

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

# VILLACRYL ORTHO LIQUID

Creation date 06th May 2024

Revision date Version 2.0

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

1.1. Product identifier VILLACRYL ORTHO LIQUID

Substance / mixture mixture Number V160L

UFI K5C0-R0CT-S00T-TSRK

Other mixture names

UFI: K5C0-R0CT-S00T-TSRK, Villacryl ORTHO Liquid 1000 ml - V160L02 UFI: K5C0-R0CT-S00T-TSRK, Villacryl ORTHO Liquid 12 ml - V160L05 UFI: K5C0-R0CT-S00T-TSRK, Villacryl ORTHO Liquid 250 ml - V160L03 UFI: K5C0-R0CT-S00T-TSRK, Villacryl ORTHO Liquid 500 ml - V160L04

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

#### Mixture's intended use

Liquid component of acrylic material for making removable orthodontic appliances Villacryl Ortho.

Main intended use

PC-MED-OTH Other medical devices

The use descriptors

PW Widespread use by professional workers

Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

### 1.3. Details of the supplier of the safety data sheet

**Supplier** 

Name or trade name Everall7 Sp. z o.o.

Address Augustówka 14, Warszawa , 02-981

Poland

Identification number (CRN)002028511VAT Reg NoPL5210124886Phone+48 22 858 82 72E-mailinfo@everall7.plWeb addresseverall7.pl

Competent person responsible for the safety data sheet

Name Everall7 Sp. z o.o. E-mail info@everall7.pl

# 1.4. Emergency telephone number

European emergency number: 112

# **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

#### Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335

#### 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.



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#### 2.2. **Label elements**

### **Hazard pictogram**





#### Signal word

Danger

#### **Hazardous substances**

methyl methacrylate ethylene dimethacrylate

### **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 vapours.

P264 Wash hands and exposed parts of the body thoroughly after handling.

P280 Wear protective gloves.

P362+P364 Take off contaminated clothing and wash it before reuse.

P370+P378 In case of fire: Use powder extinguisher/sand/carbon dioxide to extinguish.

#### 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**

#### **Mixtures**

### **Chemical characterization**

Mixture.

#### 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	methyl methacrylate	>90	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335	2, 3
Index: 607-114-00-5 CAS: 97-90-5 EC: 202-617-2	ethylene dimethacrylate	<10	Skin Sens. 1, H317 STOT SE 3, H335	2
Index: 612-056-00-9 CAS: 99-97-8 EC: 202-805-4	N,N-dimethyl-p-toluidine	<1	Acute Tox. 3, H301+H311+H331 STOT RE 2 (**), H373 Aquatic Chronic 3, H412	1

#### Notes

\*\* another exposure route cannot be ruled out

Note C: Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers. In this case the supplier must state on the label whether the substance is a specific isomer or a mixture of isomers.



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- 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".
- 3 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 eves

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.

#### If on skin

May cause an allergic skin reaction.

### If in eyes

Not expected.

#### If swallowed

Irritation, nausea.

### 4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

### **SECTION 5: Firefighting measures**

#### 5.1. Extinguishing media

#### Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

#### Unsuitable extinguishing media

Water - full jet.

#### 5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

#### 5.3. Advice for firefighters

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.



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#### **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.

#### 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

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. 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.

### 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. Store locked up. Keep container tightly closed. Keep cool.

Content	Packaging type	Material of package
250 ml	bottle	HDPE
12 ml	bottle	GL
500 ml	bottle	HDPE
1000 ml	bottle	HDPE

Storage class

3 - Flammable liquids

Storage temperature

min 5 °C, max 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)

not available

### **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
methyl methycmilate (CAS, 90, 62, 6)	OEL 8 hours	50 ppm
methyl methacrylate (CAS: 80-62-6)	OEL 15 minutes	100 ppm



