Kettenbach GmbH & Co. KG

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## **Safety Data Sheet**

#### Mucopren adhesive

Revision date: 08/29/2023 Product code: Mucopren\_Adhesive Page 1 of 10

## 1. Identification

#### **Product identifier**

Mucopren adhesive

#### Further trade names

Mucopren Adhesive Mucopren Adhesive Fast

#### 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

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 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

Signal word: Danger



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## Pictograms:





#### **Hazard statements**

H225 Highly flammable liquid and vapor
 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.

P233 Keep container tightly closed.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P403+P235 Store in a well-ventilated place. Keep cool.

## **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				
	EC No	Index No	REACH No		
	Classification (Regulation (EC) No	1272/2008)			
141-78-6	ethyl acetate			90 - < 95 %	
	205-500-4	607-022-00-5	01-2119475103-46		
	Flam. Liq. 2, Eye Irrit. 2, STOT SE				
	Reaction mass of 9011-14-7 and 9		<10 %		
	933-551-9				
	Skin Irrit. 2, Eye Irrit. 2; H315 H319				
1330-20-7	xylene		<0,5 %		
	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. L	Specific Conc. Limits, M-factors and ATE			
141-78-6	205-500-4	ethyl acetate	90 - < 95 %		
	inhalation: Data lacking (gases); dermal: LD50 = >20000 mg/kg; oral: LD50 = 5620 mg/kg				
1330-20-7	215-535-7	xylene	<0,5 %		
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: ATE = 1100 mg/kg				

## 4. First-aid measures

## **Description of first aid measures**



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#### **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.

#### After contact with skin

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

#### After indestion

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 (CO2)

#### 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

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

# 7. Handling and storage



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#### 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/m³	f/cc	Category	Origin
141-78-6	Ethyl acetate	400	1400		TWA (8 h)	PEL
		400	1400		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

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



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#### 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

Test method

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 DIN 51758

Auto-ignition temperature:

Decomposition temperature:

PH-Value:

Viscosity / kinematic:

No data available

not applicable

No data available

No data available

available

viscosity / kinematic:

No data available

Vater solubility:

ca. 85 g/L

(at 20 °C)

Dissolution rate:

Partition coefficient n-octanol/water:

Dispersion stability:

Vapor pressure:

No data available

No data available

(at 20 °C)

Vapor pressure:

Density (at 20 °C):

Relative density:

No data available

> 0,9 g/cm³

No data available

not applicable

Relative vapour density:

No data available g/cm³

(at 20 °C)

Particle characteristics: not applicable

## **Other information**

#### 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

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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: > 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

CAS No	Components								
	Exposure route	Dose		Species	Source	Method			
141-78-6	ethyl acetate	ethyl acetate							
	oral	LD50 mg/kg	5620	Rat					
	dermal	LD50 mg/kg	>20000	Rabit					
	inhalation	Data lack	king						
1330-20-7	xylene								
	dermal	ATE mg/kg	1100						
	inhalation vapour	ATE	11 mg/l						
	inhalation dust/mist	ATE	1,5 mg/l						

#### Irritation and corrosivity

Causes serious eye irritation

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

Skin corrosion/irritation: not applicable

## Sensitizing effects

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



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#### Carcinogenic/mutagenic/toxic effects for reproduction

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.

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 mg/l	>100		Desmodesmus subspicatus		

## Persistence and degradability

No data available

## 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



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#### 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

Transport hazard class(es):

Packing group:

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):3Packing group:IIHazard 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):3Packing group:IIHazard label:3



Special Provisions:

Limited quantity:

Excepted quantity:

E2

EmS:

F-E, S-D

Air transport (ICAO-TI/IATA-DGR)

UN 1173

UN proper shipping name: ETHYL ACETATE



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Transport hazard class(es):

Packing group:

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
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

## **Chemical Safety Assessment**

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

#### 16. Other information

### Changes

Date of preparation / Revised on: 29/08/2023

Version number: 3,10

Replaces version number: 3,09 (03/03/2021)

## 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 – 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.



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## Classification for mixtures and used evaluation method according to GHS

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Eye Irrit. 2; H319	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
H319	Causes serious eye irritation
⊔າາາ	Harmful if inhalad

H332 Harmful if inhaled

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.

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