# **Alendronate Solid Formulation**



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#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Alendronate Solid Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

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

Hazard pictograms :







Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.





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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.

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/ atten-

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.

### 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	>= 25 -< 30

### **SECTION 4. 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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May be harmful if swallowed.

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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Phosphorus compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

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

SO.





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Evacuate area.

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

for fire-fighters Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

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

Avoid release to the environment. **Environmental precautions** 

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.

#### **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.

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 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. Take care to prevent spills, waste and minimize release to the



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environment.

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	CMP	10 mg/m <sup>3</sup>	AR OEL	
	Further information: Irritation				
		TWA	10 mg/m <sup>3</sup>	ACGIH	
Alendronate	121268-17-5	TWA	20 μg/m3 (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.

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide





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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.

#### **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



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Autoignition 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

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

#### **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:



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Acute oral toxicity : LD50 (Rat): 552 - 626 mg/kg

LD50 (Mouse): 966 - 1.280 mg/kg

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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





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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

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 hu-

mans.

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



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Result: negative

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 - As-

sessment

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.



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#### Repeated dose toxicity

### **Components:**

### Cellulose:

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

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 tox-

icity)

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 (Chron-

ic 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:



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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

**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.

**SECTION 15. REGULATORY INFORMATION** 

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

Argentina. Carcinogenic Substances and Agents

Registry.

Not applicable

Control of precursors and essential chemicals for the

Not applicable

preparation of drugs.

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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

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

Sources of key data used to compile the Material Safety

compile the Material Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB



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- 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.

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