

Safety Data Sheet

according to Regulation (EC) No 1907/2006

picopreci plus

Revision date: 11.09.2023

Product code: 13522XX

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

1.1. Product identifier

picopreci plus

Further trade names

picopreci plus rosa
picopreci plus zahnfarben
picopreci plus rosa-opak

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

Use of the substance/mixture

light curing dental resin

1.3. Details of the supplier of the safety data sheet

Manufacturer

| | | |
|-------------------------|--------------------------|---------------------------|
| Company name: | DeltaMed GmbH | |
| Street: | Raiffeisenstraße 8a | |
| Place: | 61169 Friedberg | |
| Telephone: | +49 6031 7283-0 | Telefax: +49 6031 7283-29 |
| E-mail: | info@deltamed.de | |
| Internet: | www.deltamed.de | |
| Responsible Department: | F&E | |
| | Telefax +49 6031 7283-29 | |

Supplier

| | |
|-------------------------|--------------------------|
| Company name: | picodent GmbH |
| Street: | Lüdenscheider Str. 24-26 |
| Place: | 51688 Wipperfürth |
| Telephone: | +49 2267 6580-0 |
| Internet: | picodent@picodent.de |
| Responsible Department: | Mo.-Fr. 7.30 - 16.45 Uhr |

1.4. Emergency telephone number: Giftinformationszentrum Universitätsklinikum Mainz
Telefon +49 6131 19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Sens. 1; H317
Aquatic Chronic 2; H411

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

urethane dimethacrylate (UDMA)
acrylic resin
1,4 Butanediol dimethacrylate (1,4-BDDMA)
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)

Signal word: Warning

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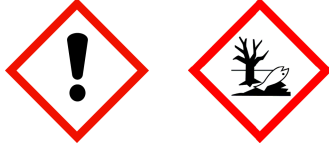
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Pictograms:



Hazard statements

- H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

- P261 Avoid breathing dust/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P391 Collect spillage.
P501 Dispose of contents/container in accordance with local regulation.

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of acrylic resins, fillers and initiators.

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|--|--------------|----------|-----------|
| | EC No | Index No | REACH No | |
| | Classification (Regulation (EC) No 1272/2008) | | | |
| 72869-86-4 | urethane dimethacrylate (UDMA) | | | 50 - 70 % |
| | Skin Sens. 1B, Aquatic Chronic 2; H317 H411 | | | |
| | acrylic resin | | | 20 - 40 % |
| | Skin Sens. 1B, Aquatic Chronic 2; H317 H411 | | | |
| 2082-81-7 | 1,4 Butanediol dimethacrylate (1,4-BDDMA) | | | < 20 % |
| | Skin Sens. 1B; H317 | | | |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | | | < 1 % |
| | 278-355-8 | 015-203-00-X | | |
| | Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411 | | | |

Full text of H and EUH statements: see section 16.

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Specific Conc. Limits, M-factors and ATE

| CAS No | EC No | Chemical name | Quantity |
|------------|-----------|---|-----------|
| | | Specific Conc. Limits, M-factors and ATE | |
| 72869-86-4 | | urethane dimethacrylate (UDMA) | 50 - 70 % |
| | | inhalation: LC50 = >5 mg/l (dusts or mists); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg | |
| | | acrylic resin | 20 - 40 % |
| | | dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 mg/kg | |
| 2082-81-7 | | 1,4 Butanediol dimethacrylate (1,4-BDDMA) | < 20 % |
| | | dermal: LD50 = > 3000 mg/kg; oral: LD50 = > 5000 mg/kg | |
| 75980-60-8 | 278-355-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | < 1 % |
| | | dermal: LD50 = >2000 mg/kg; oral: LD50 = > 5000 mg/kg | |

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product or by inhalation of its vapours. Take off all contaminated clothing immediately.

After inhalation

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

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. If eye irritation persists: Get medical advice/attention.

After ingestion

Do NOT induce vomiting. Medical treatment necessary.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

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

Foam, Extinguishing powder, Carbon dioxide.

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide, Carbon dioxide, Hazardous decomposition products.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

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

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6.1. Personal precautions, protective equipment and emergency procedures

General advice

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Other information

Larger quantities: Take up mechanically (by pumping). Smaller quantities and/or residues: Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Do not breathe gas/fumes/vapour/spray.
Provide fresh air.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Advice on general occupational hygiene

Avoid contact with skin, eyes and clothes. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

Hints on joint storage

No special measures are necessary.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

| CAS No | Name of agent | Exposure route | Effect | Value |
|------------|---|----------------|----------|-------------------------|
| 72869-86-4 | urethane dimethacrylate (UDMA) | | | |
| | Worker DNEL, long-term | dermal | systemic | 1,3 mg/kg bw/day |
| | Worker DNEL, long-term | inhalation | systemic | 3,3 mg/m ³ |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | | | |
| | Worker DNEL, long-term | dermal | systemic | 0,233 mg/kg bw/day |
| | Consumer DNEL, long-term | inhalation | systemic | 0,145 mg/m ³ |
| | Consumer DNEL, long-term | oral | systemic | 0,0833 mg/kg bw/day |

