

Softalind ViscoRub / Softa-Man ViscoRub

Safety Data Sheet

according to UK REACH Regulation

Issue date: 18/01/2023

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Version: 2.1

SDS No: 00056-0216

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

1.1. Product identifier

Product form : Mixture
Product name : Softalind ViscoRub / Softa-Man ViscoRub

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 : Hand disinfectant

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

Flammable liquids, Category 2	H225
Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity – Single exposure, Category 3, Narcosis	H336

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

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness.

2.2. Label elements

Labelling according to GB CLP Regulation

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Contains

: Propan-1-ol

Hazard statements (CLP)

: H225 - Highly flammable liquid and vapour.
H318 - Causes serious eye damage.
H336 - May cause drowsiness or dizziness.

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Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 - Do not breathe vapours.
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.
P310 - Immediately call a POISON CENTER, a doctor.
P501 - Dispose of contents and container to an approved waste disposal plant.

Extra phrases : Applies for those countries where this product is classified as medicinal product; as ready for use medicinal product, 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

Hazard pictograms (CLP) :



Signal word (CLP) : Danger

Hazardous ingredients : Propan-1-ol

Hazard statements (CLP) : H318 - Causes serious eye damage.

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.
P310 - Immediately call a POISON CENTER, a doctor.
P501 - Dispose of contents/container to an approved waste disposal plant.

Extra phrases : Applies for those countries where this product is classified as medicinal product; as ready for use medicinal product, 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

Comments : Alcoholic solution

Name	Product identifier	%	Classification according to GB CLP Regulation
Ethanol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	< 80	Flam. Liq. 2, H225 Eye Irrit. 2, H319
Propan-1-ol	(CAS-No.) 71-23-8 (EC-No.) 200-746-9 (EC Index-No.) 603-003-00-0 (REACH-no) 01-2119486761-29	< 25	Flam. Liq. 2, H225 Eye Dam. 1, H318 STOT SE 3, H336

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Specific concentration limits:		
Name	Product identifier	Specific concentration limits
Ethanol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	(50 ≤ C ≤ 100) Eye Irrit. 2, H319

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. Call a poison center or a doctor if you feel unwell.
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	: No specific measures are necessary.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye specialist.
First-aid measures after ingestion	: Immediately give plenty of water. Rinse mouth. Call a physician immediately. Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice.

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

Symptoms/effects after inhalation	: May cause drowsiness or dizziness.
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	: Water spray. Dry powder. Alcohol resistant foam. Carbon dioxide.
Unsuitable extinguishing media	: high volume water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable liquid and vapour.
Explosion hazard	: Product is not explosive. Explosive vapour/air mixtures may be formed.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂).

5.3. Advice for firefighters

Precautionary measures fire	: Eliminate all ignition sources if safe to do so. 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	: Vapours are heavier than air and may spread along floors. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Remove ignition sources.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid breathing vapours. 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

Prevent entry to sewers and public waters. Avoid release to the environment.

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, e.g.: sand, earth, vermiculite. 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

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing vapours. Avoid contact with skin and eyes.

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

Technical measures : Ground/bond container and receiving equipment.

Storage conditions : Keep container tightly closed in a dry, cool and well-ventilated place.

Incompatible materials : alkali metals. alkaline earth metals. oxidizing materials.

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

Ethanol (64-17-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m ³
WEL TWA (OEL TWA) [2]	1000 ppm

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Ethanol (64-17-5)	
WEL STEL (OEL STEL)	5760 mg/m ³ (calculated)
WEL STEL (OEL STEL) [ppm]	3000 ppm (calculated)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

Propan-1-ol (71-23-8)	
United Kingdom - Occupational Exposure Limits	
Local name	Propan-1-ol
WEL TWA (OEL TWA) [1]	500 mg/m ³
WEL TWA (OEL TWA) [2]	200 ppm
WEL STEL (OEL STEL)	625 mg/m ³
WEL STEL (OEL STEL) [ppm]	250 ppm
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
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	Butyl rubber	6 (> 480 minutes)	0,7		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

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Respiratory protection:

Device	Filter type	Condition	Standard
Respiratory protective device with a gas filter	Type A - High-boiling (>65 °C) organic compounds	In the event of insufficient ventilation:	EN 14387

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Liquid.
Colour	: Colourless.
Odour	: characteristic.
Odour threshold	: \geq mg/m ³
pH	: 8
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: -114 °C Ethanol
Freezing point	: No data available
Boiling point	: 78 °C Ethanol
Flash point	: 21 °C DIN 51755
Auto-ignition temperature	: 425 °C Ethanol
Decomposition temperature	: > 700 °C Ethanol
Flammability (solid, gas)	: Not applicable
Vapour pressure	: 59 hPa Ethanol
Relative vapour density at 20°C	: 2.07 Ethanol
Relative density	: No data available
Density	: 0.854 – 0.861 g/cm ³
Solubility	: Miscible with water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 200 – 600 mPa·s (25°C)
Explosive properties	: Product is not explosive. Explosive vapour/air mixtures may be formed.
Oxidising properties	: Not oxidising.
Lower explosive limit (LEL)	: 3.5 vol % Ethanol
Upper explosive limit (UEL)	: 15 vol % Ethanol

9.2. Other information

VOC content	: < 80 %
Additional information	: Solvent content < 80 %

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reacts with: alkaline earth metals. alkali metals. oxidizing materials.

10.4. Conditions to avoid

Vapour/air-mixtures are explosive at intense warming. Heating can release vapours which can be ignited.

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10.5. Incompatible materials

alkali metals. alkaline earth metals. Oxidizing agent.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide.

