

Safety Data Sheet

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



Trade name : MIKROSANA
Revision date : 21.08.2017
Print date : 03.07.2018

Version : 3.0.0 (2.0.0)

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

1.1 Product identifier

MIKROSANA

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

Relevant identified uses

Preparation for building and construction: Mixture of colloidal calcium and silica active for consolidating injections.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

AZICHEM Srl

Street : Via G. Gentile16/A

Postal code/city : 46044 Goito (MN)

Telephone : +390376604185/604365

Telefax : +39 0376 604398

Information contact : info@azichem.com

1.4 Emergency telephone number

Centro Antiveleni di Milano +39 02 66101029 (CAV Ospedale Niguarda Ca' Granda -Milano) (24h)

Centro Antiveleni di Pavia +39 0382 24444 (CAV IRCCS Fondazione Maugeri - Pavia)

Centro Antiveleni di Bergamo +39 800 883300 (CAV Ospedali Riuniti - Bergamo)

Centro Antiveleni di Firenze +39 055 7947819 (CAV Ospedale Careggi - Firenze)

Centro Antiveleni di Roma +39 06 3054343 (CAV Policlinico Gemelli - Roma)

Centro Antiveleni di Roma +39 06 49978000 (CAV Policlinico Umberto I - Roma)

Centro Antiveleni di Napoli +39 081 7472870 (CAV Ospedale Cardarelli - Napoli)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Eye Dam. 1 ; H318 - Serious eye damage/eye irritation : Category 1 ; Causes serious eye damage.

Skin Irrit. 2 ; H315 - Skin corrosion/irritation : Category 2 ; Causes skin irritation.

Skin Sens. 1 ; H317 - Skin sensitisation : Category 1 ; May cause an allergic skin reaction.

STOT SE 3 ; H335 - STOT-single exposure : Category 3 ; May cause respiratory irritation.

2.2 Label elements

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

Hazard pictograms



Corrosion (GHS05) · Exclamation mark (GHS07)

Signal word

Danger

Hazard components for labelling

LIME (CHEMICAL), HYDRAULIC ; CAS No. : 85117-09-5

CEMENT, PORTLAND, CHEMICALS ; CAS No. : 65997-15-1

FLUE DUST ; CAS No. : 68475-76-3

Hazard statements

H318 Causes serious eye damage.

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H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P310 Immediately call a POISON CENTER/doctor
P403+P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Hazardous ingredients

LIME (CHEMICAL), HYDRAULIC ; REACH registration No. : 01-2119475523-36 ; EC No. : 285-561-1; CAS No. : 85117-09-5

Weight fraction : $\geq 20 - < 30$ %
Classification 1272/2008 [CLP] : Eye Dam. 1 ; H318 Skin Irrit. 2 ; H315 STOT SE 3 ; H335

CEMENT, PORTLAND, CHEMICALS ; EC No. : 266-043-4; CAS No. : 65997-15-1

Weight fraction : $\geq 20 - < 30$ %
Classification 1272/2008 [CLP] : Eye Dam. 1 ; H318 Skin Irrit. 2 ; H315 Skin Sens. 1 ; H317 STOT SE 3 ; H335

FLUE DUST (*) ; REACH registration No. : 01-2119486767-17 ; EC No. : 270-659-9; CAS No. : 68475-76-3

Weight fraction : $\geq 0,5 - < 2$ %
Classification 1272/2008 [CLP] : Eye Dam. 1 ; H318 Skin Irrit. 2 ; H315 Skin Sens. 1 ; H317 STOT SE 3 ; H335

Further ingredients

CALCIUM CARBONATE ; EC No. : 207-439-9; CAS No. : 471-34-1

Weight fraction : $\geq 20 - < 30$ %

Additional information

(*) Flue dust refers to powders deriving from the Portland cement clinker production process.

Cement-containing cements and mixtures are finely ground mixtures consisting of clinker, gypsum (or other forms of calcium sulphate) and other specific constituents (limestone, pozzolan, etc.) within the composition limits specified by the respective product standards referred to in point 15.1.

