

## SAFETY DATA SHEET

### 1. Identification

Product identifier

Alendronate Sodium

Other means of identification

Catalog number A1368

Chemical name

Phosphonic acid, (4-amino-1-hydroxybutylidene)bis-, monosodium salt, trihydrate

Recommended use

Laboratory chemicals. Research and Development. Manufacture of substances.

Recommended restrictions

No information available

Supplier: Spectrum Chemical Mfg. Corp

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Gardena, CA 90248

(310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Tom Tyner (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

### 2. Hazard(s) identification

Signal Word: DANGER



Acute toxicity, oral: Category 4

Health hazards: Skin corrosion/irritation: Category 2

Serious eye damage/eye irritation: Category 1

Reproductive toxicity: Category 2

Specific target organ toxicity, single exposure: Category 1 (Bone)

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Hazard statement

Harmful if swallowed. Causes skin irritation. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs (Bone).

Precautionary statement

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response

If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. 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. If exposed or concerned: Get medical advice/attention. If exposed: Call a poison center/doctor.

Storage

Store locked up.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

Other hazards which do not result in classification: None known.

### 3. Composition/information on ingredients

Substance	CAS number	%	Common name and synonyms, Chemical name
Alendronate Sodium	121268-17-5	100	

### 4. First-aid measures

#### Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

#### Skin contact

Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention.

#### Eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.

#### Ingestion

**IF SWALLOWED:** Call a **POISON CENTER** or doctor/physician if you feel unwell. Rinse mouth.

Most important symptoms/effects, acute and delayed

Irritation of eyes and mucous membranes. Skin irritation.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

If ingested, give milk or antacids to prevent absorption. Do not induce vomiting. Administer activated charcoal as a slurry.

For esophagitis, administer omeprazole.

For hypocalcemia, administer calcium salts and/or calcium gluconate.

Monitor vital signs. Monitor for signs and symptoms of upper gastrointestinal ulceration or hemorrhage.

Dialysis will not effectively remove this material.

#### General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is

1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

#### Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO<sub>2</sub>.

#### Unsuitable extinguishing media

None known.

#### Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

#### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

#### Fire-fighting equipment/instructions

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

#### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

#### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

#### Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 7. Handling and storage

#### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

#### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product

integrity.

## 8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Alendronate Sodium (CAS 121268-17-5)	TWA	0.1 mg/m <sup>3</sup>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing

dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex

gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

Appearance	White crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	4.5 - 5 (1% aqueous solution)
Melting point/freezing point	482 - 536 °F (250 - 280 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.

Solubility in water	Soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Bisphosphonate.
Molecular formula	C <sub>4</sub> H <sub>12</sub> NNaO <sub>7</sub> P <sub>2</sub> · 3H <sub>2</sub> O
Molecular weight	325.12
Solubility (other)	Very slightly soluble in dimethyl sulfoxide, in methyl alcohol, and in propylene glycol; practically insoluble in acetone, in acetonitrile, in ethanol, in chloroform, and in isopropyl alcohol.

#### 10. Stability and reactivity

Reactivity  
Not available.

Chemical stability  
Material is stable under normal conditions.

Possibility of hazardous reactions  
No dangerous reaction known under conditions of normal use.

Conditions to avoid  
None known.

Incompatible materials  
Strong oxidizing agents. Bases.

Hazardous decomposition products  
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NO<sub>x</sub>. NaO<sub>x</sub>. PO<sub>x</sub>.

#### 11. Toxicological information

Information on likely routes of exposure

Ingestion  
Harmful if swallowed.

Inhalation  
Due to lack of data the classification is not possible.

Skin contact  
Causes skin irritation.

Eye contact  
Causes severe eye burns.

Symptoms related to the physical, chemical, and toxicological characteristics  
Permanent eye damage including blindness could result. Shortness of breath. Irritant effects. Nausea. Vomiting. Abdominal pain. Heartburn. Difficulty swallowing. Flu symptoms. Back pain. Bone pain. Joint pain. Chest pain. Skin discoloration. Blisters. Skin rash. Dizziness. Headache.

