

Mucopren adhesive

Revision date: 01/30/2024

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## 1. Identification

### Product identifier

Mucopren adhesive

### Recommended use of the chemical and restrictions on use

#### Use of the substance/mixture

Adhesive

Medical device for use in dentistry, observe instructions for use.

#### Uses advised against

Use by untrained dental personnel and/or unapproved areas of application.

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

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	D-35713 Eschenburg	
Telephone:	+ 49(0) 2774/705-0	Telefax: +49 (0)2774/705-66
E-mail:	info@kettenbach.com	
Internet:	www.kettenbach.com	
Responsible Department:	R&D	

### Further Information

The product is intended for professional use.

## 2. Hazard(s) identification

### Classification of the chemical

#### Regulation (EC) No 1272/2008

Flam. Liq. 2; H225  
Eye Irrit. 2; H319  
Skin Sens. 1; H317  
STOT SE 3; H336

Full text of hazard statements: see SECTION 16.

\*Safety Information Sheet for Medical Devices\* The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. In particular, they serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required in accordance with FDA regulations. This product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (29 CFR § 1910.1200). They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

### Label elements

#### Regulation (EC) No 1272/2008

#### Hazard components for labelling

ethyl acetate  
methyl methacrylate

Signal word: Danger

Pictograms:



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**Hazard statements**

H225	Highly flammable liquid and vapor
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness

**Precautionary statements**

P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P280	Wear protective gloves and eye protection/face protection.
P302+P352	If on skin: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Disposal of the contents/container in accordance with local/regional/national international regulations.

**Special labelling of certain mixtures**

95 - < 100 percent of the mixture consists of ingredient(s) of unknown toxicity (inhalation).  
< 1 % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment.

**Hazards not otherwise classified**

Formation of potentially explosive vapor/air mixtures is possible.

**3. Composition/information on ingredients**
**Mixtures**
**Chemical characterization**

Polymethyl methacrylate Copolymer in ethyl acetate.

**Hazardous components**

CAS No	Components			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
141-78-6	ethyl acetate			95 - < 100 %
	205-500-4	607-022-00-5	01-2119475103-46	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			
80-62-6	methyl methacrylate			1 - < 5 %
	201-297-1	607-035-00-6	01-2119452498-28	
	Flam. Liq. 2, Skin Irrit. 2, Skin Sens. 1, STOT SE 3; H225 H315 H317 H335			
1330-20-7	xylene			< 1 %
	215-535-7	601-022-00-9	01-2119488216-32	
	Flam. Liq. 3, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2; H226 H332 H312 H315			

Full text of H and EUH statements: see section 16.

**Specific Conc. Limits, M-factors and ATE**

CAS No	EC No	Components	Quantity
		Specific Conc. Limits, M-factors and ATE	
141-78-6	205-500-4	ethyl acetate	95 - < 100 %
		inhalation: Data lacking (gases); dermal: LD50 = >20000 mg/kg; oral: LD50 = 5620 mg/kg	
1330-20-7	215-535-7	xylene	< 1 %
		inhalation: LC50 = 19,8 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: ATE = 1100 mg/kg; oral: LD50 = 5000 mg/kg	

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#### 4. First-aid measures

##### Description of first aid measures

###### General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

###### After inhalation

Provide fresh air.

Seek medical attention if problems persist.

###### After contact with skin

After contact with skin, wash immediately with plenty of water and soap.

###### After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention.

Do NOT induce vomiting.

Give sodium sulfate as laxative (1 tablespoon in 1 glass of water).

##### Most important symptoms and effects, both acute and delayed

No known symptoms to date.

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

No data available

#### 5. Fire-fighting measures

##### Extinguishing media

###### Suitable extinguishing media

Extinguishing powder

Foam

Carbon dioxide (CO<sub>2</sub>)

###### Unsuitable extinguishing media

Water spray jet

##### Additional information

Take precautionary measures against static discharges.

#### 6. Accidental release measures

##### Personal precautions, protective equipment and emergency procedures

###### General advice

Remove all sources of ignition.

Use personal protection equipment.

###### For non-emergency personnel

Do not allow to enter into surface water or drains.

##### Environmental precautions

Do not allow to enter into surface water or drains.

##### Methods and material for containment and cleaning up

###### For containment

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

###### Other information

Wipe up with absorbent material (eg. cloth, fleece).

##### Reference to other sections

Safe handling: see section 7

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Personal protection equipment (PPE): see section 8  
Section 12: Ecological Information (non-mandatory)

## 7. Handling and storage

### Precautions for safe handling

#### Advice on safe handling

Wear personal protection equipment (refer to section 8).  
Avoid breathing vapours.

