

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 12/18/2003 Revision date: 3/6/2023 Supersedes version of: 9/27/2022 Version: 12.0

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

1.1. Product identifier		
Product form	: Substance	
Trade name	: METOPROLOL TARTRATE	
Chemical name	: (2R,3R)-2,3-Dihydroxybutanedioic acid; 1-[4-(2-methoxyethyl)phenoxy]-3-(propan- 2ylamino)propan-2-ol	
IUPAC name	<ul> <li>: (2R,3R)-2,3-Dihydroxybutanedioic acid; 1-[4-(2-methoxyethyl)phenoxy]-3-(propan- 2ylamino)propan-2-ol</li> </ul>	
EC-No.	: 260-148-9	
CAS-No.	: 056392-17-7	
Product code	: 75200	
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use	
Formula	: C15H25NO3.½C4H6O6	
Synonyms	: Metoprolol Tartrate; 1-[4-(2-methoxyethyl)phenoxy]-3-[(1-methylethyl)amino]2-propanol (2R,3R)-2,3-dihydroxybutanedioate (2:1) salt; 1-(isopropylamino)-3-[p-(beta-	
	methoxyethyl)phenoxy]2-propanol tartrate salt	
Other means of identification	: SMILES: COCCC1=CC=C(OCC(O)CNC(C)C)C=C1 (Free Metoprolol base)	
1.2. Relevant identified uses of the substance or mixture and uses advised against		
1.2.1. Relevant identified uses		
Main use category	: API,Industrial use,Professional use	
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use	
	For professional use only Industrial	
Use of the substance/mixture	<ul> <li>Antihypertensive; antianginal ; Metoprolol is a cardioselective β1-adrenergic blocking agent used for acute myocardial infarction (MI), heart failure, angina pectoris and mild to moderate hypertension.</li> </ul>	
Function or use category	: Pharmaceuticals	
1.2.2. Uses advised against		
No additional information available		
1.3. Details of the supplier of the safety	data sheet	
Supplier Manufacturer		
Supplier	Manufacturer	
<b>Supplier</b> MOEHS IBÉRICA, S.L.	Manufacturer MOEHS CATALANA, S.L.	
••		
MOEHS IBÉRICA, S.L.	MOEHS CATALANA, S.L.	
MOEHS IBÉRICA, S.L. Roma, 8 - P.I. Cova Solera	MOEHS CATALANA, S.L. Cesar Martinell i Brunet, 12 A P.I. Rubi Sud	
MOEHS IBÉRICA, S.L. Roma, 8 - P.I. Cova Solera 08191 Rubi	MOEHS CATALANA, S.L. Cesar Martinell i Brunet, 12 A P.I. Rubi Sud 08191 Rubi	

## **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]		
Skin corrosion/irritation, Category 2	H315	
Serious eye damage/eye irritation, Category 2	H319	
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335	
Hazardous to the aquatic environment – Chronic Hazard, Category 3 Full text of H- and EUH-statements: see section 16	H412	

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## Adverse physicochemical, human health and environmental effects

Causes eye irritation. Causes skin irritation. May cause respiratory irritation. May cause long lasting harmful effects to aquatic life.

## 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]		
Hazard pictograms (CLP)	GHS07	
Signal word (CLP)	: Warning	
Hazard statements (CLP)	: H315 - Causes skin irritation.	
	H319 - Causes serious eye irritation.	
	H335 - May cause respiratory irritation.	
	H412 - Harmful to aquatic life with long lasting effects.	
Precautionary statements (CLP)	: P261 - Avoid breathing dust, fume, mist, vapours, spray.	
	P271 - Use only outdoors or in a well-ventilated area.	
	P280 - Wear eye protection, protective gloves, face protection.	
	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.	
	P313 - Get medical advice/attention.	
	P273 - Avoid release to the environment.	
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	%
METOPROLOL TARTRATE	CAS-No.: 056392-17-7 EC-No.: 260-148-9	100

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	<ul> <li>Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.</li> </ul>	
First-aid measures after skin contact	: Wash with plenty of water/ Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.	
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and eas to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.	
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.	