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PNEC values

| CAS No | Name of agent | |
|--|---|--------------|
| Environmental compartment | | Value |
| 72869-86-4 | urethane dimethacrylate (UDMA) | |
| Freshwater | | 0,01 mg/l |
| Marine water | | 0,001 mg/l |
| Freshwater sediment | | 4,56 mg/kg |
| Marine sediment | | 0,46 mg/kg |
| Micro-organisms in sewage treatment plants (STP) | | 3,61 mg/l |
| Soil | | 0,91 mg/kg |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | |
| Marine water | | 0,00014 mg/l |
| Freshwater sediment | | 0,115 mg/kg |
| Marine sediment | | 0,0115 mg/kg |
| Soil | | 0,0222 mg/kg |

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Eye glasses with side protection

Hand protection

butyl rubber gloves (0.7 mm), Break through time ca. 300 min (EN 374). Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | | |
|---|----------------------------------|-----------------------|
| Physical state: | Gel | |
| Colour: | various, depending on coloration | |
| Odour: | aromatic | |
| Melting point/freezing point: | | not determined |
| Boiling point or initial boiling point and boiling range: | | not determined |
| Flammability: | | flammable liquids |
| Lower explosion limits: | | not determined |
| Upper explosion limits: | | not determined |
| Flash point: | | > 100 °C °C |
| Auto-ignition temperature: | | not determined |
| Decomposition temperature: | | not determined |
| pH-Value: | | not determined |
| Viscosity / kinematic: | | not determined |
| Water solubility: | | not determined |
| Solubility in other solvents | | not determined |
| Partition coefficient n-octanol/water: | | not determined |
| Vapour pressure: | | not determined |
| Density: | | 1,1 g/cm ³ |

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Relative vapour density: not determined
Particle characteristics: not applicable

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid: not applicable
Gas: not applicable

Other safety characteristics

Evaporation rate: not determined
Solid content: not determined

Further Information

Product has not been tested. The statement is derived from the properties of the components.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.

10.4. Conditions to avoid

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Can polymerize with intense heat release.

10.5. Incompatible materials

Oxidising agent, Reducing agent, Heavy metals, Acids, Alkali (lye)

10.6. Hazardous decomposition products

No known hazardous decomposition products.

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.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

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| CAS No | Chemical name | | | | |
|------------|---|-------------------|---------|----------|----------|
| | Exposure route | Dose | Species | Source | Method |
| 72869-86-4 | urethane dimethacrylate (UDMA) | | | | |
| | oral | LD50 >5000 mg/kg | Rat | OECD 401 | |
| | dermal | LD50 >2000 mg/kg | Rat | OECD 402 | |
| | inhalation (4 h) dust/mist | LC50 >5 mg/l | | | |
| | acrylic resin | | | | |
| | oral | LD50 > 2000 mg/kg | Rat | OECD 423 | |
| | dermal | LD50 > 2000 mg/kg | Rat | OECD 402 | |
| 2082-81-7 | 1,4 Butanediol dimethacrylate (1,4-BDDMA) | | | | |
| | oral | LD50 > 5000 mg/kg | Rat | OECD 401 | |
| | dermal | LD50 > 3000 mg/kg | Rabbit | | |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | | | | |
| | oral | LD50 > 5000 mg/kg | Rat | ECHA | OECD 401 |
| | dermal | LD50 >2000 mg/kg | Rat | ECHA | |

Irritation and corrosivity

Based on available data, the classification criteria are not met.
May cause mild skin and eye irritation.

Sensitising effects

May cause an allergic skin reaction. (urethane dimethacrylate (UDMA); acrylic resin; 1,4 Butanediol dimethacrylate (1,4-BDDMA); Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO))
May cause sensitization by skin contact.

Carcinogenic/mutagenic/toxic effects for reproduction

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

Further information

The product has not been tested. The statement is derived from the properties of the single components.

SECTION 12: Ecological information

12.1. Toxicity

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| CAS No | Chemical name | | | | | |
|------------|---|----------------|-----------|---------|---------------------------------|------------------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 72869-86-4 | urethane dimethacrylate (UDMA) | | | | | |
| | Acute fish toxicity | LC50 mg/l | 10,1 | 96 h | Danio rerio (zebrafish) | OECD 203 |
| | Acute algae toxicity | ErC50 mg/l | >0,68 | 72 h | Desmodesmus subspicatus | OECD 201 |
| | Acute crustacea toxicity | EC50 mg/l | >1,2 | 48 h | Daphnia magna (Big water flea) | |
| | acrylic resin | | | | | |
| | Acute fish toxicity | LC50 mg/l | 1,65 | 96 h | Danio rerio (zebrafish) | OECD 203 |
| | Acute algae toxicity | ErC50 | 1,6 mg/l | 72 h | Pseudokirchneriella subcapitata | OECD 201 |
| | Acute crustacea toxicity | EC50 mg/l | 2,36 | 48 h | Daphnia magna (Big water flea) | OECD 202 |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | | | | | |
| | Acute fish toxicity | LC50 | 1,4 mg/l | 96 h | Cyprinus carpio (Common Carp) | ECHA OECD 203 |
| | Acute algae toxicity | ErC50 mg/l | >2,01 | 72 h | Daphnia magna (Big water flea) | ECHA OECD 201 |
| | Acute crustacea toxicity | EC50 mg/l | 3,53 | 48 h | Daphnia magna (Big water flea) | ECHA OECD 202 |
| | Acute bacteria toxicity | (EC50 mg/l) | >1000 | 3 h | Activated sludge | ECHA OECD 209 |

