

CaviWipes (All Sizes)

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 3/23/2012 Revision date: 4/4/2022 Supersedes version of: 2/12/2020 Version: 8.0

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

1.1. Product identifier

Product form Mixture

Product name CaviWipes (All Sizes)

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

Relevant identified uses

Main use category

: Cleaner and disinfectant of medical device surfaces. Function or use category

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Kerr Italia S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy T +39 081 850 3511 safety@envistaco.com

1.4. Emergency telephone number

Emergency number

: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Official advisory body	Address	Emergency number	Comment
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266	
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

H319 Eve Irrit. 2

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)

GHS07

Signal word (CLP)

Warning

Hazard statements (CLP) H319 - Causes serious eye irritation.

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Precautionary statements (CLP) P264 - Wash hands, forearms and face thoroughly after handling.

> P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing 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.

Extra phrases On basis of test data:

The mixture need not be classified as corrosive in spite of the extreme pH.

2.3. Other hazards

Other hazards which do not result in classification None under normal conditions. 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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
isopropanol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 67-63-0 (EC-No.) 200-661-7 (EC Index-No.) 603-117-00-0 (REACH-no) 01-2119457558-25	17.2	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
ethyleneglycol monobutyl ether (2-butoxyethanol) substance with national workplace exposure limit(s) (GB, GI, IE, MT); substance with a Community workplace exposure limit	(CAS-No.) 111-76-2 (EC-No.) 203-905-0 (EC Index-No.) 603-014-00-0 (REACH-no) 01-2119475108-36	1 – 5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=2000 mg/kg bodyweight) Acute Tox. 4 (Inhalation), H332 (ATE=11 mg/l/4h) Skin Irrit. 2, H315 Eye Irrit. 2, H319
Benzethonium Chloride	(CAS-No.) 121-54-0 (EC-No.) 204-479-9 (REACH-no) N/A	0.1 – 1	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Corr. 1A, H314 STOT SE 3, H335 Aquatic Chronic 2, H411

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 : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel

Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after skin contact First-aid measures after eye contact Rinse cautiously with water for several minutes. Obtain medical attention if pain, blinking or redness

First-aid measures after ingestion : Rinse mouth. If you feel unwell, seek medical advice.

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

Symptoms/effects In all cases of doubt, or when symptoms persist, seek medical attention.

Symptoms/effects after inhalation May cause drowsiness or dizziness. Symptoms/effects after eye contact Causes serious eye irritation.

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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Combustible liquid.

Explosion hazard : Product is not explosive.

Hazardous decomposition products in case of fire : Carbon monoxide. Carbon dioxide

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection

(EN137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes. Concerning personal protective equipment to use, see section 8. No

open flames. No smoking. Use special care to avoid static electric charges. No flames, no sparks.

Eliminate all sources of ignition.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container

for disposal. Take up large spills with pump or vacuum and finish with dry chemical absorbent.

6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and

when leaving work. Wear personal protective equipment. Keep away from heat, hot surfaces, sparks,

open flames and other ignition sources. No smoking.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild

soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Keep only in original container. Do not expose to temperatures exceeding

50 °C/ 122 °F. Keep cool. Store in a well-ventilated place. Keep away from heat, hot surfaces, sparks,

open flames and other ignition sources. No smoking.

Incompatible materials : Refer to Section 10 on Incompatible Materials. Oxidizing materials.

Storage area : Store in a well-ventilated place.

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7.3. Specific end use(s)

No additional data.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

isopropanol (67-63-0)		
Ireland - Occupational Exposure Limits		
Local name	Isopropyl alcohol [Propan-2-ol]	
OEL TWA [2]	200 ppm	
OEL STEL [ppm]	400 ppm	
Remark	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body)	
Regulatory reference	Chemical Agents Code of Practice 2021	
Ireland - Biological limit values		
Local name	2-Propanol	
BLV	40 mg/l Parameter: acetone - Medium: urine - Sampling time: End of shift at end of workweek - Notations: B (Background), Ns (Non-specific)	
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)	
United Kingdom - Occupational Exposure Limits		
Local name	Propan-2-ol	
WEL TWA (OEL TWA) [1]	999 mg/m³	
WEL TWA (OEL TWA) [2]	400 ppm	
WEL STEL (OEL STEL)	1250 mg/m³	
WEL STEL (OEL STEL) [ppm]	500 ppm	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

