

# Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 5/21/2012 Revision date: 10/16/2023 Supersedes version of: 8/24/2022 Version: 13.0

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

1.1. Product identifier		
Product form Trade name Chemical name IUPAC name EC-No. CAS-No. Product code Type of product Formula Synonyms	<ul> <li>Substance</li> <li>FENOFIBRATE</li> <li>2-[4-(4-Chlorobenzoyl)phenoxy]-2-methylpropanoic acid 1-methylethyl ester</li> <li>Propan-2-yl 2-[4-(4-chlorobenzoyl)phenoxy]-2-methylpropanoate</li> <li>256-376-3</li> <li>49562-28-9</li> <li>72770</li> <li>Active Ingredient for Medicinal / Pharmaceutical Use</li> <li>C20H21CIO4</li> <li>propan-2-yl 2-[4-(4-chlorobenzoyl - phenoxy]-2-methylpropanoate ; Isopropyl 2-(p-(pchlorobenzoyl)- / phenoxy)-2-methylpropionate</li> </ul>	
Other means of identification	: CC(C)OC(=0)C(C)(C)OC1=CC=C(C=C1)C(=0)C1=CC=C(CI)C=C1	
1.2. Relevant identified uses of the substance or mixture and uses advised against		
1.2.1. Relevant identified uses		
Main use category Industrial/Professional use spec	<ul> <li>API,Industrial use,Professional use</li> <li>Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial</li> </ul>	
Use of the substance/mixture	: Antilipemic Agent. Fenofibrate is a lipid regulating agent indicated as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia	
Function or use category	: Pharmaceuticals	
1.2.2. Uses advised against		
No additional information available		

Manufacturer

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

#### Supplier

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#### Manufacturer

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# 1.4. Emergency telephone number

Emergency number

: +34 93 586 05 20 (9:00 - 17:00)

SECTION 2: Hazards identification	
2.1. Classification of the substance or mixture	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	
Specific target organ toxicity – Repeated exposure, Category 2	H373
Hazardous to the aquatic environment – Chronic Hazard, Category 4	H413

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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)	GHS08	
Signal word (CLP)	: Danger	
Hazard statements (CLP)	<ul> <li>H373 - May cause damage to organs (liver) through prolonged or repeated exposure (if swallowed).</li> <li>H413 - May cause long lasting harmful effects to aquatic life.</li> </ul>	
Precautionary statements (CLP)	<ul> <li>P280 - Wear eye protection, face protection.</li> <li>P273 - Avoid release to the environment.</li> <li>P301+P330+P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</li> <li>P332+P313 - If skin irritation occurs: Get medical advice/attention.</li> <li>P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.</li> </ul>	
2.3. Other hazards		

Other hazards which do not result in classification

: Dust may form explosive mixture in air.

SECTION 3: Composition/information on ingredients		
3.1. Substances		
Substance type	: Mono-constituent	
Name	Product identifier	%
FENOFIBRATE	CAS-No.: 49562-28-9 EC-No.: 256-376-3	≈ 100
3.2 Mixtures	1	1

# 3.2. Mixtures

Not applicable

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	: Allow affected person to breathe fresh air. Allow the victim to rest.	
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.	
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.	
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.	
4.2. Most important symptoms and effects, both acute and delayed		
Symptoms/effects	: May cause damage to organs (liver).	
4.3. Indication of any immediate medical attention and special treatment needed		

Never give anything by mouth to an unconscious person.

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SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media Unsuitable extinguishing media	<ul><li>Foam. Dry powder. Carbon dioxide. Water spray. Sand.</li><li>Do not use a heavy water stream.</li></ul>	
5.2. Special hazards arising from the substance or mixture		
Fire hazard Hazardous decomposition products in case of fire	<ul><li>May form combustible dust concentrations in air.</li><li>Carbon monoxide. Carbon dioxide. Toxic fumes may be released.</li></ul>	
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. Eliminate all ignition sources if safe to do so. Fight fire with normal precautions from a reasonable distance.	
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.	

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equipment and emergency procedures		
General measures	: No open flames. No smoking. Eliminate every possible source of ignition.	
6.1.1. For non-emergency personnel		
Emergency procedures	: Evacuate unnecessary personnel. Do not breathe dust.	
Measures in case of dust release	: Dust formation: dust mask.	
6.1.2. For emergency responders		
Protective equipment	: Equip cleanup crew with proper protection. Dust/aerosol mask.	
Emergency procedures	: Ventilate area. Shovel or sweep up and put in a closed container for disposal.	
6.2. Environmental precautions		

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up	
For containment Methods for cleaning up Other information	<ul> <li>Collect spillage.</li> <li>On land, sweep or shovel into suitable containers. Minimise generation of dust.</li> <li>Dispose of materials or solid residues at an authorized site.</li> </ul>

# 6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Additional hazards when processed	: Keep away from Strong acids, strong bases and strong oxidants, Heat and ignition sources. No smoking.
Precautions for safe handling	: Avoid dust formation. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust. Do not get in eyes, on skin, or on clothing. Ensure good ventilation of the work station.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Separate working clothes from town clothes. Launder separately.
7.2. Conditions for safe storage, includi	ng any incompatibilities
Technical measures	: Provide local exhaust or general room ventilation. Comply with applicable regulations.

