SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

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 Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A

Telephone: 551-430-6000

E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, 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

H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H361d: Suspected of damaging the unborn child.
H335: May cause respiratory irritation.
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.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate</td>
<td>121268-17-5</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4; H302 Skin Irrit.2; H315 Eye Dam.1; H318 Repr.2; H361d STOT SE; H335 STOT RE; H373</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Colecalciferol</td>
<td>67-97-0</td>
<td>200-673-2</td>
<td>603-180-00-4</td>
<td></td>
<td>Acute Tox.2; H300 Acute Tox.2; H330 Acute Tox.2; H310 STOT RE1; H372 Aquatic Chronic4; H413</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

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 ad-
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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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

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.

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 determine 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures
Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, 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:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s)
No data available
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL (Dust)</td>
<td>20 mg/m³</td>
<td>ZA OEL</td>
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<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>

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.

Filter type: Particulates type (P)
SECTION 9: Physical and chemical properties

9.1 Information on basic 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>Colour</td>
<td>off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<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>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Density</td>
<td>No data available</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
<td>No data available</td>
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<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition 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>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

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
**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
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 4.3  Revision Date: 23.03.2020  SDS Number: 22066-00016  Date of last issue: 13.09.2019  Date of first issue: 15.10.2014

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.
Carcinogenicity
Not classified based on available information.

Components:

Alendronate:
Species: Rat, male
Application Route: Oral
Exposure time: 2 Years
Exposure: 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.
**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
- **NOAEL:** 0,01 mg/kg
- **LOAEL:** 0,06 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:** 0,3 mg/kg
  - **LOAEL:** 0,06 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

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 aquatic invertebrates: NOEC: 4.7 mg/l
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
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 4.3
Revision Date: 23.03.2020
SDS Number: 22066-00016
Date of last issue: 13.09.2019
Date of first issue: 15.10.2014

12.6 Other adverse effects
No data available

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.

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.

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.
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
SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 4.3  Revision Date: 23.03.2020  SDS Number: 22066-00016  Date of last issue: 13.09.2019

Date of first issue: 15.10.2014

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:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
<th>Procedure</th>
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</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H302</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
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</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
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<tr>
<td>STOT SE 3</td>
<td>H335</td>
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</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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ZA / EN