

**Alendronate Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 22279-00014      Date of last issue: 24.04.2019  
Date of first issue: 15.10.2014

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Alendronate Solid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Treze de Maio, 1161  
Campinas, São Paulo, Brazil 13106-054

Telephone : 908-740-4000

Emergency telephone : 55 19 3758 2000

E-mail address : EHSDATASTEWARD@msd.com

Telefax : 908-735-1496

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

Recommended use : Pharmaceutical

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification in accordance with ABNT NBR 14725 Standard**

Acute toxicity (Oral) : Category 5

Skin irritation : Category 2

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity -  
single exposure : Category 3

Specific target organ toxicity -  
repeated exposure : Category 2 (Bone, Stomach, Kidney)

Short-term (acute) aquatic  
hazard : Category 3

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.

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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 (Bone, Stomach, Kidney) through prolonged or repeated exposure.  
 H402 Harmful to aquatic life.

## Precautionary Statements

:

**Prevention:**

P201 Obtain special instructions before use.  
 P260 Do not breathe dust.  
 P264 Wash skin thoroughly after handling.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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.

**Other hazards which do not result in classification**

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

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 30 -< 50
Alendronate	121268-17-5	Acute toxicity (Oral), Category 4 Skin irritation, Category 2 Serious eye damage, Category 1 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure, Category 3 Specific target organ toxicity - repeated exposure (Bone, Stomach, Kidney), Category 2 Short-term (acute) aquatic hazard, Category 3	>= 25 -< 30

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### SECTION 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.

### SECTION 5. FIRE-FIGHTING 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.

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Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

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### SECTION 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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### SECTION 7. HANDLING AND STORAGE

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 sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.  
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.

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- Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
 : 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.
- Conditions for safe storage : Keep in properly labeled 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

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	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 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
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.

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Skin and body protection : Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.  
: 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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : white

Odor : odorless

Odor Threshold : No data available

pH : No data available

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.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor 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

Autoignition temperature : No data available

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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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**SECTION 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.

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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**SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : 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

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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.

**Components:****Alendronate:**

Species : Rabbit  
Result : Severe irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

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



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Result: negative

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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.

**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

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Effects on fetal 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 fetal 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 (Bone, Stomach, Kidney) 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:**

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Species : Rat  
NOAEL : >= 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  
Application Route : Intravenous  
Exposure time : 3 y  
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****Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h

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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
- 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

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**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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**SECTION 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.

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**SECTION 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.

**Domestic regulation****ANTT**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

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**International Regulations****The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION****Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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

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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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