

Softaskin / Softaskin pure

Safety Data Sheet

according to UK REACH Regulation

Issue date: 01/06/2015

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Version: 2.1

SDS No: 00056-0297

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

1.1. Product identifier

Product form : Mixture
Product name : Softaskin / Softaskin pure

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Wash lotion

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach - Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

Supplier

B. Braun Medical Ltd.
Thornccliffe Park Estate, Brookdale Road
Sheffield S35 2PW, UK - Medical Information Department
T +44 (0)114 225 9000
medinfo.bbmuk@bbraun.com

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to GB CLP Regulation

Serious eye damage/eye irritation, Category 2 H319

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

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation.

2.2. Label elements

Labelling according to GB CLP Regulation

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P280 - Wear eye protection.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P501 - Dispose of contents and container to an approved waste disposal plant.

Extra phrases :

Applies for those countries where this product is classified as cosmetic; as ready for use cosmetic, this product is not subject to labelling obligation according to the CE directives in these countries.

Labelling according to: exemption for packages of a capacity of 125ml or less

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Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Extra phrases

: Applies for those countries where this product is classified as cosmetic; as ready for use cosmetic, this product is not subject to labelling obligation according to the CE directives in these countries.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to GB CLP Regulation
Alcohols, C12-14, ethoxylated, sulfated, sodium salts	(CAS-No.) 68891-38-3 (EC-No.) 500-234-8 (REACH-no) 01-2119488639-16	< 5	Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412
1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 (even-numbered) und C18 unsat.)-acylderivates, hydroxides, inner salts	(CAS-No.) 147170-44-3 (EC-No.) 931-333-8 (REACH-no) 01-2119489410-39	< 5	Eye Dam. 1, H318 Aquatic Chronic 3, H412

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Alcohols, C12-14, ethoxylated, sulfated, sodium salts	(CAS-No.) 68891-38-3 (EC-No.) 500-234-8 (REACH-no) 01-2119488639-16	(5 \leq C < 10) Eye Irrit. 2, H319 (10 \leq C < 100) Eye Dam. 1, H318
1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C8-18 (even-numbered) und C18 unsat.)-acylderivates, hydroxides, inner salts	(CAS-No.) 147170-44-3 (EC-No.) 931-333-8 (REACH-no) 01-2119489410-39	(4 \leq C < 10) Eye Irrit. 2, H319 (10 \leq C < 100) Eye Dam. 1, H318

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Data of item 4 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Take off immediately all contaminated clothing. If you feel unwell, seek medical advice.

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing. In the event of persistent symptoms receive medical treatment.

First-aid measures after skin contact

: Wash skin with plenty of water.

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First-aid measures after eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Do NOT induce vomiting. Call a doctor. Attention in case of vomiting - acute danger of suffocating, produced by foaming ingredients. Rinse mouth. Drink plenty of water. Do not induce vomiting without medical advice.

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

Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Watch out. Beware, hazard of foam aspiration.

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	: Product does not burn, fire-extinguishing activities according to surrounding. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: high volume water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon monoxide. Carbon dioxide. Sulphur oxides. Nitrous gasses.

5.3. Advice for firefighters

Precautionary measures fire	: Cool endangered containers with water spray jet.
Firefighting instructions	: Fight fire from safe distance and protected location.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Spills of this product present a serious slipping hazard. Avoid contact with skin, eyes and clothing.
6.1.1. For non-emergency personnel	
Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes.
6.1.2. For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Do not discharge into drains or the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Dike and contain spill.
Methods for cleaning up	: Take up liquid spill into absorbent material.
Other information	: Flush/dilute with water. Dispose of materials or solid residues at an authorized site.

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6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in original container. Keep container tightly closed. Store in a well-ventilated place. Keep cool.
Storage temperature	: room temperature
Information on mixed storage	: Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Monitoring methods	
Monitoring methods	A specific exposure sampling method is not available
Biological monitoring methods	A specific exposure sampling method is not available

1-Propanaminium, 3-amino-N-{carboxymethyl}-N,N-dimethyl-, N-(C8-18 (even-numbered) und C18 unsat.)-acylderivates, hydroxides, inner salts (147170-44-3)

DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	12.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	44 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	7.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	13.04 mg/m ³
Long-term - systemic effects, dermal	7.5 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.0135 mg/l
PNEC aqua (marine water)	0.00135 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	14.8 mg/kg dwt
PNEC sediment (marine water)	1.48 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.8 mg/kg dwt

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PNEC (STP)	
PNEC sewage treatment plant	3000 mg/l
Alcohols, C12-14, ethoxylated, sulfated, sodium salts (68891-38-3)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	2750 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	175 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	15 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	52 mg/m ³
Long-term - systemic effects, dermal	1650 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.24 mg/l
PNEC aqua (marine water)	0.024 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.9168 mg/kg
PNEC sediment (marine water)	0.09168 mg/kg bw
PNEC (Soil)	
PNEC soil	7.5 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	10000 mg/l

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

Eye protection:

Eyewash bottle with clean water (EN 15154)

Type	Field of application	Characteristics	Standard
Safety glasses with side shields	Liquid splashes may occur		EN 166

Respiratory protection:

No personal breathing protective equipment is normally required

Environmental exposure controls:

Avoid release to the environment.

