

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Identium® Adhesive

Revision date: 01/11/2024

Product code: 14204

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1. Identification

Product identifier

Identium® Adhesive

Recommended use of the chemical and restrictions on use

Use of the substance/mixture

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

Details of the supplier of the safety data sheet

Company name:	Kettenbach GmbH & Co. KG	
Street:	Im Heerfeld 7	
Place:	NL-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

29 CFR Part 1910.1200

Flammable liquids: Flam. Liq. 2

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Dam. 1

Specific target organ toxicity single exposure: STOT SE 3 (narcotic effects)

Specific target organ toxicity repeated or prolonged exposure: STOT RE 2

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

29 CFR Part 1910.1200

Signal word: Danger

Pictograms:



Hazard statements

Highly flammable liquid and vapor

Causes skin irritation

Causes serious eye damage

May cause drowsiness or dizziness

May cause damage to organs through prolonged or repeated exposure

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Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.
In case of fire: Use sand, extinguishing powder or alcohol-resistant foam to extinguish.
Get medical advice/attention if you feel unwell.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Hazards not otherwise classified

Formation of potentially explosive vapor/air mixtures is possible.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Mixture based on silicone resin in organic solvents.

Hazardous components

CAS No	Components	Quantity
141-78-6	ethyl acetate	45 - <50 %
1330-20-7	xylene	5 - <10 %
5593-70-4	Tetrabutyl orthotitanate	1 - <5 %
100-41-4	ethylbenzene	1 - <5 %

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.

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.

Most important symptoms and effects, both acute and delayed

Symptoms may be delayed. Narcotic effect. Vapor concentrations above recommended exposure levels are irritating to the eyes and the respiratory tract, may cause headaches and dizziness, are anesthetic and may have other severe central nervous system effects. Drowsiness, dizziness, disorientation, vertigo.

Indication of any immediate medical attention and special treatment needed

Wash off promptly and flush contaminated skin with water. Promptly remove clothing if soaked through and flush skin with water. If swallowed, do NOT induce vomiting. Give a glass of water. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.

5. Fire-fighting measures

Extinguishing media

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Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

Avoid water in straight hose stream; will scatter and spread fire.

Special protective equipment and precautions for fire-fighters

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

Do not allow to enter into surface water or drains.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General advice

Remove all sources of ignition.

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

Other information

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

Reference to other sections

No release of hazardous substances.

Personal protection equipment (PPE): see section 8

7. Handling and storage

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.

Wash hands before breaks and after work.

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

Keep container tightly closed and store in a cool place.

Hints on joint storage

Keep away from food and drink.

Further information on storage conditions

Protect against:

8. Exposure controls/personal protection

Control parameters

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Exposure limits

CAS No	Substance	ppm	mg/m ³	f/cc	Category	Origin
141-78-6	Ethyl acetate	400	1400		TWA (8 h)	PEL
		400	1400		TWA (8 h)	REL
100-41-4	Ethyl benzene	100	435		TWA (8 h)	PEL
		100	435		TWA (8 h)	REL
		125	545		STEL (15 min)	REL
1330-20-7	Xylenes (o-,m-,p-isomers)	100	435		TWA (8 h)	PEL

Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses.

Hand protection

Disposable gloves

Suitable material: Butyl caoutchouc (butyl rubber)

Wash hands before breaks and after work.

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.

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:	Liquid
Color:	blue
Odor:	Aromatic
Odour threshold:	No data available
Melting point/freezing point:	<-60 °C
Boiling point or initial boiling point and boiling range:	>70 °C
Flammability:	No data available
Lower explosion limits:	2,1 vol. %
Upper explosion limits:	11,5 vol. %
Flash point:	3 °C
Auto-ignition temperature:	> 400 °C
Decomposition temperature:	No data available
pH-Value:	No data available
Viscosity / kinematic:	No data available
Water solubility: (at 20 °C)	practically insoluble
Solubility in other solvents	
No data available	
Dissolution rate:	No data available

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Partition coefficient n-octanol/water:	No data available
Dispersion stability:	not applicable
Vapor pressure: (at 20 °C)	< 102 hPa
Density (at 20 °C):	<1,1 g/cm ³
Relative density:	No data available
Bulk density:	not applicable
Relative vapour density:	No data available
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

Gas:

not applicable

Oxidizing properties

not applicable

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.

Incompatible materials

None by intended use.

