

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

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

1.1 Product identifier

Lunos® Fissure sealing (Clear/Opaque)

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

Relevant identified uses

Light-curing fissure sealant for dental purposes.

Product Categories [PC]

PC0 - Other

Uses advised against

None, if handled according to order.

Remark

The product is intended for professional use.

1.3 Details of the supplier of the safety data sheet

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

orochemie GmbH + Co. KG

Street : Max-Planck-Straße 27

Postal code/city : 70806 Kornwestheim

Telephone : +49 7154 1308-0

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Information contact : DÜRR DENTAL SE, Höpfigheimer Str. 17, 74321 Bietigheim-Bissingen, Germany

Tel: [+49 7142 705-0](tel:+4971427050), Fax: [+49 7142 705-500](tel:+497142705500), info@duerrdental.com

in Great Britain/Ireland:

DÜRR DENTAL [Products] UK Ltd., 14 Linnell Way - Telford Way Industrial Estate, Kettering Northants NN16 8PS, United Kingdom

Tel: [+44 1536 526740](tel:+441536526740), Fax.: [+44 1536 526749](tel:+441536526749), info@duerruk.com

1.4 Emergency telephone number

INT: +49 6132 84463 (24 h/7 d)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Aquatic Chronic 3 ; H412 - Hazardous to the aquatic environment : Category 3 ; Harmful to aquatic life with long lasting effects.

Acute Tox. 4 ; H332 - Acute toxicity (inhalative) : Category 4 ; Harmful if inhaled.

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

Skin Corr. 1B ; H314 - Skin corrosion/irritation : Category 1B ; Causes severe skin burns and eye damage.

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

Classification procedure

The classification was carried out according to the calculation method of Regulation No. (EC) 1272/2008 [CLP].

2.2 Label elements

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

Hazard pictograms

Safety Data Sheet

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Revision : 01.01.2018
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Corrosion (GHS05) · Exclamation mark (GHS07)

Signal word

Danger

Hazard components for labelling

2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE ; CAS No. : 24599-21-1
2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2

Hazard statements

H314 Causes severe skin burns and eye damage.
H332 Harmful if inhaled.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash ... thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P310 Immediately call a POISON CENTER/doctor/....
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P501 Dispose of contents/container to hazardous or special waste collection point.

Special rules for labelling of plant protection products

According to Directive (EC) 1272/2008, Art. 1 No. 5(d) this product, as a medical device, is exempted from the labelling requirements.

2.3 Other hazards

None

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Description

Mixture of methacrylate resins and excipients.

Hazardous ingredients

BIS(METHACRYLOXYETHYL)HYDROGE PHOSPHATE ; CAS No. : 32435-46-4

Weight fraction : $\geq 10 - < 15$ %
Classification 1272/2008 [CLP] : Skin Irrit. 2 ; H315 Eye Irrit. 2 ; H319 STOT SE 3 ; H335

2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE ; EC No. : 246-342-6; CAS No. : 24599-21-1

Weight fraction : $\geq 5 - < 10$ %
Classification 1272/2008 [CLP] : Flam. Liq. 3 ; H226 Skin Corr. 1B ; H314 Skin Sens. 1 ; H317 STOT SE 3 ; H335

2-DIMETHYLAMINOETHYL METHACRYLATE ; EC No. : 220-688-8; CAS No. : 2867-47-2

Weight fraction : $\geq 1 - < 5$ %
Classification 1272/2008 [CLP] : Acute Tox. 4 ; H302 Acute Tox. 4 ; H312 Skin Irrit. 2 ; H315 Skin Sens. 1 ; H317 Eye Irrit. 2 ; H319

TRIMETHYLOLPROPANE TRIMETHACRYLATE ; EC No. : 221-950-4; CAS No. : 3290-92-4

Weight fraction : $\geq 1 - < 5$ %
Classification 1272/2008 [CLP] : Aquatic Chronic 2 ; H411

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
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Additional information

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

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

Remove contaminated, saturated clothing immediately. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Following inhalation

Provide fresh air. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

In case of skin contact

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off contaminated clothing and wash it before reuse. Medical treatment necessary.

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person or a person with cramps. Call a physician immediately. Do not allow a neutralisation agent to be drunk. The following symptoms may occur: Gastric perforation

Self-protection of the first aider

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

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 mist The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media

Full water jet

5.2 Special hazards arising from the substance or mixture

None known.

Hazardous combustion products

None known.

5.3 Advice for firefighters

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

Special protective equipment for firefighters

Adapt protective equipment to surrounding fire.

5.4 Additional information

Suppress gases/vapours/mists with water spray jet. 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

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
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Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment. See protective measures under point 7 and 8.

For non-emergency personnel

Use personal protection equipment. See protective measures under point 7 and 8.

For emergency responders

Personal protection equipment

See protective measures under point 7 and 8.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Other information

Treat the recovered material as prescribed in the section on waste disposal.

