

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

Product form	: Substance
Trade name	: SUMATRIPTAN BASE
Chemical name	: 1-{3-[2-(Dimethylamino)ethyl]-1H-indol-5-yl}-N-methylmethanesulfonamide
IUPAC name	: 1-{3-[2-(Dimethylamino)ethyl]-1H-indol-5-yl}-N-methylmethanesulfonamide
EC-No.	: 600-462-9
CAS-No.	: 103628-46-2
C&L notification reference no	: 02-2119932046-44-0000
Product code	: 78080
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C <sub>14</sub> H <sub>21</sub> N <sub>3</sub> O <sub>2</sub> S
Synonyms	: 1H-Indole-5-methanesulfonamide, 3-[2-(dimethylamino)ethyl]-N-methyl-
Product group	: Pharmaceutical
Other means of identification	: SMILE: CNS(=O)(=O)Cc1ccc2c(c1)c(c[nH]2)CCN(C)C

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Main use category	: API,Laboratory use,Medicinal use,Industrial use,Professional use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Laboratory activities Industrial For professional use only
Use of the substance/mixture	: Sumatriptan, an antimigraine drug, is a selective agonist of vascular serotonin
Use of the substance/mixture	: Pharmaceuticals Laboratory chemicals Scientific research and development
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****Head office**

MOEHS IBÉRICA, S.L.  
Roma, 8 - P.I. Cova Solera  
08191 Rubi  
Spain  
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[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

MOEHS CATALANA, S.L.  
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08191 Rubi  
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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)

**1.4. Emergency telephone number**

Emergency number	: +34 93 586 05 20 (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]**

Serious eye damage/eye irritation, Category 2	H319
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**

No additional information available

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## Safety Data Sheet

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

### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H319 - Causes serious eye irritation.  
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) :

P264 - Wash hands, forearms and face thoroughly after handling.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P280 - Wear protective gloves, protective clothing, eye protection, face protection.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P501 - Dispose of contents and container to an approved waste disposal plant.  
P273 - Avoid release to the environment.

### 2.3. Other hazards

vPvB: not relevant – no registration required

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type :

Mono-constituent

Name	Product identifier	%
SUMATRIPTAN BASE	CAS-No.: 103628-46-2 EC-No.: 600-462-9	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 :

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. If eye irritation persists: Get medical advice/attention.

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 :

Symptoms of ingestion include drowsiness, weakness, headache, dizziness, nausea, vomiting. Shortness of breath. Depression of the central nervous system. Fatigue. Erythema.

Symptoms/effects after eye contact :

mild eye irritation. Causes serious eye irritation.

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

### 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

- Explosion hazard : Avoid raising powdered material due to explosion hazard.  
Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide. fume. Nitrogen oxides.

#### 5.3. Advice for firefighters

- Precautionary measures fire : Keep away from combustible materials.  
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 : Remove ignition sources. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous.

##### 6.1.1. For non-emergency personnel

- Emergency procedures : Avoid contact with skin and eyes. Avoid breathing dust, mist or spray. Evacuate unnecessary personnel.  
Measures in case of dust release : Dust formation: dust mask.

##### 6.1.2. For emergency responders

- Protective equipment : Use personal protective equipment as required. Dust/aerosol mask. Protective gloves. Safety glasses. Equip cleanup crew with proper protection.  
Emergency procedures : 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

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. 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 : Avoid dust formation. 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 : Wash hands, forearms and face thoroughly after handling.

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

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

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### 7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use. 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: 3 (0.01 - 0.1 mg/m3)

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Ensure that there is a suitable ventilation system. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Provide local exhaust or general room ventilation. Local exhaust or breathing protection.

#### 8.2.2. Personal protection equipment

##### Personal protective equipment:

Dust/aerosol mask with filter type P3. Protective clothing. 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	Standard
Safety glasses	Dust	EN 166

##### 8.2.2.2. Skin protection

##### Skin and body protection:

Long sleeved protective clothing

##### Hand protection:

Wear protective gloves.

