

# Safety Data Sheet

according to UK REACH Regulation

## Universal Adhesive

Revision date: 31.07.2023

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

#### 1.1. Product identifier

Universal Adhesive

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

##### Use of the substance/mixture

Adhesive for Kettenbach addition-curing impression material and reline impression materials.  
Medical device for use in dentistry, observe instructions for use.

#### 1.3. 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.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### GB CLP Regulation

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. 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 according to the Article 31 and Annex II of Regulation (EC) No 1907/2006 (REACH Regulation). This product is classified as a medical device. Medical devices are exempt from the labelling provisions. 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.

#### 2.2. Label elements

##### GB CLP Regulation

##### Hazard components for labelling

ethyl acetate

Signal word: Danger

##### Pictograms:



##### Hazard statements

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

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### Precautionary statements

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P280 Wear protective gloves/protective clothing and 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.

### Special labelling of certain mixtures

- EUH066 Repeated exposure may cause skin dryness or cracking.  
55 - < 60 per cent of the mixture consists of component(s) of unknown acute toxicity (inhalation).

### 2.3. Other hazards

Formation of potentially explosive vapor/air mixtures is possible.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Chemical characterization

Preparation based on silicone resin in organic solvents.

#### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (GB CLP Regulation)			
141-78-6	ethyl acetate			40-70 %
	205-500-4	607-022-00-5	01-2119475103-46	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336 EUH066			

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

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

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
141-78-6	205-500-4	ethyl acetate	40-70 %
	inhalation: Data lacking (gases); dermal: LD50 = >20000 mg/kg; oral: LD50 = 5620 mg/kg		

## SECTION 4: First aid measures

### 4.1. 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.

#### After contact with skin

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

#### After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

#### After ingestion

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

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

No known symptoms to date.

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

No data available

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

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Extinguishing powder  
Foam  
Carbon dioxide (CO<sub>2</sub>)

##### **Unsuitable extinguishing media**

Water

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

Vapours may form explosive mixtures with air.

#### **5.3. Advice for firefighters**

Co-ordinate fire-fighting measures to the fire surroundings.

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

##### **General advice**

Remove all sources of ignition.  
Use personal protection equipment.

#### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

#### **6.3. Methods and material for containment and cleaning up**

##### **For containment**

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

#### **6.4. Reference to other sections**

No release of hazardous substances.  
Personal protection equipment: see section 8

### **SECTION 7: Handling and storage**

#### **7.1. Precautions for safe handling**

##### **Advice on safe handling**

Keep away from sources of ignition - No smoking.  
Wear personal protection equipment (refer to section 8).

##### **Advice on protection against fire and explosion**

Take precautionary measures against static discharges.

##### **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.

#### **7.2. Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage rooms and vessels**

Keep container tightly closed and store in a cool place.  
Store in the original container only.

##### **Hints on joint storage**

Keep away from food and drink.

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### Further information on storage conditions

Please pay attention to the information on the package!

### 7.3. Specific end use(s)

Not applicable.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
141-78-6	Ethyl acetate	200	734		TWA (8 h)	WEL
		400	1468		STEL (15 min)	WEL

### 8.2. Exposure controls

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

##### Eye/face protection

Safety glasses.

##### Hand protection

Disposable gloves

Hand protection: Suitable material: Butyl caoutchouc (butyl rubber)

Wash hands before breaks and after work.

Protect skin by using skin protective cream.

##### Skin protection

Protective clothing.

Avoid contact with skin, eyes and clothes.

Take off contaminated clothing and wash it before reuse.

##### Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Provide adequate ventilation.