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Storage conditions	: Store at room temperature. Keep only in the original container in a cool, well ventilated place away from : Heat sources, Direct sunlight. Keep container closed when not in use.
Incompatible products Incompatible materials	<ul><li>Strong bases. Strong acids. Oxidizing agent.</li><li>Sources of ignition. Direct sunlight.</li></ul>

7.3. Specific end use(s)

Industrial use.

# 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

Control banding

: MOEHS occupational exposure band: 2 (0.1 - 1 mg/m3)

# 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

## Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Local exhaust or breathing protection.

#### 8.2.2. Personal protection equipment

# Personal protective equipment:

Avoid all unnecessary exposure. Safety glasses. Gloves. Dust/aerosol mask with filter type P3.

Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

### Eye protection:

Chemical goggles or safety glasses

Eye protection			
	Туре	Field of application	Standard
	Safety glasses	Dust, Fine dust	EN 166

### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing

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Skin and body protection	
Туре	Standard
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

# Hand protection:

Wear protective gloves.

Hand protection		
Туре	Material	Standard
Disposable gloves	Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Fluoroelastomer (FKM), Neoprene rubber (HNBR), Latex	EN 374-2

Other skin protection Materials for protective clothing		
Condition	Material	Standard
Good resistance:	Polyethylene, Tyvek®, Synthetic material	EN 13034, EN ISO 13982-1

# 8.2.2.3. Respiratory protection

# **Respiratory protection:**

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask, Powered mask	Туре РЗ	High dust protection	EN 143

# 8.2.2.4. Thermal hazards

No additional information available

## 8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

### Other information:

Do not eat, drink or smoke during use.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state Colour	: Solid : white.
Appearance	: Dust.
Molecular mass	: 360.84 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 80 (80 – 81) °C
Freezing point	: Not available
Boiling point	: ≈ 469.8 °C at 760 mmHg [Predicted by ACD/Labs]
Flammability	: May form combustible dust concentrations in air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: ≈ 165.4 °C [Predicted by ACD/Labs]

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Auto-ignition temperature	: ≈ 540 °C [oven GODBERT-GREENWALD]
Decomposition temperature	: Not available
На	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in dichloromethane.
	Water: 0.25 g/l 25 °C
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 5.3
Vapour pressure	: 0.0±1.2 mmHg at 25°C [Predicted by ACD/Labs]
Vapour pressure at 50°C	: Not available
Density	: ≈ 1.177 g/cm³ [Predicted by ACD/Labs]
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available
0.2 Other information	

# 9.2. Other information

# 9.2.1. Information with regard to physical hazard classes

No additional information available

### 9.2.2. Other safety characteristics

Minimum ignition energy Additional information  < 1 mJ</li>
 Layer Minimum flammability Temperature Melt - Funde. Dust Cloud minimum Flammability Temperature 510 ° C. Explosivity Pmax 8.6 bar.g. Explosion Severity Factor Kmax (bar.m/s) 324 bar.m/s. Explosion Class St3

# **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

Stable under use and storage conditions as recommended in section 7. Dust may form explosive mixture in air.

## 10.2. Chemical stability

Combustible Dust.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Sparks. Avoid contact with hot surfaces. Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition.

**10.5. Incompatible materials** 

Strong acids. Strong bases.

**10.6. Hazardous decomposition products** 

fume. Carbon monoxide. Carbon dioxide.

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SECTION 11: Toxicological information		
11.1. Information on hazard classes as defin	ed in Regulation (EC) No 1272/2008	
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	<ul> <li>Not classified</li> <li>Not classified</li> <li>Not classified</li> </ul>	
FENOFIBRATE (49562-28-9)		
LD50 oral rat	> 5000 mg/m³	
LD50, Dog, acute, oral, Dog	4000 mg/kg	
LD50, acute, oral, mouse	1600 mg/kg	
Skin corrosion/irritation Additional information Serious eye damage/irritation Additional information	<ul> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> </ul>	
Respiratory or skin sensitisation Additional information Germ cell mutagenicity	<ul> <li>Dased on available data, the classification criteria are not met</li> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> <li>AMES test Non mutagenic in the AMES TEST and in the Mouse Lynphoma chromosomal aberration and scheduled DNA sinthesys test (Did not show mutagenic effects in animal experiments)</li> </ul>	
Additional information Carcinogenicity Additional information Reproductive toxicity Additional information STOT-single exposure Additional information	<ul> <li>Based on available data, the classification criteria are not met</li> <li>Not Listed on IARC (International Agency for Research on Cancer)</li> <li>Based on available data, the classification criteria are not met</li> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> <li>Based on available data, the classification criteria are not met</li> </ul>	
FENOFIBRATE (49562-28-9)		
In animals, systemic toxicity was observed in the following target organs: NOEL, liver, oral	13 mg/kg (rat) 25 mg/kg (dog)	
STOT-repeated exposure Aspiration hazard Additional information	<ul> <li>May cause damage to organs (liver) through prolonged or repeated exposure (if swallowed).</li> <li>Not classified</li> <li>Based on available data, the classification criteria are not met</li> </ul>	
11.2. Information on other hazards		
<b>11.2.1. Endocrine disrupting properties</b> Adverse health effects caused by endocrine disrupting properties	: The substance is not 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	
<b>11.2.2. Other information</b> Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met	

