SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Alendronate / Vitamin D Formulation

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.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)

GHS label elements
Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
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.

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.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.  
P302 + P352 IF ON SKIN: Wash with plenty of 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 + 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**
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Alendronate</td>
<td>121268-17-5</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Colecalciferol</td>
<td>67-97-0</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

### 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.
### Section 3. Personal Protection

**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.

### 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 (NOx)
- 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 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. 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
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Alendronate</td>
<td>121268-17-5</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Colecalciferol</td>
<td>67-97-0</td>
<td>TWA</td>
<td>5 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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: 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance :</td>
<td>powder</td>
</tr>
<tr>
<td>Color :</td>
<td>off-white</td>
</tr>
<tr>
<td>Odor :</td>
<td>odorless</td>
</tr>
<tr>
<td>Odor Threshold :</td>
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</tr>
<tr>
<td>pH :</td>
<td>No data available</td>
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<tr>
<td>Melting point/freezing point :</td>
<td>No data available</td>
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<tr>
<td>Initial boiling point and boiling range :</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point :</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate :</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas) :</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids) :</td>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit :</td>
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</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit :</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure :</td>
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<tr>
<td>Relative vapor density :</td>
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<tr>
<td>Relative density :</td>
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<tr>
<td>Density :</td>
<td>No data available</td>
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<tr>
<td>Solubility(ies) :</td>
<td>Water solubility :</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water :</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature :</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature :</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity :</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

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.
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
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
SAFETY DATA SHEET
Alendronate / Vitamin D Formulation

Version 6.2 Revision Date: 13.09.2019 SDS Number: 22056-00015 Date of last issue: 24.04.2019 Date of first issue: 15.10.2014

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.

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: 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
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:
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.

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 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.

**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: >= 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  
NOAEL: 0.01 mg/kg  
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

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
    - 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

- **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

Other adverse effects
No data available
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 6.2  Revision Date: 13.09.2019  SDS Number: 22056-00015  Date of last issue: 24.04.2019  Date of first issue: 15.10.2014

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.

Domestic regulation
NOM-002-SCT  Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.
Not applicable

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 6.2  Revision Date: 13.09.2019  SDS Number: 22056-00015  Date of last issue: 24.04.2019

the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT: Time weighted average 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; IECS - 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 Standardisation; 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


Revision Date: 13.09.2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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