PoliDent

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

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# **POLICOLD LIQUID**

Creation date 14th May 2021

Revision date 16th December 2022 Version 3.0

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

**1.1. Product identifier** POLICOLD LIQUID

Substance / mixture mixture

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

#### Mixture's intended use

Material for the fabrication of dentures, repairs and rebasing by using the cast technique and the cold curing.

### Mixture uses advised against

The product should not be used in ways other then 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

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#### **Hazardous substances**

Methyl methacrylate Ethylene dimethacrylate

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

## **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, dimethacrylate 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	80-95	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335	2
Index: 607-114-00-5 CAS: 97-90-5 EC: 202-617-2 Registration number: 01-2119965172-38	Ethylene dimethacrylate	2,5-10	Skin Sens. 1, H317 STOT SE 3, H335	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	
Index: 607-124-00-X CAS: 868-77-9 EC: 212-782-2 Registration number: 01-2119490169-29	2-hydroxyethyl methacrylate	<0,1	Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	1

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#### **Notes**

- 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 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.

#### 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. When intruding eyes, it can evoke irritation. 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.

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### 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.

#### 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 of the liquid 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)	Туре	Value	Note
	OEL 8 hours	50 ppm	
Methyl methacrylate (CAS: 80-62-6)	OEL 15 minutes	100 ppm	

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### Slovenia

## Uradni list RS, Št. 72/2021

Substance name (component)	Туре	Value	Note
	8 hours	210 mg/m <sup>3</sup>	
Mathyl mathyamilata (CAS) 90 62 6)	8 hours	50 ppm	Substances representing no risk
Methyl methacrylate (CAS: 80-62-6)	KTV (15 min)	420 mg/m <sup>3</sup>	to the foetus with reference to the limit values.
	KTV (15 min)	100 ppm	

## **United Kingdom**

## EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Substance name (component)	Туре	Value	Note
	WEL 8h	208 mg/m <sup>3</sup>	
Mathyl mathagradata (CAS) 90 62 6)	WEL 8h	50 ppm	
Methyl methacrylate (CAS: 80-62-6)	WEL 15min	416 mg/m <sup>3</sup>	
	WEL 15min	100 ppm	

## **DNEL**

# Ethylene dimethacrylate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	2.45 mg/m <sup>3</sup>	Systemic chronic effects		ECHA REACH
Workers	Dermal	1.3 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	1.45 mg/m <sup>3</sup>	Systemic chronic effects		ECHA REACH
Consumers	Dermal	0.83 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Oral	0.83 mg/kg bw/day	Systemic chronic effects		ECHA REACH

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## Methyl methacrylate

Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	348.4 mg/m <sup>3</sup>	Systemic chronic effects		ECHA REACH
Workers	Inhalation	208 mg/m <sup>3</sup>	Local chronic effects		ECHA REACH
Workers	Inhalation	416 mg/m <sup>3</sup>	Local acute effects		ECHA REACH
Workers	Dermal	13.67 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Local chronic effects		ECHA REACH
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Local acute effects		ECHA REACH
Consumers	Inhalation	74.3 mg/m <sup>3</sup>	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	104 mg/m <sup>3</sup>	Local chronic effects		ECHA REACH
Consumers	Inhalation	208 mg/m <sup>3</sup>	Local acute effects		ECHA REACH
Consumers	Dermal	8.2 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	Local chronic effects		ECHA REACH
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	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 <sup>3</sup>	Systemic chronic effects		ECHA REACH
Workers	Dermal	1.4 mg/kg bw/day	Systemic chronic effects		ECHA REACH
Consumers	Inhalation	1.74 mg/m³	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

## PNEC

### Ethylene dimethacrylate

Route of exposure	Value	Value determination	Source
Freshwater environment	0.139 mg/l		ECHA REACH
Seawater	0.014 mg/l		ECHA REACH
Microorganisms in wastewater treatment plants	57 mg/l		ECHA REACH
Freshwater sediment	1.6 mg/kg of dry substance of sediment		ECHA REACH
Sea sediments	0.16 mg/kg of dry substance of sediment		ECHA REACH
Soil (agricultural)	0.239 mg/kg of dry substance of soil		ECHA REACH

## Methyl methacrylate

Route of exposure	Value	Value determination	Source
Freshwater environment	0.94 mg/l		WCHA REACH

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#### Methyl methacrylate

Route of exposure	Value	Value determination	Source
Seawater	0.094 mg/l		WCHA REACH
Microorganisms in wastewater treatment plants	10 mg/l		WCHA REACH
Freshwater sediment	10.2 mg/kg of dry substance of sediment		WCHA REACH
Sea sediments	1.02 mg/kg of dry substance of sediment		WCHA REACH
Soil (agricultural)	1.48 mg/kg of dry substance of soil		WCHA 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

## 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.

When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. 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.

