

Product: ULTRACLEAN-3

SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) Article 31, Annex II as amended

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: ULTRACLEAN-3
UFI: CSXW-Y8XS-R00H-HRV1
Substance type: Mixture
Use of the substance/mixture: Cleaner

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

Identified uses: ULTRACLEAN-3 is a powerful concentrate for the cleaning of surgical and dental instruments in an ultrasonic cleaning device. The alkaline-based concentrate facilitates the removal of residual protein, blood, plaster, and cement.

Uses advised against: Do not use for purposes other than those prescribed.

Recommended restrictions on use: For professional use only.

1.3 Details of the supplier of the safety data sheet

| | Manufacturer | EU only representative |
|--------------------------------------|---|---|
| Address: | Oro Clean Chemie AG Allmendstrasse 21 8320 Fehraltorf Switzerland | Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic |
| Telephone: | +41 (0)44 226 44 44 | |
| Email: | info@oroclean.com | info@oroclean.cz |
| Website: | www.oroclean.com | www.oroclean.cz |
| Downstream user/importer/distributor | | |
| Address: | Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic | |
| Telephone: | | |
| Email: | info@oroclean.cz | |
| Website: | www.oroclean.cz | |

Person responsible for preparing the SDS

Lee Moi Wong | Research & Development | Chief Research Officer (CRO)
Telephone: +41 (0)44 226 44 44
Email: ra@oroclean.com

1.4 Emergency telephone number

Emergency telephone number: 145 / +41 (0)44 251 51 51

* Please check the above numbers regularly as they might be subject to change.

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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

| Hazard type | Hazard category | Hazard statement code(s) | Classification procedure |
|-----------------|-----------------|--------------------------|------------------------------------|
| Physical hazard | Met. Corr. 1 | H290 | On basis of test data. |
| Health hazard | Skin Corr. 1A | H314 | Harmonised (legal) classification. |

The full text for all H-statements is displayed in section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms:



GHS05

| | | |
|---------------------------|--------------------|--|
| Signal word: | Danger | |
| Hazard statements: | H290 | May be corrosive to metals. |
| | H314 | Causes severe skin burns and eye damage. |
| Precautionary statements: | P260 | Do not breathe fume/mist/vapours/spray. |
| | P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| | P301 + P330 + P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. |
| | P303 + P361 + P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. |
| | P305 + P351 + P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| | P501 | Dispose of contents/container in accordance with local and national regulations. |
| Supplemental information: | Not applicable. | |

2.3 Other hazards

| | |
|----------------------------------|---|
| PBT or vPvB properties: | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
| Endocrine disrupting properties: | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

Classification according to Regulation (EC) No 1272/2008

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| Substance name | Identification | Classification | SCL, M-factor, ATE | Concentration |
|---------------------|--|---|---|---------------|
| Potassium hydroxide | CAS no.: 1310-58-3 EC no.: 215-181-3 Index no.: 019-002-00-8 REACH no.: 01-2119487136-33-0000 | Acute Tox. 4, H302 Skin Corr. 1A, H314 | Eye Irrit. 2, H319: 0,5 % ≤ C < 2 %; Skin Corr. 1A, H314: C ≥ 5 %; Skin Corr. 1B, H314: 2 % ≤ C < 5 %; Skin Irrit. 2, H315: 0,5 % ≤ C < 2 % | 15% - < 30% |

The full text for all H-statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|--------------------------|---|
| General notes: | Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician. No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. When it is suspected, that there may still be harmful vapours/fumes present in the air, respiratory protection (mask; self contained breathing apparatus) must be used. Wash contaminated clothing with water before removing or use gloves. |
| After inhalation: | Remove patient to fresh air - move out of dangerous area. In case of unconsciousness bring patient into stable side position and seek medical attention. If breathing is irregular or respiratory arrest occurs provide artificial respiration. Keep at rest in a position comfortable for breathing. Seek medical help immediately. |
| After contact with skin: | Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. Immediately obtain professional medical help. |
| After contact with eyes: | Immediately flush eyes with running water, keeping eyelids apart. After 5 minutes of rinsing, remove contact lenses, if present, and continue rinsing. Consult a physician immediately. |
| After ingestion: | Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Immediately consult a doctor. Show the physician the safety data sheet or label. |

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more detailed information on health effects and symptoms.

