# **SAFETY DATA SHEET**



#### 1. Identification

Product identifier Etidronate Disodium

Other means of identification

 Catalog number
 1268502

 CAS number
 7414-83-7

Synonyms EHDP \* Etidronic acid disodium

Chemical name Phosphonic acid, (1-hydroxyethylidene)bis-, disodium salt

**Recommended use** For analytical laboratory 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** Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Serious eye damage/eye irritation Category 2A Reproductive toxicity Category 2

Specific target organ toxicity, single exposure Category 1 (bone)

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Harmful if swallowed. Causes serious eye irritation. Causes damage to organs (bone). Suspected

of damaging fertility or the unborn child.

**Precautionary statement** 

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust. 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 in eyes: Rinse

cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned:

Get medical advice/attention.

Storage Store locked up.

Material name: Etidronate Disodium

**Disposal** 

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

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmacologically active material.

# 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Etidronate Disodium	EHDP	7414-83-7	100
	Ftidronic acid disodium		

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

#### 4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical Eye contact

attention if irritation develops and persists.

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Do not use mouth-to-mouth method if substance is ingested. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell. Pharmacologically active material. Occupational exposure may cause physiological effects.

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically.

**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 Specific methods

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.

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

General fire hazards No unusual fire or explosion hazards noted.

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#### 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.

Avoid discharge into drains, water courses or onto the ground. **Environmental precautions** 

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# 7. Handling and storage

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. This material should be handled and stored per label instructions to ensure

product integrity.

### 8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

**Biological limit values** 

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

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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** 

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 lab coat. 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

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters 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

Handling practices in this SDS are recommendations for laboratory use of USP materials.

### 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.
Odor Odorless.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 374 - 390.2 °F (190 - 199 °C)

Initial boiling point and boiling

range

> 442.4 °F (> 228 °C) (decomposes)

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** < 0.0000001 kPa (77 °F (25 °C))

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Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Freely soluble.

**Solubility (other)** Alcohol: Practically insoluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

**Chemical family** Bisphosphonate. **Molecular formula** C2H6Na2O7P2

Molecular weight 249.99

pH in aqueous solution 4.2 - 5.2 Solution: 1%

# 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.

Hazardous decomposition

products

POx. Na2O. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

### 11. Toxicological information

### Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.

**Eye contact** Causes serious eye irritation.

**Ingestion** Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Gastrointestinal disturbances. Abdominal pain.. Difficulty swallowing. Leg cramps. Back pain.

Chest pain. Bone pain. Joint pain. Headache. Skin rash.

### Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product Species Test Results

Etidronate Disodium (CAS 7414-83-7)

Oral

LD50 Mouse 1900 mg/kg
Rat 1340 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye

irritation

Causes serious eye irritation.

### Local effects

Eye irritation Result: Irritant. Species: Rabbit Skin irritation Result: Negative. 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.

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Guinea pig maximization test Result: Non-sensitizing.

Germ cell mutagenicity Knowledge about health hazard is incomplete.

Mutagenicity

Ames test Result: Negative. Micronucleus test Result: Negative.

Mouse lymphoma assay

Result: Negative.

Species: Mouse

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

0 - 493 mg/kg/day Carcinogenicity

Result: Negative. Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

**US. National Toxicology Program (NTP) Report on Carcinogens** 

Not listed.

Suspected of damaging fertility or the unborn child. Reproductive toxicity

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

< 100 mg/kg Reproductivity

Result: No adverse or terotogenic effects.

Species: Rat

300 mg/kg Reproductivity

Result: Skeletal birth defects were observed.

Species: Rat

Specific target organ toxicity -

single exposure

Causes damage to organs (bone).

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Pharmacologically active material. Occupational exposure may cause physiological effects. **Further information** 

12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this substance. Persistence and degradability

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

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the **Disposal instructions** 

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Dispose in accordance with all applicable regulations. Local disposal 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).

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#### Contaminated packaging

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

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

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.

**Toxic Substances Control Act (TSCA)** 

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 1910.1001-1053)

Yes

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Z Mazaruous

chemical Classified hazard

categories

Acute toxicity (any route of exposure) 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

Not regulated.

(SDWA)

### **US state regulations**

#### **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. 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)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes

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Country(s) or region Inventory name On inventory (yes/no)\*

Europe European Inventory of Existing Commercial Chemical

Substances (EINECS)

Europe European List of Notified Chemical Substances (ELINCS)

Japan Inventory of Existing and New Chemical Substances (ENCS)

Korea Existing Chemicals List (ECL)

New Zealand

New Zealand Inventory

Yes

(PICCS)

Taiwan Chemical Substance Inventory (TCSI)

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

Yes

Philippine Inventory of Chemicals and Chemical Substances

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

 Issue date
 07-01-2010

 Revision date
 03-08-2022

Version # 03

**Philippines** 

**Disclaimer** USP materials are sold for analytical laboratory use only, and NOT for human consumption. The

information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A

PARTICULAR PURPOSE is made with respect to the information contained herein.

Material name: Etidronate Disodium usp sds us

Yes

<sup>\*</sup>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).