



# RAVICTI® Safety Data Sheet

Revision Number: 1

Date Issued 23-May-2024

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

### 1.1 Product identifier

**Product Name:** RAVICTI®  
**Common Name:** Glycerol phenylbutyrate  
**Chemical Name:** Glycerol phenylbutyrate  
**Synonyms:** AMG 109

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

**Manufacturer:** Amgen Inc.  
 One Amgen Center Drive  
 Thousand Oaks, California 91320-1799  
 1-805-447-7233  
 1-805-447-1000

**Emergency Telephone Number:** Chemtrec  
 NORTH AMERICA 1-800-424-9300,  
 INTERNATIONAL 1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

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.

### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable)

REGULATION (EC) No 1272/2008, WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA)

Reproductive Toxicity	Category 2
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### 2.2 Label elements



Signal Word

Warning

SGHH0999

H361 - Suspected of damaging fertility or the unborn child



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### GHSP0642

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - If exposed or concerned: Get medical advice/ attention

**2.3 Other Hazards** No information available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

**Ingredients:** See below

**Chemical Name:** Glycerol phenylbutyrate

**CAS-No:** 611168-24-2

The RAVICTI drug product is supplied as undiluted and unformulated glycerol phenylbutyrate drug substance filled into glass bottles (1.1 g/mL of glycerol phenylbutyrate delivers 1.02 g/mL of phenylbutyrate).

## 4. FIRST AID MEASURES

### 4.1 Description of first-aid measures

**Eye Contact:** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

**Inhalation:** Move to fresh air. If symptoms persist, call a physician.

**Ingestion:** If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**Notes to Physician:** Treat symptomatically.



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### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

**Flammable Properties:** No information available.

**Extinguishing Media:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### 5.2 Special hazards arising from the substance or mixture

**Hazardous Combustion Products:** No information available.

#### 5.3 Advice for firefighters

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

**Spill Procedures:** 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.

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for Safe Handling

**Handling and Storage:** 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.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** 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 µg/m<sup>3</sup> - 20 µg/m<sup>3</sup>) with the following suffix: R (reproductive and/or developmental effects)

**Engineering Controls:** When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

#### 8.2 Exposure controls

##### Personal Protective Equipment

**Eye/face Protection:** 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.

**Skin Protection:** 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.

**Respiratory Protection:** 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.

**Other:** Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colorless to pale yellow
Physical State:	Liquid
Molecular Weight:	530.67 g/mol
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting Point:	No information available
Boiling point:	No information available
Flash Point:	No information available
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	No information available
Relative density:	No information available
Water Solubility:	No information available
Partition Coefficient (log Kow):	No information available
Viscosity:	No information available

### 10. STABILITY AND REACTIVITY

10.1 Reactivity	No information available
10.2 Chemical stability	No information available
10.3 Possibility of hazardous reactions	No information available
10.4 Conditions to avoid	No Information available
10.5 Incompatible materials	No information available
10.6 Hazardous decomposition products	No information available
10.7 Other information	None

### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute Toxicity:	No information available
Skin corrosion/irritation:	Does not meet GHS Classification Criteria and therefore is not classified.
Serious eye damage/eye irritation:	Does not meet GHS Classification Criteria and therefore is not classified.
Respiratory or skin sensitization:	Does not meet GHS Classification Criteria and therefore is not classified.
Germ cell mutagenicity:	Based on available data, the GHS classification criteria are not met.
Carcinogenicity:	Does not meet GHS Classification Criteria and therefore is not classified.
Reproductive toxicity:	GHS Category 2 - Suspected human reproductive toxicant based
STOT - single exposure:	Does not meet GHS Classification Criteria and therefore is not classified.
STOT - repeated exposure:	Does not meet GHS Classification Criteria and therefore is not classified.
Aspiration Hazard:	No information available



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### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Ecotoxicity effects: No information available

#### 12.2 Persistence and degradability

Persistence/Degradability: No information available

#### 12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation: No information available

#### 12.4 Mobility in soil

Mobility in Environmental Media: No information available

#### 12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

#### 12.6 Other adverse effects

Other Adverse Effects: No information available

### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Waste Disposal Method: Dispose of waste according to prescribed federal, state, local and competent authority guidelines.

### 14. TRANSPORT INFORMATION

DOT: Not regulated by U.S. DOT, IATA, ADR, or IMDG.



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### 15. REGULATORY INFORMATION

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

##### International Inventories

TSCA:	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS:	-
ENCS:	-
CHINA:	-
AICS:	-
KECL:	-

##### Legend

- TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
- EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
- DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- ENCS - Japan Existing and New Chemical Substances
- IECSC - China Inventory of Existing Chemical Substances
- AICS - Australian Inventory of Chemical Substances
- KECL - Korean Existing and Evaluated Chemical Substances

##### State Regulations

**California Proposition 65:** This product does not contain any Proposition 65 chemicals.

#### 15.2 Chemical safety assessment

No CSA has been conducted.



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### 16. OTHER INFORMATION

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To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

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