

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Glycerol Phenylbutyrate Oral Liquid
Identified uses of the substance or mixture	Pharmaceutical
Manufacturer	Lyne Laboratories Inc. 10 Burke Drive, Brockton, Massachusetts 02301 United States
Distributor	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.

Section 2: Hazard(s) Identification

Health	The 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. Please refer to the product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	No information available, Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No.
Glycerol phenylbutyrate	611168-24-2

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

Inhalation	Move to fresh air. If symptoms persist, call a physician.
Skin contact	Immediately remove all contaminated clothing, including footwear. Wash skin with soap and water. If skin irritation persists, call a physician.
Eye contact	Rinse thoroughly with plenty of water and seek Medical advice.
If swallowed	Rinse mouth with copious amounts of water. Do not induce vomiting or give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

Section 5: Fire-Fighting Measures

Flammable properties	No information available.
Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use carbon dioxide, dry chemical powder, or water spray.
Special Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	No information available.

Section 6: Accidental Release Measures

Personal Precautions	Ensure adequate ventilation. Avoid contact with eyes and skin.
Environmental Precautions	Avoid release to the environment.
Clean-up Methods	Absorb spills with inert absorbent material and transfer them into a labeled container for disposal. Dispose of according to applicable regulations.

Section 7: Handling and Storage

Handling	Avoid contact with skin, eyes, or clothing. Use adequate ventilation to minimize exposure. Wash your hands, face, and other potentially exposed areas immediately after handling this material.
Storage	Store tightly closed container. Keep out of the reach of children.

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	When practicable, handle material in enclosed processes or processes with effective local exhaust ventilation or within a chemical hood.
Personal Protective Equipment:	Respiratory: Respiratory protection is generally not needed during routine conditions of use of this product if handled with effective local exhaust ventilation or containment. Eye/Face: No special protective equipment required. If splashes are likely to occur, wear: Safety glasses with side-shields. Skin/Body: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective overgarment if splashing is possible.
Occupational Exposure Limit :	OEL has not been established by OSHA, NIOSH, ACGIH.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Glycerol Phenylbutyrate Oral Liquid:

It is supplied as a colorless to pale yellow solution. 1.1 grams per mL strength in a pack size of 25 mL.
NDC: 70748-425-01.

Section 10: Stability and Reactivity

Stability	No information is available
Reactivity	No information is available
Hazardous reactions	No information is available
Conditions to avoid	No information is available
Hazardous decomposition products	No information is available

Section 11: Toxicological Information

Acute Toxicity	No information is available.
Skin corrosion/irritation	Does not meet GHS Classification Criteria and therefore is not classified.
Eye Contact	Does not meet GHS Classification Criteria and therefore is not classified.
Carcinogenicity	Does not meet GHS Classification Criteria and therefore is not classified.
Reproduction toxicity	GHS Category 2 - Suspected human reproductive toxicant based.

Section 12: Ecological Information

Eco toxicity	No information is available.
Persistence and Degradability	No information is available.
Bioaccumulative potential	No information is available.
Mobility in Environmental Media	No information is available.

Section 13: Disposal Considerations

Dispose of material according to federal, state and local disposal regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper Shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper Shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper Shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

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