

0206 29  
033634



# SAFETY DATA SHEET

## PHARMACAL

Issue Date 02-Jun-2014

Revision Date 03-Jul-2014

Version 1

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Product identifier**

Product Name PRN Pharmacal Proin 25 mg, 60 count

**Other means of identification**

Product Code PRN FP 30031748  
NDC Number 49427-315-48

**Recommended use of the chemical and restrictions on use**

Recommended Use Pharmaceutical.  
Uses advised against No information available.

**Details of the supplier of the safety data sheet**

<b>Supplier</b>	<b>Company Name</b>
Pegasus Laboratories, Inc.	Pegasus Laboratories, Inc.
8809 Ely Road	8809 Ely Road
Pensacola, FL 32514	Pensacola, FL 32514

**Emergency telephone number**

Emergency Telephone Chemtrec 1-800-424-9300

### 2. HAZARDS IDENTIFICATION

**Classification**

**OSHA Regulatory Status**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

**Label elements**

**Emergency Overview**

The product contains no substances which at their given concentration, are considered to be hazardous to health

<b>Appearance</b> Tablet	<b>Physical state</b> Solid	<b>Odor</b> Garlic-like
--------------------------	-----------------------------	-------------------------

**Hazards not otherwise classified (HNOC)**

Product is intended for consumption. Please see the product label for instructions for use and precautions.

**Other Information**

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Chemical Name	CAS No.	Weight-%	Trade Secret
Phenylpropanolamine Hydrochloride	154-41-6	1-2	****
Stearic acid	57-11-4	0.5-1.5	*

\* The exact percentage (concentration) of composition has been withheld as a trade secret

#### 4. FIRST AID MEASURES

##### First aid measures

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**Skin Contact** Wash skin with soap and water.

**Inhalation** Remove to fresh air.

**Ingestion** Product is intended for consumption. Please see the product label for instructions for use and precautions.

##### Most important symptoms and effects, both acute and delayed

**Symptoms** No information available.

##### Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

#### 5. FIRE-FIGHTING MEASURES

##### Suitable extinguishing media

Dry chemical. Water spray (fog). Foam. Carbon dioxide (CO2).

##### Specific hazards arising from the chemical

No information available.

##### Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

##### Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

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

**Personal precautions** Ensure adequate ventilation, especially in confined areas.

##### Environmental precautions

**Environmental precautions** See Section 12 for additional ecological information.

##### Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place.

**Incompatible materials** Incompatible with oxidizing agents. Bleaching agent.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Control parameters

**Exposure Guidelines** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Appropriate engineering controls

**Engineering Controls** Showers  
Eyewash stations  
Ventilation systems.

Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Skin and body protection** Wear protective gloves and protective clothing.

**Respiratory protection** If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

**General Hygiene Considerations** Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Information on basic physical and chemical properties

<b>Physical state</b>	Solid	<b>Odor</b>	Garlic-like
<b>Appearance</b>	Tablet	<b>Odor threshold</b>	No information available
<b>Color</b>	Dark brown		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not Applicable	
Melting point/freezing point	No information available	
Boiling point / boiling range	No information available	
Flash point	No information available	
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Flammability Limit in Air		
Upper flammability limit:	No information available	

---

Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	Partially soluble
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Oxidizing properties	No information available

**Other Information**

Density 43 lbs./ft<sup>3</sup>

**10. STABILITY AND REACTIVITY**

**Reactivity**

No data available

**Chemical stability**

Stable.

**Possibility of Hazardous Reactions**

None under normal processing.

**Hazardous polymerization**

Will not occur.

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

Incompatible with oxidizing agents. Bleaching agent.

**Hazardous Decomposition Products**

May emit toxic fumes under fire conditions. Hydrocarbons. Carbon monoxide. Carbon dioxide (CO<sub>2</sub>). Thermal decomposition can lead to release of toxic/corrosive gases and vapors. Hydrogen chloride. Nitrogen oxides (NO<sub>x</sub>).

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Product Information**

Inhalation	May cause irritation of respiratory tract.
Eye contact	May cause irritation.
Skin Contact	May cause irritation.
Ingestion	May cause irritation.

**Information on toxicological effects**

Symptoms No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Sensitization No information available.

---

<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	The table below indicates whether each agency has listed any ingredient as a carcinogen.
<b>IARC (International Agency for Research on Cancer)</b>	
<i>Not classifiable as a human carcinogen</i>	
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 100% of the mixture consists of ingredient(s) of unknown toxicity

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

100% of the mixture consists of components(s) of unknown hazards to the aquatic environment

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Other adverse effects**

No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container.

**14. TRANSPORT INFORMATION**

**DOT**

**Description**

The following guidelines apply for domestic ground transport. If shipping by air or ocean, please contact our Transportation Dept.

MEDICINES, NOI NMFC 58770, SUB 2

**15. REGULATORY INFORMATION**

This chemical is classified as a food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, and is therefore subject to labeling requirements under the Food and Drug Administration. These requirements differ from the classification criteria and hazard information required for safety data sheets and workplace labeling of chemicals.

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not Applicable

**International Inventories**

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed

EINECS/ELINCS Not Listed  
 ENCS Not Listed  
 IECSC Not Listed  
 KECL Not Listed  
 PICCS Not Listed  
 AICS Not Listed

**Legend:**

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

Chemical Name	TSCA	DSL	NDSL	EINECS	ELINCS	ENCS	IECSC	KECL	PICCS	AICS
Phenylpropanolamine Hydrochloride	X	X		X					X	X
Stearic acid	X	X		X		X	X	X	X	X

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

Acute health hazard No  
 Chronic Health Hazard No  
 Fire hazard No  
 Sudden release of pressure hazard No  
 Reactive Hazard No

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

**US State Regulations**

**U.S. State Right-to-Know Regulations**

**International Regulations**

**16. OTHER INFORMATION**

<b>NFPA</b>	Health hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties -
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of PBI Gordon Corporation's knowledge, information and belief at the date of this publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process, unless specified in the text. PBI GORDON CORPORATION MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. Given the variety of factors that can affect the use and application of this product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the product to determine whether it is fit for a particular purpose and suitable for user's method of use or application. Each user is also responsible for evaluating the conditions of use and designing the appropriate protective mechanisms to prevent employee exposures, property damage, or release to the environment. PBI Gordon Corporation assumes no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.

End of Safety Data Sheet