##### Environmental exposure controls

Do not allow to enter into surface water or drains.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	red
Odour:	ester-like
Odour threshold:	No data available

#### Test method

Melting point/freezing point:	-84 °C °C	
Boiling point or initial boiling point and boiling range:	77 °C	
Flammability:	No data available	
Lower explosion limits:	2,1 vol. %	
Upper explosion limits:	11,5 vol. %	
Flash point:	-4 °C	DIN EN ISO 2719
Auto-ignition temperature:	No data available	
Decomposition temperature:	No data available	
pH-Value:	No data available	

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Viscosity / kinematic:	No data available
Water solubility:	No data available
Solubility in other solvents	
No data available	
Dissolution rate:	No data available
Partition coefficient n-octanol/water:	No data available
Dispersion stability:	No data available
Vapour pressure:	No data available
Vapour pressure:	No data available
Density:	No data available
Relative density (at 20 °C):	>0,9
Bulk density:	not applicable
Relative vapour density:	No data available
Particle characteristics:	not applicable

#### **9.2. 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

Gas:

not applicable

Oxidizing properties

not applicable

### SECTION 10: Stability and reactivity

#### **10.1. Reactivity**

Vapours can form explosive mixtures with air.

#### **10.2. Chemical stability**

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

#### **10.3. Possibility of hazardous reactions**

None by intended use.

#### **10.4. Conditions to avoid**

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

#### **10.5. Incompatible materials**

None by intended use.

Oxidizing agent

#### **10.6. Hazardous decomposition products**

Formaldehyde

#### **Further information**

Heating may cause a fire.

### SECTION 11: Toxicological information

#### **11.1. Information on hazard classes as defined in GB CLP Regulation**

##### **Acute toxicity**

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

##### **ATEmix calculated**

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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CAS No	Chemical name				
	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			

#### 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.

Repeated exposure may cause skin dryness or cracking.

#### Sensitising effects

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

#### 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.

#### STOT-single exposure

May cause drowsiness or dizziness. (ethyl acetate)

#### 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.

## SECTION 12: Ecological information

### 12.1. Toxicity

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

CAS No	Chemical name					
	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		

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

#### BCF

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

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

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

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#### **12.6. 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.

#### **12.7. Other adverse effects**

None known.

### SECTION 13: Disposal considerations

#### **13.1. Waste treatment methods**

##### **Disposal recommendations**

Do not remove with domestic waste.

##### **List of Wastes Code - residues/unused products**

180106 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE); wastes from natal care, diagnosis, treatment or prevention of disease in humans; chemicals consisting of or containing hazardous substances; hazardous waste

##### **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

##### **Contaminated packaging**

Non-contaminated packages may be recycled.

### SECTION 14: Transport information

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

<b><u>14.1. UN number or ID number:</u></b>	UN 1866
<b><u>14.2. UN proper shipping name:</u></b>	RESIN SOLUTION
<b><u>14.3. Transport hazard class(es):</u></b>	3
<b><u>14.4. Packing group:</u></b>	II
Hazard label:	3



Classification code:	F1
Special Provisions:	640D
Limited quantity:	5 L
Excepted quantity:	E2
Transport category:	2
Hazard No:	33
Tunnel restriction code:	D/E

#### **Inland waterways transport (ADN)**

<b><u>14.1. UN number or ID number:</u></b>	UN 1866
<b><u>14.2. UN proper shipping name:</u></b>	Resin solution
<b><u>14.3. Transport hazard class(es):</u></b>	3
<b><u>14.4. Packing group:</u></b>	II

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Hazard label: 3



Classification code: F1  
 Special Provisions: 640D  
 Limited quantity: 5 L  
 Excepted quantity: E2

#### Marine transport (IMDG)

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** RESIN SOLUTION  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Special Provisions: -  
 Limited quantity: 5 L  
 Excepted quantity: E2  
 EmS: F-E, S-E

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

**14.1. UN number or ID number:** UN 1866  
**14.2. UN proper shipping name:** RESIN SOLUTION  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** II  
 Hazard label: 3



Special Provisions: A3  
 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

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No  
 Danger releasing substance: not applicable

#### 14.6. Special precautions for user

not applicable

#### 14.7. Maritime transport in bulk according to IMO instruments

not applicable

### SECTION 15: Regulatory information

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

##### EU regulatory information



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Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

#### National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

#### 15.2. Chemical safety assessment

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

### SECTION 16: Other information

#### Changes

Date of preparation / Revised on: 31/07/2023

Version number: 1,01

Replaces version number: 1,00 (01/06/2023)

#### 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 GB CLP Regulation

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 and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.  
EUH066 Repeated exposure may cause skin dryness or cracking.

#### Further Information

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