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)

Ethanol (64-17-5)	
LD50 oral rat	10470 mg/kg
LD50 oral	6200 mg/kg
LD50 dermal rabbit	15800 mg/kg
LD50 dermal	20000 mg/kg
LC50 Inhalation - Rat (Vapours)	30 mg/l/4h

Propan-1-ol (71-23-8)	
LD50 oral rat	> 8000 mg/kg
LD50 dermal rabbit	4032 mg/kg
LC50 Inhalation - Rat	> 33 mg/l 4 h

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 8
Serious eye damage/irritation : Causes serious eye damage.
pH: 8
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 : May cause drowsiness or dizziness.
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 : Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product. At high concentrations, the vapours may cause narcosis.

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)

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Ethanol (64-17-5)	
LC50 fish 1	11200 mg/l 96 h
EC50 Daphnia 1	5012 mg/l 48 h, Daphnia magna
ErC50 algae	275 mg/l

Propan-1-ol (71-23-8)	
LC50 fish 1	4555 mg/l 96 h, Pimephales promelas
EC50 Daphnia 1	3644 ml/l 48 h, Daphnia magna
NOEC chronic crustacea	> 100 mg/l 21 d, Daphnia magna
NOEC chronic algae	1150 mg/l 2 d, Chlorella sp.

12.2. Persistence and degradability

Softalind ViscoRub / Softa-Man ViscoRub	
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.

Ethanol (64-17-5)	
Persistence and degradability	Readily biodegradable.

Propan-1-ol (71-23-8)	
BOD (% of ThOD)	75 % ThOD 20 d

12.3. Bioaccumulative potential

Ethanol (64-17-5)	
Bioconcentration factor (BCF REACH)	0.06
Log Pow	-0.3

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Softalind ViscoRub / Softa-Man ViscoRub	
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 : Slightly hazardous to water.
Additional information : Prevent entry to sewers and public waters

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Can be incinerated according to local regulations. Recycling is preferred to disposal or incineration.
- 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 04* - other organic solvents, washing liquids and mother liquors

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1987	UN 1987	UN 1987	UN 1987	UN 1987
14.2. UN proper shipping name				
ALCOHOLS, N.O.S. (Ethanol ; Propan-1-ol)	ALCOHOLS, N.O.S. (Ethanol ; Propan-1-ol)	Alcohols, n.o.s. (Ethanol ; Propan-1-ol)	ALCOHOLS, N.O.S. (Ethanol ; Propan-1-ol)	ALCOHOLS, N.O.S. (Ethanol ; Propan-1-ol)
Transport document description				
UN 1987 ALCOHOLS, N.O.S. (Ethanol ; Propan-1- ol), 3, II, (D/E)	UN 1987 ALCOHOLS, N.O.S. (Ethanol ; Propan-1- ol), 3, II	UN 1987 Alcohols, n.o.s. (Ethanol ; Propan-1-ol), 3, II	UN 1987 ALCOHOLS, N.O.S. (Ethanol ; Propan-1- ol), 3, II	UN 1987 ALCOHOLS, N.O.S. (Ethanol ; Propan-1- ol), 3, II
14.3. Transport hazard class(es)				
3	3	3	3	3
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

14.6. Special precautions for user

Overland transport

- Classification code (ADR) : F1
Special provisions (ADR) : 274, 601, 640D
Limited quantities (ADR) : 1I
Excepted quantities (ADR) : E2
Packing instructions (ADR) : P001, IBC02, R001
Mixed packing provisions (ADR) : MP19
Transport category (ADR) : 2
Hazard identification number (Kemler No.) : 33

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Orange plates	:	
Tunnel restriction code (ADR)	:	D/E
EAC code	:	•3YE
Transport by sea		
Special provisions (IMDG)	:	274
Limited quantities (IMDG)	:	1 L
Excepted quantities (IMDG)	:	E2
Packing instructions (IMDG)	:	P001
IBC packing instructions (IMDG)	:	IBC02
Tank instructions (IMDG)	:	T7
Tank special provisions (IMDG)	:	TP1, TP8, TP28
EmS-No. (Fire)	:	F-E
EmS-No. (Spillage)	:	S-D
Stowage category (IMDG)	:	B
Air transport		
PCA Excepted quantities (IATA)	:	E2
PCA Limited quantities (IATA)	:	Y341
PCA limited quantity max net quantity (IATA)	:	1L
PCA packing instructions (IATA)	:	353
PCA max net quantity (IATA)	:	5L
CAO packing instructions (IATA)	:	364
CAO max net quantity (IATA)	:	60L
Special provisions (IATA)	:	A3, A180
ERG code (IATA)	:	3L
Inland waterway transport		
Classification code (ADN)	:	F1
Special provisions (ADN)	:	274, 601, 640D
Limited quantities (ADN)	:	1 L
Excepted quantities (ADN)	:	E2
Carriage permitted (ADN)	:	T
Equipment required (ADN)	:	PP, EX, A
Ventilation (ADN)	:	VE01
Number of blue cones/lights (ADN)	:	1
Rail transport		
Classification code (RID)	:	F1
Special provisions (RID)	:	274, 601, 640D
Limited quantities (RID)	:	1L
Excepted quantities (RID)	:	E2
Packing instructions (RID)	:	P001, IBC02, R001
Transport category (RID)	:	2
Hazard identification number (RID)	:	33

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 : < 80 %

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Directive 2012/18/EU (SEVESO III)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	Upper-tier
P5c FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5a and P5b	5000	50000

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:	
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.

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Full text of H- and EUH-statements:	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

Classification and procedure used to derive the classification for mixtures according to GB CLP Regulation		
Flam. Liq. 2	H225	On basis of test data
Eye Dam. 1	H318	Calculation method
STOT SE 3	H336	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.