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#### **DNEL**

ethylene dimethacrylate							
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source		
Workers	Inhalation	2.45 mg/m <sup>3</sup>	Chronic effects systemic	Toxicity test	ECHA		
Workers	Dermal	1.3 mg/kg bw/day	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Inhalation	1.45 mg/m³	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Dermal	830 μg/kg bw/24h	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Oral	830 µg/kg bw/24h	Chronic effects systemic	Toxicity test	ECHA		

methyl methacrylate							
Workers / consumers	' I I Value I Effect		Value determination	Source			
Workers	Inhalation	348.4 mg/m <sup>3</sup>	Chronic effects systemic	Toxicity test	ECHA		
Workers	Inhalation	208 mg/m <sup>3</sup>	Chronic effects local		ECHA		
Workers	Inhalation	416 mg/m <sup>3</sup>	Acute effects local	Toxicity test	ECHA		
Workers	Dermal	13.67 mg/kg bw/day	Chronic effects systemic	Toxicity test	ECHA		
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Chronic effects local	Toxicity test	ECHA		
Workers	Dermal	1.5 mg/cm <sup>2</sup>	Acute effects local	Toxicity test	ECHA		
Consumers	Inhalation	74.3 mg/m <sup>3</sup>	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Inhalation	104 mg/m <sup>3</sup>	Chronic effects local	Toxicity test	ECHA		
Consumers	Inhalation	208 mg/m <sup>3</sup>	Acute effects local	Toxicity test	ECHA		
Consumers	Dermal	8.2 mg/kg bw/day	Chronic effects systemic	Toxicity test	ЕСНА		
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	Acute effects local	Toxicity test	ECHA		
Consumers	Oral	8.2 mg/kg bw/day	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Dermal	1.5 mg/cm <sup>2</sup>	Chronic effects local		ECHA		

N,N-dimethyl-p-toluidine							
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source		
Workers	Inhalation	128 μg/m <sup>3</sup>	Chronic effects systemic	Toxicity test	ECHA		
Workers	Dermal	624 µg/kg bw	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Inhalation	22.7 μg/m <sup>3</sup>	Chronic effects systemic				
Consumers	Dermal	223 µg/kg bw	Chronic effects systemic	Toxicity test	ECHA		
Consumers	Oral	20 μg/kg bw	Chronic effects systemic	Toxicity test	ECHA		

#### **PNEC**

ethylene dimethacrylate					
Route of exposure	Value	Value determination	Source		
Drinking water	69.3 μg/l	Experimentally	ECHA		
Water (intermittent release)	150 μg/l	Experimentally	ECHA		



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ethylene dimethacrylate			
Route of exposure	Value	Value determination	Source
Marine water	6.93 μg/l	Experimentally	ECHA
Microorganisms in sewage treatment	57 mg/l	Experimentally	ECHA
Freshwater sediment	411 μg/kg of dry substance	Experimentally	ECHA
Sea sediments	41.1 μg/kg of dry substance	Experimentally	ECHA
Soil (agricultural)	41.5 μg/kg of dry substance	Experimentally	ECHA

methyl methacrylate			
Route of exposure	Value	Value determination	Source
Drinking water	940 µg/l	Experimentally	ECHA
Water (intermittent release)	690 μg/l	Experimentally	ECHA
Marine water	94 mg/kg	Experimentally	ECHA
Microorganisms in sewage treatment	10 mg/l	Experimentally	ECHA
Freshwater sediment	10.2 mg/kg of dry substance of sediment	Experimentally	ECHA
Sea sediments	1.02 mg/kg of dry substance of sediment	Experimentally	ECHA
Soil (agricultural)	1.48 mg/kg of dry substance of soil	Experimentally	ECHA

N,N-dimethyl-p-toluidine			
Route of exposure	Value	Value determination	Source
Drinking water	152.59 μg/l	Experimentally	ECHA
Water (intermittent release)	152.59 μg/l	Experimentally	ECHA
Marine water	15.259 μg/l	Experimentally	ECHA
Microorganisms in sewage treatment	4.286 μg/l	Experimentally	ECHA
Freshwater sediment	45.378 mg/kg of dry substance of sediment	Experimentally	ECHA
Sea sediments	45.378 mg/kg of dry substance of sediment	Experimentally	ECHA
Soil (agricultural)	18.677 mg/kg of dry substance of soil	Experimentally	ECHA



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#### 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 goggles.

#### Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

#### Respiratory protection

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

#### Thermal hazard

Data not available.

#### **Environmental exposure controls**

Observe usual measures for protection of the environment, see Section 6.2.

