

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date	14th May 2021		
Revision date	12th January 2023	Version	3.0

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

- 1.1. Product identifier**
Substance / mixture POLITRAY LIQUID mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
Material for the fabrication of individual impression trays.
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.
- Flam. Liq. 2, H225
Skin Irrit. 2, H315
Skin Sens. 1, H317
STOT SE 3, H335
- Full text of all classifications and hazard statements is given in the section 16.
- Most serious adverse physico-chemical effects**
Highly flammable liquid and vapour.
- Most serious adverse effects on human health and the environment**
Causes skin irritation. May cause an allergic skin reaction. May cause respiratory irritation.
- 2.2. Label elements**
Hazard pictogram
-
- Signal word**
Danger
- Hazardous substances**
Methyl methacrylate
Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

SAFETY DATA SHEET

PoliDent

according to Regulation (EC) No 1907/2006 (REACH) as amended -
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POLITRAY LIQUID

Creation date	14th May 2021		
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Hazard statements

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P501	Dispose of contents/container to in accordance with local/regional/national/international 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

Chemical characterization

Product contents methyl methacrylate and activator.

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	85-98	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335	1
CAS: 8042-47-5 EC: 232-455-8 Registration number: 01-2119487078-27	White mineral oil (petroleum)	<10	Asp. Tox. 1, H304	1
EC: 911-490-9 Registration number: 01-2119979579-10-0001	Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-	<1	Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Dam. 1, H318 Aquatic Chronic 3, H412	

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 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. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

SAFETY DATA SHEET

PoliDent

according to Regulation (EC) No 1907/2006 (REACH) as amended -
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POLITRAY LIQUID

Creation date	14th May 2021		
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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. 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. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

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

May cause respiratory irritation. Cough, headache.

If on skin

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

If in eyes

Not expected. It can cause irritation and restorable damage. Irritation, lacrimation, pain.

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

Highly flammable liquid. 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. Closed containers with the product near the fire should be cooled with water. 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

Provide sufficient ventilation. Highly flammable liquid and vapour. Remove all ignition sources. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes.

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

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.

SAFETY DATA SHEET

PoliDent

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COMMISSION REGULATION (EU) 2020/878



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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 formation of gases and vapours in flammable or explosive concentrations and concentrations exceeding the occupational exposure limits. The product should be used only in the areas where it is not in contact with open fire and other ignition sources. Use non-sparking tools. Use of antistatic clothes and footwear is recommended. The vapour is heavier than air; beware of pits and confined spaces. Do not inhale mist/vapours/spray. Prevent contact with skin and eyes. No smoking. Wash hands and exposed parts of the body thoroughly after handling. Use only outdoors or in a well-ventilated area. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Take action to prevent static discharges. Keep away from children.

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. Keep cool. Keep away from sources of ignition - No Smoking. Keep away from children.

Keep the liquid only in the original vessel at a temperature preferably not exceeding 25°C

The specific requirements or rules relating to the substance/mixture

Solvent vapours are heavier than air and accumulate especially near the floor where they may form an explosive mixture with the air.

7.3. Specific end use(s)

Expiry date: Considering the instructions for safety storage and handling the expiry date is three 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	Note
Methyl methacrylate (CAS: 80-62-6)	OEL 8 hours	50 ppm	
	OEL 15 minutes	100 ppm	

Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
Methyl methacrylate (CAS: 80-62-6)	8 hours	210 mg/m ³	Substances representing no risk to the foetus with reference to the limit values.
	8 hours	50 ppm	
	KTV (15 min)	420 mg/m ³	
	KTV (15 min)	100 ppm	
White mineral oil (petroleum) (CAS: 8042-47-5)	8 hours	5 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar., Substances representing no risk to the foetus with reference to the limit values.

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date	14th May 2021	Version	3.0
Revision date	12th January 2023		

Slovenia

Uradni list RS, Št. 72/2021

Substance name (component)	Type	Value	Note
White mineral oil (petroleum) (CAS: 8042-47-5)	KTV (15 min)	20 mg/m ³	Alveolar fraction - respirable fraction which can penetrate the sac alveolar., Substances representing no risk to the foetus with reference to the limit values.