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: | Carbon dioxide. Dry chemical powder. Water spray. Alcohol resistant foam. |
| Unsuitable extinguishing media: | Full water jet. |

5.2 Special hazards arising from the substance or mixture

| | |
|---------------------------------------|--|
| Specific hazards during firefighting: | In case of a fire toxic gases can be generated; do not inhale gases/smoke. |
| Hazardous combustion products: | No data available. |

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5.3 Advice for firefighters

Special protective equipment for firefighters:

Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (BS EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (BS EN 137).

Additional information:

In case of fire or heating do not breathe fumes/vapours. No action shall be taken involving any personal risk or without suitable training. Contaminated firefighting water and fire residues must be disposed of in accordance with the local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Use personal protective equipment (section 8). Ensure adequate ventilation. No action shall be taken involving any personal risk or without suitable training. Prevent access to unprotected personnel. Evacuate the danger zone. Do not breathe vapour or mist. Avoid contact with skin, eyes and clothing.

Advice for emergency responders:

Use personal protective equipment.

6.2 Environmental precautions

Do not allow to enter drains or waterways. Prevent product from getting into subsoil/soil.

6.3 Methods and material for containment and cleaning up

Stem the spill if this does not pose risks. Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. Clean contaminated area with plenty of water.

6.4 Reference to other sections

See also sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

General advice:

Use general or local exhaust ventilation to prevent inhaling vapours and aerosols. Do not discharge into drains, surface water and soil. After use immediately close container tightly.

Instructions for protection against fire and explosion:

Ensure adequate ventilation.

Advice on general occupational hygiene:

Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Do not breathe vapours/mist. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage room and containers:

Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers.

Further information about storage conditions:

Keep in a cool, dry and well ventilated place. Keep away from food, drink and animal feeding stuffs. Store only in original container.

Stocking with different products:

Store separately from beverages, food and feed. Store separately from strong

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acids, bases and oxidation agents.

7.3 Specific end use(s)

See identified uses in section 1.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Please refer to the latest edition of the appropriate source text and consult an industrial hygienist or similar professional, or local agencies, for further information.

Biological limit values

No biological exposure limits noted for the ingredient(s).

DNEL values

| Substance name | Pattern of exposure | Route of exposure | Limit value |
|--|-------------------------------------|-------------------|---------------------|
| Potassium hydroxide CAS no.:1310-58-3 | Worker (long term, local effects) | Inhalation | 1 mg/m ³ |
| | Consumer (long term, local effects) | Inhalation | 1 mg/m ³ |

PNEC values

| Substance name | Route of exposure | Limit value |
|--|--------------------|--------------------|
| Potassium hydroxide CAS no.:1310-58-3 | No data available. | No data available. |

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures

| | |
|-------------------------|--|
| Eye/face protection: | Wear tightly fitting safety goggles or protective face shield. |
| Hand protection: | Short-term contact: Gloves with Protection Index of at least Class 2 (Norm EN 374, permeation time > 30 min) for substances of Classes G and K. Long-term contact: Gloves with Protection Index of at least Class 6 (Norm EN 374, permeation time > 480 min) for substances of Classes G and K. (Class G: amines; Class K: inorganic bases). |
| Body protection: | Apron and work shoes or boots. Emergency responders should wear appropriate body protection. |
| Respiratory protection: | Avoid aerosol formation. Use respiratory protection if aerosol is formed. |
| Thermal hazards: | No data available. |
| Hygiene measures: | Use good personal hygiene practices – wash hands at breaks and when done working with material. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols. |

Environmental exposure controls

Observe the usual precautions for handling chemicals. Do not empty concentrate into drains. Avoid releasing the concentrate to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Liquid

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| | |
|---|---------------------------------|
| Form: | Clear, non-viscous liquid |
| Colour: | Light yellow |
| Odour: | Aromatic |
| Melting point: | No data available. |
| Freezing point: | No data available. |
| Boiling point or initial boiling point and boiling range: | No data available. |
| Flammability: | The product is not flammable. |
| Lower explosion limit: | Not applicable. |
| Upper explosion limit: | Not applicable. |
| Flash point: | Not applicable. |
| Auto-ignition temperature: | Not self-igniting. |
| Decomposition temperature: | Not applicable. |
| pH-value (undiluted product): | 14.0 |
| pH-value (diluted product): | 12.5 - 13.5 (5%) |
| Kinematic viscosity: | No data available. |
| Solubility: | Completely miscible with water. |
| Partition coefficient n-octanol/water: | Not applicable. |
| Vapour pressure at 50 °C: | No data available. |
| Density: | 1.16 g/cm ³ |
| Relative density: | 1.16 |
| Relative vapour density at 20 °C: | No data available. |

9.2 Other information

| | |
|-----------------------|---------------------------------|
| Oxidising properties: | Not oxidising. |
| Explosive properties: | Product is not explosive. |
| Evaporation rate: | No data available. |
| Miscibility: | Completely miscible with water. |
| Other information: | No data available. |

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture is not reactive.

