFI: 5S00-50Q8-S005-T8TQ

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

Mixture's intended use

3D printing material for dentistry field.
Non-medical use.
For professional use.

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, 5293 Volčja Draga 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.

European emergency number: 112

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.

Skin Sens. 1B, H317
Aquatic Chronic 2, H411

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction.
Toxic to aquatic life with long lasting effects.

2.2. Label elements

Hazard pictogram

Signal word

Warning

Hazardous substances

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Hazard statements

H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P280	Wear protective gloves.

P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
P501	Dispose of contents/container to in accordance with national regulations.

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

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
Index: 607-767-00-6 CAS: 72869-86-4 EC: 276-957-5	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	40-80	Skin Sens. 1B, H317 Aquatic Chronic 2, H411	
CAS: 3290-92-4 EC: 221-950-4 Registration number: 01-2119542176-41	Trimethylolpropane trimethacrylate	10-40	Aquatic Chronic 2, H411 Specific concentration limit: ATE Oral = 5660 mg/kg bw ATE Dermal = 17120 mg/kg bw	
CAS: 6606-59-3 EC: 229-551-7	1,6-hexanediyl bismethacrylate	10-40	Aquatic Chronic 3, H412	
Index: 015-203-00-X CAS: 75980-60-8 EC: 278-355-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	<2.5	Skin Sens. 1B, H317 Repr. 2, H361 Aquatic Chronic 2, H411	1

Notes

1 *Substance of very high concern - SVHC.*

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 unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. 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. 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. 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

May cause an allergic skin reaction. Irritation, itching, redness.

If in eyes

Not expected.

If swallowed

Irritation, nausea.

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

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). Stop leak if safe to do so. 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. Do not allow to enter drains.

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. Ventilate the room.

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.

Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace.
Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.
Avoid release to the environment.

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

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

DNEL

Trimethylolpropane trimethacrylate				
Workers / consumers	Route of exposure	Value	Effect	Source
Workers	Inhalation	29.6 mg/m³	Chronic effects systemic	ECHA REACH
Workers	Dermal	42 mg/kg bw/day	Chronic effects systemic	ECHA REACH
Workers	Dermal	9.33 mg/cm²	Chronic effects local	ECHA REACH
Consumers	Inhalation	5.2 mg/m³	Chronic effects systemic	ECHA REACH
Consumers	Dermal	15 mg/kg bw/day	Chronic effects systemic	ECHA REACH
Consumers	Dermal	4.67 mg/cm²	Chronic effects local	ECHA REACH
Consumers	Oral	1.5 mg/kg bw/day	Chronic effects systemic	ECHA REACH

PNEC

Trimethylolpropane trimethacrylate		
Route of exposure	Value	Source
Freshwater environment	2.76 µg/l	ECHA REACH
Marine water	0.276 µg/l	ECHA REACH
Water (intermittent release)	20 µg/l	ECHA REACH
Microorganisms in sewage treatment	10 mg/l	ECHA REACH
Freshwater sediment	0.495 mg/kg of dry substance of sediment	ECHA REACH
Sea sediments	0.05 mg/kg of dry substance of sediment	ECHA REACH
Soil (agricultural)	0.097 mg/kg of dry substance of soil	ECHA REACH

8.2. Exposure controls

Take off contaminated clothing and wash before reuse.
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: according to the manufacturer's instructions; Penetration time: > 480 min; Thickness: 0.062 mm). When choosing the appropriate thickness, material and permeability of the gloves, observe the recommendations of their particular manufacturer.
Replace gloves if contamination occurs or if activity duration exceeds breakthrough time. Breakthrough time of glove material: see glove manufacturer's information.

Respiratory protection

Under regular circumstances it is not necessary.
In case of inadequate ventilation wear respiratory protection. Half mask with vapor filter (ABEK) - EN 405:2002+A1:2010, EN 136:1998/AC:2004, EN 14387:2021.

