

## Alendronate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.0	06.04.2024	22307-00023	Date of first issue: 15.10.2014

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**Section 1: Identification**

**Product identifier** : Alendronate Solid Formulation

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

Recommended use : Pharmaceutical  
 Restrictions on use : Not applicable


**Manufacturer or supplier's details**

Company : Organon & Co.  
 Address : 30 Hudson Street, 33rd floor  
 Jersey City, New Jersey, U.S.A 07302  
 Telephone : +1-551-430-6000  
 Emergency telephone number : +1-215-631-6999  
 E-mail address : EHSSTEWARD@organon.com

**Section 2: Hazard identification****Classification of the substance or mixture**

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 (Bone, Stomach, Kidney)

**GHS Label elements, including precautionary statements**

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 (Bone, Stomach, Kidney) through prolonged or repeated exposure.

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.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing 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.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.

**Storage:**  
 P405 Store locked up.

**Disposal:**  
 P501 Dispose of contents/ container to an approved waste disposal plant.

**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.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Alendronate	121268-17-5	>= 20 -< 30

**Section 4: First-aid measures****Description of necessary first-aid measures**

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- 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**

- 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.
- 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).

**Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically and supportively.
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**Section 5: Fire-fighting measures****Extinguishing media**

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

**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.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)

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Phosphorus compounds  
Metal oxides

**Special protective actions for fire-fighters**

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****Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**

Environmental precautions : Avoid release to the environment. 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**

Methods for cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. 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. Clean up remaining materials from spill with suitable absorbent. 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****Precautions for safe handling**

Technical measures : Static electricity may accumulate and ignite suspended dust

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- 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.  
Wash skin thoroughly after handling.  
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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, 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.

**Conditions for safe storage, including any incompatibilities**

- 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

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**Section 8: Exposure controls/personal protection**

**Control parameters**

**Occupational Exposure Limits**

Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration	
Cellulose	9004-34-6	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		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

**Appropriate engineering control 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.

**Individual protection measures, such as personal protective equipment (PPE)**

**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 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

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Section 9: 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.

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 characteristics  
Particle size : No data available

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### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

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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**

Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 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:**



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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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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

Remarks	: No data available
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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

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Genotoxicity in vivo	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
	:	Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: equivocal
	:	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
	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative
	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

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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.
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**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:**

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

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**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

**Section 12: Ecological information****Toxicity****Components:****Cellulose:**

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

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 70.3 % Exposure time: 7 d
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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 : Do not dispose of waste into sewer.  
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

UN number : Not applicable  
UN proper shipping name : Not applicable  
Transport hazard class(es) : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

##### IATA-DGR

UN/ID No. : Not applicable  
UN proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

UN number : Not applicable  
UN proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable

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Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

**The components 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**

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**Further information**

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

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health (General Provisions)  
Regulations - First Schedule Permissible Exposure Limits of  
Toxic Substances.

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ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; 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; TECL - Thailand Existing Chemicals Inventory; 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

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.

SG / EN