10.2 Chemical stability

Stable at normal temperatures and pressure at least up to the expiry date printed on the container.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Avoid conditions beyond those mentioned in section 7.

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10.5 Incompatible materials

Avoid contact with strong acids, bases or oxidation agents, danger of exothermic reactions.

10.6 Hazardous decomposition products

No dangerous decomposition products occur under normal storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Inhalation: Information on effects are given below.
 Skin contact: Information on effects are given below.
 Eye contact: Information on effects are given below.
 Ingestion: Information on effects are given below.

Acute toxicity

Mixture: ATEmix: LD50 (rat, ingestion) > 1400 mg/kg
 Component: No data available.

Skin corrosion/irritation

Mixture: Causes severe burns.
 Component: No data available.

Serious eye damage/irritation

Mixture: Causes serious eye damage.
 Component: No data available.

Respiratory or skin sensitization

Mixture: The product is not classified as sensitising.
 Component: No data available.

Germ cell mutagenicity

Mixture: Not a mutagen. Does not contain ingredients with known mutagenic properties.
 Component: No data available.

Carcinogenicity

Mixture: Does not contain ingredients with known carcinogenic properties.
 Component: No data available.

Reproductive toxicity

Mixture: This product contains no ingredients with known reproductive toxicity effects.
 Component: No data available.

STOT-single exposure

Mixture: This product exhibits no known STOT-single exposure.
 Component: No data available.

STOT-repeated exposure

Mixture: This product exhibits no known STOT-repeated exposure.
 Component: No data available.

Aspiration hazard

Mixture: This product exhibits no known aspiration hazard.
 Component: No data available.

11.2 Information on other hazards

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Endocrine disrupting properties

Mixture: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Component: No data available.

Other hazards

Mixture: No data available.

Component: No data available.

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity

The release of the diluted ready-to-use solution of this product is not expected to have any ecotoxic effects. The concentrated solution can have prolonged and widespread toxic effects on aquatic and terrestrial organisms. The release of concentrated solution may negatively affect the function of sewage treatment plants. There is no data available from ecotoxicological tests regarding the entire product. The ecotoxicological risk has been estimated based on available data on product ingredients and concentrations, where available.

12.2 Persistence and degradability

The product ingredients possess good biodegradation properties. The surfactants included in the product comply with the requirements for the biological decomposition of Regulation (EC) No. 648/2004 on detergents. Based on available data, the biodegradability in sewage treatment plants can be categorized as high. High product concentrations can affect the biodegradability potential of the activated sludge. Obtain the consent of the local authorities before discharging the concentrated solution to wastewater treatment plants.

| Substance name | Biodegradation | Basis | Remark |
|---------------------|-----------------|-----------------|-----------------|
| Potassium hydroxide | Not applicable. | Not applicable. | Not applicable. |

12.3 Bioaccumulative potential

Mixture: Based on available data, no product ingredient is expected to exhibit bioaccumulative potential.

Component:

12.4 Mobility in soil

Mixture: The product is not expected to be mobile over long distances because most of the product ingredients possess good biodegradability. The remaining ingredients (e.g. mineral salts) are absorbed into the soil without negative ecological effects. This product reduces the surface tension of water.

Component:

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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12.7 Other adverse effects

The product contains no ingredients with ozone depletion potential or global warming potential. The product contains no heavy metals or their compounds as defined in 2006/11/EG. The product contains no absorbable organic halogens (AOX) or volatile organic compounds (VOC).

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal methods: Dispose of this product according to national and regional provisions. Waste code EWC Nr: 070699 (Group: waste material of MFSU from fats, lubricants, soaps, detergents, disinfectants and personal protection products). The correctly diluted ready-to-use solution of this product can be disposed of via the sewage system. Small amounts of the product (up to about 100 ml per day) can be disposed of via the sewage system after dilution 1:30 with tap water.

Contaminated packaging: Empty packaging can be treated like household waste. Handle the packaging containing the product in the same way as the product itself. Where available, references to local regulations regarding disposal are given in section 15 of the SDS. The user has sole responsibility for acquaintance and compliance with the applicable regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/ADN/RID)

14.1 UN number

UN 1814

14.2 UN proper shipping name

POTASSIUM HYDROXIDE SOLUTION (Potassium hydroxide)

14.3 Transport hazard class(es)

8

14.4 Packing group

II | Danger label: 8 | LQ: 1 L

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user

See sections 6 to 8.

