



SAFETY DATA SHEET

1. Identification

Product identifier	Esomeprazole Strontium
Other means of identification	
Catalog number	1249803
CAS number	934714-36-0
Chemical name	(-)-5-Methoxy-2-[(S)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl]-1H-benzimidazole strontium salt tetrahydrate
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	Customer Service	301-881-0666
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
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	Harmful if swallowed. May cause an allergic skin reaction.
Precautionary statement	
Prevention	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.
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 or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
Storage	Not available.
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	%
Esomeprazole Strontium		934714-36-0	100

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

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. For minor skin contact, avoid spreading material on unaffected skin. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects. Gastrointestinal disturbances.
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	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.
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 materials, 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. 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

Crystalline powder.

Color

White. Off-white.

Odor

Not available.

Melting point/freezing point

383 °F (195 °C) (approximate)

Boiling point or initial boiling point and boiling range

Not available.

Flammability

Not available.

Upper/lower flammability or explosive limits

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Flash point

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

pH

Not available.

Kinematic viscosity

Not available.

Solubility

Solubility (water)

Sparingly soluble.

Solubility (other)	Acetone: Freely soluble. Dimethylformamide: Freely soluble. Dichloromethane: Sparingly soluble. Ethanol: Freely soluble. Methanol: Very slightly soluble.
Partition coefficient (n-octanol/water)	Not available.
Vapor pressure	Not available.
Density and/or relative density	Not available.
Vapor density	Not available.
Particle characteristics	Not available.
Other information	
Molecular formula	C ₃₄ H ₃₆ N ₆ O ₆ S ₂ Sr · 4H ₂ O
Molecular weight	848.5
pH in aqueous solution	> 10.4 - < 10.8 (0.1g in 10.0 mL)

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. Acids.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. Sr.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	May cause an allergic skin reaction.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics	Proton pump inhibitors: Headache. Gastrointestinal disturbances. Dizziness. Drowsiness. Cough. Chills. Fever. Sore throat. Confusion. Anxiety. Blurred vision. Loss of appetite. Chest pain. Joint pain. Tiredness. Weakness.
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Information on toxicological effects

Acute toxicity	Harmful if swallowed.
Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.
Respiratory or skin sensitization	
Respiratory sensitization	Knowledge about health hazard is incomplete.
Skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	Knowledge about health hazard is incomplete.

Mutagenicity

Ames test in *S. typhimurium*
Result: Negative.
In vitro mouse lymphoma assay
Result: Negative.
In vivo chromosome aberration test in rat bone marrow
Result: Negative.
In vivo mouse micronucleus test
Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.
Proton pump inhibitors increase serum gastrin, stimulating proliferation of gastric enterochromaffin-like (ECL) cells. Over time, this may result in ECL cell hyperplasia in rats and mice and gastric carcinoids in rats. Therapeutic use of proton pump inhibitors has not been conclusively associated with gastric cancer in humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.
Epidemiological studies have not shown an association between the use of proton pump inhibitors during pregnancy and an increased risk of birth defects.

Reproductivity

Developmental study, 138 mg/kg/day (base).
Result: Changes in bone morphology in offspring noted.
Species: Rat
Embryofetal development study, 14 to 280 mg/kg/day (base)
administered orally.
Result: No adverse effects on fetal development; no
teratogenicity noted.
Species: Rat

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

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

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

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

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.

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

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

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to IMO instruments Not applicable.

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)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Acute toxicity (any route of exposure)
Respiratory or skin sensitization

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 Industrial Chemicals (AICIS)	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

Country(s) or region	Inventory name	On inventory (yes/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	12-28-2021
Revision date	02-17-2026
Version #	03
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