

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

#### 1.1. Product identifier

Product form : Mixture  
Trade name : VPS Hydro Bite 2 x 50ml  
Product code : 9001268

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

##### 1.2.1. Relevant identified uses

Main use category : Industrial use  
Use of the substance/mixture : Addition silicone for dental impression.

##### 1.2.2. Uses advised against

Restrictions on use : Reserved for industrial and professional use

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer/Supplier

Henry Schein Inc.  
135 Duryea Road  
Melville, NY 11747  
USA

##### Importer

Henry Schein UK Holdings Limited  
Medcare House  
Centurion Close, Gillingham Business Park, Gillingham,  
Kent, United Kingdom, ME8 0SB  
Tel No.: 01634 878750

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to GB CLP (SI 2019:720 as amended)

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to GB CLP (SI 2019:720 as amended)

EUH-statements (GB CLP) : EUH210 - Safety data sheet available on request.  
Extra phrases (GB CLP) : The Regulation GB CLP (SI 2019:720 as amended) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the GB CLP labeling requirements.

#### 2.3. Other hazards

Other hazards which do not result in classification : There is no exposure to breathable free crystalline silica during normal use of this product.

# VPS Hydro Bite 2 x 50ml

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Component	
Substance(s) meeting the PBT criteria of UK REACH regulation, in accordance with Annex XIII	octamethylcyclotetrasiloxane; (D4) (556-67-2)( <sup>1</sup> ), octamethylcyclotetrasiloxane; (D4) (556-67-2)( <sup>1</sup> )
Substance(s) meeting the vPvB criteria of UK REACH regulation, in accordance with Annex XIII	octamethylcyclotetrasiloxane; (D4) (556-67-2)( <sup>1</sup> ), octamethylcyclotetrasiloxane; (D4) (556-67-2)( <sup>1</sup> )
Substance(s) not meeting the PBT criteria of UK REACH regulation, in accordance with Annex XIII	cristobalite (14464-46-1), Silicon dioxide (7631-86-9)
Substance(s) not meeting the vPvB criteria of UK REACH regulation, in accordance with Annex XIII	cristobalite (14464-46-1), Silicon dioxide (7631-86-9)

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of UK 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 GB BPR and GB PPP at a concentration equal to or greater than 0,1 %

Component	
Substance(s) not included in the list established in accordance with Article 59(1) of UK REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in GB BPR and GB PPP	Silicon dioxide(7631-86-9), cristobalite(14464-46-1), octamethylcyclotetrasiloxane; (D4)(556-67-2)( <sup>1</sup> ), octamethylcyclotetrasiloxane; (D4)(556-67-2)( <sup>1</sup> )

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to GB CLP (SI 2019:720 as amended)
Silicon dioxide	CAS-No.: 7631-86-9 EC-No.: 231-545-4	10 – 12.5	Not classified
cristobalite	CAS-No.: 14464-46-1 EC-No.: 238-455-4	8 – 10	STOT RE 1, H372
octamethylcyclotetrasiloxane; (D4) substance listed on UK REACH candidate (Octamethylcyclotetrasiloxane)	CAS-No.: 556-67-2 EC-No.: 209-136-7 UK Index-No.: 014-018-00-1	< 0.05	Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10)
octamethylcyclotetrasiloxane; (D4) substance listed on UK REACH candidate (Octamethylcyclotetrasiloxane)	CAS-No.: 556-67-2 EC-No.: 209-136-7 UK Index-No.: 014-018-00-1	< 0.05	Flam. Liq. 3, H226 Repr. 2, H361f Aquatic Chronic 1, H410 (M=10)

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

### Components - Nanoform

Silicon dioxide (7631-86-9)	
Additional information	No additional information available

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
First-aid measures after skin contact : Wash skin with plenty of water.

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First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

First-aid measures after ingestion : Do not induce vomiting. Call a poison center or a doctor if you feel unwell.

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

No additional information available

### 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 : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide.

### 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.

Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

#### 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 sub-soil penetration. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

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

Storage conditions : Store in a well-ventilated place. Keep cool.

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 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

octamethylcyclotetrasiloxane; (D4) (556-67-2)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, inhalation	73 mg/m <sup>3</sup>
Long-term - local effects, inhalation	73 mg/m <sup>3</sup>
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	3.7 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	13 mg/m <sup>3</sup>
Long-term - local effects, inhalation	13 mg/m <sup>3</sup>
PNEC (Water)	
PNEC aqua (freshwater)	0.0015 mg/l
PNEC aqua (marine water)	0.00015 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3 mg/kg dwt
PNEC sediment (marine water)	0.3 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.84 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	41 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	10 mg/l

#### 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.

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use eye protection according to EN 166, designed to protect against liquid splashes. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN 14605. EN ISO 13688. EN 13034

##### Hand protection:

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. A-P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 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	: white.
Odour	: odourless.
Odour threshold	: Not available
pH	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flash point	: > 135 °C (EN ISO 3679)
Flammability	: Not available
Explosive limits	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Relative vapour density at 20°C	: Not available
Relative density	: Not available
Density	: 1.45 g/cm <sup>3</sup>
Solubility	: Insoluble.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
Viscosity, kinematic	: Not available
Explosive properties	: Product is not explosive
Oxidising properties	: Non oxidizing.

### 9.2. Other information

Particle characteristics	: Not applicable
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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

### 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

No additional information available

#### 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 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)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met).