Sea transport (IMDG/IMO)

14.1 UN number

UN 1814

14.2 UN proper shipping name

POTASSIUM HYDROXIDE SOLUTION (Potassium hydroxide)

Product: ULTRACLEAN-3

14.3 Transport hazard class(es)

8

14.4 Packing group

II | Danger label: 8 | LQ: 1 L

14.5 Environmental hazards

Environmental hazards: No
Marine pollutant: No

14.6 Special precautions for user

See sections 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

Air transport (IATA)

14.1 UN number

UN 1814

14.2 UN proper shipping name

POTASSIUM HYDROXIDE SOLUTION (Potassium hydroxide)

14.3 Transport hazard class(es)

8

14.4 Packing group

II | Danger label: 8 | LQ: 1 L

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user

See sections 6 to 8.

SECTION 15: REGULATORY INFORMATION

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

The product has been classified and marked in accordance with Regulation (EC) No.1272/2008 (CLP). The product complies with requirements of Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 648/2004 (Detergents Regulation), Regulation (EU) No. 528/2012 (Biocides Regulation), Directive 93/42/EC (Medical Devices Directive), and Regulation (EU) No. 2017/745 on medical devices (MDR), if applicable.

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this product.

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SECTION 16: OTHER INFORMATION

Indication of changes

- 1.1 Product identifier - Updated.
- 1.2 Relevant identified uses of the substance or mixture and uses advised against - Updated.
- 1.3 Details of the supplier of the safety data sheet - Updated.
- 1.4 Emergency telephone number - Updated.
- 4.1 Description of first aid measures - Updated.
- 5.2 Special hazards arising from the substance or mixture - Updated.
- 5.3 Advice for firefighters - Updated.
- 6.1 Personal precautions, protective equipment and emergency procedures - Updated.
- 6.2 Environmental precautions - Updated.
- 7.1 Precautions for safe handling - Updated.
- 7.2 Conditions for safe storage, including any incompatibilities - Updated.
- 8.1 Control parameters - Updated.
- 8.2 Exposure controls - Updated.
- 9.1 Information on basic physical and chemical properties - Updated.
- 9.2 Other information - Updated.
- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 / Information on toxicological effects - Updated.
- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture - Updated.

Abbreviations and acronyms

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM - American Society for Testing and Materials
AwSV - Ordinance on facilities for handling substances that are hazardous to water
BOD - Biochemical Oxygen Demand
c.c. - Closed cup
CAS - Chemical Abstract Services
CESIO - European Committee of Organic Surfactants and their Intermediates
COD - Chemical Oxygen Demand
DMEL - Derived Minimum Effect Level
DNEL - Derived No Effect Level
EbC50 - Median concentration in terms of reduction of growth
EC - Effective concentration
EINECS - European Inventory of Existing Commercial Chemical Substances
EN - European Norm
ErC50 - Median concentration in terms of reduction of growth rate
GGVSEB - German ordinance for road, rail and inland waterway transportation of dangerous goods
GGVSee - German ordinance for sea transportation of dangerous goods
GLP - Good Laboratory Practice
GMO - Genetic Modified Organism
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
ISO - International Organization For Standardization
LD/LC - Lethal dose/concentration
LOAEL - Lowest Observed Adverse Effect Level
LOEL - Lowest Observed Effect Level
LQ - Limited Quantity
M-Factor - Multiplying factor
NOAEL - No Observed Adverse Effect Level
NOEC - No Observed Effect Concentration
NOEL - No Observed Effect Level
o.c. - Open cup

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OECD - Organisation for Economic Cooperation and Development
OEL - Occupational Exposure Limit
PBT - Persistent, bioaccumulative, toxic
PNEC - Predicted No Effect Concentration
REACH - REACH registration
RID - Convention concerning International Carriage by Rail
SVHC - Substances of Very High Concern
TA - Technical Instructions
TRGS - Technical Rules for Hazardous Substances
vPvB - Very persistent, very bioaccumulative
WGK - Water Hazard Class

Key literature references and sources for data

No data available.

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

| Hazard category | Hazard statement code(s) | Classification procedure |
|-----------------|--------------------------|------------------------------------|
| Met. Corr. 1 | H290 | On basis of test data. |
| Skin Corr. 1A | H314 | Harmonised (legal) classification. |

List of relevant phrases

H290 May be corrosive to metals.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.

Training information

Comply with national laws regulating employee instruction.

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.