

**SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Glycerol Phenylbutyrate Oral Liquid 1.1 g/mL
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India
<b>Manufactured For</b>	Endo USA
<b>Section 2: Hazard(s) Identification</b>	
<b>Emergency Overview</b>	Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains glycerol phenylbutyrate, a nitrogen-binding agent indicated for chronic management of patients with urea cycle disorders (UCDs). Avoid inhalation, skin contact, eye contact and accidental ingestion.
Do not handle until all safety precautions have been read and understood Obtain special instructions before use Use personal protective equipment as required If exposed or concerned: Get medical advice/ attention	
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Ingredient</b>	<b>CAS#</b>
Glycerol phenylbutyrate	611168-24-2
<b>Section 4: First-Aid Measures</b>	
<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary
<b>Inhalation</b>	Move to fresh air. If symptoms persist, call a physician
<b>Ingestion</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person
<b>Notes to Physician</b>	Treat symptomatically
<b>Flammable Properties</b>	No information available
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
<b>Special hazards arising from the substance or mixture</b>	
<b>Hazardous Combustion Products</b>	No information available
<b>Advice for firefighters</b>	

<b>Protective Equipment and Precautions for Firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear
<b>Section 6: Accidental Release Measures</b>	
<b>Spill Procedures</b>	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment
<b>Section 7: Handling and Storage</b>	
<b>Handling and Storage</b>	Avoid contact with skin, eyes, or clothing. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material
<b>8. Exposure controls / personal protection</b>	
<b>Control parameters</b>	
<b>Occupational Exposure Limit</b>	OEL has not been established by OSHA, NIOSH, ACGIH or Amgen. RAVICTI has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 4 compound ( $5 \mu\text{g}/\text{m}^3$ - $20 \mu\text{g}/\text{m}^3$ ) with the following suffix: R (reproductive and/or developmental effects)
<b>Engineering Controls</b>	When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood
<b>Exposure controls Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.
<b>Skin Protection</b>	Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.
<b>Respiratory Protection</b>	When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure

<b>Other</b>	Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use
<b>Environmental exposure controls</b>	Avoid release to the environment.
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical State</b>	Liquid
<b>Description</b>	Glycerol Phenylbutyrate Oral Liquid 1.1 g/mL is supplied in multi-use, 25 mL glass bottles. The bottles are supplied in the following configurations:  NDC 49884-264-95:                      Single 25 mL bottle per carton NDC 49884-264-86:                      Four 25 mL bottles per carton  Store at 20° to 25° C (68° to 77° F), with excursions permitted to 15° to 30° C (59° to 86° F) [see USP Controlled Room Temperature]. Discard bottle 28 days after opening.
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	No information available
<b>Chemical stability</b>	No information available
<b>Possibility of hazardous reactions</b>	No information available
<b>Conditions to avoid</b>	No Information available
<b>Incompatible materials</b>	No information available
<b>Hazardous decomposition products</b>	No information available
<b>Section 11: Toxicological Information</b>	
Information on toxicological effects	
<b>Acute Toxicity</b>	No information available
<b>Skin corrosion/irritation</b>	Does not meet GHS Classification Criteria and therefore is not classified
<b>Serious eye damage/eye irritation</b>	Does not meet GHS Classification Criteria and therefore is not classified
<b>Respiratory or skin sensitization</b>	Does not meet GHS Classification Criteria and therefore is not classified
<b>Germ cell mutagenicity</b>	Based on available data, the GHS classification criteria are not met
<b>Reproductive toxicity</b>	GHS Category 2 - Suspected human reproductive toxicant based
<b>STOT - single exposure</b>	Does not meet GHS Classification Criteria and therefore is not classified
<b>STOT - repeated exposure</b>	Does not meet GHS Classification Criteria and therefore is not classified
<b>Aspiration Hazard</b>	No information available

Section 12: Ecological Information	
<b>Toxicity Ecotoxicity effects</b>	No information available
<b>Persistence/Degradability</b>	No information available
<b>Bioaccumulation/ Accumulation</b>	No information available
<b>Mobility in Environmental Media</b>	No information available
<b>Results of PBT and vPvB assessment</b>	No information available
<b>Other Adverse Effects</b>	No information available
Section 13: Disposal Considerations	
<b>Waste Disposal Method</b>	Dispose of waste according to prescribed federal, state, local and competent authority guidelines
Section 14: Transport Information	
<b>DOT:</b> Not regulated by U.S. DOT, IATA, ADR, or IMDG.	
Section 15: Regulatory Information	
<p><b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b></p> <p><b>International Inventories</b></p> <p><b>TSCA:</b> -</p> <p><b>EINECS/ELINCS</b> -</p> <p><b>DSL/NDSL</b> -</p> <p><b>PICCS:</b> -</p> <p><b>ENCS:</b> -</p> <p><b>CHINA:</b> -</p> <p><b>AICS:</b> -</p> <p><b>KECL:</b> -</p> <p><b>Legend</b></p> <p><b>TSCA</b> - United States Toxic Substances Control Act Section 8(b) Inventory</p> <p><b>EINECS/ELINCS</b> - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances</p> <p><b>DSL/NDSL</b> - Canadian Domestic Substances List/Non-Domestic Substances List</p> <p><b>PICCS</b> - Philippines Inventory of Chemicals and Chemical Substances</p> <p><b>ENCS</b> - Japan Existing and New Chemical Substances</p> <p><b>IECSC</b> - China Inventory of Existing Chemical Substances</p> <p><b>AICS</b> - Australian Inventory of Chemical Substances</p> <p><b>KECL</b> - Korean Existing and Evaluated Chemical Substances</p> <p><b>State Regulations</b></p> <p><b>California Proposition 65:</b> This product does not contain any Proposition 65 chemicals</p>	

## Section 16: Other Information, including date of preparation or last revision

**Issue Date: 08-05-2025**

**Version: 00**

**Further information**

**Revision date: NA**

**Revision note: NA**

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.

Annora shall not be held liable for any damage resulting from handling or from contact with the above product. Annora reserves the right to revise this SDS.