

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Reference number: 15716 / PF 454

Issue date: 11/19/2015 Revision date: 2/3/2023 Supersedes version of: 11/19/2015 Version: 2.0

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Substance
Trade name	: ROPIVACAINE HYDROCHLORIDE MONOHYDRATE
Chemical name	: (2S)-N-(2,6-dimethylphenyl)-1-propyl-2-piperidinecarboxamide hydrochloride monohydrate
IUPAC name	: (2S)-N-(2,6-dimethylphenyl)-1-propyl-2-piperidinecarboxamide hydrochloride monohydrate
CAS-No.	: 132112-35-7
Product code	: 15716 / PF 454
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C <sub>17</sub> H <sub>26</sub> N <sub>2</sub> O · HCl · H <sub>2</sub> O
Synonyms	: 2-Piperidinecarboxamide, N-(2,6-dimethylphenyl)-1-propyl-, hydrochloride, hydrate (1:1:1), / (2S)- / 2-Piperidinecarboxamide, N-(2,6-dimethylphenyl)-1-propyl-, monohydrochloride, / monohydrate, (S)- / 2-Piperidinecarboxamide, N-(2,6-dimethylphenyl)-1-propyl-, / monohydrochloride, monohydrate, (2S)- / Ropivacaine hydrochloride monohydrate / (2S)-2- / [(Dimethylphenyl)carbamoyl]-1-propylpiperidin-1-ium chloride monohydrate
Other means of identification	: SMILE : O.Cl.CCCN1CCCC1C(=O)NC1=C(C)C=CC=C1C

**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 Industrial For professional use only
Use of the substance/mixture	: Local anesthetic ; The hydrochloride salt of ropivacaine, a local anesthetic of the amide type with analgesic activity. Ropivacaine binds to voltage-gated sodium ion channels in the neuronal membrane, thereby preventing the permeability of sodium ions and resulting in a stabilization of the neuronal membrane and inhibition of depolarization ; nerve impulse generation and propagation are blocked, resulting in a reversible loss of sensation.
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**

MOEHS IBÉRICA, S.L.  
Roma, 8 - P.I. Cova Solera  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

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T +34 93 586 05 20 - F +34 93 699 8350  
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**Manufacturer**

BENECHIM S.R.L.  
rue René Magritte 163 (North Zoning)  
B-7860 Lessines  
Belgium  
T + 32 68 33 49 13

**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 // +32 (0)70 245 245 (9:00 - 17:00)
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### SECTION 2: Hazards identification

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

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

Acute toxicity (oral), Category 4 H302  
Serious eye damage/eye irritation, Category 1 H318  
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412  
Full text of H- and EUH-statements: see section 16

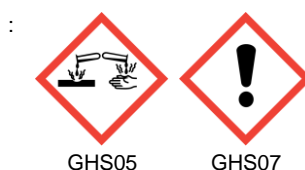
##### Adverse physicochemical, human health and environmental effects

Causes serious eye damage.

#### 2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed.  
H318 - Causes serious eye damage.  
H412 - Harmful to aquatic life with long lasting effects.  
Precautionary statements (CLP) : P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P261 - Avoid breathing dust.  
P284 - Wear respiratory protection.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor.  
P301+P312 - IF SWALLOWED: Call doctor if you feel unwell.  
P314 - Get medical advice/attention if you feel unwell.  
P273 - Avoid release to the environment.  
P501 - Dispose of contents and container to an approved waste disposal plant.

#### 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	%
ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	CAS-No.: 132112-35-7	100

#### 3.2. Mixtures

Not applicable

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### 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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects	: May cause drowsiness or dizziness.
Symptoms/effects after inhalation	: None under normal use. May cause drowsiness or dizziness. Anxious. Sore throat. Disorientation.
Symptoms/effects after skin contact	: Contact during a long period may cause light irritation.
Symptoms/effects after eye contact	: Direct contact with the eyes is likely to be irritating. Blurred vision. Causes serious eye damage.
Symptoms/effects after ingestion	: Disorientation. Anxious. Symptoms of overexposure to vapours include drowsiness, weakness, headache, dizziness, nausea, vomiting, dimming of vision. Swallowing a small quantity of this material will result in serious health hazard.

#### 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	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

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

Fire hazard	: Dust may form explosive mixture in air.
Hazardous decomposition products in case of fire	: fume. Carbon dioxide. Carbon monoxide. Toxic fumes may be released. Nitrogen oxides.

#### 5.3. Advice for firefighters

Precautionary measures fire	: Stop leak if safe to do so.
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.
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.
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##### 6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Avoid breathing spray, dust. No open flames, no sparks, and no smoking. Evacuate unnecessary personnel.
Measures in case of dust release	: Dust formation: dust mask.

##### 6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
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Emergency procedures : Stop leak if safe to do so. Shovel or sweep up and put in a closed container for disposal. Ventilate area.

