

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Alendronate Solid Formulation

Version 4.2      Revision Date: 09/13/2019      SDS Number: 22293-00014      Date of last issue: 24.04.2019  
Date of first issue: 15.10.2014

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

#### 1.1 Product identifier

Trade name : Alendronate Solid Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

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

Company : MSD  
Innishannon  
County Cork - Ireland

Telephone : 353 214329300

Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Danger

Hazard statements : H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H335 May cause respiratory irritation.

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H361d Suspected of damaging the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements :

### Prevention:

P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.  
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 POISON CENTER/doctor.

Hazardous components which must be listed on the label:

Alendronate

### 2.3 Other hazards

May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Alendronate	121268-17-5	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Repr. 2; H361d STOT SE 3; H335 STOT RE 2; H373	>= 20 - < 30

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

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- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

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

- Risks : Causes skin irritation.  
Causes serious eye damage.  
May cause respiratory irritation.  
Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated exposure.

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

- Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

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

- Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

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Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Phosphorus compounds  
Metal oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

### 6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

#### 7.3 Specific end use(s)

- Specific use(s) : No data available
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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m <sup>3</sup>	IE OEL
Further information	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used			
Alendronate	121268-17-5	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

### 8.2 Exposure controls

#### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

#### Personal protective equipment

- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : powder
- Colour : white
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	1 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### Alendronate:

Acute oral toxicity : LD50 (Rat): 552 - 626 mg/kg  
LD50 (Mouse): 966 - 1,280 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Causes skin irritation.

#### Components:

##### Alendronate:

Species : Rabbit  
Remarks : Severe skin irritation



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### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### Alendronate:

Species : Rabbit  
Result : Severe irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Alendronate:

Remarks : No data available

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Alendronate:

Genotoxicity in vitro : Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Metabolic activation: with and without metabolic activation  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: equivocal

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Result: negative

### Carcinogenicity

Not classified based on available information.

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**Components:**

**Alendronate:**

Species : Rat, male  
 Application Route : Oral  
 Exposure time : 2 Years  
                                : 1 mg/kg body weight  
                                : 3.75 mg/kg body weight  
 Target Organs : Thyroid  
 Remarks : The mechanism or mode of action may not be relevant in humans.

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**Alendronate:**

Effects on fertility : Test Type: Fertility  
                                Species: Rat, male and female  
                                Application Route: Oral  
                                Fertility: NOAEL: 5 mg/kg body weight  
                                Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Development  
                                Species: Rat, female  
                                Application Route: Oral  
                                Developmental Toxicity: LOAEL: 1 - 15 mg/kg body weight  
                                Symptoms: Reduced number of viable fetuses, Reduced body weight, Skeletal malformations  
                                Result: Embryotoxic effects and adverse effects on the offspring were detected.

  Test Type: Development  
   Species: Rabbit, female  
   Application Route: Oral  
   Developmental Toxicity: NOAEL: 40 mg/kg body weight  
   Result: No adverse effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

May cause respiratory irritation.

**Components:**

**Alendronate:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

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### Components:

#### **Alendronate:**

Target Organs : Bone, Stomach, Kidney  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

#### Components:

#### **Alendronate:**

Species : Rat  
NOAEL : 2.5 mg/kg  
LOAEL : > 2.5 mg/kg  
Application Route : Intravenous  
Exposure time : 53 Weeks  
Target Organs : Stomach

Species : Dog  
LOAEL : 0.01 mg/kg  
Application Route : Intravenous  
Exposure time : 3 yr  
Target Organs : Stomach, Bone, Kidney

Species : Dog  
NOAEL : 2 mg/kg  
LOAEL : 4 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Target Organs : Kidney

### **Aspiration toxicity**

Not classified based on available information.

#### Components:

#### **Alendronate:**

Not applicable

### **Experience with human exposure**

#### Components:

#### **Alendronate:**

Inhalation : Symptoms: respiratory tract irritation  
Skin contact : Symptoms: Severe irritation, skin blistering  
Eye contact : Symptoms: Severe irritation  
Ingestion : Symptoms: Gastrointestinal disturbance, musculoskeletal pain

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **Alendronate:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 27 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l  
Exposure time: 96 h  
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 170 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to fish (Chronic toxicity) : NOEC: 1.1 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210
- LOEC: 1.9 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 4.7 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

#### 12.2 Persistence and degradability

##### Components:

##### **Alendronate:**

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 70.3 %  
Exposure time: 7 d
- Stability in water : Degradation half life (DT50): 375 d

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Method: OECD Test Guideline 111

### 12.3 Bioaccumulative potential

#### Components:

##### **Alendronate:**

Partition coefficient: n-octanol/water : log Pow: -1.73

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

#### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

#### Full text of H-Statements

H302 : Harmful if swallowed.

H315 : Causes skin irritation.

H318 : Causes serious eye damage.

H335 : May cause respiratory irritation.

H361d : Suspected of damaging the unborn child.

H373 : May cause damage to organs through prolonged or repeated exposure.

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### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Dam. : Serious eye damage  
Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Skin Irrit. 2      H315  
Eye Dam. 1      H318

### Classification procedure:

Calculation method  
Calculation method

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Repr. 2	H361d	Calculation method
STOT SE 3	H335	Calculation method
STOT RE 2	H373	Calculation method

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