ethyleneglycol monobutyl ether (2-butoxyethanol) (111-76-2)		
Gibraltar - Occupational Exposure Limits		
Local name	2-Butoxyethanol	
OEL TWA	98 mg/m³	
OEL TWA [ppm]	20 ppm	
OEL STEL	246 mg/m³	
OEL STEL [ppm]	50 ppm	
Remark	Skin	
Regulatory reference	Factories (Control of Chemical Agents at Work) Regulations 2003 (LN. 2018/181)	
Ireland - Occupational Exposure Limits		
Local name	2-Butoxyethanol (EGBE) [Ethylene glycol monobutyl ether]	
OEL TWA [1]	98 mg/m³	
OEL TWA [2]	20 ppm	
OEL STEL	246 mg/m³	
OEL STEL [ppm]	50 ppm	
Remark	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body), IOELV (Indicative Occupational Exposure Limit Values)	

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Regulatory reference	Chemical Agents Code of Practice 2021	
reland - Biological limit values		
Local name	2-Butoxyethanol	
BLV	200 mg/g creatinine Parameter: BAA - Medium: urine - Sampling time: End of shift	
Regulatory reference	Biological Monitoring Guidelines (HSA, 2011)	
Malta - Occupational Exposure Limits		
Local name	2-Butoxyethanol	
OEL TWA	98 mg/m³	
OEL TWA [ppm]	20 ppm	
OEL STEL	246 mg/m³	
OEL STEL [ppm]	50 ppm	
Remark	Skin # Ġilda	
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)	
United Kingdom - Occupational Exposure Limits		
Local name	2-Butoxyethanol	
WEL TWA (OEL TWA) [1]	123 mg/m³	
WEL TWA (OEL TWA) [2]	25 ppm	
WEL STEL (OEL STEL)	246 mg/m³	
WEL STEL (OEL STEL) [ppm]	50 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	
Inited Kingdom - Biological limit values		
Local name	2-Butoxyethanol	
BMGV	240 mmol/mol Creatinine Parameter: butoxyacetic acid - Medium: urine - Sampling time: Post shift	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	
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8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:





8.2.2.1. Eye and face protection

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Eye protection:

Use splash goggles when eye contact due to splashing is possible. Safety glasses (EN 166)

8.2.2.2. Skin protection

Skin and body protection:

In case of possible repeated skin contact wear protective clothing

Hand protection:

In case of repeated or prolonged contact wear gloves. Butylrubber protective gloves. Nitrile rubber gloves. Breakthrough time: > 60 minutes. Layer thickness: 0,1mm. STANDARD EN 374.

8.2.2.3. Respiratory protection

Respiratory protection:

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liauid Colour Clear. Odour : Alcohol. Odour threshold 0.001 ppm Melting point Not determined. Freezing point : Not determined. Boiling point : Not determined. Flammability : Not available

Explosive properties Product is not explosive : Combustible liquid. Oxidising properties Explosive limits : Not available Lower explosive limit (LEL) : 2 vol % Upper explosive limit (UEL) : 12.7 vol % Flash point : 64 °C : Not determined. Auto-ignition temperature Decomposition temperature Not determined. 85-1249 Viscosity, kinematic : Not determined.

Viscosity, dynamic : Not determined.
Solubility : In water, material soluble.

Partition coefficient n-octanol/water (Log Kow) : Not available

Vapour pressure : 43.3 mm Hg 43.3 mmHg @ 20°C (Isopropanol)

Vapour pressure at 50 °C : Not available Density : 0.927 g/cm3 Relative density Relative vapour density at 20 °C 2.1 (Isopropanol) Particle size Not applicable Particle size distribution Not applicable Particle shape Not applicable Particle aspect ratio Not applicable Particle aggregation state Not applicable Particle agglomeration state Not applicable Not applicable Particle specific surface area Particle dustiness Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

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9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

: 20 % VOC content Additional information : None to our knowledge.

SECTION 10: Stability and reactivity

10.1. Reactivity

None to our knowledge.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Oxidizing agent. Acids. reducing materials.

10.6. Hazardous decomposition products

No decomposition if stored and used normally. Thermal decomposition generates: Carbon dioxide. Carbon monoxide. Nitrogen oxides. Amines. Chlorine. Hydrogen chloride.

