

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

1.1. Product identifier

Product form : Mixture
Product name : Helizyme

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 : Instrument cleaner

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

Distributor

B. Braun Melsungen AG
Carl-Braun-Straße 1
D-34212 Melsungen - Germany
T +49(0) 5661 / 71-4422
logistics.service@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 1 H318
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye damage. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to GB CLP Regulation

Hazard pictograms (CLP)



GHS05

Signal word (CLP) : Danger
Contains : Fatty alcohol polyglycolether; Glycolic acid ethoxylate octyl ether
Hazard statements (CLP) : H318 - Causes serious eye damage.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)	: P280 - Wear protective gloves, 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. P310 - Immediately call a POISON CENTER, a doctor. P501 - Dispose of contents and container to an approved waste disposal plant. P273 - Avoid release to the environment.
EUH-statements	: EUH208 - Contains 1-dodecyl-2-pyrrolidone. May produce an allergic reaction.
Labelling according to: exemption for packages of a capacity of 125ml or less	
Hazard pictograms (CLP)	: 
	GHS05
Signal word (CLP)	: Danger
Hazardous ingredients	: Fatty alcohol polyglycolether; Glycolic acid ethoxylate octyl ether
Hazard statements (CLP)	: H318 - Causes serious eye damage. H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P280 - Wear protective gloves, 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. P310 - Immediately call a POISON CENTER, a doctor.
EUH-statements	: EUH208 - Contains 1-dodecyl-2-pyrrolidone. May produce an allergic reaction.

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
2-(2-butoxyethoxy)ethanol Substance with a Community workplace exposure limit	(CAS-No.) 112-34-5 (EC-No.) 203-961-6 (EC Index-No.) 603-096-00-8 (REACH-no) 01-2119475104-44	$\geq 5 - < 10$	Eye Irrit. 2, H319
Fatty alcohol polyglycolether	(CAS-No.) 127036-24-2 (EC-No.) 603-182-5	< 5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318
Glycolic acid ethoxylate octyl ether	(CAS-No.) 53563-70-5 (EC-No.) 611-013-1	< 5	Skin Irrit. 2, H315 Eye Dam. 1, H318
1-dodecyl-2-pyrrolidone	(CAS-No.) 2687-96-9 (EC-No.) 403-730-1 (EC Index-No.) 613-099-00-6	$\geq 0.5 - < 1$	Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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	: Gently wash with plenty of soap and water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 15 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 skin contact	: Prolonged or repeated skin contact can cause irritation.
Symptoms/effects after eye contact	: Serious damage to eyes.

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 itself 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	: Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

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

6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes.
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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".
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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.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. 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	: Keep container tightly closed. Store in a well-ventilated place. Keep cool.
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**

2-(2-butoxyethoxy)ethanol (112-34-5)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	2-(2-Butoxyethoxy)ethanol
IOEL TWA	67.5 mg/m ³
IOEL STEL	101.2 mg/m ³
IOEL STEL [ppm]	15 ppm
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
United Kingdom - Occupational Exposure Limits	
Local name	2-(2-Butoxyethoxy)ethanol
WEL TWA (OEL TWA) [1]	67.5 mg/m ³
WEL TWA (OEL TWA) [2]	10 ppm
WEL STEL (OEL STEL)	101.2 mg/m ³
WEL STEL (OEL STEL) [ppm]	15 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
1,2-propanediol (57-55-6)	
United Kingdom - Occupational Exposure Limits	
Local name	Propane-1,2-diol
WEL TWA (OEL TWA) [1]	10 mg/m ³ particulates 474 mg/m ³ total vapour and particulates

1,2-propanediol (57-55-6)

WEL TWA (OEL TWA) [2]	150 ppm total vapour and particulates
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Monitoring methods

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

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.

Hand protection:

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Natural rubber	6 (> 480 minutes)	0,6		EN ISO 374

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

Skin and body protection:

Type	Standard
Long sleeved protective clothing	EN ISO 6530

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.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Colour	: Blue.
Odour	: Product-specific.

Odour threshold	: No data available
pH	: 5.8 – 6.2 Concentrate
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	: 1.06 – 1.08 g/cm ³
Solubility	: Water: completely miscible
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: No data available



9.2. Other information

VOC content	: < 5 %
Solvent separation test (%)	: 0 %
Solvent content	: 50 % - 70 %

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

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No hazardous decomposition products known. Thermal decomposition generates : Carbon oxides (CO, CO₂). Nitrous fumes. Sulphur oxides.

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)

Glycolic acid ethoxylate octyl ether (53563-70-5)

LD50 oral rat	> 2000 mg/kg
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2-(2-butoxyethoxy)ethanol (112-34-5)

LD50 oral rat	5560 mg/kg
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LD50 dermal rabbit	4120 mg/kg
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1-dodecyl-2-pyrrolidone (2687-96-9)

LD50 oral rat	> 5000 mg/kg
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LD50 dermal rabbit	> 2000 mg/kg
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Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 5.8 – 6.2 Concentrate
Additional information	: Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation	: Causes serious eye damage. pH: 5.8 – 6.2 Concentrate
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. Harmful to aquatic life with long lasting effects.
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)	: Harmful to aquatic life with long lasting effects.

Glycolic acid ethoxylate octyl ether (53563-70-5)

LC50 fish 1	> 100 mg/l (OECD 203 method)
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2-(2-butoxyethoxy)ethanol (112-34-5)

EC50 Daphnia 1	> 100 mg/l Daphnia magna (Water flea)
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ErC50 algae	> 100 mg/l Scenedesmus subspicatus
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1-dodecyl-2-pyrrolidone (2687-96-9)

LC50 fish 1	0.59 mg/l Oncorhynchus mykiss (Rainbow trout)
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EC50 Daphnia 1	0.14 mg/l Daphnia magna (Water flea)
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ErC50 algae	0.053 mg/l
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12.2. Persistence and degradability**Helizyme**

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.
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1-dodecyl-2-pyrrolidone (2687-96-9)

Persistence and degradability	Readily biodegradable.
Biodegradation	87.4 % 28 days

12.3. Bioaccumulative potential**2-(2-butoxyethoxy)ethanol (112-34-5)**

Log Pow	0.56 (25 °C)
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment**Helizyme**

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 : Significantly hazardous to water.
Additional information : Prevent entry to sewers and public waters

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, EC 2000/532) : 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

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**

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:

Reference code	Applicable on	Entry title or description
3(b)	Fatty alcohol polyglycolether ; Glycolic acid ethoxylate octyl ether ; 2-(2-butoxyethoxy)ethanol ; 1-dodecyl-2-pyrrolidone	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
3(c)	1-dodecyl-2-pyrrolidone	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1
55.	2-(2-butoxyethoxy)ethanol	2-(2-butoxyethoxy)ethanol (DEGBE)

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 : < 5 %

Detergent Regulation (648/2004/EC): Labelling of contents:

Component	%
anionic surfactants	<5%
enzymes	

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:			
Section	Changed item	Change	Comments
9.2	VOC content	Modified	
15.1	VOC content	Modified	

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
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:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
EUH208	Contains 1-dodecyl-2-pyrrolidone. May produce an allergic reaction.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Classification and procedure used to derive the classification for mixtures according to GB CLP Regulation		
Eye Dam. 1	H318	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.

