

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Alendronate / Vitamin D Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : 30 Hudson Street, 33rd 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 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 : Category 2 (Bone, Stomach, Kidney)

Short-term (acute) aquatic  
hazard : Category 3

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.

---

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

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.  
P270 Do not eat, drink or smoke when using this product.  
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:**  
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
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.  
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

# SAFETY DATA SHEET



## Alendronate / Vitamin D Formulation



Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

Colecalciferol	67-97-0	>= 0,025 -< 0,1
----------------	---------	-----------------

### 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.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : 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

## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

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

**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.
- 

**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.
-

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

- 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.
- 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/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal
Colecalciferol	67-97-0	TWA	5 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	50 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.

## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

- 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 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 : off-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 : Not applicable
- Relative vapor density : Not applicable
- Relative density : No data available

# SAFETY DATA SHEET



## Alendronate / Vitamin D Formulation



Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

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 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

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### **Acute toxicity**

Harmful if swallowed.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: 1.965 mg/kg  
Method: Calculation method

#### **Components:**

#### **Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

---

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

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

**Colecalciferol:**

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 0,05 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg  
Method: Expert judgment

**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

**Colecalciferol:**

Species : Rabbit  
Result : No eye irritation

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

Not classified based on available information.



## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

**Respiratory sensitization**

Not classified based on available information.

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

Remarks : No data available

**Colecalciferol:**

Test Type	: Maurer optimisation test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negativeTest Type: In vitro mammalian cell gene mutation test  
Result: negativeGenotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative**Alendronate:**Genotoxicity in vitro : Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negativeTest Type: Bacterial reverse mutation assay (AMES)  
Metabolic activation: with and without metabolic activation  
Result: negativeTest Type: In vitro mammalian cell gene mutation test  
Result: negativeTest Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: equivocalGenotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Result: negative**Colecalciferol:**

## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: equivocal
- Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative
- Test Type: In vivo mammalian alkaline comet assay  
Species: Rat  
Application Route: Ingestion  
Result: positive
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**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:**

## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

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

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

**Colecalciferol:**

Routes of exposure : Ingestion  
Target Organs : Kidney, Blood, Bone  
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

**Repeated dose toxicity****Components:****Cellulose:**

Species : Rat  
NOAEL :  $\geq 9.000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Alendronate:**

Species : Rat  
NOAEL : 2,5 mg/kg  
LOAEL :  $> 2,5$  mg/kg  
Application Route : Intravenous  
Exposure time : 53 Weeks  
Target Organs : Stomach

Species : Dog  
LOAEL : 0,01 mg/kg  
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

**Colecalciferol:**

Species : Rat  
NOAEL : 0,06 mg/kg  
LOAEL : 0,3 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408

**Aspiration toxicity**

Not classified based on available information.

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

Not applicable

## Alendronate / Vitamin D Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

---

**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 ( <i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
------------------	---	--

**Alendronate:**

Toxicity to fish	:	LC50 ( <i>Pimephales promelas</i> (fathead minnow)): 27 mg/l Exposure time: 96 h Method: OECD Test Guideline 203  LC50 ( <i>Oncorhynchus mykiss</i> (rainbow trout)): > 1.000 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 170 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 10 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC ( <i>Pimephales promelas</i> (fathead minnow)): 1,1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210  LOEC ( <i>Pimephales promelas</i> (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 ( <i>Daphnia magna</i> (Water flea)): 4,7 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

## Alendronate / Vitamin D Formulation

Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

**Colecalciferol:**

- Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EL50 (Scenedesmus capricornutum (fresh water algae)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

**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

**Colecalciferol:**

- Biodegradability : Result: Not readily biodegradable.  
Biodegradation: <= 7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

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

- Partition coefficient: n-octanol/water : log Pow: -1,73

**Colecalciferol:**

- Partition coefficient: n-octanol/water : log Pow: > 6,2  
Method: OECD Test Guideline 107

**Mobility in soil**

No data available

# SAFETY DATA SHEET



## Alendronate / Vitamin D Formulation



Version 5.3      Revision Date: 23.03.2020      SDS Number: 22028-00016      Date of last issue: 13.09.2019  
Date of first issue: 15.10.2014

---

### 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 preparation of drugs. : Not applicable

### 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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

---

# SAFETY DATA SHEET



## Alendronate / Vitamin D Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.3	23.03.2020	22028-00016	Date of first issue: 15.10.2014

Data Sheet 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)

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 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.

AR / Z8