#### Advice on protection against fire and explosion

Take precautionary measures against static discharges.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

#### Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes.  
When using do not eat, drink, smoke, sniff.

#### Further information on handling

Keep locked up and out of reach of children.

### Conditions for safe storage, including any incompatibilities

#### Requirements for storage rooms and vessels

After use replace the closing cap immediately.  
Keep container tightly closed in a cool, well-ventilated place.

#### Hints on joint storage

Keep away from food and drink.

#### Further information on storage conditions

Please pay attention to the information on the package!

### Specific end use(s)

Not applicable.

## 8. Exposure controls/personal protection

### Control parameters

#### Exposure limits

CAS No	Substance	ppm	mg/m <sup>3</sup>	f/cc	Category	Origin
141-78-6	Ethyl acetate	400	1400		TWA (8 h)	PEL
		400	1400		TWA (8 h)	REL
80-62-6	Methyl methacrylate	100	410		TWA (8 h)	PEL
		100	410		TWA (8 h)	REL
1330-20-7	Xylenes (o-,m-,p-isomers)	100	435		TWA (8 h)	PEL

### Exposure controls

#### Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. If handled uncovered, arrangements with local exhaust ventilation have to be used.

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Eye glasses with side protection EN 166

##### Hand protection

When handling with chemical substances, protective clothing with CE-labels including the four control digits must be worn. Recommended glove articles EN ISO 374

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By short-term hand contact Suitable material:

Thickness of the glove material: 0,38mm

Breakthrough time:: -

By long-term hand contact: PE (polyethylene)

Thickness of the glove material: -

Breakthrough time:: >480 min

### Skin protection

Protective clothing.

Avoid contact with skin, eyes and clothes.

Take off contaminated clothing and wash it before reuse.

### Respiratory protection

Respiratory protection is not required when used properly and under normal conditions. Provide adequate ventilation.

Respiratory protection necessary at:

Suitable respiratory protection apparatus: Full-/half-/quarter-face masks (EN 136/140)

Suitable material: A2, B2, E2, K2, P3

### Environmental exposure controls

Do not allow to enter into surface water or drains.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state:

Color:

Odour threshold: No data available

Melting point/freezing point:

-84 °C

Boiling point or initial boiling point and

76,5 - 77,5 °C

boiling range:

Flammability:

No data available ISO 10156

Lower explosion limits:

2,1 vol. %

Upper explosion limits:

11,5 vol. %

Flash point:

ca. - 4 °C

Auto-ignition temperature:

No data available

Decomposition temperature:

No data available

pH-Value:

not applicable

Viscosity / kinematic:

No data available

Water solubility:

ca. 85 g/L

(at 20 °C)

Dissolution rate:

No data available

Partition coefficient n-octanol/water:

0,73

Dispersion stability:

No data available

Vapor pressure:

No data available

(at 20 °C)

Vapor pressure:

No data available

Density (at 20 °C):

> 0,9 g/cm<sup>3</sup>

Relative density:

No data available

Bulk density:

not applicable

Relative vapour density:

No data available g/cm<sup>3</sup>

(at 20 °C)

Particle characteristics:

not applicable

### Other information

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### Information with regard to physical hazard classes

Explosive properties

Formation of potentially explosive vapor/air mixtures is possible.

Sustaining combustion:

No data available

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

Oxidizing properties

none

### Other safety characteristics

Viscosity / dynamic:

0,44 mPa·s

## 10. Stability and reactivity

### Reactivity

Vapors may form explosive mixtures with air.

### Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

### Possibility of hazardous reactions

None by intended use.

### Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

### Hazardous decomposition products

No data available

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

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

: LD50: &gt; 5000 mg/kg Rat

#### ATEmix tested

	Dose	Species	Source
LD50, oral	5000 mg/kg	Rat	
LD50, dermal	18000 mg/kg	Rabbit	
LC50, inhalation (vapor)	mg/l	not applicable	

#### ATEmix calculated

ATE (inhalation vapour) &gt; 20 mg/l; ATE (inhalation dust/mist) &gt; 5 mg/l

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CAS No	Components				
	Exposure route	Dose	Species	Source	Method
141-78-6	ethyl acetate				
	oral	LD50 5620 mg/kg	Rat		
	dermal	LD50 >20000 mg/kg	Rabbit		
	inhalation	Data lacking			
1330-20-7	xylene				
	oral	LD50 5000 mg/kg	Rat	GESTIS	
	dermal	ATE 1100 mg/kg			
	inhalation (4 h) vapour	LC50 19,8 mg/l	Rat	GESTIS	
	inhalation dust/mist	ATE 1,5 mg/l			

