



SAFETY DATA SHEET

1. Identification

Product identifier	Ibandronate Sodium	
Other means of identification		
Catalog number	1335417	
CAS number	138926-19-9	
Chemical name	3-(N-methyl-N-pentyl)amino-1-hydroxypropane-1,1-diphosphonic acid, monosodium salt, monohydrate	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Skin corrosion/irritation	Category 1
	Serious eye damage/eye irritation	Category 1
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure	Category 1 (bone)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. Causes severe skin burns and eye damage. May damage fertility or the unborn child. Causes damage to organs (bone) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response	If exposed: Immediately call a poison center/doctor. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Ibandronate Sodium		138926-19-9	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician if symptoms develop or persist.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention immediately. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	If ingestion of a large amount does occur, call a poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Corrosive effects. Hypocalcemia. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of bisphosphonate overdose may include the following: Immediately after ingestion, give milk or antacids to prevent absorption. Do not induce vomiting. If necessary, administer activated charcoal as a slurry; treat esophagitis with omeprazole. In case of hypocalcemia, use intravenous calcium salts: 10 milliliters of 10% calcium gluconate or calcium chloride (initial bolus) intravenously over 10 to 15 minutes. More rapid administration may be necessary in patients with dysrhythmias. Monitor vital signs. Do continuous ECG monitoring. Monitor for signs and symptoms of upper gastrointestinal ulceration or hemorrhage which has occurred with some bisphosphonates. Dialysis is not generally considered effective in treatment of bisphosphonate overdose. However, intravenously administered ibandronate was removed by hemodialysis during an analysis of 12 patients on chronic hemodialysis.
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	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
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	Use water spray to cool unopened containers. 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.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material	Type	Value
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Ibandronate Sodium (CAS 138926-19-9)	TWA	0.002 mg/m3
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Biological limit values

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

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White. Off-white.

Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	329 - 347 °F (165 - 175 °C) 347 - 365 °F (175 - 185 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Sparingly soluble.
Solubility (other)	Organic solvents: Practically insoluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Nitrogen-containing bisphosphonate.
Molecular formula	C ₉ H ₂₂ NO ₇ P ₂ . Na . H ₂ O
Molecular weight	359.24

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Strong acids. Strong bases.
Hazardous decomposition products	NO _x , PO _x , NaO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Causes severe skin burns.
Eye contact	Causes severe eye burns.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Bisphosphonates: Nausea. Vomiting. Abdominal pain. Flu-like symptoms. Fever. Chills. Headache. Fatigue. Sleepiness. Burning, prickling, itching, or tingling of skin. Skin rash. Vision problems. Bone, joint, or muscle pain. Seizures.

Information on toxicological effects

Acute toxicity	Harmful if swallowed.
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Product	Species	Test Results
Ibandronate Sodium (CAS 138926-19-9)		
Oral		
LD50	Rat	811 mg/kg
<u>Acute</u>		
Oral		
LD50	Mouse	1494 mg/kg
	Rat	811 mg/kg
Skin corrosion/irritation	Causes severe skin burns.	
Serious eye damage/eye irritation	Causes severe eye burns.	
Local effects		
Skin irritation		
Result: Corrosive.		
Species: Rabbit		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Sensitization		
Result: Negative.		
Species: Guinea pig		
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames test		
Result: Negative.		
Chromosome aberration		
Result: Negative.		
Micronucleus test		
Result: Negative.		
Mutagenicity: Chinese hamster V79 cells		
Result: Negative.		
Carcinogenicity	Based on available data, the classification criteria are not met.	
3 - 15 mg/kg/day Carcinogenicity, administered orally.		
Result: Negative.		
Species: Rat		
Test Duration: 104 weeks		
5 - 40 mg/kg/day Carcinogenicity, administered orally.		
Result: Negative.		
Species: Mouse		
Test Duration: 78 weeks		
5 - 80 mg/kg/day Carcinogenicity, administered in drinking water.		
Result: Adrenal adenomas and carcinomas at the highest dose.		
Species: Mouse		
Test Duration: 90 weeks		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	May damage 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

0.03 - 0.2 mg/kg/day Reproductivity / developmental, administered intravenously during organogenesis.

Result: Maternal and fetal toxicity.

Species: Rabbit

0.05 - 1 mg/kg/day Reproductivity / developmental, administered intravenously during gestation.

Result: Maternal mortality; reduced offspring weight at birth.

Species: Rat

1.2 mg/kg/day Fertility study, administered intravenously.

Result: Decreased fertility.

Species: Rat

>= 0.3 mg/kg/day Fertility study, administered intravenously.

Result: Decreased sperm and altered sperm morphology.

Species: Mouse

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Causes damage to organs () through prolonged or repeated exposure.

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

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Ibandronate Sodium (CAS 138926-19-9)		
Aquatic		
<i>Acute</i>		
Algae	EC50	1.4 mg/l, 72 hours
Persistence and degradability	Not readily biodegradable. Not inherently biodegradable.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

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	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN1759
UN proper shipping name	Corrosive solid, n.o.s. (Ibandronate Sodium)
Transport hazard class(es)	
Class	8
Subsidiary risk	-
Packing group	III

IATA

UN number	UN1759
UN proper shipping name	Corrosive solid, n.o.s. (Ibandronate Sodium)

Transport hazard class(es)**Class** 8**Subsidiary risk** -**Packing group** III**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**Transport in bulk according to** Not applicable.**Annex II of MARPOL 73/78 and the IBC Code****DOT****IATA****General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categoriesAcute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)**SARA 313 (TRI reporting)**

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date	09-20-2011
Revision date	08-13-2019
Version #	03
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