Oxidizing agent

Hazardous decomposition products

Formaldehyde

Further information

Heating may cause a fire.

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

non-irritant.

irritant.

Respiratory or skin sensitization:

ATEmix calculated

ATE (oral) 70000,0 mg/kg; ATE (dermal) 11000,0 mg/kg; ATE (inhalation vapour) 58,83 mg/l; ATE (inhalation dust/mist) 10,000 mg/l

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CAS No	Components					
	Exposure route	Dose	Species	Source	Method	
1330-20-7	xylene					
	dermal	ATE 1100 mg/kg				
	inhalation vapour	ATE 11 mg/l				
	inhalation dust/mist	ATE 1,5 mg/l				
5593-70-4	Tetrabutyl orthotitanate					
	oral	LD50 2000 mg/kg	Rat			
	dermal	LD50 5300 mg/kg				
	inhalation vapour	LC50 20 mg/l				
100-41-4	ethylbenzene					
	oral	LD50 3500 mg/kg	Rat	GESTIS		
	dermal	LD50 15400 mg/kg	Rabbit	GESTIS		
	inhalation (4 h) vapour	LC50 17,2 mg/l	Rat			
	inhalation dust/mist	ATE 1,5 mg/l				

Irritation and corrosivity

- Causes skin irritation
- Causes serious eye damage

Sensitizing effects

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

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

May cause damage to organs through prolonged or repeated exposure (ethylbenzene)

Carcinogenicity (IARC): Ethylbenzene (CAS 100-41-4) is listed in group 2B.

Aspiration hazard

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

Additional information on tests

No data available.

Further information

- Harmful by inhalation and if swallowed.
- : Vapors may cause drowsiness and dizziness.
- Harmful: may cause lung damage if swallowed.

12. Ecological information

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.

13. Disposal considerations

Waste treatment methods

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Disposal recommendations

Do not remove with domestic waste. Do not allow to enter drains or watercourses.
Dispose in accordance with official regulations.

14. Transport information

U.S. DOT 49 CFR 172.101

UN number or ID number: UN 1866
Proper shipping name: RESIN SOLUTION
Transport hazard class(es): 3
Packing group: II
 Hazard label: 3



Marine transport (IMDG)

UN number or ID number: UN 1866
UN proper shipping name: RESIN SOLUTION
Transport hazard class(es): 3
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)

UN number or ID number: UN 1866
UN proper shipping name: RESIN SOLUTION
Transport hazard class(es): 3
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

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No
 Danger releasing substance: Not applicable.

Special precautions for user

not relevant

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

not applicable

15. Regulatory information

U.S. Regulations

National regulatory information

SARA Section 304 CERCLA:

Ethyl acetate (141-78-6): Reportable quantity = 5,000 (2270) lbs. (kg)

Xylene (mixed isomers) (1330-20-7): Reportable quantity = 100 (45.4) lbs. (kg)

Ethylbenzene (100-41-4): Reportable quantity = 1,000 (454) lbs. (kg)

SARA Section 311/312 Hazards:

Ethyl acetate (141-78-6): Fire hazard, Immediate (acute) health hazard

Xylene (mixed isomers) (1330-20-7): Fire hazard, Immediate (acute) health hazard

Tetrabutyl orthotitanate (5593-70-4): Fire hazard, Immediate (acute) health hazard

Ethylbenzene (100-41-4): Fire hazard, Immediate (acute) health hazard, Delayed (chronic) health hazard

SARA Section 313 Toxic release inventory:

Xylene (mixed isomers) (1330-20-7): De minimis limit = 1.0 %, Reportable threshold = Standard

Ethylbenzene (100-41-4): De minimis limit = 0.1 %, Reportable threshold = Standard

Clean Air Act Section 112(b):

Xylene (mixed isomers) (1330-20-7), Ethylbenzene (100-41-4)

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

WARNING: This product can expose you to chemicals including Ethylbenzene (cancer), which are known to the State of California to cause cancer, birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

16. Other information

Hazardous Materials Information Label (HMIS)

Health: 3

Flammability: 3

Physical Hazard: 0

Personal Protection: B

NFPA Hazard Ratings

Health: 3

Flammability: 3

Reactivity: 0

Unique Hazard:



Changes

Revision date: 01/11/2024

Revision No: 1,02

Date of preparation / Revised on: 11/01/2024

Version number: 1,02

Replaces version number: 1,01 (17/05/2018)

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:

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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.

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.)