#### cristobalite (14464-46-1)

STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
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Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
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#### 11.2. Information on other hazards

##### 11.2.1. Endocrine disrupting properties

No additional information available

##### 11.2.2. Other information

Other information	: Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.
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### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met).

Additional information : A test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates.

octamethylcyclotetrasiloxane; (D4) (556-67-2)	
LC50 - Fish [1]	> 22 µg/l (96 h; Oncorhynchus mykiss; EPA OTS 797.1400)
EC50 - Crustacea [1]	> 15 µg/l (48 h; Daphnia magna; EPA OTS 797.1300)
ErC50 algae	> 22 µg/L (96 h; Raphidocelis subcapitata; EPA OTS 797.1050)
NOEC chronic fish	≥ 4.4 µg/L (93 d; Oncorhynchus mykiss; 40 CFR 797.1600)
NOEC chronic crustacea	7.9 µg/L (21 d; Daphnia magna; EPA 797.1330)
NOEC chronic algae	< 22 µg/L (96 h; Raphidocelis subcapitata; EPA OTS 797.1050)

### 12.2. Persistence and degradability

VPS Hydro Bite 2 x 50ml	
Persistence and degradability	No additional information available.
cristobalite (14464-46-1)	
Persistence and degradability	Not applicable.
octamethylcyclotetrasiloxane; (D4) (556-67-2)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	3.7 % (29 d; (OECD 310 method))
Silicon dioxide (7631-86-9)	
Persistence and degradability	Not applicable for inorganic substances.

### 12.3. Bioaccumulative potential

cristobalite (14464-46-1)	
Bioaccumulative potential	Not applicable.
octamethylcyclotetrasiloxane; (D4) (556-67-2)	
BCF - Fish [1]	14900 l/kg (28 d; Pimephales promelas; EPA OTS 797.1520)
Partition coefficient n-octanol/water (Log Pow)	6.98 (21.7 °C; pH 7)
Silicon dioxide (7631-86-9)	
Bioaccumulative potential	Not applicable for inorganic substances.

### 12.4. Mobility in soil

octamethylcyclotetrasiloxane; (D4) (556-67-2)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	4.22 (OECD 106 method)

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

### 12.5. Results of PBT and vPvB assessment

Component	
cristobalite (14464-46-1)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII
octamethylcyclotetrasiloxane; (D4) (556-67-2)	This substance meets the PBT criteria of UK REACH regulation, annex XIII This substance meets the vPvB criteria of UK REACH regulation, annex XIII
octamethylcyclotetrasiloxane; (D4) (556-67-2)	This substance meets the PBT criteria of UK REACH regulation, annex XIII This substance meets the vPvB criteria of UK REACH regulation, annex XIII
Silicon dioxide (7631-86-9)	This product does not contain substances at $\geq 0.1\%$ that meet the PBT criteria of UK REACH regulation, annex XIII This product does not contain substances at $\geq 0.1\%$ that meet the vPvB criteria of UK REACH regulation, annex XIII

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not regulated for transport				
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>Transport document description</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated



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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

### Transport by sea

Not regulated

### Air transport

Not regulated

### Inland waterway transport

Not regulated

### Rail transport

Not regulated

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

##### UK REACH Annex XVII (Restriction List)

This product contains no substance(s) listed on UK REACH Annex XVII (Restriction List) equal to or above the level of SDS disclosure

##### UK REACH Annex XIV (Authorisation List)

This product contains no substance(s) listed on UK REACH Annex XIV (Authorisation List) equal to or above the 0.1% level of disclosure

##### UK REACH Candidate List (SVHC)

Contains substance(s) listed on the UK REACH Candidate List in concentrations  $\geq 0.1\%$  or SCL: Octamethylcyclotetrasiloxane (EC 209-136-7, CAS 556-67-2), Octamethylcyclotetrasiloxane (EC 209-136-7, CAS 556-67-2)

##### GB PIC regulation (Prior Informed Consent)

This product contains no substance(s) listed on the GB PIC List equal to or above the level of SDS disclosure

##### POP Regulation (Persistent Organic Pollutants)

This product contains no substance(s) listed on the GB POP List equal to or above the level of SDS disclosure

##### Ozone Regulation (S.I. No. 168 of 2015)

This product contains no substance(s) listed on the GB Ozone Depletion List equal to or above the level of SDS disclosure

##### Control of Poisons and Explosives Precursors Act

This product contains no substance(s) listed as a reportable poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This product contains no substance(s) listed as a reportable explosive precursor on the Control of Poisons and Explosives Precursors Regulations equal to or above the level of SDS disclosure

This substance is not listed as a regulated poison on the Control of Poisons and Explosives Precursors Regulations

##### Drug Precursors Regulation (273/2004)

This product contains no substance(s) listed on the GB Drug Precursors List equal to or above the level of SDS disclosure

#### 15.1.2. Other information

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Data sources : MSDSs of the suppliers.  
Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim  
  
Phone: +49 69 305 34 700  
Fax: +49 69 305 86 500  
SDS Service: +49 69 305 34 740  
  
Contact person : Saskia Vetter

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH210	Safety data sheet available on request.
Flam. Liq. 3	Flammable liquids, Category 3
H226	Flammable liquid and vapour.

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law.

H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

KFT SDS UK 06 - Version 24.1

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.