### 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 : Collect spillage.  
Methods for cleaning up : Minimise generation of dust. Mechanically recover the product. On land, sweep or shovel into suitable containers. This material and its container must be disposed of in a safe way, and as per local legislation. Store away from other materials.

### 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

Precautions for safe handling : Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Mist formation: aerosol mask with filter type P3. Do not get in eyes, on skin, or on clothing. Prevent the build-up of electrostatic charge. Safety glasses with side guards should be worn to prevent injury from airborne particles and/or other eye contact with this product. Do not eat, drink or smoke when using this product. Do not breathe dust. 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.  
Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Provide local exhaust or general room ventilation.  
Storage conditions : Store at room temperature. Keep container closed when not in use. Store in a well-ventilated place.  
Incompatible products : Strong bases. Strong acids.  
Incompatible materials : Sources of ignition. Direct sunlight.  
Special rules on packaging : Store in a closed container.

### 7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical 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: 3 (0.01 - 0.1 mg/m<sup>3</sup>)

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### 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. Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### Personal protective equipment:

Gloves. Safety glasses. Mist formation: aerosol mask with filter type P3. Avoid all unnecessary exposure.

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



##### 8.2.2.1. Eye and face protection

##### Eye protection:

Chemical goggles or safety glasses

Eye protection		
Type	Field of application	Characteristics
Safety glasses	Dust, Fine dust	With side shields

##### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing

##### Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Polyvinylchloride (PVC), Latex, Natural rubber, Butyl rubber	EN ISO 374

##### 8.2.2.3. Respiratory protection

##### Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Short term exposure, Dust protection, Protection for Solid particles	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.

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Dust.
Molecular mass	: 328.87 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 269.5 – 270.6 °C [External SDS]
Freezing point	: Not available
Boiling point	: 410 [Ropivacaine base; 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	: 202 °C [Ropivacaine base; Predicted by ACD/Labs]
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: 4.5 – 6 (2 % aqous solution)
Viscosity, kinematic	: Not applicable
Solubility	: Water: 57.6 mg/l [Ropivacaine base; Estimate from Log Kow (WSKOW v1.41)] Ethanol: Soluble
Partition coefficient n-octanol/water (Log Kow)	: 2.9 [Ropivacaine base; Exper. database match; Exper. Ref: Hansch,C et al. (1995)]
Partition coefficient n-octanol/water (Log Pow)	: 2.15 [external SDS]
Vapour pressure	: 0.000000039 mm Hg
Vapour pressure at 50°C	: Not available
Density	: Not available
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

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

The product is stable at normal handling and storage conditions. Not established.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

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### 10.4. Conditions to avoid

Direct sunlight. No flames, no sparks. Eliminate all sources of ignition. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Nitrogen oxides. fume. Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Additional information	: For local anesthetics: Change in blood pressure. Slow or irregular heartbeat. Cessation of breathing. Circulatory depression. Shock. Cardiac arrest. Coma. Death.

### ROPIVACAINE HYDROCHLORIDE MONOHYDRATE (132112-35-7)

LD50 oral rat	980 mg/kg
LD50, oral, mouse	= 300 mg/kg

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: May cause sensitisation of susceptible persons by skin contact
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 Listed on IARC (International Agency for Research on Cancer)
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	: Not classified
Additional information	: Based on available data, the classification criteria are not met
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

#### 11.2.1. Endocrine disrupting properties

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
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#### 11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if swallowed.
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## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - water	: Harmful to aquatic life with long lasting effects.
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Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

### ROIIVACAINE HYDROCHLORIDE MONOHYDRATE (132112-35-7)

LC50 - Fish [1]	38 mg/l
EC50 - Crustacea [1]	34 mg/l
ErC50 algae	59 mg/l

### 12.2. Persistence and degradability

#### ROIIVACAINE HYDROCHLORIDE MONOHYDRATE (132112-35-7)

Persistence and degradability : May cause long-term adverse effects in the environment.

### 12.3. Bioaccumulative potential

#### ROIIVACAINE HYDROCHLORIDE MONOHYDRATE (132112-35-7)

Partition coefficient n-octanol/water (Log Pow)	2.15 [external SDS]
Partition coefficient n-octanol/water (Log Kow)	2.9 [Ropivacaine base; Exper. database match; Exper. Ref: Hansch,C et al. (1995)]
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

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : 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)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

### 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

**RID**  
Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

### 14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

### 14.6. Special precautions for user

**Overland transport**  
No data available

**Transport by sea**  
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) : 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

### SECTION 16: Other information

#### Abbreviations and acronyms:

	non-classified PBT substance
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor

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Abbreviations and acronyms:	
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
vPvB	Very Persistent and Very Bioaccumulative
LOAEL	Lowest Observed Adverse Effect Level
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PBT	Persistent Bioaccumulative Toxic

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.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.

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.