

Alendronate Solid Formulation

Version 5.7 Revision Date: 09/13/2019 SDS Number: 22304-00014 Date of last issue: 24.04.2019
Date of first issue: 15.10.2014

Section 1: Identification

Product name : Alendronate Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification**GHS Classification**

Skin corrosion/irritation : 2

Serious eye damage/eye irritation : 1

Reproductive toxicity : Repr.2

Specific target organ toxicity - single exposure : STOT SE3

Specific target organ toxicity - repeated exposure : STOT RE2 (Bone, Stomach, Kidney)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : 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.

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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/ eye protection/ face protection.
 P281 Use personal protective equipment as required.

Response:
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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 or doctor/ physician.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P332 + P313 If skin irritation occurs: Get medical advice/ attention.
 P362 Take off contaminated clothing and wash before reuse.

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 -< 60
Alendronate	121268-17-5	>= 20 -< 30

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.

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- In case of skin contact : Get medical attention.
 : 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 : 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 (CO₂)
 : 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_x)
 : 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.

Section 6: Accidental release measures

- Personal precautions, protec- : Use personal protective equipment.

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| tive equipment and emergency procedures | : | 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 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, |

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- appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 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

Section 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	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
Alendronate	121268-17-5	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	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.
 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

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contaminated clothing.

Section 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
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 ³
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

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Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

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.

Section 11: Toxicological information

Exposure routes : 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

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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 sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Alendronate:**

Remarks : No data available

Chronic toxicity**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

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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

Effects on foetal development : 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.

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 : $\geq 9,000$ 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

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

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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

Bioaccumulative potential**Components:****Alendronate:**

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

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Mobility in soil

No data available

Other adverse effects

No data available

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.

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.

National Regulations**NZS 5433**

Not regulated as a dangerous good

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

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IECSC : not determined

Section 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/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - 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

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

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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.

NZ / EN