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4.2. Most important symptoms and effects, both acute and delayed			
Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal you feel unwell, seek medical advice. May cause drowsiness or dizziness.			
Symptoms/effects after inhalation	: May cause respiratory irritation.		
Symptoms/effects after skin contact	: Causes skin irritation.		
Symptoms/effects after eye contact	: Causes serious eye irritation.		
Symptoms/effects after ingestion	: May cause drowsiness or dizziness.		

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

Never give anything by mouth to an unconscious person.

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		
Hazardous decomposition products in case of fire	: Carbon dioxide. fume. Carbon monoxide. Toxic fumes may be released.	
5.3. Advice for firefighters		
Precautionary measures fire Firefighting instructions	<ul> <li>Stop leak if safe to do so.</li> <li>Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.</li> </ul>	
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. No flames, no sparks. Eliminate all sources of ignition.			
6.1.1. For non-emergency personnel			
Protective equipment	: Breathing equipment.		
Emergency procedures	: Evacuate unnecessary personnel.		
Measures in case of dust release	: Dust formation: dust mask.		
6.1.2. For emergency responders			
Protective equipment	rotective equipment : Equip cleanup crew with proper protection.		
Emergency procedures	: Ventilate area. Shovel or sweep up and put in a closed container for disposal. Stop leak if safe to do so.		

## 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		
Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials. This material and its container must be disposed of in a safe way, and as per local legislation.	
Other information	: Dispose of materials or solid residues at an authorized site.	
6.4. Reference to other sections		

See Section 8. Exposure controls and personal protection.

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7.1. Precautions for safe handling		
Additional hazards when processed	: Keep away from Strong acids, strong bases and oxidation agents, Heat and ignition sources. No smoking.	
Precautions for safe handling Hygiene measures	<ul> <li>Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Use only outdoors or in a well-ventilated area. Avoid breathing dust, mist. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust. Avoid raising powdered material due to explosion hazard. Wear personal protective equipment.</li> <li>Wash hands, forearms and face thoroughly after handling. Do not eat, drink or smoke wher using this product. Separate working clothes from town clothes. Launder separately. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Wash hands and other exposed areas with mild soap</li> </ul>	
	and water before eating, drinking or smoking and when leaving work.	
7.2. Conditions for safe storage, including any incompatibilities		
Storage conditions	: Store in a well-ventilated place. Store at room temperature. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	
Incompatible products	: Strong bases. Strong acids. Oxidizing agent.	
Incompatible materials	: Sources of ignition. Direct sunlight.	
Storage area	: Store in a well-ventilated place. Store away from heat.	

Pharmaceuticals.

## **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:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

#### 8.2.2. Personal protection equipment

## Personal protective equipment:

Avoid all unnecessary exposure. Gloves. Safety glasses. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Dust/aerosol mask.

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#### Personal protective equipment symbol(s):



### 8.2.2.1. Eye and face protection

## Eye protection:

Chemical goggles or safety glasses

## 8.2.2.2. Skin protection

## Skin and body protection:

## Wear suitable protective clothing

Skin and body protection		
•	Туре	Standard
I	Disposable gowns	EN 13034

#### Hand protection:

Wear protective gloves.

Hand protection		
Туре	Material	Standard
Disposable gloves	Latex, Vinyl, Natural rubber, Polyvinylchloride (PVC), Polyvinylalcohol (PVA)	EN ISO 374

## 8.2.2.3. Respiratory protection

## **Respiratory protection:**

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Туре РЗ	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	: Solid
Colour	: white.
Molecular mass	: 342.4 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 121 – 124 °C
Freezing point	: Not available
Boiling point	: Not available

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Flammability	: May form combustible dust concentrations in air
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: 6 – 7 [2% aq. Sol.]
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 17 mg/l
	Ethanol: 200 g/l [20ºC]
	Acetone: 2 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 1.6
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 170 kg/m³
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

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	<ul> <li>5 mJ</li> <li>Dust Cloud minimum Flammability Temperature : 460°C. Layer Minimum flammability Temperature : 130°C. Minimum Explosive Concentration : 30 g/m3. Explosivity Pmax : 7.1. Explosion Severity Factor Kmax (bar.m/s) : 131.</li> </ul>
	Explosion Class : 1

# **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. Stable under use and storage conditions as recommended in section 7.

## **10.2. Chemical stability**

The product is stable at normal handling and storage conditions.

## 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

## **10.4. Conditions to avoid**

Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition. Direct sunlight.