#### **SECTION 9: Physical and chemical properties**

### Information on basic physical and chemical properties

Colour colourless

Odour Typical for methacrylic acid esters

Melting point/freezing point -48.2 °C Boiling point or initial boiling point and boiling range >100 °C

inflammable Flammability

Lower and upper explosion limit

bottom 2 1 % 12.5 % upper 10 °C Flash point 430 °C Auto-ignition temperature

>50 °C Decomposition temperature data not available

Kinematic viscosity data not available

Solubility in water 15.9 g/l Partition coefficient n-octanol/water (log value) 1.38

Vapour pressure 38.7 hPa at 20 °C

Density and/or relative density

Density 940 g/cm3

Relative vapour density data not available Particle characteristics data not available

Form liquid

#### 9.2. Other information

not available

### **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

#### Chemical stability

The product is stable under normal conditions. The product is stable in normal conditions of use and storage. Liquid is stabilized by hydroquinone (CAS no. 123-31-9). Nevertheless, the occurrence of self-polymerization reaction is possible after the expiry date, if the storage temperature is exceeded significantly or in case of direct and strong influence of UV radiation



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#### 10.3. Possibility of hazardous reactions

Uncontrolled polymerization reaction in the presence of factors which initiate occurration of free radicals. The polymerization reaction is exothermic (heat releasing) and in uncontrolled conditions proceed very vigotous.

#### 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

Protect against strong acids, bases and oxidizing agents.

#### 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.

ethylene dimethacrylate								
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Value determinatio n	Source
Oral	LD50		8300 ml/kg bw	14 days	Rat (Wistar)	F/M	Experimentall	ECHA
							У	
Dermal	LD50	OECD 402	2000 mg/kg bw	24 hours	Rat (Wistar)	F/M	Experimentall	ECHA
							У	

methyl met	hacrylate							
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Value determinatio n	Source
Oral	LD50		7900 mg/kg		Rat (Rattus norvegicus)		Mortal	ECHA Dossier
Inhalation	LC50		29.8 mg/l	4 hours	Rat (Rattus norvegicus)			ECHA Dossier
Dermal	LD50	OECD 402	>5000 mg/kg	24 hours	Rabbit	М		ECHA Dossier
Oral	NOAEL		7900 mg/kg bw/day		Rat (Rattus norvegicus)		Mortal	ECHA
Inhalation	NOAEL		29.8 mg/l	4 hours	Rat (Rattus norvegicus)			ECHA Dossier
Dermal	NOAEL	OECD 402	5000 mg/kg		Rabbit			ECHA Dossier

N,N-dimethyl	N,N-dimethyl-p-toluidine											
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Value determinatio n	Source				
Oral	LD50	OECD 401	139 mg/kg bw		Mouse	F/M	Experimentall y	ECHA				
Oral	LD50	OECD 401	1300-1950 mg/kg bw		Rat (Rattus norvegicus)	F/M	Experimentall y	ECHA				
Dermal	LD50	OECD 402	>2000 mg/kg bw		Rabbit	F/M	Experimentall y	EHA				



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N,N-dimethyl	N,N-dimethyl-p-toluidine										
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Value determinatio n	Source			
Inhalation	LC50		1.4 mg/l		Rat (Rattus norvegicus)	F/M	Experimentall y	ECHA			

### Skin corrosion/irritation

Causes skin irritation.

ethylene dimethacrylate									
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source			
Dermal	Not irritating	in vivo	24 hours	Rabbit (New Zelend White)	Observation method	ECHA			

methyl methacrylate									
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source			
Dermal	Irritating		24 hours	Rabbit	Toxicity test	ECHA			

## Irritation

methyl methacrylate									
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source			
Inhalation	Irritating					ECHA			

N,N-dimethyl	N,N-dimethyl-p-toluidine										
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source					
Dermal	Not irritating	OECD 404	4 hours	Rabbit	Experimentally	ECHA					
Eye	Not irritating	OECD 405	4 hours	Rabbit	Experimentally	ECHA					

### Serious eye damage/irritation

Based on available data the classification criteria are not met.

ethylene dimethacrylate									
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source			
Eye	Not irritating	in vivo	72 hours	Rabbit (New Zelend White)	Observation method	ECHA			

methyl metha	methyl methacrylate									
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source				
Eye	Not sensitizing			Rabbit		ECHA				

## Respiratory or skin sensitisation

May cause an allergic skin reaction.

ethylene dimethacrylate										
Route of exposure	Result	Method	Exposure time	Species	Sex	Value determination	Source			
Dermal	Sensitizing	OECD 406		Mouse	F	Literary studies	ECHA			



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methyl metha	methyl methacrylate										
Route of exposure	Result	Method	Exposure time	Species	Sex	Value determination	Source				
Dermal	Sensitizing	OECD 429		Mouse		Observation method	ECHA				
Inhalation	Not sensitizing						ECHA				

