

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

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N/A



# HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.  
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250  
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	Esomeprazole Magnesium Delayed Release Capsules USP 20 mg & 40 mg
<b>Other means of identification Synonyms</b>	None
<b>Recommended use</b>	Pharmaceutical product
<b>Recommended restrictions</b>	NA
<b>Manufacturer</b>	<b>Hetero Labs Limited</b> <b>At:</b> Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Classification of the Substance or Mixture</b>	
<b>GHS - Classification</b>	Not classified as hazardous
<b>Label Elements</b>	
<b>Signal Word:</b>	Not required
<b>Hazard Statements:</b>	Not classified in accordance with international standards for workplace safety.
<b>Other Hazards</b>	No data available
<b>Note:</b>	This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	<b>CAS</b>
Esomeprazole magnesium	161973-10-0
Section 4: First-Aid Measures	
<b>Eye:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.



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<b>Skin:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Most Important Symptoms and Effects, Both Acute and Delayed Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
<b>Medical Conditions Aggravated by Exposure:</b>	None known
<b>Indication of the Immediate Medical Attention and Special Treatment Needed</b> <b>Notes to Physician:</b>	None
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media:</b>	Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water
<b>Special Hazards Arising from the Substance or Mixture</b>	
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Advice for Fire-Fighters</b> During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.	
<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Environmental Precautions:</b>	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Methods and Material for Containment and Cleaning Up Measures for Cleaning / Collecting</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from



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	affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
<b>Section 7: Handling and Storage</b>	
<b>Precautions for Safe Handling</b>	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Conditions for Safe Storage, Including any Incompatibilities Storage Conditions:</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep esomeprazole magnesium delayed-release capsules, USP container tightly closed.
<b>Specific end use(s):</b>	Consumer healthcare product for the treatment of heartburn
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Engineering Controls:</b>	General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.



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<b>Respiratory protection:</b>	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
<b>Section 9: Physical and Chemical Properties</b>	
<b>Appearance</b>	Capsule
<b>Color</b>	As per Description
<b>Physical State</b>	Solid
<b>Description</b>	<p>Esomeprazole magnesium delayed-release capsules USP, 20 mg are White opaque size '4' hard gelatin capsule imprinted with "H" on cap and 'E2' on body filled with off white to pale yellow pellets.</p> <p>NDC 31722-664-30 bottles of 30 NDC 31722-664-90 bottles of 90 NDC 31722-664-10 bottles of 1000</p> <p>Esomeprazole magnesium delayed-release capsules USP, 40 mg are white opaque size '3' hard gelatin capsule imprinted with "H" on cap and 'E3' on body filled with off white to pale yellow pellets.</p> <p>NDC 31722-665-30 bottles of 30 NDC 31722-665-90 bottles of 90 NDC 31722-665-10 bottles of 1000</p>
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available
<b>Section 11: Toxicological Information</b>	
<b>Information on Toxicological Effects General Information:</b>	The information included in this section describes the potential hazards of various forms of the active



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	ingredient. The toxicities of the two materials can be expected to be similar. The remaining information describes the potential hazards of the individual ingredients
<b>Known Clinical Effects:</b>	Adverse effects associated with therapeutic use include headache, abdominal pain, diarrhea, nausea, vomiting, flatulence, constipation.
<b>12. ECOLOGICAL INFORMATION</b>	
<b>Environmental Overview:</b>	Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. The following information is available for the individual ingredients.
<b>13. DISPOSAL CONSIDERATIONS</b>	
<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
<b>14. TRANSPORT INFORMATION</b>	
<b>The following refers to all modes of transportation unless specified below.</b>	
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	
<b>15. REGULATORY INFORMATION</b>	
<b>Other US EPA or State Lists:</b> CAA HAP, ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No	



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## 16. OTHER INFORMATION

**Issue Date : 13-08-2021**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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