

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 3/15/2024 Version: 1.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking **1.1. Product identifier** Product form : Mixture Product name : Porcelain Etch (4%HF) 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 : For Rx Only 1.2.2. Uses advised against No additional information available 1.3. Details of the supplier of the safety data sheet Manufacturer/Importer/Representative/User/Distributor: **U.S. Federal Register:** Reliance Orthodontic Products, Inc. According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 1540 W. Thorndale Ave / Rules and Regulations Itasca, IL 60143 USA FDA Registration: 1420089 T 630-773-4009, during normal business hours regulatory@relianceorthodontics.com www.RelianceOrthodontics.com Australian Sponsor: EC Representative: Emergo Australia, 201 Sussex St. Emergo Europe Darling Park, Tower II, Level 20 Westervoortsedijk 60 Sydney, NSW 2000 Australia 6827 AT Arnhem T +61 2 9006 1662 The Netherlands T +31 70 345 8570 Switzerland Representative: U.K. Person Responsible: MedEnvoy Global BV Emergo Consulting (UK) Limited Leidschendam-Voorburg, Zug Branch Office c/o Cr360 - UL International Compass House, Vision Park Histon Gotthardstrasse 28, 6302 Zug, Switzerland Cambridge CB24 9BZ T +41 41 462 01 42 England, United Kingdom T +44(0) 1223 772 671 1.4. Emergency telephone number

Emergency number

: CHEMTREC - 24-Hour Hazmat Emergency Communications Center Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]		
Acute toxicity (dermal), Category 2	H310	
Skin corrosion/irritation, Category 1, Sub-Category 1A	H314	
Full text of H- and EUH-statements: see section 16		

Adverse physicochemical, human health and environmental effects

Fatal in contact with skin. Toxic if inhaled. Toxic if swallowed. Causes severe skin burns and eye damage.

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Hazard pictograms (CLP) GHS05 GHS06 Signal word (CLP) : Danger Contains Hydrofluoric Acid Hazard statements (CLP) : H310 - Fatal in contact with skin. H314 - Causes severe skin burns and eye damage. Precautionary statements (CLP) : P260 - Do not breathe fume, mist, vapours. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves, protective clothing, eye protection. P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. 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. P310 - Immediately call a POISON CENTER, a doctor. P321 - Specific treatment (see supplemental first aid instruction on this label). P361+P364 - Take off immediately all contaminated clothing and wash it before reuse. P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste. 2.3. Other hazards Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component		
Hydrofluoric Acid (7664-39-3)	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	
Sodium Fluoride (7681-49-4)	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 %

Component	
Hydrofluoric Acid(7664-39-3)	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

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3.2. Mixtures			
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hydrofluoric Acid substance with a Community workplace exposure limit	CAS-No.: 7664-39-3 EC-No.: 231-634-8 EC Index-No.: 009-003-00-1	5 - 10	Acute Tox. 1 (Dermal), H310 Skin Corr. 1, H314
Sodium Fluoride substance with a Community workplace exposure limit	CAS-No.: 7681-49-4 EC-No.: 231-667-8 EC Index-No.: 009-004-00-7	< 1	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT RE 1, H372

Specific concentration limits:		
Name	Product identifier	Specific concentration limits (%)
Hydrofluoric Acid	EC-No.: 231-634-8	(0.1 ≤ C < 1) Eye Irrit. 2, H319 (1 ≤ C < 7) Skin Corr. 1B, H314 (7 ≤ C ≤ 100) Skin Corr. 1A, H314

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	: 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	 Rinse skin with water/shower. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water. Do not induce vomiting. Get medical advice/attention if you feel unwell.
4.2. Most important symptoms and effe	cts, both acute and delayed
Symptoms/effects after skin contact	: Burns.
Symptoms/effects after eye contact	: Serious damage to eyes.
Symptoms/effects after ingestion	: Burns.

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. Foam. Carbon dioxide.
5.2. Special hazards arising from the subs	tance or mixture
Hazardous decomposition products in case of fire	: Toxic fumes may be released.
5.3. Advice for firefighters	
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measure	es
6.1. Personal precautions, protective equipr	nent and emergency procedures
6.1.1. For non-emergency personnel	
Emergency procedures	: Ventilate spillage area. Only qualified personnel equipped with suitable protective equipment may intervene. Do not breathe fume, mist, vapours.
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	
Avoid release to the environment.	
6.3. Methods and material for containment a	and cleaning up
Methods for cleaning up Other information	Take up liquid spill into absorbent material.Dispose of materials or solid residues at an authorized site.
6.4. Reference to other sections	
For further information refer to section 13	

SECTION 7: Handling and storage			
7.1. Precautions for safe handling			
Precautions for safe handling	: Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. Do not breathe fume, mist, vapours.		
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			
Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep cool.		