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Hand protection		
Type	Material	Standard
Disposable gloves, Reusable gloves	Natural rubber, Butyl rubber, Latex, Neoprene rubber (HNBR), Fluoroelastomer (FKM), Polyvinylchloride (PVC), Polyvinylalcohol (PVA), Nitrile rubber (NBR)	EN 374-2

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

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

Wear respiratory protection. Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask, Full face mask, Powered mask	P3	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 creating or spreading dust. 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.
Appearance	: Dust.
Molecular mass	: 295.4 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 169 – 170 °C Jean-Claude Bradley Open Melting Point Dataset (8991,16303,21520)
Freezing point	: Not available
Boiling point	: 497 °C (predicted by ACDLAB)
Flammability	: No data available,Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 223 – 285 °C (Predicted by ACDLABS)
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 21.4 mg/l
Partition coefficient n-octanol/water (Log Kow)	: 0.93 Estimated by (WSKOW v1.41)
Vapour pressure	: ≈ 0.0±1.3 mmHg at 25°C (Predicted by ACDLAB)
Vapour pressure at 50°C	: Not available
Density	: 1.1 – 1.3 g/cm <sup>3</sup> (ACDLAB)

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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

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

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

### 10.3. Possibility of hazardous reactions

None under normal use. Not established.

### 10.4. Conditions to avoid

Avoid dust formation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Direct sunlight. 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)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

SUMATRIPTAN BASE (103628-46-2)	
LD50 oral rat	> 2000 mg/kg
LD50, acute, oral, mouse	> 2000 mg/kg
LD50, acute, intravenous, rat	43.1 mg/kg (ChemIDplus for Sumatriptan Succinate)
LD50, acute, oral, Dog	> 700 mg/kg (ChemIDplus for Sumatriptan Succinate)
LD50, acute, subcutaneous, rat	1680 mg/kg (ChemID Plus for Sumatriptan Succinate)
NOAEL, Chronic, rat	5 mg/kg bw/day (18 months)

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TD, subchronic, oral, Dog	≤ 50 mg/kg bw/day (60 weeks)
Skin corrosion/irritation	: Slightly irritant but not relevant for classification
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Slightly irritant but not relevant for classification. Slightly irritating to rabbits on ocular application
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 AMES, GLP Chromosomal aberration test Assay in vitro, Negative 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

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NOAEL (animal/male, F0/P)	60 mg/kg bodyweight (Rabbit, Oral, Embryo-foetal development, Result: Maternal toxicity, adverse foetal effects)
NOAEL (animal/female, F0/P)	> 100 mg/kg bodyweight (Rat, Oral, Embryo-foetal development, Result: Maternal toxicity, adverse foetal effects)
NOAEL, Fertility, rat	100 mg/kg bw/day (Reduced succes of insemination)
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

### 11.2.2. Other information

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 : Harmful to aquatic life with long lasting effects.  
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.

### SUMATRIPTAN BASE (103628-46-2)

LC50 - Fish [1]	> 100 mg/l
LC50 - Fish [2]	> 71 mg/l (Rainbow Trout - Juvenile <i>Salmo gairdneri</i> )
EC50 - Crustacea [1]	206 mg/l Water Flea ( <i>Daphnia Tulex</i> ) OECD 202
EC50 - Crustacea [2]	290 mg/l <i>Daphnia Magna</i>
EC50 72h - Algae [1]	26 mg/l ( <i>Scenedesmus Subspicatus</i> ) OECD 201

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### SUMATRIPTAN BASE (103628-46-2)

NOEC chronic crustacea	23 mg/l water Flea (Daphnia Pulex)
Activated Sludge Respiration IC50, acute	536 mg/l (3 Hours, Nominal, OECD 209)

### 12.2. Persistence and degradability

#### SUMATRIPTAN BASE (103628-46-2)

Persistence and degradability	Not readily biodegradable. May cause long-term adverse effects in the environment.
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### 12.3. Bioaccumulative potential

#### SUMATRIPTAN BASE (103628-46-2)

Bioconcentration factor (BCF REACH)	3.162 Bioaccumulation Estimates from Log Kow (BCFWIN v2.17)
Partition coefficient n-octanol/water (Log Kow)	0.93 Estimated by (WSKOW v1.41)
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

#### SUMATRIPTAN BASE (103628-46-2)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	3.52 – 3.57
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### 12.5. Results of PBT and vPvB assessment

#### SUMATRIPTAN BASE (103628-46-2)

vPvB: not relevant – no registration required

### 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

Sewage disposal recommendations : Disposal must be done according to official regulations.  
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**  
Not applicable

**Transport by sea**  
Not applicable

**Air transport**  
Not applicable

**Inland waterway transport**  
Not applicable

**Rail transport**  
Not applicable

### 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

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

###### 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:

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
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IATA	International Air Transport Association

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Abbreviations and acronyms:	
EC50	Median effective concentration
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
vPvB	Very Persistent and Very Bioaccumulative
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
LD50	Median lethal dose

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:	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H319	Causes serious eye irritation.
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.