# 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

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Physical state liquid
Colour colourless
Odour characteristic
Melting point/freezing point -48 °C
Boiling point or initial boiling point and boiling range 100,5 °C
Flammability data not available

Flammability
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
Viscosity
Viscosity

O,53 mPas at 20 °C
Solubility in water

soluble

Partition coefficient n-octanol/water (log value) 1,38

Vapour pressure 3600 Pa at 20 °C

Density and/or relative density

Density 0,94 g/cm<sup>3</sup> at 20 °C

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 exotermically 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.

### 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.

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### **Acute toxicity**

Based on available data the classification criteria are not met.

2-hydroxyethyl methacrylate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Source
	LD50		>5000 mg/kg		Rat		raw material SDS
	LD50		>5000 mg/kg		Rabbit		raw material SDS

Ethylene dimethacrylate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Source
Oral	LD50		>5000 mg/kg		Rat		raw material SDS
Dermal	LD50		>2000 mg/kg				raw material SDS

Methyl methacrylate

Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Source
Oral	LD50		>5000 mg/kg				raw material SDS
Inhalation	LC50		7093 ppm	4 hour			vapour, raw material SDS
Dermal	LD50		>5000 mg/kg				raw material SDS

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	Source
Oral	EC50	OECD 401	619 mg/kg				raw material SDS
Dermal	EC50	OECD 402	>2000 mg/kg				raw material SDS

### Skin corrosion/irritation

Causes skin irritation.

2-hydroxyethyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Source
Dermal	Not irritating		24 hour	Rabbit	Draize test, raw material SDS

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## Ethylene dimethacrylate

Route of exposure	Result	Method	Exposure time	Species	Source
Dermal	Not irritating		24 hour	Rabbit	FDA 1959 Drazie, raw material SDS

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	Source
Dermal	Irritating	OECD 439			raw material SDS
Eye	Irritating	OECD 405			raw material SDS

### Serious eye damage/irritation

 $Based\ on\ available\ data\ the\ classification\ criteria\ are\ not\ met.\ High\ vapour\ concentration\ will\ cause\ irritation.$ 

## 2-hydroxyethyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Source
Eye	Irritating		24 hour	Rabbit	Draize test, Category 2 B, raw material SDS

## Ethylene dimethacrylate

Route of exposure	Result	Method	Exposure time	Species	Source
Eye	Not irritating	OECD 405		Rabbit	raw material SDS

## Methyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Source
Eye	Slightly irritating	OECD 405		Rabbit	raw material SDS

## Respiratory or skin sensitisation

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

# 2-hydroxyethyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing			Guinea-pig (Cavia aperea f. porcellus)		Category 1 B, raw material SDS
Dermal	Sensitizing			Human		raw material SDS

## Ethylene dimethacrylate

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing			Mouse (lymphoma)		raw material SDS

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## Methyl methacrylate

Route of exposure	Result	Method	Exposure time	Species	Sex	Source
Dermal	Sensitizing	OECD 429		Mouse		raw material SDS
Dermal	Sensitizing			Human		raw material SDS

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	Source
Dermal	Sensitizing	OECD 429				raw material SDS

### 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, raw material SDS
Negative	OECD 478					Rodent dominant lethal test, raw material SDS
Negative	OECD 474			mammalian erythrocyte micronucleus		in vivo, raw material SDS
Positive	OECD 473					In vitro mammali an cell gene mutation test, raw material SDS

# Carcinogenicity

Based on available data the classification criteria are not met.

Methyl methacrylate

Route of exposure	Parameter	Method	Value	Result	Species	Sex	Source
		OECD 451		Not carcinogenic			raw material SDS

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### Reproductive toxicity

Based on available data the classification criteria are not met. Teratogenic and fetotoxic effects only observed in presevce of maternal toxicity.

Methyl methacrylate

Effect	Parameter	Method	Value	Result	Species	Sex	Source
Effects on fertility	NOAEC	OECD 414	>2028 ppm		Rat		inhalation, raw material SDS
Developmenta I toxicity	NOAEL		450 mg/kg bw		Rabbit		oral, raw material SDS

## Toxicity for specific target organ - single exposure

May cause respiratory irritation.