6.4 Reference to other sections

See protective measures under point 7 and 8. Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep/Store only in original container. Please note safety instructions and directions for use on the drum. Handle and open container with care. If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective measures

Measures to prevent fire

Usual measures for fire prevention. When using do not smoke.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep/Store only in original container. Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Hints on joint storage

Do not store together with Acid Base Oxidising agent, strong. Store the foodstuffs separately.

Further information on storage conditions

Keep/Store only in original container. Store in a cool dry place. Ensure adequate ventilation of the storage area. Store completely away from light.

7.3 Specific end use(s)

Sealant for sealing fissures and enamel defects in dentistry . For use by trained specialist personnel.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

DNEL/DMEL and PNEC values

There are no data available on the preparation itself.

8.2 Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Personal protection equipment

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
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Version (Revision): 1.0.1 (1.0.0)

Eye/face protection

Goggles DIN EN 166

Skin protection

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. 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. Suitable material Butyl caoutchouc (butyl rubber)

Body protection

Wear suitable protective clothing.

Respiratory protection

insufficient ventilation

General health and safety measures

Keep away from food, drink and animal feedstuffs. Avoid contact with skin, eyes and clothes. Remove contaminated, saturated clothing. Wash hands and face before breaks and after work and take a shower if necessary. Draw up and observe skin protection programme. When using do not eat, drink, smoke, sniff.

Occupational exposure controls

Technical measures to prevent exposure

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Paste

Colour : light yellow

Odour : aromatic

Safety relevant basis data

Melting point/melting range :	(1013 hPa)		not determined
Initial boiling point and boiling range :	(1013 hPa)		not determined
Decomposition temperature :	(1013 hPa)		not determined
Flash point :		>	100 °C
Lower explosion limit :			not determined
Upper explosion limit :			not determined
Vapour pressure :	(50 °C)	<	1 hPa
Density :	(20 °C)		1,54 g/cm ³
Water solubility :	(20 °C)		insoluble
pH :			1,6
log P O/W :			not determined
Solid content :			not determined
Odour threshold :			not determined
Relative vapour density :	(20 °C)		not determined
Vapourisation rate :			not determined
Flammable solids :			Not applicable.
Flammable gases :			Not applicable.
Oxidising liquids :			Not oxidizing.
Oxidising solids :			Not oxidizing.
Corrosive to metals :			No data available.

9.2 Other information

None

SECTION 10: Stability and reactivity

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

10.1 Reactivity

None, if handled according to order.

10.2 Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3 Possibility of hazardous reactions

Reacts with: strong oxidants, radical formers, heavy metal ions.

10.4 Conditions to avoid

The product cures under the influence of visible and UV light. Therefore keep in sealed containers completely away from light and not over 25 °C.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

Acrid acrylate vapours may occur in case of fire.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Harmful by inhalation. There are no data available on the mixture itself. The statement is derived from products of similar composition.

Acute effects

Acute oral toxicity

Parameter :	LD50
Exposure route :	Oral
Species :	Rat
Effective dose :	> 5000 mg/kg
Parameter :	ATEmix calculated
Exposure route :	Oral
Effective dose :	10000 mg/kg
Parameter :	LD50 (2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2)
Exposure route :	Oral
Species :	Rat
Effective dose :	1750 mg/kg
Parameter :	LD50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Exposure route :	Oral
Species :	Rat
Effective dose :	> 2000 mg/kg

Practical experience/human evidence

Causes severe skin burns and eye damage.

Acute dermal toxicity

Parameter :	ATEmix calculated
Exposure route :	Dermal
Effective dose :	22000 mg/kg
Parameter :	LD50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Exposure route :	Dermal
Species :	Rat
Effective dose :	> 2000 mg/kg
Method :	OECD 402
Parameter :	ATE (2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2)
Exposure route :	Dermal
Effective dose :	1100 mg/kg

STOT-single exposure

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

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

Acute inhalation toxicity

Parameter : ATEmix calculated
Exposure route : Inhalative (vapour)
Effective dose : 15,5 mg/l

Irritant and corrosive effects

Causes severe skin burns and eye damage.

Sensitisation

May cause an allergic skin reaction.

Repeated dose toxicity (subacute, subchronic, chronic)

Subacute oral toxicity

STOT-repeated exposure

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

Subacute inhalation toxicity

STOT-repeated exposure

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

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

Aspiration hazard

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

11.5 Additional information

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Harmful to aquatic life with long lasting effects.

