SAFETY DATA SHEET

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

DD poly Y ML

Creation date	30th January 2023		
Revision date	29th August 2024	Version	4.0

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

1.1. Product identifier DD poly Y ML

Substance / mixture mixture

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

Mixture's intended use

Material for professional dental use by using CAD/CAM techniques.

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 not classified as dangerous according to Regulation (EC) No 1272/2008.

2.2. Label elements

Signal word

none

Supplemental information

EUH208 Contains Methyl methacrylate. May produce an allergic reaction.

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

Pigmented polymer on the base of polymethylmethacrylate.

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: 607-035-00-6 CAS: 80-62-6 EC: 201-297-1 Registration number: 01-2119452498-28	Methyl methacrylate	<1	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1B, H317 STOT SE 3, H335 Specific concentration limit: STOT SE 3, H335: C ≥ 10 %	1, 2

Notes

1 *Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".*

2 *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

Remove the casualty into fresh air. In case of complaints get medical advice.

If on skin

Wash off with water and soap. Consult a physician if irritation persists.

If in eyes

There are not any particular first aid measures required. When dust comes into contact with the eyes wash eyes immediately with running water; if the affected person wears contact lenses, remove them immediately. Depending on the situation, call medical rescue service or ensure medical treatment.

If swallowed

Not likely. Wash out mouth with water and drink water. In case of complaints get medical advice.

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

If inhaled

Not expected.

If on skin

Not expected. May cause an allergic skin reaction. Redness, irritation or blisters.

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. Accommodate extinguishing components to the location of fire.

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. Burning or thermal decomposition produces toxic, irritating and flammable fumes.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with gas-tight suit when close proximity to the substance or its vapours is likely. 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

Pick up the product mechanically. Dispose of the collected material according to the instructions in the section 13.

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. Keep out of reach of children. Do not eat, drink or smoke when using this product. Ensure the area is well ventilated. Do not inhale dust.

7.2. Conditions for safe storage, including any incompatibilities

Store the product only in its original packaging.
Store in a dry place.

7.3. Specific end use(s)

Expiry date: Considering the instructions for safety storage and handling the expiry date of the product is 5 years.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

European Union — **Commission Directive 2009/161/EU**

Substance name (component)	Type	Value
Methyl methacrylate (CAS: 80−62−6)	OEL 8 hours	50 ppm
	OEL 15 minutes	100 ppm

United Kingdom — **EH40/2005 Workplace exposure limits (Fourth Edition 2020)**

Substance name (component)	Type	Value
Methyl methacrylate (CAS: 80−62−6)	WEL 8h	208 mg/m³
	WEL 8h	50 ppm
	WEL 15min	416 mg/m³
	WEL 15min	100 ppm

DNEL

Methyl methacrylate				
Workers / consumers	Route of exposure	Value	Effect	Source
Workers	Inhalation	348.4 mg/m³	Chronic effects systemic	ECHA REACH
Workers	Inhalation	208 mg/m³	Chronic effects local	ECHA REACH
Workers	Inhalation	416 mg/m³	Acute effects local	ECHA REACH
Workers	Dermal	13.67 mg/kg bw/day	Chronic effects systemic	ECHA REACH
Workers	Dermal	1.5 mg/cm²	Chronic effects local	ECHA REACH
Workers	Dermal	1.5 mg/cm²	Acute effects local	ECHA REACH
Consumers	Inhalation	74.3 mg/m³	Chronic effects systemic	ECHA REACH
Consumers	Inhalation	104 mg/m³	Chronic effects local	ECHA REACH
Consumers	Inhalation	208 mg/m³	Acute effects local	ECHA REACH
Consumers	Dermal	8.2 mg/kg bw/day	Chronic effects systemic	ECHA REACH
Consumers	Dermal	1.5 mg/cm²	Chronic effects local	ECHA REACH
Consumers	Dermal	1.5 mg/cm²	Acute effects local	ECHA REACH
Consumers	Oral	8.2 mg/kg bw/day	Chronic effects systemic	ECHA REACH

PNEC

Methyl methacrylate		
Route of exposure	Value	Source
Freshwater environment	0.94 mg/l	ECHA REACH
Marine water	0.094 mg/l	ECHA REACH
Microorganisms in sewage treatment	10 mg/l	ECHA REACH
Freshwater sediment	10.2 mg/kg of dry substance of sediment	ECHA REACH
Sea sediments	1.02 mg/kg of dry substance of sediment	ECHA REACH
Soil (agricultural)	1.48 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. 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.