Flue dust, if present in the cement formulation, are dosed as a secondary constituent. For some types of cements and mixtures containing cement, other components may be used as secondary constituents, grinding additives and any reducing agents, which have toxicological characteristics and levels of risk equal or inferior to those of the clinker.

The full text of the hazard statements (phrases) H and EUH is given in Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

When in doubt or if symptoms are observed, get medical advice.

Following inhalation

Remove victim out of the danger area. Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

In case of skin contact

Wash immediately with: Water Remove contaminated, saturated clothing immediately. In case of skin irritation, consult a physician. In case of skin reactions, consult a physician.

After eye contact

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

Never give anything by mouth to an unconscious person or a person with cramps.

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4.2 Most important symptoms and effects, both acute and delayed

On contact with moist skin may cause thickening, cracking and cracking of the skin. Prolonged contact in combination with existing abrasions can cause burns. Direct contact with the product may cause corneal injury due to mechanical stress, immediate or delayed irritation or inflammation. The direct contact with large quantities of product dry or with projections of wet product can cause effects ranging from irritation ocular moderate (eg. Conjunctivitis or blepharitis) to chemical burns and blindness. Dust may irritate throat and respiratory system. Coughing, sneezing and panting may occur as a result of exposure above the occupational exposure limits. May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Extinguishing powder alcohol resistant foam Carbon dioxide (CO₂) Water mist

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for firefighters

Remove persons to safety.

Special protective equipment for firefighters

Do not inhale explosion and combustion gases. Use appropriate respiratory protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

For non-emergency personnel

Remove persons to safety.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

For cleaning up

The contaminated area should be cleaned up immediately with: Water Retain contaminated washing water and dispose it.

6.4 Reference to other sections

Reference to other sections Safe handling: see section 7 Personal protection equipment: see section 8

SECTION 7: Handling and storage



7.1 Precautions for safe handling

Protective measures

Specific requirements or handling rules

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Do not breathe dust. Do not breathe gas/fumes/vapour/spray. See section 8.

Advices on general occupational hygiene

Normal precautions taken when handling chemicals should be observed.

7.2 Conditions for safe storage, including any incompatibilities

Only use containers specifically approved for the substance/product.

Requirements for storage rooms and vessels

Keep in a cool, well-ventilated place. Protect against UV-radiation/sunlight Humidity.

Hints on joint storage

Storage class : 13

Storage class (TRGS 510) : 13

Keep away from

Store at least 3 metres apart from: Chemicals/products that react together readily

Further information on storage conditions

Keep container tightly closed and in a well-ventilated place.

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

CALCIUM CARBONATE ; CAS No. : 471-34-1

Limit value type (country of origin) : PEL (EC)

Limit value : 15 mg/m³

Remark : Polveri totali

Version :

Limit value type (country of origin) : TLV/TWA (EC)

Limit value : 10 mg/m³

Remark : Polveri totali

Version :

DNEL/DMEL and PNEC values

DNEL/DMEL

Limit value type : DNEL Consumer (systemic) (CALCIUM CARBONATE ; CAS No. : 471-34-1)

Exposure route : Oral

Exposure frequency : Short-term (acute)

Limit value : 6,1 mg/kg

Limit value type : DNEL Consumer (systemic) (CALCIUM CARBONATE ; CAS No. : 471-34-1)

Exposure route : Inhalation

Exposure frequency : Long-term (repeated)

Limit value : 10 mg/m³

Limit value type : DNEL Consumer (systemic) (CALCIUM CARBONATE ; CAS No. : 471-34-1)

Exposure route : Oral

Exposure frequency : Long-term (repeated)

Limit value : 6,1 mg/kg

Limit value type : DNEL worker (systemic) (CALCIUM CARBONATE ; CAS No. : 471-34-1)

Exposure route : Inhalation

Exposure frequency : Long-term (repeated)

Limit value : 10 mg/m³

Limit value type : DNEL worker (local) (CEMENT, PORTLAND, CHEMICALS ; CAS No. : 65997-15-1)