12.2. Persistence and degradability

The product has not been tested.

| CAS No | Chemical name | | | |
|------------|--|--------|----|------------|
| | Method | Value | d | Source |
| | Evaluation | | | |
| 72869-86-4 | urethane dimethacrylate (UDMA) | | | |
| | Biodegradation | 22 % | 28 | OECD 301 F |
| | acrylic resin | | | |
| | OECD 301 F | 27 % | 56 | |
| | Not readily biodegradable (according to OECD criteria) | | | |
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | | | |
| | OECD 301 F | 0-10 % | 28 | |
| | Not readily biodegradable (according to OECD criteria) | | | |

12.3. Bioaccumulative potential

The product has not been tested.

BCF

| CAS No | Chemical name | BCF | Species | Source |
|------------|---|-------|---------|--------|
| 75980-60-8 | Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) | 47-55 | | |

12.4. Mobility in soil

The product has not been tested.

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.

The product has not been tested.

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12.6. 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.

12.7. Other adverse effects

No information available.

Further information

Do not allow uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities. Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

List of Wastes Code - used product

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

List of Wastes Code - contaminated packaging

070208 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues; hazardous waste

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

| | |
|---|--|
| <u>14.1. UN number or ID number:</u> | UN 3082 |
| <u>14.2. UN proper shipping name:</u> | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ACRYLIC RESIN) |
| <u>14.3. Transport hazard class(es):</u> | 9 |
| <u>14.4. Packing group:</u> | III |
| Hazard label: | 9 |
| Classification code: | M6 |
| Special Provisions: | 274 335 375 601 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |
| Transport category: | 3 |
| Hazard No: | 90 |
| Tunnel restriction code: | E |

Other applicable information (land transport)

SV 375: These substances, when carried in single or combination packagings of a net quantity not exceeding 5 litres of liquids or a net mass not exceeding 5 kg of solids per single or combination packaging, are not subject to the other provisions of ADR, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

Inland waterways transport (ADN)

| | |
|---|---------|
| <u>14.1. UN number or ID number:</u> | UN 3082 |
|---|---------|

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| | |
|--|--|
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ACRYLIC RESIN) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Classification code: | M6 |
| Special Provisions: | 274 335 375 601 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |

Marine transport (IMDG)

| | |
|--|--|
| 14.1. UN number or ID number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ACRYLIC RESIN) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Special Provisions: | 274, 335, 969 |
| Limited quantity: | 5 L |
| Excepted quantity: | E1 |
| EmS: | F-A, S-F |

Air transport (ICAO-TI/IATA-DGR)

| | |
|--|--|
| 14.1. UN number or ID number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ACRYLIC RESIN) |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Special Provisions: | A97 A158 A197 |
| Limited quantity Passenger: | 30 kg G |
| Passenger LQ: | Y964 |
| Excepted quantity: | E1 |
| IATA-packing instructions - Passenger: | 964 |
| IATA-max. quantity - Passenger: | 450 L |
| IATA-packing instructions - Cargo: | 964 |
| IATA-max. quantity - Cargo: | 450 L |

Other applicable information (air transport)

A 197: These substances are not subject to other provisions of these Regulations when carried in single or combination packagings with a net quantity per single or inner packaging not exceeding 5L for liquids and a net weight not exceeding 5kg for substances, provided the packagings meet the general requirements of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

14.5. Environmental hazards

| | |
|-----------------------------|---------------|
| ENVIRONMENTALLY HAZARDOUS: | Yes |
| Danger releasing substance: | ACRYLIC RESIN |

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

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Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO)

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

National regulatory information

Water hazard class (D): 2 - obviously hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

This data sheet contains changes from the previous version in section(s): 2,5,9,16.

Matter of revision: Regulation (EU) No. 2020/878, Annex II.

Abbreviations and acronyms

ADR: Accord européen sur le transport 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 Harmonized 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

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Skin Sens: Skin sensitisation

Repr: Reproductive toxicity

Aquatic Chronic: Chronic aquatic hazard

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

| Classification | Classification procedure |
|-------------------------|--------------------------|
| Skin Sens. 1; H317 | Calculation method |
| Aquatic Chronic 2; H411 | Calculation method |

Relevant H and EUH statements (number and full text)

H317 May cause an allergic skin reaction.
H361f Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

Further Information

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.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)