

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.01.2024

Version: 8

Revision: 23.01.2024

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

- **1.1 Product identifier**
- **Trade name:** Link-Automix Attachment Kleber
- **Article number:** 438225, 438227, 160002
- **UFI:** J330-D0NV-P00S-NY2H
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** see point 3)
- **1.3 Details of the supplier of the safety data sheet**
- **Further information obtainable from:** R&D, MANI MEDICAL GERMANY GmbH, Tel: +049 6003/8286-0
- **1.4 Emergency telephone number:**
+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or
+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate
dibenzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
H413 May cause long lasting harmful effects to aquatic life.
- **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
tetramethylene dimethacrylate

(Contd. on page 2)

Safety data sheet

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Trade name: Link-Automix Attachment Kleber

(Contd. of page 1)

*dibenzoyl peroxide***· Hazard statements***H317 May cause an allergic skin reaction.**H413 May cause long lasting harmful effects to aquatic life.***· Precautionary statements***P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves.**P333+P313 If skin irritation or rash occurs: Get medical advice/attention.**P321 Specific treatment (see on this label).**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 Mixtures****· Description:** Adhesive material for dental use.**· Dangerous components:**

CAS: 56744-60-6 EINECS: 260-363-8	Bisphenol-A-ethoxylat(4)dimethacrylat Aquatic Chronic 4, H413	25-50%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate ⚠ Skin Sens. 1B, H317	2.5-10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ⚠ Org. Perox. B, H241; ⚠ Aquatic Chronic 1, H410; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	<2.5%

· Additional information For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information** Immediately remove any clothing soiled by the product.**· After inhalation** Supply fresh air; consult doctor in case of complaints.**· After skin contact***If skin irritation continues, consult a doctor.**Immediately wash with water and soap and rinse thoroughly.***· After eye contact***Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.***· After swallowing** Seek medical treatment.**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 4.3 Indication of any immediate medical attention and special treatment needed***No further relevant information available.***SECTION 5: Firefighting measures****· 5.1 Extinguishing media****· Suitable extinguishing agents** Use fire extinguishing methods suitable to surrounding conditions.**· 5.2 Special hazards arising from the substance or mixture** No further relevant information available.**· 5.3 Advice for firefighters****· Protective equipment:** Wear self-contained respiratory protective device.

(Contd. on page 3)

Safety data sheet

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Revision: 23.01.2024

Trade name: *Link-Automix Attachment Kleber*

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid eye and skin contact with the substance.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Send for recovery or disposal in suitable receptacles.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Store in refrigerator.
Storage between 15 °C and 30 °C in a dry and well-aired place. Avoid heating the material to over 50 °C and cooling it below 5 °C.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Hand protection** Protective gloves.
- **Material of gloves**
Nitrile rubber, NBR
Butyl rubber, BR
- **Penetration time of glove material**
0,3 mm
Penetration time 60 min.
0,11 mm
Penetration time 10 min.
- **Eye/face protection** Safety glasses

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.01.2024

Version: 8

Revision: 23.01.2024

Trade name: Link-Automix Attachment Kleber

(Contd. of page 3)

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	Different according to colouring
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	< - 20 ° C undetermined
· Boiling point or initial boiling point and boiling range	151 ° C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	201 ° C
· Auto-ignition temperature:	>370 ° C
· Decomposition temperature:	Not determined.
· pH	Mixture is non-soluble (in water). Not determined.
· Viscosity:	
· Kinematic viscosity	Not determined.
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	1,3 mbar (110 ° C) Not determined.
· Density and/or relative density	
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.

· 9.2 Other information

· Appearance:	
· Form:	Viscous
· Important information on protection of health and environment, and on safety.	
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Change in condition	
· Evaporation rate	Not determined.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void

(Contd. on page 5)

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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.01.2024

Version: 8

Revision: 23.01.2024

Trade name: Link-Automix Attachment Kleber

(Contd. of page 4)

· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:**
In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **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** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

· Endocrine disrupting properties

128-37-0 Butylated hydroxytoluene

List II

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

(Contd. on page 6)

Safety data sheet

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(Contd. of page 5)

· **12.7 Other adverse effects**

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

· **Recommendation**

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

08 04 10	waste adhesives and sealants other than those mentioned in 08 04 09
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· **Uncleaned packaging:**

· **Recommendation:**

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information

· **14.1 UN number or ID number**

· **ADR, ADN, IMDG, IATA** Void

· **14.2 UN proper shipping name**

· **ADR, ADN, IMDG, IATA** Void

· **14.3 Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** Void

· **14.4 Packing group**

· **ADR, IMDG, IATA** Void

· **14.5 Environmental hazards:**

· **Marine pollutant:** No

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **UN "Model Regulation":**

Void

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

(Contd. on page 7)

Safety data sheet

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(Contd. of page 6)

· **REGULATION (EU) 2019/1148**· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

· **National regulations**· **Technical instructions (air):**

Class	Share in %
III	2.5-10

· **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.* **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS: F & E**· **Contact:** Fr. R.Naveenakumar· **Date of previous version:** 07.11.2022· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides – Type B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**