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

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

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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 symbol(s):



8.2.2.1. Eye and face protection

Eye protection: Safety glasses

8.2.2.2. Skin protection

Skin and body protection: Wear suitable protective clothing

Hand protection: Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection: [In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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
Colour	:	Orange.
Appearance	:	Gel.
Odour	:	Odourless.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not applicable
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	≈ 1
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	:	Not available
Relative density	:	Not available

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Particle characteristics	: Not applicable	
9.2. Other information		

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008		
Acute toxicity (dermal)	Not classified Fatal in contact with skin. Not classified	
Porcelain Etch (4%HF)		
ATE CLP (dermal)	61.275 mg/kg bodyweight	
Hydrofluoric Acid (7664-39-3)		
LD50 dermal rabbit	≤ 50 mg/kg Source: ECHA	
Sodium Fluoride (7681-49-4)		
LD50 oral rat	223 mg/kg bodyweight (EPA OPPTS 870.1100: Acute Oral Toxicity, Rat, Male, Experimental value, Oral, 14 day(s))	
LD50 dermal rat	> 2000 mg/kg Source: ECHA	
Skin corrosion/irritation :	Causes severe skin burns. pH: ≈ 1	
Hydrofluoric Acid (7664-39-3)		
рН	< 1	

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Sodium Fluoride (7681-49-4)	
рН	7.4
Serious eye damage/irritation	: Assumed to cause serious eye damage pH: ≈ 1
Hydrofluoric Acid (7664-39-3)	
рН	< 1
Sodium Fluoride (7681-49-4)	
рН	7.4
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Sodium Fluoride (7681-49-4)	
IARC group	3 - Not classifiable
Reproductive toxicity	Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Sodium Fluoride (7681-49-4)	
LOAEL (oral, rat, 90 days)	≈ 4 mg/kg bodyweight Animal: rat, Guideline: other:
NOAEL (oral, rat, 90 days)	≈ 25 mg/kg bodyweight Animal: rat, Guideline: other:
STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified
Sodium Fluoride (7681-49-4)	
Viscosity, kinematic	0.38 mm²/s
44.0. Information on other because	

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Hazardous to the aquatic environment, short-term : (acute) Hazardous to the aquatic environment, long-term : (chronic)	Before neutralisation, the product may represent a danger to aquatic organisms. Not classified Not classified
Hydrofluoric Acid (7664-39-3)	
LC50 - Fish [1]	51 mg/l Test organisms (species): other:
LC50 - Fish [2]	165 mg/l Test organisms (species): other:
EC50 72h - Algae [1]	43 - 122 mg/l Source: ECHA
NOEC (chronic)	14.1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	4 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '21 d'
Sodium Fluoride (7681-49-4)	
LC50 - Fish [1]	38 - 68 mg/l Source: NCIS; Toxic Substances Information Report
LC50 - Fish [2]	165 mg/l Test organisms (species): other:

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Sodium Fluoride (7681-49-4)	
EC50 - Crustacea [1]	97 mg/l (48 h, Daphnia magna, Static system, Fresh water, Experimental value, Fluorine ion)
EC50 72h - Algae [1]	850 mg/l Source: NCIS; Toxic Substances Information Report
EC50 96h - Algae [1]	43 mg/l (Scenedesmus sp., Static system, Experimental value, Fluorine ion)
NOEC (chronic)	14.1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	4 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '21 d'

12.2. Persistence and degradability

Hydrofluoric Acid (7664-39-3)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable
Sodium Fluoride (7681-49-4)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

12.3. Bioaccumulative potential

Hydrofluoric Acid (7664-39-3)	
Partition coefficient n-octanol/water (Log Pow)	-0.9 (Calculated)
Bioaccumulative potential	Not bioaccumulative.
Sodium Fluoride (7681-49-4)	
BCF - Fish [1]	53 - 58 (Pisces, Fresh water, Literature study, Fresh weight)
Partition coefficient n-octanol/water (Log Pow)	-0.77 Source: EPISUITE
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

Hydrofluoric Acid (7664-39-3)	
Ecology - soil	No (test)data on mobility of the component(s) available.
Sodium Fluoride (7681-49-4)	
Ecology - soil	Adsorbs into the soil. Toxic to flora.

12.5. Results of PBT and vPvB assessment

Component	
Hydrofluoric Acid (7664-39-3)	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
Sodium Fluoride (7681-49-4)	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

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12.6. Endocrine disrupting properties
No additional information available
12.7. Other adverse effects
No additional information available
SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose of contents/container in accordance with licensed collector's sorting instructions.

