

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Alendronate Solid Formulation

Version 5.8      Revision Date: 09/13/2019      SDS Number: 22286-00014      Date of last issue: 2019/04/24  
Date of first issue: 2014/10/15

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Alendronate Solid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road  
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : powder  
**Colour** : white  
**Odour** : odourless

May be harmful if swallowed. 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. Harmful to aquatic life.

#### GHS Classification

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2


Short-term (acute) aquatic hazard : Category 3

#### GHS label elements

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- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H303 May be 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.  
H402 Harmful to aquatic life.
- Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of water.  
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.  
P312 Call a POISON CENTER/doctor if you feel unwell.  
P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.
- Storage:**  
P405 Store locked up.
- Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

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### Health hazards

May be harmful if swallowed. Causes skin irritation. Causes serious eye damage. Suspected of damaging the unborn child. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure.

### Environmental hazards

Harmful to aquatic life.

### Other hazards which do not result in classification

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name | CAS-No.     | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Cellulose     | 9004-34-6   | >= 30 -< 50           |
| Alendronate   | 121268-17-5 | >= 25 -< 30           |

## 4. 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.
- 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.
- Most important symptoms and effects, both acute and delayed : May be harmful if swallowed.  
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.
- 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).
- Notes to physician : Treat symptomatically and supportively.

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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- 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.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Phosphorus compounds  
Metal oxides
- 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.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.
- 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.
- Methods and materials for containment and 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.

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### 7. HANDLING AND STORAGE

#### 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.
- Avoidance of contact : Oxidizing agents

#### Storage

- Conditions for safe storage : 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.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components  | CAS-No.     | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis        |
|-------------|-------------|-------------------------------|------------------------------------------------|--------------|
| Cellulose   | 9004-34-6   | PC-TWA                        | 10 mg/m <sup>3</sup>                           | GBZ 2.1-2007 |
|             |             | TWA                           | 10 mg/m <sup>3</sup>                           | ACGIH        |
| Alendronate | 121268-17-5 | TWA                           | 20 µg/m <sup>3</sup> (OEB 3)                   | Internal     |
|             |             | Wipe limit                    | 200 µg/100 cm <sup>2</sup>                     | Internal     |

- Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

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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

- 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
- Eye/face 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.
- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Colour : white
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available

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

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

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Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

May be harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 2,115 mg/kg  
Method: Calculation method

#### Components:

##### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### 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

#### Serious eye damage/eye irritation

Causes serious eye damage.



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### 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:

#### **Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

#### **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

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

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

#### **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:**

#### **Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **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

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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.

#### Components:

##### Alendronate:

Target Organs : Bone, Stomach, Kidney

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

### Repeated dose toxicity

#### Components:

##### Cellulose:

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

##### 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

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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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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

### Components:

#### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

#### 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

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- 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 (Pimephales promelas (fathead minnow)): 1.1 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- LOEC (Pimephales promelas (fathead minnow)): 1.9 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 4.7 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Persistence and degradability

#### Components:

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Alendronate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 70.3 %  
Exposure time: 7 d

Stability in water : Degradation half life (DT50): 375 d  
Method: OECD Test Guideline 111

### Bioaccumulative potential

#### Components:

##### **Alendronate:**

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

##### **Mobility in soil**

No data available

##### **Other adverse effects**

No data available

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### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
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.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

##### GB 6944/12268

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

#### National regulatory information

##### Law on the Prevention and Control of Occupational Diseases

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 16. OTHER INFORMATION

#### 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/>

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Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
GBZ 2.1-2007 : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average  
GBZ 2.1-2007 / PC-TWA : Permissible concentration - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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