Ethylene dimethacrylate

Route of exposure	Parameter	Value	Result	Species	Sex	Source
Inhalation			Irritating			raw material SDS

### 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	Source
Oral	NOEL		>2000 ppm	104 week		Rat		raw material SDS
Inhalation	NOAEC	OECD 453	100 ppm	104 week		Rat		raw material SDS
Inhalation	NOAEC	OECD 412	1000 ppm	14 week		Mouse		raw material SDS

## Repeated dose toxicity

2-hydroxyethyl methacrylate

= 11/41/01/1/	= myanaxyaanyi maanaa yaas										
Route of exposure	Parameter	Result	Value	Exposure time	Species	Sex	Source				
Oral	NOAEL	No effect	100 mg/kg	7 week	Rat		raw material SDS				

## **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.

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# **POLICOLD LIQUID**

Creation date 14th May 2021

Revision date 16th December 2022 Version 3.0

## **SECTION 12: Ecological information**

### 12.1. Toxicity

### **Acute toxicity**

2-hydroxyethyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source
LC50	OECD 203	>100 mg/l	96 hour	Fishes (Oryzias latipes)			raw material SDS
EC50	OECD 202	380 mg/l	48 hour	Daphnia (Daphnia magna)			raw material SDS
EC50	OECD 201	836 mg/l	72 hour	Algae (Selenastrum capricornutum)			raw material SDS
EC50		>3000 mg/l	16 hour	Microorganisms (Pseudomonas fluorescens)			raw material SDS
NOEC	OECD 201	400 mg/l	72 hour	Algae (Selenastrum capricornutum)			raw material SDS

## Ethylene dimethacrylate

Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source
LC50	OECD 203	15.95 mg/l	96 hour	Fishes (Oncorhynchus mykiss)			raw material SDS
EC50	OECD 202	44.9 mg/l	48 hour	Daphnia (Daphnia magna)			raw material SDS
EC50	OECD 201	17.3 mg/l	72 hour	Algae (Selenastrum capricornutum)			raw material SDS
EC50	OECD 209	570 mg/l	3 hour	Microorganisms (Pseudomonas putida)			raw material SDS

## Methyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source
LC50		>100 mg/l		Fishes			raw material SDS
LC50		130 mg/l	96 hour	Fishes (Fathead minnow)		Static system	raw material SDS
EC50		69 mg/l	48 hour	Daphnia (Daphnia magna)			raw material SDS
EC50		170 mg/l	96 hour	Algae (Selenastrum capricornutum)			raw material SDS

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	Environm ent	Value determination	Source
LC50	OECD 203	>100 mg/l	96 hour	Fishes (Oncorhynchus mykiss)			raw material SDS

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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	Environm ent	Value determination	Source
EC50	OECD 202	48 mg/l	48 hour	Daphnia (Daphnia magna)			raw material SDS
EC50	OECD 201	>100 mg/l		Algae (Selenastrum capricornutum)			raw material SDS

## **Chronic toxicity**

2-hydroxyethyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environme nt	Source
NOEC	OECD 202	24.1 mg/l	21 day	Daphnia (Daphnia magna)		raw material SDS

## Ethylene dimethacrylate

Parameter	Method	Value	Exposure time	Species	Environme nt	Source
NOEC	OECD 211	5.05 mg/l	21 day	Daphnia (Daphnia magna)		raw material SDS

### Methyl methacrylate

Parameter	Method	Value	Exposure time	Species	Environme nt	Source
NOEC		8.4 mg/l	35 day	Fishes (Zebra fish)		raw material SDS

## 12.2. Persistence and degradability

## **Biodegradability**

Methyl methacrylate

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

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	Source
	OECD 301B	>100 mg/l	96 hour		Hardly biodegradable	raw material SDS

Readily biodegradable.

## 12.3. Bioaccumulative potential

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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	Temperatur e [°C]	Source
Log Kow	OECD 117	2.17					raw material SDS

The product has low potential for bioacumulation.

### 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	Source
Log Koc	OECD 122	2.33		20°C	raw material SDS

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 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

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

### 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

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#### **Additional information**

Safety signs

Hazard identification No. 339
UN number 1247
Classification code F1



### Road transport - ADR

Special provisions386Limited quantities1 LExcepted quantitiesE2

**Packaging** 

Packing instructions P001, IBC02, R001

Mixed packing provisions MP19

Portable tanks and bulk containers

Guidelines T4
Special provisions TP1

**ADR tank** 

Tank codeLGBFVehicles for tank carriageFLTransport category2Tunnel restriction code(D/E)

Special provision for

packages V8

operation S2, S4, S20

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

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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# **POLICOLD LIQUID**

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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 IIa 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. H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 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.

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

EC50 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

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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

LC50 Lethal concentration of a substance in which it can be expected death of 50% of the

population

LD50 Lethal dose of a substance in which it can be expected death of 50% of the

population

log Kow 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)

Eye Dam. Serious eye damage
Eye Irrit. Eye irritation
Flam. Liq. Flammable liquid
Skin Irrit. Skin irritation
Skin Sens. Skin sensitization

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 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

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# **POLICOLD LIQUID**

Creation date 14th May 2021

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Classification procedure - calculation method.

Safety data sheets 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.

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