

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 12 Jul 2021

Print date: 22 Jul 2021

Version: 2.0

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Metal adhesive (resin)

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

1.1 Product identifier

Trade name/designation:

Metal adhesive (resin)

Other means of identification:

UFI: XRVY-38TV-6008-1DH2

Article No.:

10070, 10071

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

Use of the substance/mixture:

dental application.

For professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Mälzer Dental GmbH & Co. KG

Schlesierweg 27

31515 Wunstorf

GERMANY

Telephone: +49 (0) 5033 963099-0

Telefax: +49 (0) 5033 963099-99

E-mail: info@maelzer-dental.de

Website: <https://www.maelzer-dental.de>

E-mail (competent person): info@maelzer-dental.de

1.4 Emergency phone number

24h: +49 (0) 551 19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard classes and hazard categories	Hazard statements	Classification procedure
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	Calculation
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	Calculation
Serious eye damage/eye irritation (<i>Eye Irrit. 2</i>)	H319: Causes serious eye irritation.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	Calculation

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms:



GHS07

Exclamation mark



GHS09

Environment

Signal word: Warning

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Hazard components for labelling:

Bisphenol A Epoxid Resin

Hazard statements for health hazards

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Hazard statements for environmental hazards

H411	Toxic to aquatic life with long lasting effects.
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Precautionary statements - Prevention

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response

P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.

Special rules on packaging:

Labelling for packages ≤ 125 ml:

Hazard pictograms: GHS07, GHS09

Signal word: Warning

Hazard components for labelling: Contains Bisphenol A Epoxid Resin.

Safety information: May cause an allergic skin reaction. IF ON SKIN: Wash with plenty of soap and water.

Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs:

Get medical advice/attention.

2.3 Other hazards

No data available.



SECTION 3: Composition / information on ingredients

3.2 Mixtures

Additional information:

The product does not contain substances of very high concern (SVHC) $\geq 0,1$ %.

Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
CAS No.: 25068-38-6 EC No.: 500-033-5 REACH No.: 01-2119456619-26	Bisphenol A Epoxid Resin Aquatic Chronic 2, Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1   Warning H315-H317-H319-H411	25 - \leq 50 weight-%
CAS No.: 7727-43-7 EC No.: 231-784-4 REACH No.: 01-2119491274-35	barium sulfate Aquatic Chronic 3 H412	10 - \leq 25 weight-%
CAS No.: 14807-96-6 EC No.: 238-877-9 REACH No.: 01-2120140278-58	Talc (Mg₃H₂(SiO₃)₄) The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	\leq 10 weight-%

Full text of H- and EUH-phrases: see section 16.

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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). Remove victim out of the danger area. Remove contaminated, saturated clothing immediately. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air. Get medical advice/attention if you feel unwell.

In case of skin contact:

After contact with skin, wash immediately with plenty of water and soap. If skin irritation or rash occurs: Get medical advice/attention.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion:

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Get immediate medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, Extinguishing powder, Carbon dioxide (CO₂)

5.2 Special hazards arising from the substance or mixture

Pressurised container: May burst if heated.

Hazardous combustion products:

In case of fire may be liberated: carbon oxides (CO_x); sulphur oxides (SO_x); halogenated hydrocarbons; metal oxides

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4 Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Personal precautions:

Provide adequate ventilation. Avoid contact with eyes and skin. Clear spills immediately. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection. See section 8.

6.1.2 For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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6.3 Methods and material for containment and cleaning up

For containment:

Wipe up with absorbent material (eg. cloth, fleece). Handling larger quantities: Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

For cleaning up:

Water with tenside additive

6.4 Reference to other sections

Safe handling: see section 7.

Personal protection equipment: see section 8.

Disposal: see section 13.

6.5 Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures

Advices on safe handling:

Provide adequate ventilation as well as local exhaustion at critical locations. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes and clothes. Persons with a history of skin sensitisation problems should not be employed in any process in which this product is used. Take off immediately all contaminated clothing. Wear personal protection equipment (refer to section 8).

Fire prevent measures:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Environmental precautions:

Discharge into the environment must be avoided.

Advices on general occupational hygiene

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Take off contaminated clothing and wash it before reuse. Apply skin care products after work.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Protect from sunlight.

Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container.

Hints on storage assembly:

Do not store together with: Acids, Alkali (lye), Oxidising agent. Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

Recommendation:

dental application.

Observe instructions for use.

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SECTION 8: Exposure controls / Personal protection

8.1 Control parameters

8.1.1 Occupational exposure limit values

Limit value type (country)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
WEL (GB)	barium sulfate CAS No.: 7727-43-7	① 10 mg/m ³ ⑤ (inhalable fraction)
WEL (GB)	barium sulfate CAS No.: 7727-43-7	① 4 mg/m ³ ⑤ (respirable fraction)
WEL (GB)	Talc (Mg ₃ H ₂ (SiO ₃) ₄) CAS No.: 14807-96-6	① 1 mg/m ³ ⑤ (respirable fraction)

8.1.2 Biological limit values

No data available.