Exposure route : Inhalation

Exposure frequency : Short-term (acute)

Limit value : 1 mg/m³

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Limit value type : DNEL Consumer (local) (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Inhalation
Exposure frequency : Short-term (acute)
Limit value : 1 mg/m³
Limit value type : DNEL Consumer (local) (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Inhalation
Exposure frequency : Long-term (repeated)
Limit value : 4 mg/m³
Limit value type : DNEL worker (local) (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Inhalation
Exposure frequency : Long-term (repeated)
Limit value : 1 mg/m³
Limit value type : DNEL worker (local) (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Inhalation
Exposure frequency : Short-term (acute)
Limit value : 4 mg/m³

PNEC

Limit value type : PNEC sewage treatment plant (STP) (CALCIUM CARBONATE ; CAS No. : 471-34-1)
Limit value : 100 mg/l
Limit value type : PNEC aquatic, freshwater (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 28 mg/m³
Limit value type : PNEC aquatic, intermittent release (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 282 mg/m³
Limit value type : PNEC aquatic, marine water (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 3 mg/m³
Limit value type : PNEC sediment, freshwater (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 0,875 mg/kg
Limit value type : PNEC sediment, marine water (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 0,088 mg/kg
Limit value type : PNEC soil, freshwater (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 5 mg/kg
Limit value type : PNEC sewage treatment plant (STP) (FLUE DUST ; CAS No. : 68475-76-3)
Limit value : 6 mg/l

8.2 Exposure controls

Appropriate engineering controls

If local exhaust ventilation is not possible or not sufficient, the entire working area must be ventilated by technical means. If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Personal protection equipment



When using do not eat, drink, smoke, sniff.

Eye/face protection

Suitable eye protection

Eye glasses with side protection DIN EN 166

Skin protection

Hand protection

Tested protective gloves must be worn DIN EN 374

Respiratory protection

Quarter-face mask (DIN EN 140) Half-face mask (DIN EN 140) Filtering Half-face mask (DIN EN 149)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Safety relevant basis data

Aspect		powder
Colour		greyish
Odour		none
Melting point/melting range :	(1013 hPa)	No data available
Vapour density	(air = 1)	Data not available
Initial boiling point and boiling range :	(1013 hPa)	No data available
Decomposition temperature :		No data available
Self flammability		not applicable
Flash point :		Not flammable
Flammability (solid, gas)		Data not available
Lower explosion limit :		No data available
Upper explosion limit :		No data available
Explosive properties		Not applicable
Vapour pressure	(20 °C)	negligible
Density :	(20 °C)	No data available
Water solubility :	(20 °C)	almost insoluble
pH :	>	11
Log Pow	(20 °C)	not applicable
Viscosity :	(20 °C)	No data available
Odour threshold		Data not available
Evaporation rate		Data not available
Maximum VOC content (EC) :		0 Wt %
Oxidizing properties		Not oxidising

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

Basic reaction when in mixed with water before to became a solid inert compound.

10.2 Chemical stability

Stable under recommended storage and handling conditions. See section 7. No additional measures necessary.

10.3 Possibility of hazardous reactions

No hazardous reactions when stored and handled properly.

10.4 Conditions to avoid

Protect from contact with water to avoid solidification of the product.

10.5 Incompatible materials

Acid

10.6 Hazardous decomposition products

None

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute effects

Acute oral toxicity

Parameter :	LD50 (LIME (CHEMICAL), HYDRAULIC ; CAS No. : 85117-09-5)
Exposure route :	Oral
Species :	Rat

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Effective dose : > 2000 mg/kg bw/day
Method : OECD 425
Parameter : LD50 (CALCIUM CARBONATE ; CAS No. : 471-34-1)
Exposure route : Oral
Species : Rat (female)
Effective dose : > 2000 mg/kg
Parameter : LD50 (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Oral
Species : Rat
Effective dose : > 1848 mg/kg bw/day
Exposure time : 7 days

It has no significant toxicity properties.