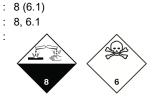
SECTION 14: Transport information

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

UN-No. (ADR) UN-No. (IMDG) UN-No. (IATA) UN-No. (ADN) UN-No. (RID)	 : UN 1790
14.2. UN proper shipping name	
Proper Shipping Name (ADR) Proper Shipping Name (IMDG) Proper Shipping Name (IATA) Proper Shipping Name (ADN) Proper Shipping Name (RID) Transport document description (ADR) Transport document description (IMDG) Transport document description (IATA) Transport document description (ADN)	 HYDROFLUORIC ACID HYDROFLUORIC ACID Not applicable HYDROFLUORIC ACID HYDROFLUORIC ACID UN 1790 HYDROFLUORIC ACID, 8 (6.1), II, (E) UN 1790 HYDROFLUORIC ACID, 8 (6.1), II UN 1790, 8 UN 1790 HYDROFLUORIC ACID, 8 (6.1), II
Transport document description (RID)	: UN 1790 HYDROFLUORIC ACID, 8 (6.1), II

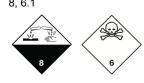
14.3. Transport hazard class(es)

ADR Transport hazard class(es) (ADR) Danger labels (ADR)



IMDG

Transport hazard class(es) (IMDG): 8 (6.1)Danger labels (IMDG): 8, 6.1



: 8

: 8 (6.1)

ΙΑΤΑ

Transport hazard class(es) (IATA)

ADN

Transport hazard class(es) (ADN)

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Danger labels (ADN)	
RID Transport hazard class(es) (RID) Danger labels (RID)	8 6 1 8 8 6 1 1 8 6 1 1 1 8 6 1 1 1 8 6 1 1 1 1 1 1 1 1 1 1 1 1 1
14.4. Packing group	Y
Packing group (ADR) Packing group (IMDG) Packing group (IATA) Packing group (ADN) Packing group (RID)	 II II Not applicable II II II
14.5. Environmental hazards	
Dangerous for the environment Marine pollutant Other information	 No No No supplementary information available
14.6. Special precautions for user	
(ADR) Tank code (ADR) Tank special provisions (ADR) Vehicle for tank carriage Transport category (ADR)	: $CT1$: 11 : $E2$: $P001, IBC02$: $MP15$: $T8$: $TP2$: $L4DH$: $TU14, TE21$: AT : 2 : $CV13, CV28$: 86 : 86 : 86 : E
Transport by sea Limited quantities (IMDG) Excepted quantities (IMDG) Packing instructions (IMDG) Special packing provisions (IMDG) IBC packing instructions (IMDG) IBC special provisions (IMDG) Tank instructions (IMDG) Tank special provisions (IMDG) EmS-No. (Fire) EmS-No. (Spillage)	 1 L E2 P001 PP81 IBC02 B20 T8 TP2 F-A S-B

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Stowage category (IMDG) Stowage and handling (IMDG) Segregation (IMDG) Properties and observations (IMDG)	 D SW1, SW2, H2 SGG1A, SG36, SG49 Colourless liquid with an irritating odour. Highly corrosive to glass, other siliceous materials and most metals. Toxic if swallowed, by skin contact or by inhalation. Both the liquid and its fumes cause severe burns to skin, eyes and mucous membranes.
Air transport No data available	
Inland waterway transport Classification code (ADN) Special provisions (ADN) Limited quantities (ADN) Excepted quantities (ADN) Equipment required (ADN) Ventilation (ADN) Number of blue cones/lights (ADN)	: CT1 : 802 : 1 L : E2 : PP, EP, TOX, A : VE02 : 2
Rail transport Classification code (RID) Limited quantities (RID) Excepted quantities (RID) Packing instructions (RID) Mixed packing provisions (RID) Portable tank and bulk container instructions (RID) Portable tank and bulk container special provisions (RID) Tank codes for RID tanks (RID) Special provisions for RID tanks (RID) Transport category (RID) Special provisions for carriage - Loading, unloading and handling (RID) Colis express (express parcels) (RID) Hazard identification number (RID)	: CT1 : 1L : E2 : P001, IBC02 : MP15 : T8 : TP2 : L4DH : TU14, TE17, TE21, TT4 : 2 : CW13, CW28 : CE6 : 86

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

15.1.1. 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 no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

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

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

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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)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Supersedes version of	Added	
	Issue date	Removed	
	Revision date	Added	
2.2	Precautionary statements (CLP)	Modified	
7.1	Precautions for safe handling	Modified	
7.2	Storage conditions	Modified	
11.1	ATE CLP (vapours)	Modified	
11.1	ATE CLP (dermal)	Modified	
11.1	ATE CLP (oral)	Modified	

Full text of H- and EUH-statements:		
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H301	Toxic if swallowed.	
H310	Fatal in contact with skin.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H319	Causes serious eye irritation.	
H372	Causes damage to organs through prolonged or repeated exposure.	
Skin Corr. 1	Skin corrosion/irritation, Category 1	
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1	

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.