8.1.3 DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	12.25 mg/m ³	① DNEL worker ② Long-term - inhalation, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	12.25 mg/m ³	① DNEL worker ② Acute - inhalation, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	8.33 mg/kg bw/day	① DNEL worker ② Long-term - dermal, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	3.571 mg/kg bw/day	① DNEL consumer ② Long-term - dermal, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	8.33 mg/kg bw/day	① DNEL worker ② Acute - dermal, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	3.571 mg/kg bw/day	① DNEL consumer ② Acute - dermal, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.75 mg/kg bw/day	① DNEL consumer ② Long-term - oral, systemic effects
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.75 mg/kg bw/day	① DNEL consumer ② Acute - oral, systemic effects
barium sulfate CAS No.: 7727-43-7	10 mg/m ³	① DNEL worker ② Long-term - inhalation, systemic effects
barium sulfate CAS No.: 7727-43-7	10 mg/m ³	① DNEL consumer ② Long-term - inhalation, systemic effects
barium sulfate CAS No.: 7727-43-7	13,000 mg/ kg bw/day	① DNEL consumer ② Long-term - oral, systemic effects

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Substance name	PNEC value	① PNEC type
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.006 mg/L	① PNEC aquatic, freshwater
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.0006 mg/L	① PNEC aquatic, marine water
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	10 mg/L	① PNEC sewage treatment plant
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.996 mg/kg	① PNEC sediment, marine water
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	11 mg/kg	① PNEC secondary poisoning
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.018 mg/L	① PNEC aquatic, intermittent release
Bisphenol A Epoxid Resin CAS No.: 25068-38-6	0.196 mg/kg bw/day	① PNEC soil, marine water

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. Technical ventilation of workplace / Provide adequate ventilation.

8.2.2 Personal protection equipment



Eye/face protection:

Eye glasses with side protection (EN 166).

Skin protection:

Tested protective gloves must be worn (EN ISO 374).

Recommended material: NBR (Nitrile rubber)

Material thickness: 0,6 mm

Breakthrough time: ≥ 480 min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Usually no personal respiratory protection necessary. Provide adequate ventilation. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Combination filtering device, Filter type A1/P2

Other protection measures:

Wear suitable protective clothing.

8.2.3 Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: liquid

Colour: black

Odour: like Ether

Safety relevant basic data

Parameter		at	Method	Remark
pH	<i>not applicable</i>			
Melting point	<i>not determined</i>			
Freezing point	<i>not determined</i>			
Initial boiling point and boiling range	> 100 °C			

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Parameter		at	Method	Remark
Decomposition temperature	not determined			
Flash point	> 93.3 °C			
Evaporation rate	not determined			
Auto-ignition temperature	not determined			
Upper/lower flammability or explosive limits	not determined			
Vapour pressure	not determined			
Vapour density	not determined			
Density	1.74 g/cm ³	20 °C		
Bulk density	not applicable			
Water solubility	miscible	20 °C		
Partition coefficient: n-octanol/water	not determined			
Dynamic viscosity	not determined			
Kinematic viscosity	not determined			

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

Exothermic reaction with: Acids, alkali (lye), Amines. oxidizing agent.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Protect from sunlight. impurities: Danger of polymerisation.

10.5 Incompatible materials

Acids, alkali (lye), Amines. oxidizing agent.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

In case of fire may be liberated: carbon oxides (COx); sulphur oxides (SOx); halogenated hydrocarbons; metal oxides

Further information

No data available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:

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

Acute dermal toxicity:

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

Acute inhalation toxicity:

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

Skin corrosion/irritation:

Causes skin irritation.

Serious eye damage/irritation:

Causes serious eye irritation.

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Respiratory or skin sensitisation:

Contains epoxy constituents. May produce an allergic 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.

Additional information:

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Toxic to aquatic life with long lasting effects.

Additional ecotoxicological information:

Discharge into the environment must be avoided.

12.2 Persistence and degradability

Biodegradation:

Not readily biodegradable (according to OECD criteria).

12.3 Bioaccumulative potential

Accumulation / Evaluation:

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Product/Packaging disposal

Waste codes/waste designations according to EWC

Waste code product:

08 04 09 *	Waste adhesives and sealants containing organic solvents or other dangerous substances
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*: Evidence for disposal must be provided.

Waste code packaging:

15 01 10 *	Packaging containing residues of or contaminated by dangerous substances
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*: Evidence for disposal must be provided.