N,N-dimethyl-p-toluidine										
Route of exposure	Result	Method	Exposure time	Species	Sex	Value determination	Source			
Dermal	Sensitizing					Literary studies	ECHA			

### Germ cell mutagenicity

Based on available data the classification criteria are not met.

methyl methacry	late						
Result	Method	Exposure time	Specific target organ	Species	Sex	Value determinati on	Source
Negative	OECD 476		Lung fibroblast	Chinese hamster (Cricetulus barabensis)			ECHA
Negative	OECD 478	5 days (6 hour/day)	Male reproductive organs	Mouse	М		ECHA

N,N-dimethyl-p-t	N,N-dimethyl-p-toluidine										
Result	Method	Exposure time	Specific target organ	Species	Sex	Value determinati on	Source				
Negative without metabolic activation, Negative with metabolic activation				Bacteria (Salmonella typhimurium )		Literary studies	ECHA				
Negative		3 months (7 days/week)	Blood	Mouse	F/M	Literary studies	ECHA				

### Carcinogenicity

Based on available data the classification criteria are not met.

methyl me	methyl methacrylate										
Route of exposure	Parameter	Value	Exposure time	Specific target organ	Result	Species	Sex	Value determina tion	Source		
Oral	NOAEL	90.3 mg/kg bw/day		Kidney	Not carcinogeni c	Rat (Rattus norvegicus )	F/M		ECHA		
Inhalation	NOAEC	2050 mg/m <sup>3</sup>			Not carcinogeni c	Rat (Rattus norvegicus )	F/M		ECHA		



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N,N-dimet	N,N-dimethyl-p-toluidine										
Route of exposure	Parameter	Value	Exposure time	Specific target organ	Result	Species	Sex	Value determina tion	Source		
Oral	LOAEL	6 mg/kg bw/day	2 years (5 days/week )	Liver	Negative	Rat (Rattus norvegicus )	F/M	Experimen tally	ECHA		

#### Reproductive toxicity

Based on available data the classification criteria are not met.

N,N-dimet	N,N-dimethyl-p-toluidine										
Effect	Parameter	Method	Value	Exposure time	Result	Species	Sex	Value determina tion	Source		
Effects on fertility	NOAEL	OECD 422	44.6 mg/kg bw/day	14 weeks (5 days/week	Negative	Rat (Rattus norvegicus )	F/M	Experimen tally	ECHA		
Developme ntal toxicity	NOAEL	OECD 422	30 mg/kg bw/day	14 weeks (5 days/week	Negative	Rat (Rattus norvegicus )	F/M	Experimen tally	ECHA		

# 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 dose toxicity

ethylene di	imethacryla	ate							
Route of exposure	Parameter	Result	Method	Value	Exposure time	Species	Sex	Value determina tion	Source
Oral	NOAEL	Body weight, Organ weight	OECD 422	100 mg/kg bw/day	49 days	Rat (Rattus norvegicus )	F/M	Analogous approach, Literary studies	
Dermal	NOAEL	Irritating, Local effects, Systemic effects, Histopatho logy		100 mg/kg bw/day	78 weeks (5 days/week)	Mouse	М	Analogous approach, Literary studies	ECHA
Inhalation	NOAEL	Irritating, Local effects, Systemic effects, Histopatho logy	OECD 413	100 ppm	90 days (6 hour/day, 5 days/week)	Rat (Rattus norvegicus )	F/M	Analogous approach, Literary studies	ECHA
Inhalation	LOAEC	Irritating, Local effects, Systemic effects, Histopatho logy	OECD 413	350 ppm	90 days (6 hour/day, 5 days/week)	Rat (Rattus norvegicus )	F/M	Analogous approach, Literary studies	ECHA



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methyl me	thacrylate								
Route of exposure	Parameter	Result	Method	Value	Exposure time	Species	Sex	Value determina tion	Source
Oral (drinking water)	NOAEL	No effect		124 mg/kg bw/day		Rat (Rattus norvegicus )	F/M		ECHA
Inhalation	NOAEC	No effect	OECD 453	2080 mg/m <sup>3</sup>		Rat (Rattus norvegicus )	F/M		ECHA
Inhalation	NOAEC	Local effects		104 mg/m <sup>3</sup>		Rat (Rattus norvegicus )			ECHA
Inhalation	LOEC	Local effects		416 mg/m <sup>3</sup>		Rat (Rattus norvegicus )			ECHA

