

## Alendronate Liquid Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 04/24/2019  
4.2                09/13/2019                28192-00015            Date of first issue: 11/05/2014

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### SECTION 1. IDENTIFICATION

Product name                    : Alendronate Liquid Formulation  
Other means of identification   : No data available

#### Manufacturer or supplier's details

Company name of supplier     : Merck & Co., Inc  
Address                         : 2000 Galloping Hill Road  
                                      Kenilworth - New Jersey - U.S.A. 07033  
Telephone                       : 908-740-4000  
Telefax                         : 908-735-1496  
Emergency telephone         : 1-908-423-6000  
E-mail address                 : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use               : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity           : Category 2

#### GHS label elements

Hazard pictograms             :



Signal Word                     : Warning

Hazard Statements             : H361d Suspected of damaging the unborn child.

Precautionary Statements    :

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

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

#### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name | CAS-No.     | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Alendronate   | 121268-17-5 | $\geq 0.1 - < 1$      |

Actual concentration or concentration range is withheld as a trade secret

### 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 : Suspected of damaging the unborn child.
- 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 (CO<sub>2</sub>)  
 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 meth- : Use extinguishing measures that are appropriate to local cir-

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ods 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### 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.  
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.

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### 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.

Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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

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,

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industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|  |   |                   |
|--|---|-------------------|
| Appearance                                       | : | liquid            |
| Color  | : | clear             |
| 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     |

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

Particle size : Not applicable

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**SECTION 10. STABILITY AND REACTIVITY**

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.

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**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

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Result : Severe 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

### **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. |

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### 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 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



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NOAEL : 2.5 mg/kg  
LOAEL : > 2.5 mg/kg  
Application Route : Intravenous  
Exposure time : 53 Weeks  
Target Organs : Stomach

Species : Dog  
LOAEL : 0.01 mg/kg  
Application Route : Intravenous  
Exposure time : 3 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

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**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

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- 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

**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

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### 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.

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### 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

##### TDG

Not regulated as a dangerous good

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### SECTION 15. REGULATORY INFORMATION

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

AICS                                : not determined

DSL                                 : not determined

IECSC                              : not determined

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

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 con-

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centration; 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

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/>

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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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