

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

1.1. Product identifier

Product form : Mixture
Trade name : ULTRAbio Ultrasonic Cleaner
UFI : 0610-E0JV-7002-VXNE

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

Relevant identified uses

Main use category : Professional use
Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Cleaning/washing agents and additives
Concentrated solution
Function or use category : Cleaning/washing agents and additives

1.3. Details of the supplier of the safety data sheet

Manufacturer

Topdental (Products) Ltd
Unit 1
Holmfield Industrial Estate
HX2 9TN Halifax, W. Yorks
United Kingdom
T +44 (0) 1535 652750
sales@topdental.co.uk, www.topdental.co.uk

EU

Directa AB
Box 723
Finvids vag 8
SE-194 27 Upplands Vasby
Sweden
T +46-8-506 505 75
directadental.com

1.4. Emergency telephone number

Emergency number : +44 (0) 1535 652750

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 3 H226
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity – Single exposure, Category 3, H336
Narcosis

Full text of H- and EUH-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) :



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	GHS02	GHS07
Signal word (CLP)	: Warning	
Contains	: PROPAN-2-OL	
Hazard statements (CLP)	: H226 - Flammable liquid and vapour. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness.	
Precautionary statements (CLP)	: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 - Avoid breathing vapours. P280 - Wear protective clothing, eye protection, face protection, protective gloves. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH 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 substance(s) are 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

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
PROPAN-2-OL (Component) substance with national workplace exposure limit(s) (GB)	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0	$\geq 15 - < 25$	Flam. Liq. 3, H226 Eye Irrit. 2, H319 STOT SE 3, H336
didecyldimethylammonium chloride	CAS-No.: 7173-51-5 EC-No.: 230-525-2 EC Index-No.: 612-131-00-6	$\geq 1 - < 5$	Acute Tox. 4 (Oral), H302 (ATE=658 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 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	: Get medical advice/attention 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	: After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult an ophtalmologist if irritation persists.
First-aid measures after ingestion	: If swallowed, seek medical advice immediately and show this container or label. Rinse mouth out with water. Do not induce vomiting because of corrosive effects.

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

Symptoms/effects after inhalation	: Depression of the central nervous system, headaches, dizziness, drowsiness, loss of coordination. Inhalation may cause irritation (cough, short breathing, difficulty in breathing).
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.
Symptoms/effects upon intravenous administration	: Unknown.

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

When in doubt or if symptoms are observed, get medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: carbon dioxide (CO ₂), powder, alcohol-resistant foam, water spray.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable liquid and vapour.
Explosion hazard	: Explosive vapour/air mixtures may be formed.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire	: Avoid contact with skin and eyes. Eliminate all ignition sources if safe to do so. Stop leak if safe to do so. Wear self-contained breathing apparatus.
Firefighting instructions	: Cool laterally with water containers exposed to flames, even after the fire is extinguished.
Protection during firefighting	: Use self-contained breathing apparatus and chemically protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Stop leak if safe to do so. Eliminate every possible source of ignition. Avoid contact with skin and eyes. Clean up any spills as soon as possible, using an absorbent material to collect it.
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For non-emergency personnel

Protective equipment	: Wear recommended personal protective equipment.
Emergency procedures	: Avoid contact with skin and eyes. Do not breathe vapours. Evacuate area. Keep upwind. No flames, no sparks. Eliminate all sources of ignition. Turn leaking containers leak-side up to prevent the escape of liquid.
Measures in case of dust release	: Ventilate the area thoroughly.

For emergency responders

Protective equipment	: Use self-contained breathing apparatus and chemically protective clothing.
Emergency procedures	: Evacuate unnecessary personnel. Stop leak if safe to do so. Ventilate area.

6.2. Environmental precautions

Do not allow to enter drains or water courses. Contain the spilled material by bunding.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb spilled material with sand or earth. Stop leak without risks if possible.
Methods for cleaning up	: Absorb excess liquid spillage on inorganic adsorbent material such as fine sand, brick dust etc. Place spent adsorbent in sealed packages and contact specialist waste disposal contractor. Use only non-sparking tools.
Other information	: No flames, no sparks. Eliminate all sources of ignition.

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6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Flammable vapours may accumulate in the container. Handle empty containers with care because residual vapours are flammable. Avoid the formation of mists in the atmosphere. In use, may form flammable vapour-air mixture.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Ensure adequate ventilation, especially in confined areas. Keep away from sources of ignition. Keep in a cool, well-ventilated place away from heat. Store in tightly closed, leak-proof containers.

Storage conditions : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Protect from sunlight. Store in a well-ventilated place. Keep container tightly closed.

7.3. Specific end use(s)

Cleaning of medical devices.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

PROPAN-2-OL (67-63-0)	
United Kingdom - Occupational Exposure Limits	
WEL STEL (OEL STEL)	1250 mg/m ³
	500 ppm

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure adequate ventilation, especially in confined areas.

Personal protection equipment

Personal protective equipment:

Safety glasses. Gloves. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Personal protective equipment symbol(s):



Skin protection

Skin and body protection:

Protective clothing

Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

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Thermal hazards

Thermal hazard protection:

Keep cool.

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment. Do not exceed the occupational exposure limits (OEL).

Consumer exposure controls:

Do not breathe vapours.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Not available
Appearance	: Yellow liquid.
Odour	: Alcoholic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: 27
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 6.5 – 7.5
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 0.96 – 0.98
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

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 of use. Flammable liquid and vapour.