Eye/face protection

Not required under normal circumstances. We recommend the use of safety glasses during mechanical processing.

Skin protection

Hand protection: protective gloves that protect against mechanical particles.

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	solid
Colour	different colours
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	data not available
Flash point	>250 °C
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	insoluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.17 g/cm³
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances.
Depolymerization starts at 250 °C.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions. According to the instructions for use, there are no known dangerous reactions.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Avoid heating above 240 °C.

10.5. Incompatible materials

No information.

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. Organic products.

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.

Methyl methacrylate					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD_{50}	>5000 mg/kg		Rat	
Inhalation	LC_{50}	29.8 mg/l	4 hours	Rat	
Dermal	LD_{50}	>5000 mg/kg		Rabbit	M

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.

Methyl methacrylate			
Route of exposure	Result	Exposure time	Species
Eye	No effect		Rabbit

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.
May cause an allergic skin reaction. Redness, irritation or blisters.

Methyl methacrylate						
Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing	OECD 429		Mouse		LLNA

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.

Methyl methacrylate						
Route of exposure	Parameter	Value	Specific target organ	Result	Species	Sex
Inhalation			Lungs	Irritating		

Toxicity for specific target organ - repeated exposure
Based on available data the classification criteria are not met.

Methyl methacrylate					
Route of exposure	Parameter	Value	Result	Species	Sex
Inhalation	NOAEL	25 ppm		Rat	
Oral	NOAEL	2000 ppm		Rat	

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
No other relevant information is available, no evidence of hazardous properties.

Acute toxicity

Methyl methacrylate					
Parameter	Method	Value	Exposure time	Species	Environment
LC_{50}		>79 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC_{50}		69 mg/l	48 hours	Daphnia (Daphnia magna)	
EC_{50}	OECD 201	>110 mg/l	72 hours	Algae (Selenastrum capricornutum)	
NOEC		48 mg/l	48 hours	Daphnia (Daphnia magna)	
NOEC	OECD 201	110 mg/l	72 hours	Algae (Selenastrum capricornutum)	
NOEC	OECD 201	49 mg/l	72 hours	Algae (Selenastrum capricornutum)	

Chronic toxicity

Methyl methacrylate					
Parameter	Method	Value	Exposure time	Species	Environment
NOEC	OECD 210	9.4 mg/l	35 days	Fish (Danio rerio)	

Methyl methacrylate					
Parameter	Method	Value	Exposure time	Species	Environment
LC_{50}	OECD 210	33.7 mg/l	35 days	Fish (Danio rerio)	
NOEC	OECD 211	37 mg/l	21 days	Daphnia (Daphnia magna)	
EC_{50}	OECD 211	49 mg/l	21 days	Daphnia (Daphnia magna)	

12.2. Persistence and degradability

No other relevant information is available, no evidence of hazardous properties.

Biodegradability

Methyl methacrylate					
Parameter	Method	Value	Exposure time	Environment	Result
					Easily biodegradable
	OECD 301C	94 %	14 days		

12.3. Bioaccumulative potential

No other relevant information is available, no evidence of hazardous properties.

Methyl methacrylate					
Parameter	Value	Exposure time	Species	Environment	Temperature [°C]
Log Kow	1.38				

12.4. Mobility in soil

No other relevant information is available, no evidence of hazardous properties.

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

No information.

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.

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

Clean Air Act 1993 as amended.
The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended.
Public health act 1961.
Environmental Protection Act 1990 as amended.
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.

The product is a class IIa medical device in accordance with the Medical Devices Ordinance MDR 2017/745.

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

EUH208	Contains Methyl methacrylate. May produce an allergic reaction.
H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.

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
Flam. Liq.	Flammable liquid
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
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
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity - single exposure
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 4.0 replaces the SDS from 22.02.2023.

Changes were made in sections:
2.2. Label elements,
4.2 Most important symptoms and effects, both acute and delayed,
8.1 Control parameters,
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 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.