United Kingdom

EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Substance name (component)	Type	Value	Note
Methyl methacrylate (CAS: 80-62-6)	WEL 8h	208 mg/m ³	
	WEL 8h	50 ppm	
	WEL 15min	416 mg/m ³	
	WEL 15min	100 ppm	

DNEL

Methyl methacrylate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	348.4 mg/m ³	Systemic chronic effects		ECHA REACH
Workers	Inhalation	208 mg/m ³	Local chronic effects		ECHA REACH
Workers	Inhalation	416 mg/m ³	Local acute effects		ECHA REACH
Workers	Dermal	13.67 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Workers	Dermal	1.5 mg/cm ²	Local chronic effects		ECHA REACH
Workers	Dermal	1.5 mg/cm ²	Local acute effects		ECHA REACH
Consumers	Inhalation	74.3 mg/m ³	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	104 mg/m ³	Local chronic effects		ECHA REACH
Consumers	Inhalation	208 mg/m ³	Local acute effects		ECHA REACH
Consumers	Dermal	8.2 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Dermal	1.5 mg/cm ²	Local chronic effects		ECHA REACH
Consumers	Dermal	1.5 mg/cm ²	Local acute effects		ECHA REACH
Consumers	Oral	8.2 mg/kg bw/day	Systemic chronic effects		ECHA REACH

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	9.8 mg/m ³	Systemic chronic effects		ECHA REACH
Workers	Dermal	1.4 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	1.74 mg/m ³	Systemic chronic effects		ECHA REACH
Consumers	Dermal	0.5 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Oral	0.5 mg/kg bw/day	Systemic chronic effects		ECHA REACH

SAFETY DATA SHEET

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



POLITRAY LIQUID

Creation date 14th May 2021
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White mineral oil (petroleum)

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	164.56 mg/m ³	Systemic chronic effects		ECHA REACH
Workers	Dermal	217.05 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	34.78 mg/m ³	Systemic chronic effects		ECHA REACH
Consumers	Dermal	93.02 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Oral	25 mg/kg bw/day	Systemic chronic effects		ECHA REACH

PNEC

Methyl methacrylate

Route of exposure	Value	Value determination	Source
Freshwater environment	0.94 mg/l		ECHA REACH
Seawater	0.094 mg/l		ECHA REACH
Microorganisms in wastewater treatment plants	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

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Route of exposure	Value	Value determination	Source
Freshwater environment	0.048 mg/l		ECHA REACH
Water (intermittent release)	0.48 mg/l		ECHA REACH
Seawater	0.005 mg/l		ECHA REACH
Microorganisms in wastewater treatment plants	10 mg/l		ECHA REACH
Freshwater sediment	1.2 mg/kg of dry substance of sediment		ECHA REACH
Sea sediments	0.12 mg/kg of dry substance of sediment		ECHA REACH
Soil (agricultural)	0.21 mg/kg of dry substance of soil		ECHA REACH

SAFETY DATA SHEET

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COMMISSION REGULATION (EU) 2020/878



POLITRAY LIQUID

Creation date	14th May 2021		
Revision date	12th January 2023	Version	3.0

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. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. 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.

Material: butyl rubber.

Change gloves, if contamination occurs or duration of activity exceed break through time. Breakthrough time of the glove material: refer to the information provided by the glove's producer. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer.

Respiratory protection

Halfmask with a filter against organic vapours type A or a self-contained breathing apparatus as appropriate if exposure limit values of substances are exceeded or in a poorly ventilated environment.

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	colourless
Odour	characteristic, strong
Melting point/freezing point	-48 °C
Boiling point or initial boiling point and boiling range	100,5 °C
Flammability	data not available
Lower and upper explosion limit	
bottom	2,1 %
upper	12,5 %
Flash point	10 °C
Auto-ignition temperature	421 °C
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	slightly soluble; 1,6 % at 20 °C
Partition coefficient n-octanol/water (log value)	1,38
Vapour pressure	3600 Pa at 20 °C
Density and/or relative density	data not available
Relative vapour density	3,5 (air = 1)
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

Will exothermically polymerise in the presence of initiators.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Susceptible to polymerisation initiated by prolonged heating or the presence of catalyst.