N,N-dimeth	nyl-p-toluid	ine							
Route of exposure	Parameter	Result	Method	Value	Exposure time	Species	Sex	Value determina tion	Source
Oral	LOAEL			6 mg/kg bw	2 years (5 days/week)	Rat (Rattus norvegicus )	F/M	Literary studies	ECHA
Inhalation (vapor)	LOAEL			67.284 mg/kg bw/day		Rat (Rattus norvegicus )	F/M	Literary studies	ECHA

#### **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

not available

## **Acute toxicity**

ethylene di	ethylene dimethacrylate										
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source				
LC50	OECD 203	15.95 mg/l	96 hours	Fish (Danio rerio)	Fresh water	Experimentally	ECHA				
LC <sub>0</sub>	OECD 203	6.25 mg/l	96 hours	Fish (Danio rerio)	Fresh water	Experimentally	ECHA				
LC100	OECD 203	25 mg/l	96 hours	Fish (Danio rerio)	Fresh water	Experimentally	ECHA				
EC <sub>0</sub>	OECD 202	19.8 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA				



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ethylene di	methacrylate						
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source
EC50	OECD 202	44.9 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	
EC100	OECD 202	100 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
NOEC	OECD 202	13.2 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
EC50	OECD 201	10.1-19 mg/l	96 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA
NOEC	OECD 201	0.804 mg/l	96 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA
EC50	OECD 201	9.1-17.3 mg/l	72 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA
EC <sub>10</sub>	OECD 201	6.93 mg/l	72 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA
EC50	OECD 209	570 mg/l	30 minutes	Microorganisms (Photobacteriu m phosphoreum)	Activated sludge	Indicator of growth	ECHA
EC10	OECD 209	100 mg/l	30 minutes	Microorganisms (Photobacteriu m phosphoreum)	Activated sludge	Indicator of growth	ECHA
EC50	OECD 209	570 mg/l	3 hours	Microorganisms (Photobacteriu m phosphoreum)	Activated sludge	Indicator of growth	ECHA
EC10	OECD 209	100 mg/l	3 hours	Microorganisms (Photobacteriu m phosphoreum)	Activated sludge	Indicator of growth	ECHA

methyl met	hacrylate						
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source
LC50	EPA OTS 797.1400	>79 mg/l	96 hours	Fish (Oncorhynchus mykiss)	Fresh water	Experimentally	ECHA
NOEC	EPA OTS 797.1400	40 mg/l	96 hours	Fish (Oncorhynchus mykiss)	Fresh water	Experimentally	ECHA
NOEC	EPA OTS 797.1300	48 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
EC50	EPA OTS 797.1300	69 mg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
EC50	OECD 201	>110 mg/kg	72 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA



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methyl met	nethyl methacrylate										
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source				
NOEC	OECD 201	110 mg/kg	72 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA				
NOEC	OECD 301C	100 mg/l	14 days	Microorganisms (Photobacteriu m phosphoreum)	Fresh water	Experimentally	ECHA				

N,N-dimethy	N,N-dimethyl-p-toluidine										
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source				
LC50	ASTM E 729	52.8 mg/l	96 hours	Fish (Pimephales promelas)	Fresh water	Experimentally	ECHA				
LC50		15.27 mg/l	48 hours	Algae (Daphnia magna)	Fresh water	Calculation of value	ECHA				
EC50	OECD 207	23.69 mg/l	72 hours	Algae (Daphnia magna)	Fresh water	Experimentally	ECHA				
EC50		100 mg/l	3 hours	Invertebrates	Fresh water	Experimentally	ECHA				

## **Chronic toxicity**

ethylene di	ethylene dimethacrylate									
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source			
EC50	OECD 211	5.05 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			
EC <sub>10</sub>	OECD 211	7.22 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			
NOEC	OECD 211	5.05 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			
LOEC	OECD 211	23.1-32.1 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			

methyl met	methyl methacrylate									
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source			
LOEC	OECD 210	18.8 mg/l	35 days	Fish (Danio rerio)	Fresh water	Experimentally	ECHA			
NOEC	OECD 210	9.4 mg/l	35 days	Fish (Danio rerio)	Fresh water	Experimentally	ECHA			
LC50	OECD 210	33.7 mg/l	35 days	Fish (Danio rerio)	Fresh water	Experimentally	ECHA			
NOEC	OECD 211	37 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			
LOEC	OECD 211	68 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA			