Acute dermal toxicity

Parameter : LD50 (CALCIUM CARBONATE ; CAS No. : 471-34-1)
Exposure route : Dermal
Species : Rat
Effective dose : > 2000 mg/kg
Parameter : LD50 (CEMENT, PORTLAND, CHEMICALS ; CAS No. : 65997-15-1)
Exposure route : Dermal
Species : Rabbit
Effective dose : > 2000 mg/kg bw/day
Exposure time : 24 days
Parameter : LD50 (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Dermal
Species : Rat
Effective dose : > 2000 mg/kg bw/day

It has no significant toxicity properties.

Acute inhalation toxicity

Parameter : LC50 (CALCIUM CARBONATE ; CAS No. : 471-34-1)
Exposure route : Inhalation
Species : Rat
Effective dose : > 3 mg/l
Exposure time : 4 h
Parameter : LD50 (FLUE DUST ; CAS No. : 68475-76-3)
Exposure route : Inhalation
Species : Rat
Effective dose : > 6,04 mg/l
Exposure time : 4 h

Irritant and corrosive effects

Primary irritation to the skin

On contact with moist skin may cause thickening, cracking and cracking of the skin. Prolonged contact in combination with existing abrasions can cause burns.

Irritation to eyes

Direct contact with the product may cause corneal injury due to mechanical stress, immediate or delayed irritation or inflammation. The direct contact with large quantities of product dry or with projections of wet product can cause effects ranging from irritation ocular moderate (eg. Conjunctivitis or blepharitis) to chemical burns and blindness.

Irritation to respiratory tract

Dust may irritate throat and respiratory system. Coughing, sneezing and panting may occur as a result of exposure above the occupational exposure limits.

Sensitisation

Eczema can be developed as a result of exposure to dust damp, caused both by the high pH which induces irritant contact dermatitis after prolonged contact, either by an immunological reaction to Cr (VI) soluble which causes allergic contact dermatitis.

In case of inhalation

not sensitising.

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Repeated dose toxicity (subacute, subchronic, chronic)

Subacute inhalation toxicity

The available evidence indicates clearly that occupational exposure to cement dust content in the product causes deficits in lung function. However, the evidence available at present are insufficient to establish with certainty the dose-response relationship for these effects.

Chronic inhalation toxicity

There were no chronic effects or effects at low concentrations.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

The ingredients in this mixture do not meet the criteria for classification as CMR according to CLP.

SECTION 12: Ecological information

Do not allow uncontrolled discharge of product into the environment.

12.1 Toxicity

Aquatic toxicity

Chronic (long-term) daphnia toxicity

Parameter :	NOEC (LIME (CHEMICAL), HYDRAULIC ; CAS No. : 85117-09-5)
Species :	Saltwater invertebrates
Effective dose :	32 mg/l
Exposure time :	96 h

12.2 Persistence and degradability

Poorly watersoluble, inorganic product. Can be mechanically precipitated to a large extent in biological sewage plants.

12.3 Bioaccumulative potential

not applicable

12.4 Mobility in soil

Low solubility in soil.

12.5 Results of PBT and vPvB assessment

This product is none, or does not contain a substance called a PBT or vPvB

12.6 Other adverse effects

No information available.

12.7 Additional ecotoxicological information

None

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product/Packaging disposal

Dispose according to legislation.

SECTION 14: Transport information

14.1 UN number

No dangerous good in sense of these transport regulations.

14.2 UN proper shipping name

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

No dangerous good in sense of these transport regulations.

14.4 Packing group

No dangerous good in sense of these transport regulations.

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14.5 Environmental hazards

No dangerous good in sense of these transport regulations.

14.6 Special precautions for user

None

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

not applicable

SECTION 15: Regulatory information

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

EU legislation

Regulation (EC) 1907/2006/CE (REACH). Regulation (EC) No 1272/2008 (CLP). Regulation (EU) 2015/830 requirements for the compilation of safety data sheets. Commission Regulation (EC) No 790/2009/CE (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 286/2011 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 1272/2008). Commission Regulation (EU) No 618/2012 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 487/2013 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 758/2013 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 944/2013 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 605/2014 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008). Commission Regulation (EU) No 1297/2015 (amending, for the purposes of its adaptation to technical and scientific progress (ATP), Regulation (EC) No 1272/2008).