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## 10.5. Incompatible materials

Strong acids. Strong bases. Oxidizing agent.

**10.6. Hazardous decomposition products** 

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

11.1. Information on hazard classes as c	lefined in Regulation (EC) No 1272/2008
Acute toxicity (oral)	: Not classified
Acute toxicity (dermal) Acute toxicity (inhalation)	: Not classified : Not classified
Additional information	: Based on available data, the classification criteria are not met
METOPROLOL TARTRATE (056392-17-7	
LD50 oral rat	5500 mg/kg
LD50 dermal rabbit	> 3000 mg/kg
LC50 Inhalation - Rat	> 2510 mg/l/4h
LD50, intraperitoneal, rat	219 mg/kg
LD50, oral, mouse	1480 mg/kg
LD50, oral, rabbit	604 mg/kg
LD50, oral, Dog	1090 mg/kg
Skin corrosion/irritation	: Causes skin irritation. pH: 6 – 7 [2% aq. Sol.]
Serious eye damage/irritation	: Causes serious eye irritation.
	pH: 6 – 7 [2% aq. Sol.]
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
11.2. Information on other hazards	
1.2.1. Endocrine disrupting properties	
Adverse health effects caused by endocrine	: The substance is not included in the list established in accordance with Article 59(1) of
disrupting properties	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
11.2.2. Other information	
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met
Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye

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SECTION 12: Ecological information	
12.1. Toxicity	
Hazardous to the aquatic environment, short-term : (acute)	Harmful to aquatic life with long lasting effects. Not classified Harmful to aquatic life with long lasting effects.
METOPROLOL TARTRATE (056392-17-7)	
LC50 - Fish [1]	54 mg/l [Bluegill sunfish]
LC50 - Fish [2]	130 mg/l [Trucha arcoiris]
EC50 - Crustacea [1]	32 mg/l
12.2. Persistence and degradability	
METOPROLOL TARTRATE (056392-17-7)	
Persistence and degradability	May cause long-term adverse effects in the environment.
Biodegradation	17 %
12.3. Bioaccumulative potential	
METOPROLOL TARTRATE (056392-17-7)	
Partition coefficient n-octanol/water (Log Pow)	1.6
Bioaccumulative potential	Not established.
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	
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	
Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment. Discharging into rivers and drains is forbidden.
Additional information	: Clean up even minor leaks or spills if possible without unnecessary risk. Industrial waste.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 16 05 08* - discarded organic chemicals consisting of or containing dangerous substances

# SECTION 14: Transport information

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

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14.1. UN number or ID number	
UN-No. (ADR) UN-No. (IMDG) UN-No. (IATA) UN-No. (ADN) UN-No. (RID)	<ul> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> <li>Not applicable</li> </ul>
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> <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> <li>Not applicable</li> </ul>
14.5. Environmental hazards	
Dangerous for the environment Marine pollutant Other information	<ul> <li>No</li> <li>No supplementary information available</li> </ul>
14.6. Special precautions for user	
Overland transport Not applicable	
Transport by sea Not applicable	
Air transport Not applicable	
Inland waterway transport Not applicable	
Rail transport Not applicable	

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## 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)**

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)	: Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV)	: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)
Netherlands	
SZW-lijst van kankerverwekkende stoffen	: The substance is not listed
SZW-lijst van mutagene stoffen	: The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	: The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	: The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	: The substance is not listed
Denmark	
Danish National Regulations	: Young people below the age of 18 years are not allowed to use the product
Switzerland	
Storage class (LK)	: LK 11/13 - Solids
15.2. Chemical safety assessment	

No chemical safety assessment has been carried out

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SECTION 16: Other information		
Abbreviations and acronyms:		
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	
BCF	Bioconcentration factor	
IARC	International Agency for Research on Cancer	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
DPD	Dangerous Preparations Directive 1999/45/EC	
DSD	Dangerous Substances Directive 67/548/EEC	
EC50	Median effective concentration	
ΙΑΤΑ	International Air Transport Association	
LC50	Median lethal concentration	
LD50	Median lethal dose	
LOAEL	Lowest Observed Adverse Effect Level	
vPvB	Very Persistent and Very Bioaccumulative	
NOAEL	No-Observed Adverse Effect Level	
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 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.