

Helimatic Cleaner neutral

Safety Data Sheet

according to UK REACH Regulation

Issue date: 14/03/2012

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Version: 2.1

SDS No: 00056-0178

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

1.1. Product identifier

Product form : Mixture
Product name : Helimatic Cleaner neutral

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

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 :

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, face 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.

P273 - Avoid release to the environment.

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

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EUH-statements : EUH208 - Contains 1-dodecyl-2-pyrrolidone, glutaral, glutaraldehyde, 1,5-pentanedial. 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

Comments : Mixture of the substances listed below with nonhazardous additives

Name	Product identifier	%	Classification according to GB CLP Regulation
Glycolic acid ethoxylate octyl ether	(CAS-No.) 53563-70-5 (EC-No.) 611-013-1	< 5	Skin Irrit. 2, H315 Eye Dam. 1, H318
Fatty alcohol alkyl glyceryl ether	(CAS-No.) 146340-16-1	< 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319
1-dodecyl-2-pyrrolidone	(CAS-No.) 2687-96-9 (EC-No.) 403-730-1 (EC Index-No.) 613-099-00-6	< 1	Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Glutaraldehyde substance listed as REACH Candidate (Glutaral)	(CAS-No.) 111-30-8 (EC-No.) 203-856-5 (EC Index-No.) 605-022-00-X (REACH-no) 01-2119455549-26	< 0,1	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1B, H314 Eye Dam. 1, H318 Resp. Sens. 1, H334 Skin Sens. 1A, H317 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 2, H411

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Glutaraldehyde	(CAS-No.) 111-30-8 (EC-No.) 203-856-5 (EC Index-No.) 605-022-00-X (REACH-no) 01-2119455549-26	(0.5 \leq C < 100) Skin Sens. 1, H317 (0.5 \leq C < 100) STOT SE 3, H335 (0.5 \leq C < 2) Eye Irrit. 2, H319 (0.5 \leq C < 10) Skin Irrit. 2, H315 (2 \leq C < 10) Eye Dam. 1, H318 (10 \leq C < 100) Skin Corr. 1B, H314

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

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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. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash off immediately with soap and plenty of water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Wash immediately with plenty water (during 20 minutes), also under eyelids. Call a physician immediately.
First-aid measures after ingestion	: Do not induce vomiting. Drink plenty of water. Do not give an unconscious person anything to drink. Do not induce vomiting without medical advice. Call a physician immediately.

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

Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: Serious damage to eyes.
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 itself does not burn. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: high volume water jet.

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

Precautionary measures fire	: Fight fire from safe distance and protected location. Cool endangered containers with water spray jet.
Firefighting instructions	: Move containers from fire area if it can be done without personal risk.
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	: Ventilate spillage area. Evacuate unnecessary personnel.
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6.1.1. For non-emergency personnel

Emergency procedures	: Avoid contact with skin and eyes. Do not breathe mist.
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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

Do not allow to enter into surface water or drains. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Methods for cleaning up	: Mechanically recover the product. Notify authorities if product enters sewers or public waters.
Other information	: 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. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Avoid contact with skin, eyes and clothing.
Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures	: Wash contaminated clothing before reuse. 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

Technical measures	: Provide for a tub to collect spills.
Storage conditions	: Keep container tightly closed in a dry, cool and well-ventilated place.
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

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	Chloroprene rubber (CR)	6 (> 480 minutes)	0,5		EN ISO 374

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Chemically resistant protective gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,35		EN ISO 374
Chemically resistant protective gloves	Butyl rubber	6 (> 480 minutes)	0,5		EN ISO 374
Chemically resistant protective gloves	Fluoro-rubber (Viton) - FKM	6 (> 480 minutes)	0,4		EN ISO 374
Chemically resistant protective gloves	Polyvinylchloride (PVC)	6 (> 480 minutes)	0,5		EN ISO 374

Eye protection:

Eyewash bottle with clean water (EN 15154)

Type	Field of application	Characteristics	Standard
Protective goggles (EN 166)	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:

Do not breathe vapours. Wash hands immediately after handling the product. Wash hands before breaks and at the end of workday. Do not eat, drink or smoke in areas where product is used. Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Liquid.
Colour	: colourless to yellowish.
Odour	: perfumed.
Odour threshold	: No data available
pH	: 5.7 – 6.4 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)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: No data available
Density	: 1.08 – 1.095 g/cm ³
Solubility	: Water: Miscible
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

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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 %

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored normally.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids. Oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Fire may produce: Carbon monoxide. Carbon dioxide. Nitrous fumes.

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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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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Glutaraldehyde (111-30-8)

LD50 oral rat	151 ml/kg (OECD 401 method)
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LD50 dermal rabbit	> 1000 mg/kg (US-EPA)
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LC50 Inhalation - Rat (Dust/Mist)	0.48 mg/l/4h (OECD 403 method)
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Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 5.7 – 6.4 Concentrate

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Serious eye damage/irritation	: Causes serious eye damage. pH: 5.7 – 6.4 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)
Potential adverse human health effects and symptoms	: Watch out. Beware, hazard of foam aspiration. Prolonged or repeated skin contact can cause irritation.

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)	: Harmful to aquatic life with long lasting effects.

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

LC50 fish 1	> 100 mg/l (OECD 201 method)
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1-dodecyl-2-pyrrolidone (2687-96-9)

LC50 fish 1	0.59 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 Daphnia 1	0.14 mg/l Daphnia magna (Water flea)
ErC50 algae	0.053 mg/l

Glutaraldehyde (111-30-8)

LC50 fish 1	3.5 mg/l 96 h, ECOTOX, Oncorhynchus mykiss (Rainbow trout)
EC50 Daphnia 1	14.87 mg/l 48 h, OECD 202, Daphnia magna (Water flea)
ErC50 algae	0.6 mg/l 72 h, OECD 201, Desmodesmus subspicatus
NOEC chronic fish	1.6 mg/l 97 d, OECD 210, Oncorhynchus mykiss (Rainbow trout)
NOEC chronic crustacea	5 mg/l 21 d, OECD 211, Daphnia magna (Water flea)

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

Persistence and degradability	Readily biodegradable.
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1-dodecyl-2-pyrrolidone (2687-96-9)

Persistence and degradability	Readily biodegradable.
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Biodegradation	87.4 % 28 days
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Glutaraldehyde (111-30-8)

Persistence and degradability	Readily biodegradable.
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Biodegradation	90 – 100 % (OECD 301A method)
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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

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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

Additional information : Prevent entry to sewers and public waters

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Can be incinerated according to local regulations. Recycling is preferred to disposal or incineration. Dispose of contents/container in accordance with licensed collector's sorting instructions.

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 substance(s) listed on the REACH Candidate List in concentrations $\geq 0.1\%$ or SCL: Glutaral (EC 203-856-5, CAS 111-30-8)

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 %

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

Component	%
polycarboxylates, anionic surfactants, non-ionic surfactants	<5%

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.

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Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

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. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
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 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
EUH208	Contains 1-dodecyl-2-pyrrolidone, glutaral, glutaraldehyde, 1,5-pentanedial. 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
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.

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H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Resp. Sens. 1	Respiratory sensitisation, Category 1
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
Skin Sens. 1A	Skin sensitisation, category 1A
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.