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal. Do not allow to enter into surface water or drains.

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Appropriate disposal / Package:

Completely emptied packages can be recycled.









Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Collect in closed and suitable containers for disposal.

13.2 Additional information

Waste for disposal is to be classified and labelled.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI-/IATA-DGR)
14.1 UN-No.			
3082	3082	3082	3082
14.2 UN proper shipping name			
ENVIRONMENTALLY HAZARDOUS SUB- STANCE, LIQUID, N.O.S. (BISPHENOL A EPOXID RESIN)	ENVIRONMENTALLY HAZARDOUS SUB- STANCE, LIQUID, N.O.S. (BISPHENOL A EPOXID RESIN)	ENVIRONMENTALLY HAZARDOUS SUB- STANCE, LIQUID, N.O.S. (BISPHENOL A EPOXID RESIN)	ENVIRONMENTALLY HAZARDOUS SUB- STANCE, LIQUID, N.O.S. (BISPHENOL A EPOXID RESIN)
14.3 Transport hazard class(es)			
 9	 9	 9	 9
14.4 Packing group			
III	III	III	III
14.5 Environmental hazards			
		 MARINE POLLUTANT	
14.6 Special precautions for user			
Special provisions: 274, 335, 601, 375 Limited Quantity (LQ): 5 L Excepted Quantities (EQ): not determined Hazard identification number (KemlerNo.): 90 Classification code: M6 Tunnel restriction code: (E) Remark: -	Special provisions: 274, 335, 601, 375 Limited Quantity (LQ): 5 L Excepted Quantities (EQ): not determined Classification code: M6 Remark: -	Special provisions: 274, 335, 969 Limited Quantity (LQ): 5 L Excepted Quantities (EQ): not determined EmS-No.: F-A; S-F Remark: -	Special provisions: A97, A158, A197 Limited Quantity (LQ): not determined Excepted Quantities (EQ): not determined Remark: -

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

not relevant

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Additional information:

Transport as "Limited Quantity" according to chapter 3.4 ADR/RID.

SECTION 15: Regulatory information

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

15.1.1 EU legislation

Other EU regulations:

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

15.1.2 National regulations

No data available.

15.2 Chemical Safety Assessment

No data available.

SECTION 16: Other information

16.1 Indication of changes

Changes executed in version 2.0:

Section 1: Trade name/designation

Section 2: Label elements

Section 3: Composition/Information on Ingredients

Section 8: Exposure Controls/Personal Protection

Section 9: Physical and Chemical Properties

General revision of all sections

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16.2 Abbreviations and acronyms

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
ATE = acute toxicity estimate
AVV = Abfallverzeichnis-Verordnung
AwSV: Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen
BGI = Berufsgenossenschaftliche Informationen
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging
DMEL = Derived Minimum Effect Level
DNEL = Derived No Effect Level
EC50 = Median effective concentration
ECB = European Chemicals Bureau
EEC = European Economic Community
EINECS = European Inventory of Existing Commercial Chemical Substances
ELINCS = European List of Notified Chemical Substances
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IC50 = Inhibition concentration, 50%
IMDG = International Maritime Code for Dangerous Goods
IUCLID = International Uniform Chemical Information Database
LC50 = Lethal concentration, 50%
LD50 = Median lethal dose
LC0 = lethal concentration, 0%
LOAEL = lowest-observed-adverse-effect level
LGK = Lagerklasse
MARPOL = International Convention for the Prevention of Marine Pollution from Ships
NOAEL = No Observed Adverse Effect Level
NOEC = No Observed Effect Content
PBT = Persistent, Bioaccumulative and Toxic substance
PNEC = Predicted No-Effect Content
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
STP = Sewage Treatment Plant
TLV®/TWA = Threshold limit value - time-weighted average
TLV®STEL = Threshold limit value - short-time exposure limit
TRGS = Technical Rules for Hazardous Substances
VOC = Volatile Organic Compounds
vPvB = very Persistent and very Bioaccumulative

16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <http://www.echa.europa.eu>
ECHA, C&L Inventory: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>
ECHA, Registered substances: <http://echa.europa.eu/information-on-chemicals/registered-substances>
GESTIS (Gefahrstoffinformationssystem der DGUV): <http://www.dguv.de/ifa/GESTIS/index.jsp>
Hörath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz
Safety data sheets of the manufacturers

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16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard classes and hazard categories	Hazard statements	Classification procedure
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	Calculation
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	Calculation
Serious eye damage/eye irritation (<i>Eye Irrit. 2</i>)	H319: Causes serious eye irritation.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	Calculation

16.5 Relevant H- and EUH-phrases

Hazard statements	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

16.6 Training advice

No data available.

16.7 Additional information

The information in this safety data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.