Muscle twitching. Numbness, pain, tingling, or weakness in hands or feet. Behavior, mood, or mental changes. Muscle weakness. Delayed and immediate effects of exposure Hypocalcemia. Hypophosphatemia.

Medical conditions aggravated by exposure  
Hypocalcemia. Gastrointestinal ulcers. Impaired kidney function.

Acute toxicity  
Harmful if swallowed.

Product	Species	Oral LD <sub>50</sub>
Alendronate Sodium (CAS 121268-17-5)	Mouse	966 mg/kg (anhydrous)
	Rat	552 mg/kg (anhydrous)

Skin corrosion/irritation  
Causes skin irritation.

Serious eye damage/eye irritation  
Causes severe eye burns.

Local effects

Eye, Species: Rabbit	Result: Extremely irritating.
Skin, Species: Rabbit	Result: Extremely irritating, with blistering and discoloration.

Respiratory or skin sensitization

Respiratory sensitization	Classification not possible.
Skin sensitization	Classification not possible.

Germ cell mutagenicity  
Classification not possible. Results of genotoxicity tests in vitro were negative.

Carcinogenicity  
Classification not possible. This material is not considered to be a carcinogen by IARC, NTP, or

OSHA.

1 - 10 mg/kg/day 92-Week oral study of alendronate

Result: Harderian gland (a retro-orbital gland not present in humans) adenomas were increased in high-dose females (5mg/kg/day).

Species: Mouse

1 - 3.75 mg/kg Two-year oral study of alendronate

Result: Increase in parafollicular cell (thyroid) adenomas in high-dose males.

Species: Rat

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Bisphosphonates are incorporated into the bone matrix and are gradually released over periods of weeks to years. Although there are no data on fetal risk in humans, bisphosphonates are associated with fetal harm in animals and animal data suggest that uptake of bisphosphonates into fetal bone is greater than into maternal bone.

Reproductivity

0.5 mg/kg/day Developmental study (alendronate)

Result: No fetal abnormalities despite maternal toxicity.

Species: Rabbit

1 mg/kg/day Developmental study (alendronate)

Result: Decreased body weight and incisor deformation.

Species: Rat

10 mg/kg/day Developmental study (alendronate)

Result: Sites of incomplete fetal bone formation significantly increased.

Species: Rat

15 mg/kg/day Reproductive study (alendronate)

Result: Maternal total and ionized calcium decreased resulting in delays and failures of delivery. Effects after doses as low as 0.5 mg/kg/day.

Species: Rat

2.5 mg/kg/day Developmental study (alendronate)

Result: No birth defects or behavioral abnormalities in offspring despite maternal toxicity.

Species: Rat

Specific target organ toxicity - Single exposure

Causes damage to organs (Bone).

Specific target organ toxicity - Repeated exposure

Classification not possible.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Not available.

Hazardous waste code

Not regulated.

Waste from residues/unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain

product residue, follow label warnings even after container is emptied.

#### 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not available.

#### 15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA)

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories, Country(s) or region

Inventory name: On inventory (yes/no)\*

Australia: Australian Inventory of Chemical Substances (AICS): No

Canada: Domestic Substances List (DSL): No

Canada: Non-Domestic Substances List (NDSL): No

China: Inventory of Existing Chemical Substances in China (IECSC): No

Europe: European Inventory of Existing Commercial Chemical Substances (EINECS): No

Europe: European List of Notified Chemical Substances (ELINCS): No

Japan: Inventory of Existing and New Chemical Substances (ENCS): Yes

Korea: Existing Chemicals List (ECL): No

New Zealand: New Zealand Inventory: No

Philippines: Philippine Inventory of Chemicals and Chemical Substances (PICCS): No

United States & Puerto Rico: Toxic Substances Control Act (TSCA) Inventory: No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

#### 16. Other information, including date of preparation or last revision

Revision Version E1

Further information not available.

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no

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End of Safety Data Sheet