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methyl methacrylate									
Parameter	Method	Value	Exposure time	Species	Environm ent	Value determination	Source		
EC50	OECD 211	49 mg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA		

### 12.2. Persistence and degradability

not available

#### **Biodegradability**

ethylene dimethacrylate									
Parameter	Method	Value	Exposure time	Environmen t	Value determinatio n	Result	Source		
	OECD 301F	69 %	28 days	Activated sludge	Experimenta Ily	Easily biodegradable	ECHA		

methyl methacrylate									
Parameter	Method	Value	Exposure time	Environmen t	Value determinatio n	Result	Source		
% Degradation	OECD 301C	94 %	14 days	Fresh water	Experimenta Ily	Easily biodegradable	ECHA		

N,N-dimethyl-p-toluidine										
Parameter	Method	Value	Exposure time	Environmen t	Value determinatio n	Result	Source			
						Hardly biodegradable				

### 12.3. Bioaccumulative potential

Data not available.

ethylene dimethacrylate										
Parameter	Value	Exposure time	Species	Environment	Temperatur e [°C]	Value determinati on	Source			
BCF	21.9					Experiment ally	ECHA			

N,N-dimethyl-p-toluidine										
Parameter	Value	Exposure time	Species	Environment	Temperatur e [°C]	Value determinati on	Source			
BCF	29.09-33.19			Activated sludge		Calculation of value	ECHA			

### 12.4. Mobility in soil

Data not available.

### 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

Data not available.



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#### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

#### Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

#### Waste type code

16 03 03\* inorganic wastes containing hazardous substances

#### Packaging waste type code

15 01 10\* packaging containing residues of or contaminated by hazardous substances

(\*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

#### **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

Π

#### 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

### **Additional information**

Hazard identification No.

**UN** number

Classification code

Safety signs

339 1247

F1





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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 0
Tunnel 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 W8

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

#### **SECTION 15: Regulatory information**

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

#### 15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

### **SECTION 16: Other information**

A list of standard risk phrases used in the safety data sheet

H225 Highly flammable liquid and vapour.



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H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H335 May cause respiratory irritation.

H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects. H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P261 Avoid breathing vapours.

P264 Wash hands and exposed parts of the body thoroughly after handling.

P280 Wear protective gloves.

P362+P364 Take off contaminated clothing and wash it before reuse.

P370+P378 In case of fire: Use powder extinguisher/sand/carbon dioxide to extinguish.

#### 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<sub>0</sub> Concentration of a substance when it is affected 0% of the population EC<sub>10</sub> Concentration of a substance when it is affected 10% of the population EC100 Concentration of a substance when it is affected 100% of the population EC50 Concentration of a substance when it is affected 50% of the population **EINECS** European Inventory of Existing Commercial Chemical Substances

EmS Emergency plan

European Union **EuPCS** European Product Categorisation System International Air Transport Association IATA

**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<sub>0</sub> Lethal concentration of a substance in which it can be expected death of 0% of the

population

I C100 Lethal concentration of a substance in which it can be expected death of 100% of

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

population LD<sub>50</sub>

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

population LOAEC Lowest observed adverse effect concentration

LOAEL Lowest observed adverse effect level log Kow Octanol-water partition coefficient NOAEC No observed adverse effect concentration

NOAEL No observed adverse effect level NOEC No observed effect concentration OEL Occupational Exposure Limits

LC50

FU



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PBT Persistent, Bioaccumulative and Toxic

ppm Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Agreement on the transport of dangerous goods by rail

UN Four-figure identification number of the substance or article taken from the UN

Model Regulations

UVCB Substances of unknown or variable composition, complex reaction products or

biological materials

VOC Volatile organic compounds

vPvB Very Persistent and very Bioaccumulative

Acute Tox. Acute toxicity

Aquatic Chronic Hazardous to the aquatic environment (chronic)

Flam. Liq. Flammable liquid Skin Irrit. Skin irritation Skin Sens. Skin sensitization

STOT RE Specific target organ toxicity - repeated exposure 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)

Version 2.0 replaces the SDS version from 27.05.2021. Data updates and changes have been made to all sections of the SDS.

### **More information**

Classification procedure - calculation method.

#### **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.