

SAFETY DATA SHEET



Alendronate Liquid Formulation



Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Alendronate Liquid Formulation

Manufacturer or supplier's details

Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil B-2220
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

GHS label elements in accordance with ABNT NBR 14725 Standard

Not a hazardous substance or mixture.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---------------|-------------|---|-----------------------|
| Alendronate | 121268-17-5 | Acute toxicity (Oral), Category 4 Skin irritation, Category 2 Serious eye damage, Category 1 Reproductive toxicity, Category 2 Specific target organ toxicity - single expo- sure, Category 3 Specific target organ toxicity - repeated exposure (Bone, Stomach, Kidney), Category 2 | $\geq 0,1 - < 0,25$ |

SAFETY DATA SHEET



Alendronate Liquid Formulation



Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

| | | | |
|--|--|---|--|
| | | Short-term (acute) aquatic hazard, Category 3 | |
|--|--|---|--|

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
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.

Alendronate Liquid Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 5.1 | 16.10.2020 | 28191-00017 | Date of first issue: 05.11.2014 |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Avoid inhalation of vapor or mist.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.

Alendronate Liquid Formulation

Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|-------------|-------------------------------|--|----------|
| Alendronate | 121268-17-5 | TWA | 20 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 200 µg/100 cm ² | Internal |

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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

Appearance : liquid

Color : clear

SAFETY DATA SHEET



Alendronate Liquid Formulation



Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

Odor : No data available

Odor Threshold : No data available

pH : 6,4 - 7,2

Melting point/freezing point : No data available

Initial boiling point and boiling range : 100 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Alendronate Liquid Formulation

Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
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

Not classified based on available information.

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Alendronate:**

Species : Rabbit
Remarks : Severe skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Alendronate:**

Species : Rabbit
Result : Severe irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Alendronate Liquid Formulation

Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

Components:**Alendronate:**

Remarks : No data available

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

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

Not classified based on available information.

Components:**Alendronate:**

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: Oral

Alendronate Liquid Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 5.1 | 16.10.2020 | 28191-00017 | Date of first issue: 05.11.2014 |

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

Not classified based on available information.

Components:**Alendronate:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Components:**Alendronate:**

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

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

Alendronate Liquid Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 5.1 | 16.10.2020 | 28191-00017 | Date of first issue: 05.11.2014 |

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|-------------------|---|-----------------------|
| 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 |

Aspiration toxicity

Not classified based on available information.

Components:**Alendronate:**

Not applicable

Experience with human exposure**Product:**

| | | |
|--------------|---|--|
| Inhalation | : | Symptoms: respiratory tract irritation |
| Skin contact | : | Symptoms: May cause, Skin irritation |
| Eye contact | : | Symptoms: May cause, Eye irritation |
| Ingestion | : | Symptoms: Gastrointestinal disturbance, musculoskeletal pain |

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:****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 | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10 |

SAFETY DATA SHEET



Alendronate Liquid Formulation



Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

plants 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

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

Bioaccumulative potential

Components:

Alendronate:

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

Alendronate Liquid Formulation

Version 5.1 Revision Date: 16.10.2020 SDS Number: 28191-00017 Date of last issue: 23.03.2020
Date of first issue: 05.11.2014

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

ANTT

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -

SAFETY DATA SHEET



Alendronate Liquid Formulation



| | | | |
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| Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 |
| 5.1 | 16.10.2020 | 28191-00017 | Date of first issue: 05.11.2014 |

Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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