10.3. Possibility of hazardous reactions

Refer to section 10.1 on Reactivity.

10.4. Conditions to avoid

Heat and ignition sources.

10.5. Incompatible materials

Aluminium. Copper alloys.

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10.6. Hazardous decomposition products

May release flammable gases. May liberate toxic gases.

SECTION 11: Toxicological information

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

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

PROPAN-2-OL (67-63-0)

LD50 oral rat	5840 mg/kg
LC50 Inhalation - Rat	37.5 mg/l 4h, male and female

didecyldimethylammonium chloride (7173-51-5)

LD50 oral	658 mg/kg
LD50 dermal rat	> 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal))
LD50 dermal rabbit	≈ 3342 mg/kg bodyweight Animal: rabbit, Guideline: other., 95% CL: 0 - 4292
LD50 dermal	> 5000 mg/kg

Skin corrosion/irritation : Causes skin irritation.
pH: 6.5 – 7.5

PROPAN-2-OL (67-63-0)

pH	7 Neutral
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Serious eye damage/irritation : Causes serious eye irritation.
pH: 6.5 – 7.5

PROPAN-2-OL (67-63-0)

pH	7 Neutral
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Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : May cause drowsiness or dizziness.

PROPAN-2-OL (67-63-0)

STOT-single exposure	May cause drowsiness or dizziness.
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STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

didecyldimethylammonium chloride (7173-51-5)

Viscosity, kinematic	≈ 24.5 mm²/s Temp.: '20°C' Parameter: 'kinematic viscosity (in mm²/s)'
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11.2. Information on other hazards

Other information

Potential adverse human health effects and symptoms : Irritation: severely irritant to eyes

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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

PROPAN-2-OL (67-63-0)

LC50 - Fish [1]	9640 mg/l fathered minnow
EC50 - Crustacea [1]	13299 mg/l Daphnia magna

didecyldimethylammonium chloride (7173-51-5)

LC50 - Fish [1]	≈ 0.97 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
LC50 - Fish [2]	≈ 0.49 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	≈ 0.057 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	≈ 0.029 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	≈ 0.062 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
LOEC (chronic)	≈ 0.047 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	≈ 0.021 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

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Persistence and degradability	Rapidly degradable
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PROPAN-2-OL (67-63-0)

Persistence and degradability	Not rapidly degradable
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didecyldimethylammonium chloride (7173-51-5)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
HP Code	: HP3 - "Flammable:" <ul style="list-style-type: none">– flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C;– flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air;– flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction;– flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa;– water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities;– other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste. HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 1993	UN 1993	UN 1993	UN 1993	UN 1993
14.2. UN proper shipping name				
FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL)	FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL)	Flammable liquid, n.o.s. (PROPAN-2-OL)	FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL)	FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL)
Transport document description				
UN 1993 FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL), 3, III, (D/E)	UN 1993 FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL), 3, III	UN 1993 Flammable liquid, n.o.s. (PROPAN-2-OL), 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL), 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S. (PROPAN-2-OL), 3, III
14.3. Transport hazard class(es)				
3	3	3	3	3
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-E EmS-No. (Spillage): S-E	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				


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14.6. Special precautions for user

Overland transport

Classification code (ADR)	: F1
Special provisions (ADR)	: 274, 601
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1, TP29
Tank code (ADR)	: LGBF
Vehicle for tank carriage	: FL
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V12
Special provisions for carriage - Operation (ADR)	: S2
Hazard identification number (Kemler No.)	: 30
Orange plates	: 

Tunnel restriction code (ADR)	: D/E
EAC code	: •3Y

Transport by sea

Special provisions (IMDG)	: 223, 274, 955
Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP01, P001
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP1, TP29
Stowage category (IMDG)	: A

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y344
PCA limited quantity max net quantity (IATA)	: 10L
PCA packing instructions (IATA)	: 355
PCA max net quantity (IATA)	: 60L
CAO packing instructions (IATA)	: 366
CAO max net quantity (IATA)	: 220L
Special provisions (IATA)	: A3
ERG code (IATA)	: 3L

Inland waterway transport

Classification code (ADN)	: F1
Special provisions (ADN)	: 274, 601
Limited quantities (ADN)	: 5 L
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T
Equipment required (ADN)	: PP, EX, A
Ventilation (ADN)	: VE01
Number of blue cones/lights (ADN)	: 0

Rail transport

Classification code (RID)	: F1
Special provisions (RID)	: 274, 601
Limited quantities (RID)	: 5L
Excepted quantities (RID)	: E1
Packing instructions (RID)	: P001, IBC03, LP01, R001

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Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions (RID) : T4
Portable tank and bulk container special provisions (RID) : TP1, TP29
Tank codes for RID tanks (RID) : LGBF
Transport category (RID) : 3
Special provisions for carriage – Packages (RID) : W12
Colis express (express parcels) (RID) : CE4
Hazard identification number (RID) : 30

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

REACH Annex XVII (Restriction List)

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

REACH Annex XIV (Authorisation List)

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

REACH Candidate List (SVHC)

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

PIC Regulation (Prior Informed Consent)

Contains substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals):
Didecyldimethylammonium chloride (7173-51-5)

POP Regulation (Persistent Organic Pollutants)

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

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out

SECTION 16: Other information

Data sources : Supplier's safety documents. Expert judgement and weight of evidence determination.

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

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Full text of H- and EUH-statements:	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

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 not therefore be construed as guaranteeing any specific property of the product.