

## Alendronate / Vitamin D Formulation

Version 4.2      Revision Date: 09/13/2019      SDS Number: 22066-00015      Date of last issue: 24.04.2019  
 Date of first issue: 15.10.2014

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Alendronate / Vitamin D Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
 117 16th Road  
 07033 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### SECTION 2: Hazards identification


#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Skin irritation, Category 2	H315: Causes skin irritation.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 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 through prolonged or repeated exposure.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.  
 P260 Do not breathe dust.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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.

Hazardous components which must be listed on the label:  
 Alendronate

**2.3 Other hazards**

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

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Alendronate	121268-17-5	Acute Tox.4; H302 Skin Irrit.2; H315 Eye Dam.1; H318 Repr.2; H361d STOT SE3; H335 STOT RE2; H373	>= 20 - < 30
Colecalciferol	67-97-0 200-673-2 603-180-00-4	Acute Tox.2; H300 Acute Tox.2; H330 Acute Tox.2; H310 STOT RE1; H372 Aquatic Chronic4; H413	>= 0,025 - < 0,1

For explanation of abbreviations see section 16.

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**SECTION 4: First aid measures****4.1 Description of 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.
- 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).
- 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.

**4.2 Most important symptoms and effects, both acute and delayed**

- Risks : 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.

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

- Treatment : Treat symptomatically and supportively.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

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Unsuitable extinguishing media : None known.

**5.2 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>)  
Phosphorus compounds  
Metal oxides

**5.3 Advice for firefighters**

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

Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

**6.2 Environmental precautions**

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.

**6.3 Methods and material for containment and cleaning up**

Methods for 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 deter-

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mine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>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.   |

### 7.2 Conditions for safe storage, including any incompatibilities

- |   |   |  |
|---|---|--|
| Requirements for storage areas and containers | : | 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. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents  |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	TWA OEL-RL (Respirable dust)	5 mg/m <sup>3</sup>	ZA OEL
Further information	Recommended Limit			
		TWA OEL-RL (inhalable dust)	10 mg/m <sup>3</sup>	ZA OEL
Further information	Recommended Limit			
		STEL OEL-RL (Dust)	20 mg/m <sup>3</sup>	ZA OEL
Further information	Recommended Limit			
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

**8.2 Exposure controls****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**

- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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Filter type : Particulates type (P)

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance : powder  
Colour : off-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.  
  
Upper explosion limit / Upper flammability limit : No data available  
  
Lower explosion limit / Lower flammability limit : No data available  
  
Vapour pressure : Not applicable  
  
Relative vapour density : Not applicable  
  
Relative density : No data available  
  
Density : No data available  
  
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.

**9.2 Other information**

Flammability (liquids) : No data available

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Particle size : No data available

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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:****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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**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 judgement

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

**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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

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

Remarks : No data available

**Colecalciferol:**

Test Type : Maurer optimisation test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 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

#### Colecalciferol:

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.

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### Carcinogenicity

Not classified based on available information.

### Components:

#### 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:

#### 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 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 through prolonged or repeated exposure.

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

Target Organs : Bone, Stomach, Kidney  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Colecalciferol:**

Exposure routes : 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:****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

**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.

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**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****12.1 Toxicity****Components:****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: 1,1 mg/l  
 Exposure time: 32 d  
 Species: Pimephales promelas (fathead minnow)  
 Method: OECD Test Guideline 210  
 LOEC: 1,9 mg/l  
 Exposure time: 32 d  
 Species: Pimephales promelas (fathead minnow)  
 Method: OECD Test Guideline 210

Toxicity to daphnia and other : NOEC: 4,7 mg/l

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aquatic invertebrates (Chronic toxicity)  
 Exposure time: 21 d  
 Species: Daphnia magna (Water flea)  
 Method: OECD Test Guideline 211

### **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

## 12.2 Persistence and degradability

### Components:

#### **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

## 12.3 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

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

Not relevant

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**12.6 Other adverse effects**

No data available

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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****14.1 UN number**

Not regulated as a dangerous good

**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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### SECTION 16: Other information

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

#### Full text of H-Statements

H300 : Fatal if swallowed.  
 H302 : Harmful if swallowed.  
 H310 : Fatal in contact with skin.  
 H315 : Causes skin irritation.  
 H318 : Causes serious eye damage.  
 H330 : Fatal if inhaled.  
 H335 : May cause respiratory irritation.  
 H361d : Suspected of damaging the unborn child.  
 H372 : Causes damage to organs through prolonged or repeated exposure.  
 H373 : May cause damage to organs through prolonged or repeated exposure.  
 H413 : May cause long lasting harmful effects to aquatic life.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
 Aquatic Chronic : Long-term (chronic) aquatic hazard  
 Eye Dam. : Serious eye damage  
 Repr. : Reproductive toxicity  
 Skin Irrit. : Skin irritation  
 STOT RE : Specific target organ toxicity - repeated exposure  
 STOT SE : Specific target organ toxicity - single exposure  
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits  
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit  
 ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New



**Alendronate / Vitamin D Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
4.2	09/13/2019	22066-00015	Date of first issue: 15.10.2014

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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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

**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/>

**Classification of the mixture:**

Acute Tox. 4	H302
Skin Irrit. 2	H315
Eye Dam. 1	H318
Repr. 2	H361d
STOT SE 3	H335
STOT RE 2	H373

**Classification procedure:**

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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