


SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

1. IDENTIFICATION

Product Identifier:	Esomeprazole Sodium for Injection, 40 mg/vial
Synonyms:	(S)-5-methoxy-2-[[[4-methoxy-3,5-dimethyl-2-pyridinyl-methyl]sulfinyl]-1 <i>H</i> -benzimidazole sodium
National Drug Code (NDC):	17478-850-10
Recommended Use:	Pharmaceutical. Esomeprazole Sodium for Injection is indicated for treatment of gastroesophageal reflux disease.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Acute Toxicity, Oral	Category 4
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H302 Harmful if swallowed.	
Precautionary Statement(s):	P264 Wash hands and other exposed areas thoroughly after handling. P301 IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician if you feel unwell. + P312 P332 If skin irritation occurs: Get medical advice/ + attention. P313 P337 If eye irritation persists: Get medical advice/ + attention. P313	

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

- P403 + P233 Store in well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Esomeprazole Sodium	(S)-5-methoxy-2[[[(4-methoxy-3,5-dimethyl-2-pyridinyl-methyl)sulfinyl]-1 <i>H</i> -benzimidazole sodium	Not Available	C ₁₇ H ₁₈ N ₃ O ₃ SNa	367.4	2.0-3.0%

The formula also contains Edetate Disodium, 1.5 mg and Sodium Hydroxide to adjust pH.

4. FIRST AID MEASURES

- Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
- Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	None known from occupational exposure.
Medical Conditions Aggravated by Exposure:	None known from occupational exposure.
Notes to Physician:	Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use extinguishing agent suitable for type of surrounding fire. Use alcohol resistant foam, carbon dioxide, water spray or dry chemical spray.
Unsuitable Extinguishing Media:	Not determined.
<u>Specific Hazards Arising from the Chemical</u>	
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment and Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.
Environmental Precautions:	Contain material and prevent release to basements, confined spaces, waterways or soil.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 25°C (77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light. Store in carton until time of use.

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Esomeprazole Sodium	No data available	No data available

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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).

Eyes Protection: Avoid contact with eyes. 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.

Hand Protection: Wear chemically compatible gloves for handling solutions and 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 non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	White to off-white, porous cake or powder.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	Not determined.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	Not determined.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Not determined.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products:	Hazardous decomposition products formed under fire conditions - carbon oxides, nitrogen oxides, sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	No data available.
Ingestion:	Harmful if swallowed.
Skin Contact:	No data available.
Eye Contact:	No data available.

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
No data available	No data available	No data available	No data available	No data available

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Doses Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Systemic Effects: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Esomeprazole Sodium	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

SAFETY DATA SHEET

Esomeprazole Sodium for Injection, 40 mg/vial

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Esomeprazole Sodium	Listed	Listed	Not Listed

California Proposition 65:

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

16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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