

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

Product form	: Substance
Trade name	: SUMATRIPTAN SUCCINATE
Chemical name	: Butanedioic acid, compd. with 3-[2-(dimethylamino)ethyl]-N-methyl-1H-indole-5-methanesulfonamide (1:1)
IUPAC name	: 1-[3-(2-dimethylaminoethyl)-1H-indol-5-yl]- N-methyl-methanesulfonamide succinate
EC-No.	: 600-463-4
CAS-No.	: 103628-48-4
Product code	: 78100
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₁₈ H ₂₇ N ₃ O ₆ S
Synonyms	: 1H-Indole-5-methanesulfonamide, 3-[2-(dimethylamino)ethyl]-N-methyl-, butanedioate (1:1)
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILE: CNS(=O)(=O)Cc1ccc2c(c1)c(c[nH]2)CCN(C)C.C(CC(=O)O)C(=O)O

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

Main use category	: Laboratory use,API,Medicinal use
Industrial/Professional use spec	: Laboratory activities Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: A serotonin agonist that acts selectively at 5HT ₁ receptors. It is used in the treatment of migraine disorders.
Use of the substance/mixture	: Pharmaceuticals
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**

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Manufacturer

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hse@moehs.es - 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

Suspected of damaging fertility. Suspected of damaging the unborn child. Dust may form explosive mixture in air.

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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) :

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves, protective clothing, eye protection.

P284 - In case of inadequate ventilation wear respiratory protection.

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.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P261 - Avoid breathing dust.

P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

Immediately call a doctor.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P314 - Get medical advice/attention if you feel unwell.

P273 - Avoid release to the environment.

P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
SUMATRIPTAN SUCCINATE	CAS-No.: 103628-48-4 EC-No.: 600-463-4	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 exposed or concerned: Get medical advice/attention. May cause harm to breast-fed children.

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.

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

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. Erythema. Fatigue. Suspected of damaging the unborn child..
- Symptoms/effects after eye contact : Causes serious eye irritation.

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

No additional information available

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 : fume. Carbon monoxide. Carbon dioxide. 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. Avoid contact with skin and eyes.

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. Safety glasses. Protective gloves. 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.

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.

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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. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Do not breathe dust.
- Hygiene measures : Wash hands, forearms and face thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

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

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. Provide local exhaust or general room ventilation. Dust extraction (suction). Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment.

8.2.2. Personal protection equipment

Personal protective equipment:

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

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

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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

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

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Natural rubber, Butyl rubber, Polyvinylchloride (PVC), Latex, Neoprene rubber (HNBR), Fluoroelastomer (FKM)	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	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.

Consumer exposure controls:

Avoid contact during pregnancy/while nursing.

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

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Colour	: white.
Appearance	: Dust.
Molecular mass	: 413.49 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 165 – 166 °C
Freezing point	: Not available
Boiling point	: 497.7 (442.7 – 552.7) °C (Scifinder, accessed 2020)
Flammability	: May form combustible dust concentrations in air, Non flammable.
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	: > 254.8 (286.3 – 223.3) °C (Scifinder, accessed 2020)
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: 4 – 5.1 (in 1.68 % aq. Sol)
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in. DMSO. Water. Water: > 83 g/l Organic solvent:> 4 g/100ml DMSO
Partition coefficient n-octanol/water (Log Kow)	: 0.93 (Sumatriptan base Log POW) Exper. Ref: Adlard, M et al. (1995)
Vapour pressure	: Not available
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

Dust Cloud minimum Flammability Temperature	: > 400 °C
Layer Minimum flammability Temperature	: > 400
Explosivity Pmax	: 7.7 bar
Explosion Severity Factor Kmax (bar.m/s)	: 163
Explosion Class	: st1

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Stable under normal conditions of use. None under normal use. Not established.

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

10.4. Conditions to avoid

No flames, no sparks. Eliminate all sources of ignition. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid creating or spreading dust. 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

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LD50 oral rat	> 2939 mg/kg ChemIDPlus
LD50, acute, oral, Dog	> 700 mg/kg
LD50, acute, subcutaneous, Dog	> 140 mg/kg
LD50, acute, subcutaneous, rat	1680 mg/kg
LD50, acute, oral, mouse	> 1500 mg/kg
NOAEL, Chronic, oral, rat	5 mg/kg bw/day (18 months)

Skin corrosion/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : 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 : Chromosomal aberration test Assay in vitro, GLP: Result Negative
AMES test : (Rat, GLP) 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 : May cause harm to breast-fed children.

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NOAEL (animal/male, F0/P)	50 mg/kg bodyweight Embryo-fetal development-oral: Rabbit
NOAEL (animal/female, F0/P)	≥ 100 mg/kg bodyweight Embryo-foetal development; Maternal Toxicity; Adverse Foetal effects on Rat
NOAEL (animal/male, F1)	100 mg/kg bodyweight Fertility; Reduces success 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

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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

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.

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LC50 - Fish [1]	> 100 mg/l Rainbow Trout (Juvenile <i>Oncorhynchus mykiss</i>) - OECD 203
EC50 - Crustacea [1]	290 mg/l Water Flea (<i>Daphnia pulex</i>) - Static Test, OECD 202
EC50 72h - Algae [1]	36 mg/l Green Algae (<i>Scenedesmus subspicatus</i>) - OECD 201
NOEC chronic crustacea	32 mg/l (<i>Daphnia</i> , 8 days)
Activated Sludge respiration ₅₀ , Sludge	> 750 mg/l (3 Hours, OECD 209)

12.2. Persistence and degradability

SUMATRIPTAN SUCCINATE (103628-48-4)

Persistence and degradability	Not readily biodegradable.
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12.3. Bioaccumulative potential

SUMATRIPTAN SUCCINATE (103628-48-4)

Bioconcentration factor (BCF REACH)	3.162 (Bioaccumulation Estimates from Log Kow (BCFWIN v2.17) in sumatriptan base)
Partition coefficient n-octanol/water (Log Kow)	0.93 (Sumatriptan base Log POW) Exper. Ref: Adlard, M et al. (1995)
Bioaccumulative potential	Not established.

12.4. Mobility in soil

SUMATRIPTAN SUCCINATE (103628-48-4)

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

SUMATRIPTAN SUCCINATE (103628-48-4)

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.

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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

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

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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

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

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

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

Indication of changes:

Exposure controls/personal protection. Stability and reactivity. Hazards identification. Ecological information. Regulatory information. Toxicological information. Handling and storage.

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
DSD	Dangerous Substances Directive 67/548/EEC
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
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant

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.

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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.