Other regulations (EU)

Regulation (CE) 1907/2006: Substance of very high concern included in the SVHC Candidate List

None

National regulations

Italy: Legislative Decree 81/2008 (Consolidated Law on protection of health and safety at work), as amended and Directive 2009/161/UE - chemical risk assessment in accordance with Title IX

Water hazard class (WGK)

Class : nwg (Non-hazardous to water) Classification according to VwVwS

15.2 Chemical safety assessment

not applicable

SECTION 16: Other information

16.1 Indication of changes

None

16.2 Abbreviations and acronyms

LEGENDA:

ADR:	Accord européen relative au transport international des marchandises dangereuses par route (accordo europeo relativo al trasporto internazionale delle merci pericolose su strada)
ASTM:	ASTM International, originariamente nota come American Society for Testing and Materials (ASTM)
EINECS:	European Inventory of Existing Commercial Chemical Substances (Registro Europeo delle Sostanze chimiche in Commercio)
EC(0/50/100):	Effective Concentration 0/50/100 (Concentrazione Effettiva Massima per 0/50/100% degli Individui)
LC(0/50/100):	Lethal Concentration 0/50/100 (Concentrazione Letale per 0/50/100% degli Individui)
IC50:	Inhibitor Concentration 50 (Concentrazione Inibente per il 50% degli Individui)
NOEL:	No Observed Effect Level (Dose massima senza effetti)
NOEC:	No Observed Effect Concentration (Concentrazione massima senza effetti)
LOEC:	Lowest Observed Effect Concentration (Concentrazione massima alla quale è possibile evidenziare un effetto)

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DNEL:	Derived No Effect Level (Dose derivata di non effetto)
DMEL:	Derived Minimum Effect Level (Dose derivata di minimo effetto)
CLP:	Classification, Labelling and Packaging (Classificazione, Etichettatura e Imballaggio)
CSR:	Rapporto sulla Sicurezza Chimica (Chemical Safety Report)
LD(0/50/100):	Lethal Dose 0/50/100 (Dose Letale per 0/50/100% degli Individui)
IATA:	International Air Transport Association (Associazione Internazionale del Trasporto Aereo)
ICAO:	International Civil Aviation Organization (Organizzazione Internazionale dell'Aviazione Civile)
Codice IMDG:	International Maritime Dangerous Goods code (Codice sul Regolamento del Trasporto Marittimo)
PBT:	Persistent, bioaccumulative and toxic (sostanze persistenti bioaccumulabili e tossiche)
RID:	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regolamento concernente il trasporto Internazionale ferroviario delle merci Pericolose)
STEL:	Short term exposure limit (limite di esposizione a breve termine)
TLV:	Threshold limit value (soglia di valore limite)
TWA:	Time Weighted Average (media ponderata nel tempo)
UE:	Unione Europea
vPvB:	Very persistent very bioaccumulative (sostanze molto persistenti e molto bioaccumulabili)
N.D.:	Non disponibile.
N.A.:	Non applicabile
VwVwS.:	Text of Administrative Regulation on the Classification of Substances hazardous to waters into Water Hazard Classes (Verwaltungsvorschrift wassergefährdende Stoffe – VwVwS)
PNEC:	Predicted No Effect Concentration
PNOS:	Particulates not Otherwise Specified
BOD:	Biochemical Oxygen Demand
COD:	Chemical Oxygen Demand
BCF:	BioConcentration Factor
TRGS :	Technische Regeln für Gefahrstoffe -Technical Rules for Hazardous Substances, defined by The Federal Institute for Occupational Safety and Health, Germany
LCLo:	Lethal Concentration Low (La minima concentrazione letale)
ThOD:	Theoretical Oxygen Demand

16.3 Key literature references and sources for data

None

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

calculated.

16.5 Relevant H- and EUH-phrases (Number and full text)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

16.6 Training advice

None

16.7 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.