SECTION 11: Toxicological information

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

: Not classified Acute toxicity (oral) Acute toxicity (dermal) Not classified Acute toxicity (inhalation) Not classified

Additional information : Based on available data, the classification criteria are not met

Benzethonium Chloride (121-54-0)	
LD50 oral rat	368 mg/kg

isopropanol (67-63-0)	
LD50 oral rat	4710 mg/kg
LD50 dermal rat	15800 mg/kg bodyweight
LD50 dermal rabbit	12800 mg/kg bodyweight
LC50 Inhalation - Rat (Vapours)	72.6 mg/l/4h

ethyleneglycol monobutyl ether (2-butoxyethanol) (111-76-2)	
LD50 dermal rabbit	2000 mg/kg

Skin corrosion/irritation : Not classified

pH: 8.5 - 12.49

Additional information : Based on available data, the classification criteria are not met Serious eye damage/irritation

Causes serious eye irritation.

pH: 8.5 - 12.49

Respiratory or skin sensitisation Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity Not classified

Additional information : Based on available data, the classification criteria are not met

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isopropanol (67-63-0)	
NOAEL (chronic, oral, animal/female, 2 years)	5000 ppm

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Benzethonium Chloride (121-54-0)	
STOT-single exposure	May cause respiratory irritation.

isopropanol (67-63-0)	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

CaviWipes (All Sizes)	
Viscosity, kinematic	Not determined.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified Hazardous to the aquatic environment, long–term (chronic) : Not classified

Benzethonium Chloride (121-54-0)		
LC50 - Fish [1]	1.4 mg/l (96 hours - Lepomis macrochirus)	
EC50 - Crustacea [1]	70 mg/l	

isopropanol (67-63-0)	
LC50 - Fish [1]	4200 mg/l
EC50 - Crustacea [1]	13300 mg/l Daphnia magna, 48 hours
EC50 72h - Algae [1]	> 1000 mg/l (Desmodesmus subspicatus)

ethyleneglycol monobutyl ether (2-butoxyethanol) (111-76-2)			
LC50 - Fish [1] 1125 mg/l Menidia berylina			
EC50 - Crustacea [1]	835 mg/l (48 hours - Daphnia magna)		
ErC50 algae	286 mg/l 72 hours - Pseudokirchnerella subcapitata		

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12.2. Persistence and degradability

CaviWipes (All Sizes)	
Persistence and degradability	No data available.

isopropanol (67-63-0)	
Persistence and degradability	Readily biodegradable.
BOD (% of ThOD)	0.3 – 0.6 % ThOD BOD5/COD
Biodegradation	84 % (OECD 301D method)

ethyleneglycol monobutyl ether (2-butoxyethanol) (111-76-2)	
Biodegradation	95 % (OECD 301E method)

12.3. Bioaccumulative potential

CaviWipes (All Sizes)	
Bioaccumulative potential	Not potentially bioaccumulable.

isopropanol (67-63-0)	
Bioconcentration factor (BCF REACH)	< 100
Partition coefficient n-octanol/water (Log Pow)	2.97

ethyleneglycol monobutyl ether (2-butoxyethanol) (111-76-2)		
Bioconcentration factor (BCF REACH)	3	
Partition coefficient n-octanol/water (Log Pow)	0.84	

12.4. Mobility in soil

CaviWipes (All Sizes)		
Ecology - soil	soluble in water.	

isopropanol (67-63-0)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.117995

12.5. Results of PBT and vPvB assessment

CaviWipes (All Sizes)

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. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Other adverse effects : None to our knowledge. Additional information : No other effects known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose as hazardous waste. Biohazardous infectious materials. Wastes presenting danger of contamination (e.g. tissue waste, waste containing blood).

Waste treatment methods : Recover the product with absorbent material. Dispose of contents/container in accordance with licensed

collector's sorting instructions.

Product/Packaging disposal recommendations

Dispose in a safe manner in accordance with local/national regulations.
 Avoid release to the environment.

Ecology - waste materials
European List of Waste (LoW) code

: 18 01 06* - chemicals consisting of or containing dangerous substances

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SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name	9	,		
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(e	s)			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information a	vailable	1	1	1

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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 REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

VOC content : 20 %

15.1.2. National regulations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

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SECTION 16: Other information

Indication of changes:			
Section	Changed item	Change	Comments
3	Composition/information on ingredients	Modified	

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)

Acute Tox. 4 (Dermal)

Acute Tox. 4 (Inhalation)

Acute Tox. 4 (Inhalation)

Acute Tox. 4 (Oral)

Aquatic Chronic 2 Hazardous to the aquatic environment – Chronic Hazard, Category 2

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2 Flam. Liq. 2 Flammable liquids, Category 2

H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.

H302 Harmful if swallowed. H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.
Skin Corr. 1A Skin corrosion/irritation, Category 1, Sub-Category 1A

Skin Irrit. 2 Skin corrosion/irritation, Category 2

STOT SE 3 Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.