Acute (short-term) fish toxicity

Parameter : LC50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Species : Oncorhynchus mykiss (Rainbow trout)
Effective dose : 2 mg/l
Exposure time : 96 h
Method : OECD 203

Acute (short-term) daphnia toxicity

Parameter : EC50 (2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2)
Species : Daphnia magna (Big water flea)
Effective dose : 33 mg/l
Exposure time : 48 h
Method : OECD 202
Parameter : EC50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Species : Daphnia magna (Big water flea)
Effective dose : > 9,22 mg/l
Exposure time : 48 h
Method : OECD 202

Acute (short-term) algae toxicity

Parameter : ErC50 (2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2)
Species : Scenedesmus subspicatus
Effective dose : 41,6 mg/l
Exposure time : 72 h
Method : OECD 201
Parameter : ErC50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Species : Pseudokirchneriella subcapitata

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

Effective dose : 0,177 mg/l
Exposure time : 72 h
Method : OECD 201

Bacteria toxicity

Parameter : EC50 (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Effective dose : > 1000 mg/l
Exposure time : 3 h
Method : OECD 209

12.2 Persistence and degradability

Abiotic degradation

No data available.

Biodegradation

Parameter : Biodegradation (2-DIMETHYLAMINOETHYL METHACRYLATE ; CAS No. : 2867-47-2)
Inoculum : Degree of elimination
Effective dose : 95,3 %
Parameter : Biodegradation (TRIMETHYLOLPROPANE TRIMETHACRYLATE ; CAS No. : 3290-92-4)
Inoculum : Biodegradation
Evaluation parameter : Aerobic
Effective dose : 53 %
Exposure time : 672 h
Method : OECD 301B/ ISO 9439/ EEC 92/69/V, C.4-C

12.3 Bioaccumulative potential

The product has not been tested.

12.4 Mobility in soil

Known or predicted distribution to environmental compartments

There are no data available on the preparation itself.

Adsorption/Desorption

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 information available.

12.7 Additional ecotoxicological information

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product/Packaging disposal

Waste treatment options

Appropriate disposal / Product

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

Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number

UN 3265

14.2 UN proper shipping name

Safety Data Sheet

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

Trade name : Lunos® Fissure sealing (Clear/Opaque)
Revision : 01.01.2018
Print date : 01.01.2018

Version (Revision): 1.0.1 (1.0.0)

Land transport (ADR/RID)

CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE)

Sea transport (IMDG)

CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE)

Air transport (ICAO-TI / IATA-DGR)

CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (2-PROPENOIC ACID, 2-METHYL-, 2-HYDROXYETHYL ESTER, PHOSPHATE)

14.3 Transport hazard class(es)

Land transport (ADR/RID)

Class(es) : 8
Classification code : C3
Hazard identification number (Kemler No.) : 80
Tunnel restriction code : E
Special provisions : LQ 1 | E 2
Hazard label(s) : 8

Sea transport (IMDG)

Class(es) : 8
EmS-No. : F-A / S-B
Special provisions : LQ 1 | E 2
Hazard label(s) : 8

Air transport (ICAO-TI / IATA-DGR)

Class(es) : 8
Special provisions : E 2
Hazard label(s) : 8

14.4 Packing group

II

14.5 Environmental hazards

Land transport (ADR/RID) : No

Sea transport (IMDG) : No

Air transport (ICAO-TI / IATA-DGR) : No

14.6 Special precautions for user

strongly corrosive.

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

not applicable

SECTION 15: Regulatory information

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

National regulations

Restrictions of occupation

According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment has not been carried out.

SECTION 16: Other information

Safety Data Sheet

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Version (Revision): 1.0.1 (1.0.0)

16.1 Indication of changes

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16.2 Abbreviations and acronyms

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimates
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
CMR = Carcinogen, Mutagen or Reproductive toxicant
CO₂ = Carbon dioxide
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EC = European Commission
EC50 = Half maximal effective concentration
EN = European Standard (Norm)
EU = European Union
EUH statement = CLP-specific Hazard statement
EWC = European Waste Catalogue
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
H statement = GHS Hazard statement
IATA = International Air Transport Association ICAO-TI = International Civil Aviation Organization-Technical Instructions
IMDG = International Maritime Dangerous Goods
LC50 = Median lethal concentration
LD50 = Median lethal dose
LogPow = Logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
NOEC/NOEL = No observed effect concentration/level
OECD = Organisation for Economic Co-operation and Development
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation [Regulation (EC) No. 1907/2006]
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
RMM = Risk Management Measure
RRN = REACH Registration Number
STOT-RE = Specific Target Organ Toxicity - Repeated Exposure
STOT-SE = Specific Target Organ Toxicity - Single Exposure
SVHC = Substances of Very High Concern
TLV/STEL = Threshold limit value/short-term exposure limit
TLV/TWA = Threshold limit value/time weighted average
UN = United Nations
VOC = Volatile Organic Compound
vPvB = Very Persistent and Very Bioaccumulative

16.3 Key literature references and sources for data

None

16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

No information available.

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

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Safety Data Sheet

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

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H335 May cause respiratory irritation.
H411 Toxic to aquatic life with long lasting effects.

16.6 Training advice

None

16.7 Additional information

Notice the directions for use on the label.

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.
