

Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/28/2017
5.0	10/05/2017	28220-00010	Date of first issue: 11/05/2014

SECTION 1. IDENTIFICATION

Product name : Alendronate Liquid Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

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

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

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:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

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

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.
Notes to physician	: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam

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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.

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.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

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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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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

- 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

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circumstance where air purifying respirators may not provide adequate protection.

Hand protection

II Material : Chemical-resistant gloves

II Remarks : Consider double gloving.

II 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.

II 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.

II Hygiene measures : Ensure that eye flushing systems and safety showers are located 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear

Odor : No information available.

Odor Threshold : No data available

II pH : 6.4 - 7.2

II Melting point/freezing point : No data available

II Initial boiling point and boiling range : 100 °C

II Flash point : No data available

II Evaporation rate : No data available

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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

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.

Ingredients:**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.

Ingredients:**Alendronate:**

Species: Rabbit
Remarks: Severe skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**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.

Ingredients:**Alendronate:**

Remarks: No data available

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Germ cell mutagenicity

Not classified based on available information.

Ingredients:**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.

Ingredients:**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.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

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Ingredients:**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.

Ingredients:**Alendronate:**

Assessment: May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Alendronate:**Target Organs: Bone, Stomach, Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.**Repeated dose toxicity****Ingredients:****Alendronate:**Species: Rat
NOAEL: 2.5 mg/kg
LOAEL: > 2.5 mg/kg
Application Route: Intravenous
Exposure time: 53 Weeks

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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.

Ingredients:**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

Ingredients:**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****Ingredients:****Alendronate:**

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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	: 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**Ingredients:****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**Ingredients:****Alendronate:**

Partition coefficient: n-octanol/water	: log Pow: -1.73
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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.

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**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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US State Regulations

Pennsylvania Right To Know

Water	7732-18-5
1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	128-44-9

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

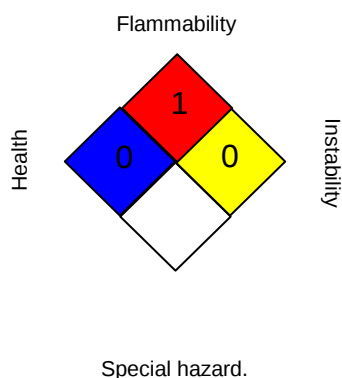
The ingredients of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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

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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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

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

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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