

## Alendronate / Vitamin D Formulation

Version Revision Date: SDS Number: Date of last issue: 2019/09/13 2020/03/23 22054-00016 Date of first issue: 2014/10/15 6.0

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Alendronate / Vitamin D Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address 30 Hudson Street, 33nd floor

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

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical

#### 2. HAZARDS IDENTIFICATION

## GHS classification of chemical product

Acute toxicity (Oral) : Category 4

Skin corrosion/irritation : Category 2

Serious eye damage/eye irri-: Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - : Category 3

single exposure

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

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 (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 protective //www.news.com/

tion/ 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/ atten-

tion.

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

Important symptoms and out: : lines of the emergency as-

sumed

May form explosive dust-air mixture during processing, han-

dling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture



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Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cellulose	9004-34-6	>= 40 - < 50	
Alendronate	121268-17-5	>= 25 - < 30	
Colecalciferol	67-97-0	>= 0.025 - < 0.1	9-1054

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water

for at least 15 minutes while removing contaminated clothing

and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

nedia

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.

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Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Phosphorus compounds

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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

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

SO.

Evacuate area.

Special protective equipment

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

## **6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective equip-

ment 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 con-

tainer 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-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

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.



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Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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.

Avoidance of contact Hygiene measures : Oxidizing agents

: 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.

Storage

Conditions for safe storage : 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.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Alendronate	121268-17-5	TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal
Colecalciferol	67-97-0	TWA	5 μg/m3 (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 con-



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> tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Particulates type Filter type

Hand protection

Material Chemical-resistant gloves

Consider double gloving. Remarks

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.

Work uniform or laboratory coat. Skin and body protection

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state powder

Colour off-white

Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper : No data available

flammability limit

Lower explosion limit / Lower :

flammability limit

No data available

Flash point Not applicable



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Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle characteristics

Particle size : No data available

### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact



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**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

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.



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#### **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

## 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)



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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 -

-

Weight of evidence does not support classification as a germ

cell mutagen.

## Carcinogenicity

**Assessment** 

Not classified based on available information.

#### **Components:**

#### Cellulose:

Species: RatApplication Route: IngestionExposure time: 72 weeksResult: negative



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Alendronate:

Species : Rat, male
Application Route : Oral
Exposure time : 2 Years

1 mg/kg body weight3.75 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 foetal develop-

ment

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 foetal develop-

ment

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 off-

spring were detected.

Test Type: Development Species: Rabbit, female Application Route: Oral

Developmental Toxicity: NOAEL: 40 mg/kg body weight

Result: No adverse effects

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT - single exposure

May cause respiratory irritation.



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#### **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:

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Bone

Assessment : Shown to produce significant health effects in animals at con-

centrations 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: RatNOAEL: 2.5 mg/kgLOAEL: > 2.5 mg/kgApplication Route: IntravenousExposure time: 53 WeeksTarget Organs: Stomach

Species : Dog

LOAEL : 0.01 mg/kg
Application Route : Intravenous

Exposure time : 3 yr

Target Organs : Stomach, Bone, Kidney

Species: DogNOAEL: 2 mg/kgLOAEL: 4 mg/kgApplication Route: OralExposure time: 53 WeeksTarget Organs: Kidney



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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

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



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Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10

plants m

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 1.1 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

LOEC (Pimephales promelas (fathead minnow)): 1.9 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 4.7 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

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:



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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

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

## 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 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.

**National Regulations** 

Refer to section 15 for specific national regulation.



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#### 15. REGULATORY INFORMATION

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### **Industrial Safety and Health Law**

### **Harmful Substances Prohibited from Manufacture**

Not applicable

#### **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

## Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

## Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable

#### **Substances Subject to be Indicated Names**

Not applicable

## Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### Ordinance on Prevention of Lead Poisoning

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

## **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

## Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

# Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

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## **High Pressure Gas Safety Act**

Not applicable

## **Explosive Control Law**

Not applicable

#### **Vessel Safety Law**

Not regulated as a dangerous good

#### **Aviation Law**

Not regulated as a dangerous good

#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

#### Waste Disposal and Public Cleansing Law

Industrial waste

## The components of this product are reported in the following inventories:

**AICS** not determined

**DSL** not determined

**IECSC** not determined

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

#### **Further information**

Sources of key data used to : compile the Safety Data

Sheet

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

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

Date format : yyyy/mm/dd

Full text of other abbreviations

**ACGIH** : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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



## Alendronate / Vitamin D Formulation

Version Revision Date: SDS Number: Date of last issue: 2019/09/13 6.0 2020/03/23 22054-00016 Date of first issue: 2014/10/15

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

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