### Irritation and corrosivity

Serious eye damage/eye irritation: Causes serious eye irritation

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: not applicable

### Sensitizing effects

May cause an allergic skin reaction (methyl methacrylate)

### Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

### Specific target organ toxicity (STOT) - single exposure

May cause drowsiness or dizziness (ethyl acetate)

### Specific target organ toxicity (STOT) - repeated exposure

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

### Aspiration hazard

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

### Information on other hazards

#### Further information

Harmful by inhalation and if swallowed.

: Vapors may cause drowsiness and dizziness.

Harmful: may cause lung damage if swallowed.

## 12. Ecological information

### Ecotoxicity

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

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CAS No	Components					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
141-78-6	ethyl acetate					
	Acute fish toxicity	LC50	230 mg/l	96 h	Pimephales promelas	
	Acute algae toxicity	ErC50	>100 mg/l	72 h	Desmodesmus subspicatus	
1330-20-7	xylene					
	Acute algae toxicity	ErC50	3,2 mg/l	72 h	Selenastrum capricornutum	Galassi et al. 1988

### Persistence and degradability

No data available

### Partition coefficient n-octanol/water

CAS No	Components	Log Pow
1330-20-7	xylene	3,15

### BCF

CAS No	Components	BCF	Species	Source
141-78-6	ethyl acetate	30		

### Mobility in soil

The product has not been tested.

### Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### Other adverse effects

None known.

## 13. Disposal considerations

### Waste treatment methods

#### **Disposal recommendations**

Do not remove with domestic waste. Do not allow to enter drains or watercourses.

Dispose in accordance with official regulations.

#### **List of Wastes Code - used product**

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

#### **List of Wastes Code - contaminated packaging**

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

## 14. Transport information

### **Land transport (ADR/RID)**

**UN number or ID number:**

UN 1173

**UN proper shipping name:**

ETHYL ACETATE



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**Transport hazard class(es):** 3

**Packing group:** II

Hazard label: 3



Classification Code: F1

Limited quantity: 1 L

Excepted quantity: E2

Transport category: 2

Hazard No: 33

Tunnel restriction code: D/E

### Inland waterways transport (ADN)

**UN number or ID number:** UN 1173

**UN proper shipping name:** ETHYL ACETATE

**Transport hazard class(es):** 3

**Packing group:** II

Hazard label: 3



Classification Code: F1

Limited quantity: 1 L

Excepted quantity: E2

### Marine transport (IMDG)

**UN number or ID number:** UN 1173

**UN proper shipping name:** ETHYL ACETATE

**Transport hazard class(es):** 3

**Packing group:** II

Hazard label: 3



Special Provisions: -

Limited quantity: 1 L

Excepted quantity: E2

EmS: F-E, S-D

### Air transport (ICAO-TI/IATA-DGR)

**UN number or ID number:** UN 1173

**UN proper shipping name:** ETHYL ACETATE

**Transport hazard class(es):** 3

**Packing group:** II

Hazard label: 3



Limited quantity Passenger: 1 L

Passenger LQ: Y341

Excepted quantity: E2

IATA-packing instructions - Passenger: 353

IATA-max. quantity - Passenger: 5 L

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IATA-packing instructions - Cargo:	364
IATA-max. quantity - Cargo:	60 L

**Environmental hazards**

ENVIRONMENTALLY HAZARDOUS:	No
Danger releasing substance:	Not applicable.

**Special precautions for user**

not relevant

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

**15. Regulatory information**
**Safety, health and environmental regulations/legislation specific for the substance or mixture**
**EU regulatory information**

Restrictions on use (REACH, annex XVII):  
Entry 3, Entry 40, Entry 75

**National regulatory information**

Water hazard class (D):	3 - highly hazardous to water
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**Chemical Safety Assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**16. Other information**
**Changes**

This data sheet contains changes from the previous version in section(s): 1,2,16.  
Date of preparation / Revised on: 30/01/2024  
Version number: 3,11  
Replaces version number: 3,10 (31/10/2023)

**Abbreviations and acronyms**

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL: Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration. GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

**Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008**

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
STOT SE 3; H336	Calculation method

**Relevant H statements (full text)**

H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H312	Harmful in contact with skin
H315	Causes skin irritation

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H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
EUH066	Repeated exposure may cause skin dryness or cracking.

### Other data

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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*(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*