Other information:

Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Do not eat, drink or smoke in areas where product is used. Avoid contact with eyes.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: perfumed.
Odour threshold	: No data available
pH	: 4.7 – 5.3 at 20 °C
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: ≈ 100 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: No data available
Density	: 1.015 – 1.025 g/cm ³ at 20 °C
Solubility	: Water: completely miscible
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 1800 – 3500 mPa·s at 25°C
Explosive properties	: Product is not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: No data available

9.2. Other information

VOC content	: 0 %
Solvent content	: 0 %
Solvent separation test (%)	: 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No hazardous decomposition products known. Fire may produce: Carbon oxides (CO, CO₂). Nitrous fumes. Sulphur oxides.

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SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

1-Propanaminium, 3-amino-N-{carboxymethyl}-N,N-dimethyl-, N-(C8-18 (even-numbered) und C18 unsat.)-acylderivates, hydroxides, inner salts (147170-44-3)

LD50 oral rat	> 5000 mg/kg (OECD 401 method)
LD50 dermal rat	> 2000 mg/kg (OECD 402 method)

Alcohols, C12-14, ethoxylated, sulfated, sodium salts (68891-38-3)

LD50 oral rat	> 2000 mg/kg (OECD 401 method)
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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 4.7 – 5.3 at 20 °C
Serious eye damage/irritation	: Causes serious eye irritation. pH: 4.7 – 5.3 at 20 °C
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: Watch out. Beware, hazard of foam aspiration

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - general	: No ecotoxicological data about this product are known.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

1-Propanaminium, 3-amino-N-{carboxymethyl}-N,N-dimethyl-, N-(C8-18 (even-numbered) und C18 unsat.)-acylderivates, hydroxides, inner salts (147170-44-3)

LC50 fish 1	1 – 10 mg/l 96 h, OECD 203, Pimephales promelas
EC50 Daphnia 1	1 – 10 mg/l 48 h, OECD 202, Daphnia magna (Water flea)
ErC50 algae	1 – 10 mg/l OECD 203, Desmodesmus subspicatus
NOEC chronic fish	≤ 1 mg/l OECD 210, Oncorhynchus mykiss (Rainbow trout)
NOEC chronic crustacea	≤ 1 mg/l OECD 211, Daphnia magna (Water flea)

Alcohols, C12-14, ethoxylated, sulfated, sodium salts (68891-38-3)

LC50 fish 1	> 10 – 100 mg/l DIN EN ISO 7346-2
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12.2. Persistence and degradability

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Persistence and degradability	The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Softaskin / Softaskin pure	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects	: The product may lead to foaming in sewage plants.
Additional information	: Prevent entry to sewers and public waters. When low concentrations are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is not likely.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Recycling is preferred to disposal or incineration. Can be incinerated according to local regulations. Dispose of contents/container in accordance with licensed collector's sorting instructions. The waste code/waste name refers to the end product. To be defined by the customer in agreement with appropriate waste disposal company.
Product/Packaging disposal recommendations	: Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.
European List of Waste (LoW) code	: 07 06 99 - wastes not otherwise specified

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

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14.4. Packing group

Not regulated

Not regulated

Not regulated

Not regulated

Not regulated

14.5. Environmental hazards

Not regulated

Not regulated

Not regulated

Not regulated

Not regulated

No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

VOC content : 0 %

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Other information, restriction and prohibition regulations

: Kosmetikum Softaskin

INCI Declaration for the following article codes (18168, 18611, 18612, 18613, 18614, 18615, 18616, 18617, 18618, 18766, 18948, 18949, 19156, 19197, 19198, 19220, 19221, 19222, 19238, 19253, 19360, 19494, 19504, 19505, 19506, 19520, 19521, 19522, 19523, 19524, 19529, 19539, 19595, 19711, 19722, 19830, 19831, 19865, 19866, 19919, 88280, 180040, 180041, 180098, 3865037, 3865401): Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Lactic Acid, Allantoin, Coco Glucoside, C12-15 Alkyl Lactate, Polyquaternium-10, PEG-6 Caprylic/Capric Glycerides, Parfum, Sodium Benzoate, Sodium Chloride

INCI Declaration for all other article codes: Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, PEG-7 Glyceryl Cocoate, PEG-120 Methyl Glucose Dioleate, Sodium Chloride, Sodium Benzoate, Sodium Lactate, Parfum, Hexyl Cinnamal.

Kosmetikum Softaskin pure

INCI Declaration for the following article codes (19320, 19366, 19541, 19628, 19651): Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Lactic Acid, Allantoin, Coco Glucoside, C12-15 Alkyl Lactate, Polyquaternium-10, PEG-6 Caprylic/Capric Glycerides, Sodium Benzoate, Sodium Chloride

INCI Declaration for all other article codes: Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, PEG-7 Glyceryl Cocoate, PEG-120 Methyl Glucose Dioleate, Sodium Chloride, Sodium Benzoate, Sodium Lactate.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

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
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer

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vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
ED	Endocrine disrupting properties

Other information : Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.

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H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2

Classification and procedure used to derive the classification for mixtures according to GB CLP Regulation

Eye Irrit. 2	H319	Calculation method
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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.