SAFETY DATA SHEET

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COMMISSION REGULATION (EU) 2020/878



POLITRAY LIQUID

Creation date	14th May 2021		
Revision date	12th January 2023	Version	3.0

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

Polymerisation catalysts, such as peroxy or azo compounds, strong acids, alkalies and oxidizing agents. Oxides and salts of transition metals. Organic Nitrogen containing compounds. Cyclohexanone / Cyclohexenol tautomer.

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.

Methyl methacrylate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	LD ₅₀		>5000 mg/kg			
Inhalation	LC ₅₀		7093 ppm	4 hour		
Dermal	LD ₅₀		>5000 mg/kg			

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex
Oral	EC ₅₀	OECD 401	619 mg/kg			
Dermal	EC ₅₀	OECD 402	>2000 mg/kg			

Skin corrosion/irritation

Causes skin irritation.

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Route of exposure	Result	Method	Exposure time	Species
Dermal	Irritating	OECD 439		
Eye	Irritating	OECD 405		

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Methyl methacrylate

Route of exposure	Result	Method	Exposure time	Species
Eye	Slightly irritating	OECD 405		Rabbit

Respiratory or skin sensitisation

May cause an allergic skin reaction. Repeated and/or prolonged contact may cause dermatitis.

Methyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Sex
Dermal	Sensitizing	OECD 429		Mouse	
Dermal	Sensitizing			Human	

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date	14th May 2021	Version	3.0
Revision date	12th January 2023		

Reaction mass of 2,2'-[[4-methylphenyl]imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Route of exposure	Result	Method	Exposure time	Species	Sex
Dermal	Sensitizing	OECD 429			

Mutagenicity

White mineral oil (petroleum)

Result	Exposure time	Specific target organ	Species	Sex
Negative				

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Methyl methacrylate

Result	Method	Exposure time	Specific target organ	Species	Sex	Source
Negative	OECD 471			Salmonella typhimurium		TA1535, 1537, 97, 98, 100
Negative	OECD 478					Rodent dominant lethal test
Negative	OECD 474			mammalian erythrocyte micronucleus		in vivo
Positive	OECD 473					In vitro mammalian cell gene mutation test

Carcinogenicity

Based on available data the classification criteria are not met.

Methyl methacrylate

Route of exposure	Parameter	Method	Value	Result	Species	Sex
		OECD 451		Not carcinogenic		

White mineral oil (petroleum)

Route of exposure	Parameter	Method	Value	Result	Species	Sex
				Negative, Not carcinogenic		

Reproductive toxicity

Based on available data the classification criteria are not met.

Methyl methacrylate

Effect	Parameter	Method	Value	Result	Species	Sex	Source
Effects on fertility	NOAEC	OECD 414	>2028 ppm		Rat		vdihavanje
Developmental toxicity	NOAEL		450 mg/kg bw		Rabbit		oralno

White mineral oil (petroleum)

Effect	Parameter	Method	Value	Result	Species	Sex	Source
				Negative			

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date	14th May 2021		
Revision date	12th January 2023	Version	3.0

Toxicity for specific target organ - single exposure

May cause respiratory irritation.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Repeated exposure to high levels produces adverse effects on the heart, lungs, liver and kidneys.

Repeated exposure of animals by inhalation to levels at or above the occupational exposure level produces adverse effects on the nasal epithelium (levels of 100 and 400 ppm).

There is no reason to believe that methyl methacrylate represents a carcinogenic or mutagenic hazard to man based upon evidence from well conducted animal studies, relevant mutagenicity studies and adequate epidemiology studies in relevant cohorts.

Recent studies in animals have shown that high exposures do not produce embryo or foetotoxic nor teratogenic effects in the presence of maternal toxicity.

Methyl methacrylate

Route of exposure	Parameter	Method	Value	Exposure time	Result	Species	Sex
Oral	NOEL		>2000 ppm	104 week		Rat	
Inhalation	NOAEC	OECD 453	100 ppm	104 week		Rat	
Inhalation	NOAEC	OECD 412	1000 ppm	14 week		Mouse	

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

It can cause harmful effects on the environment. Prevent uncontrolled release.

Methyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environment	Value determination
LC ₅₀		>100 mg/l		Fishes		
LC ₅₀		130 mg/l	96 hour	Fishes (Fathead minnow)		Static system
EC ₅₀		69 mg/l	48 hour	Daphnia (Daphnia magna)		
EC ₅₀		170 mg/l	96 hour	Algae (Selenastrum capricornutum)		

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Parameter	Method	Value	Exposure time	Species	Environment	Value determination
LC ₅₀	OECD 203	>100 mg/l	96 hour	Fishes (Oncorhynchus mykiss)		
EC ₅₀	OECD 202	48 mg/l	48 hour	Daphnia (Daphnia magna)		
EC ₅₀	OECD 201	>100 mg/l		Algae (Selenastrum capricornutum)		

Chronic toxicity

Methyl methacrylate

Parameter	Value	Exposure time	Species	Environment
NOEC	8.4 mg/l	35 day	Fishes (Zebra fish)	

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date 14th May 2021
Revision date 12th January 2023 Version 3.0

12.2. Persistence and degradability

Biodegradability

Methyl methacrylate

Parameter	Method	Value	Exposure time	Environment	Result
					Easily biodegradable
COD		88 %	28 day		
DOC removal		>95 %	28 day		

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Parameter	Method	Value	Exposure time	Environment	Result
	OECD 301B	>100 mg/l	96 hour		Hardly biodegradable

Readily biodegradable.

12.3. Bioaccumulative potential

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Parameter	Method	Value	Exposure time	Species	Environment	Temperature [°C]
Log Kow	OECD 117	2.17				

The product has low potential for bioaccumulation.

12.4. Mobility in soil

Reaction mass of 2,2'-[(4-methylphenyl)imino]bisethanol and Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl](4-methylphenyl)amino]-

Parameter	Method	Value	Environment	Temperature
Log Koc	OECD 122	2.33		20°C

The product is predicted to have high mobility in soil.

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 authorized 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

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

UN 1247

SAFETY DATA SHEET

PoliDent

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



POLITRAY LIQUID

Creation date	14th May 2021		
Revision date	12th January 2023	Version	3.0

14.2. UN proper shipping name

METHYL METHACRYLATE MONOMER, STABILIZED

14.3. Transport hazard class(es)

3 Flammable liquids

14.4. Packing group

II - substances presenting medium danger

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.

339

UN number

1247

Classification code

F1

Safety signs

3



Road transport - ADR

Special provisions

386

Limited quantities

1 L

Excepted quantities

E2

Packaging

Packing instructions

P001, IBC02, R001

Mixed packing provisions

MP19

Portable tanks and bulk containers

Guidelines

T4

Special provisions

TP1

ADR tank

Tank code

LGBF

Vehicles for tank carriage

FL

Transport category

2

Tunnel restriction code

(D/E)

Special provision for

packages

V8

operation

S2, S4, S20

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Railway transport - RID

Special provisions	386
Excepted quantities	E2

Packaging

Packing instructions	P001, IBC02, R001
Mixed packing provisions	MP19

Portable tanks and bulk containers

Guidelines	T4
Special provisions	TP1

RID Tanks

Tank code	LGBF
Transport category	0

Special provision for

packages	W 8
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Air transport - ICAO/IATA

Packaging instructions for limited amount	Y341
Packaging instructions passenger	353
Cargo packaging instructions	364

Marine transport - IMDG

EmS (emergency plan)	F-E, S-D
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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

Product is a medical device class I according to the Medical Device Regulation 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

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Guidelines for safe handling used in the safety data sheet

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P501	Dispose of contents/container to in accordance with local/regional/national/international regulations.

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P262 Do not get in eyes, on skin, or on clothing.

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
DNEL	Derived no-effect level
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
ES	Identification code for each substance listed in EINECS
EU	European Union
EuPCS	European Product Categorisation System
HOS	Volatile organic compounds
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
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 K _{ow}	Octanol-water partition coefficient
MARPOL	International Convention for the Prevention of Pollution from Ships
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOEL	No observed effect level
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted no-effect concentration
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
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Asp. Tox.	Aspiration hazard
Eye Dam.	Serious eye damage
Flam. Liq.	Flammable liquid
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization

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STOT SE Specific target organ toxicity - single 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

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 3.0 replaces the SDS version 2.0. and first version from 14.05.2021.

Changes were made in sections:

- 2.3 Other hazards,
- 3.2 Mixtures - content in % weight,
- 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.