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	peach color
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
Trimethylolpropane trimethacrylate (CAS: 3290-92-4)	360 °C
Decomposition temperature	data not available
pH	data not available
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	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Summary formula	data not available
Trimethylolpropane trimethacrylate (CAS: 3290-92-4)	C18H26O6

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable under normal conditions.

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.

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 mixture.

Acute toxicity

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD_{50}	2000 mg/kg		Rat	
Dermal	LD_{50}	2000 mg/kg		Rat	
Oral	ATE	5660 mg/kg bw			
Dermal	ATE	17120 mg/kg bw			

Skin corrosion/irritation

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate			
Route of exposure	Result	Exposure time	Species
	Not irritating		

Serious eye damage/irritation

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate			
Route of exposure	Result	Exposure time	Species
	Not irritating		

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Trimethylolpropane trimethacrylate				
Route of exposure	Result	Exposure time	Species	Sex
	No effect			

Germ cell mutagenicity

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate				
Result	Exposure time	Specific target organ	Species	Sex
No effect				

Carcinogenicity

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate					
Route of exposure	Parameter	Value	Result	Species	Sex
			No effect		

Reproductive toxicity

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate					
Effect	Parameter	Value	Result	Species	Sex
			No effect		

Toxicity for specific target organ - single exposure

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate					
Route of exposure	Parameter	Value	Result	Species	Sex
			No effect		

Toxicity for specific target organ - repeated exposure

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate					
Route of exposure	Parameter	Value	Result	Species	Sex
			No effect		

Aspiration hazard

Based on the available data, the criteria for classification of the mixture are not met.

Trimethylolpropane trimethacrylate				
Route of exposure	Result	Exposure time	Species	Sex
	No effect			

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

Toxic to aquatic life with long lasting effects.

Acute toxicity

Trimethylolpropane trimethacrylate				
Parameter	Value	Exposure time	Species	Environment
LC_{50}	2 mg/kg		Fish	
EC_{50}	9.22 mg/l		Daphnia	

Chronic toxicity

Trimethylolpropane trimethacrylate				
Parameter	Value	Exposure time	Species	Environment
NOEC	0.138 mg/l		Fish	
NOEC	0.0177 mg/l		Algae	

12.2. Persistence and degradability

Data for the mixture are not available.

Biodegradability

Trimethylolpropane trimethacrylate				
Parameter	Value	Exposure time	Environment	Result
	53 %			

12.3. Bioaccumulative potential

Data for the mixture are not available.

Trimethylolpropane trimethacrylate					
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Pow	4.39				
Log Kow	4.19				

12.4. Mobility in soil

Data for the mixture are not available.

Trimethylolpropane trimethacrylate	
Parameter	Value
Log Koc	3.25

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

Hazard of environmental contamination; 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. 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

UN 3082

14.2. UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

14.3. Transport hazard class(es)

9 Miscellaneous dangerous substances and articles

14.4. Packing group

III

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Always transport closed containers in the upright position. Make sure that the person transporting the product knows the ways of handling the product in the event of accident. Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

Additional information

Hazard identification No.	**90**
UN number	**3082**
Classification code	M6
Safety signs	9+hazardous for the environment

Tunnel restriction code	(-)

Air transport - ICAO/IATA

Packaging instructions passenger	964
Cargo packaging instructions	964

Marine transport - IMDG

EmS (emergency plan)	F-A, S-F

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

H317	May cause an allergic skin reaction.
H361	Suspected of damaging fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Guidelines for safe handling used in the safety data sheet

P280	Wear protective gloves.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
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
AGW	Occupational Exposure Limits
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
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
LD_{50}	Lethal dose of a substance in which it can be expected death of 50% of the population
log Kow	Octanol-water partition coefficient
MAK	Maximum workplace concentration
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
Repr.	Reproductive toxicity
RID	Agreement on the transport of dangerous goods by rail
Skin Sens.	Skin sensitization
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.

More information

Classification procedure - calculation method.
Safety Data Sheet created by CHEM CONSULTING (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.