SECTION 12: Ecological information			
12.1. Toxicity			
Ecology - water Hazardous to the aquatic environment, short-term (acute)	<ul><li>May cause long lasting harmful effects to aquatic life.</li><li>Not classified</li></ul>		
Hazardous to the aquatic environment, long-term (chronic)	: May cause long lasting harmful effects to aquatic life.		

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FENOFIBRATE (49562-28-9)			
EC50 - Crustacea [1]	> 0.15 mg/l		
EC50 - Crustacea [2]	> 0.12 mg/l (reproductive, 21 day)		
EC50 72h - Algae [1]	> 0.102 mg/l (selenastrum capricornutum)		
NOEC chronic crustacea	≈ 0.12 mg/l Daphnia magna (reproductive, 21 day)		
12.2. Persistence and degradability			
FENOFIBRATE (49562-28-9)			
Persistence and degradability	May cause long-term adverse effects in the environment.		
Chemical oxygen demand (COD)	2.29 g O <sub>2</sub> /g substance (calculated value)		
12.3. Bioaccumulative potential			
FENOFIBRATE (49562-28-9)			
Bioconcentration factor (BCF REACH)	287.4 Bioaccumulation Estimates from Log Kow (BCFWIN v2.17)		
Partition coefficient n-octanol/water (Log Pow)	5.3		
12.4. Mobility in soil			
FENOFIBRATE (49562-28-9)			
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	≈ 3.638 Soil Adsorption Coefficient (stimated by PCKOCWIN v1.66)		
12.5. Results of PBT and vPvB assessment			
No additional information available			
12.6. Endocrine disrupting properties			
Adverse effects on the environment caused by : endocrine disrupting properties	The substance/mixture has no endocrine disrupting properties.		
12.7. Other adverse effects			
Additional information :	Avoid release to the environment.		
SECTION 13: Disposal considerations			
13.1. Waste treatment methods			
	Disposal must be done according to official regulations. Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.		
SECTION 14: Transport information			
In accordance with / ADR / IMDG / IATA / ADN / RID			
14.1. UN number or ID number			

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

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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)	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>
14.3. Transport hazard class(es)	
ADR Transport hazard class(es) (ADR)	: Not applicable
IMDG Transport hazard class(es) (IMDG)	: Not applicable
IATA Transport hazard class(es) (IATA)	: Not applicable
ADN Transport hazard class(es) (ADN)	: Not applicable
<b>RID</b> Transport hazard class(es) (RID)	: Not applicable
14.4. Packing group	
Packing group (ADR) Packing group (IMDG) Packing group (IATA) Packing group (ADN) Packing group (RID)	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>
14.5. Environmental hazards	
Dangerous for the environment Marine pollutant Other information	<ul> <li>No</li> <li>No</li> <li>No supplementary information available</li> </ul>
14.6. Special precautions for user	
<b>Overland transport</b> No data available	
<b>Transport by sea</b> No data available	

Air transport

No data available

# Inland waterway transport

No data available

Rail transport

No data available

# 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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# **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)** 

Not listed on REACH Annex XVII

## REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

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

Not listed on the POP list (Regulation EU 2019/1021)

## Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

## **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

#### Germany

Water hazard class (WGK) Hazardous Incident Ordinance (12. BlmSchV)	<ul> <li>Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).</li> <li>Is not subject of the Hazardous Incident Ordinance (12. BImSchV)</li> </ul>
Netherlands	
SZW-lijst van kankerverwekkende stoffen SZW-lijst van mutagene stoffen SZW-lijst van reprotoxische stoffen – Borstvoeding SZW-lijst van reprotoxische stoffen – Vruchtbaarheid SZW-lijst van reprotoxische stoffen – Ontwikkeling	<ul> <li>The substance is not listed</li> </ul>
Denmark	
Classification remarks Danish National Regulations	<ul> <li>Emergency management guidelines for the storage of flammable liquids must be followed</li> <li>Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product</li> </ul>
Switzerland	
Storage class (LK)	: LK 6.1 - Toxic materials
15.2. Chemical safety assessment	

No chemical safety assessment has been carried out

SECTION 16: Other information		
Abbreviations and acronyms:		
	non-classified PBT substance	

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ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
IARC	International Agency for Research on Cancer
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
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
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

## Data sources

: 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. None.

### Other information

Full text of H- and EUH-statements:		
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4	
H373	May cause damage to organs through prolonged or repeated exposure.	
H413	May cause long lasting harmful effects to aquatic life.	
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2	

:

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.