

## **SAFETY DATA SHEETS**

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

078058973

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078944654 078944757

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078058957 078058965 078066899 078659768 078914616



**PHARMACAL**

# SAFETY DATA SHEET

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 75 mg, 60 count

**Other means of identification**

**Product Code** PRN FP 30031548

**NDC Number** 49427-316-48

**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**

**Supplier**

Pegasus Laboratories, Inc.  
8809 Ely Road  
Pensacola, FL 32514

**Company Name**

Pegasus Laboratories, Inc.  
8809 Ely Road  
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

**Appearance** Tablet

**Physical state** Solid

**Odor** 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	4-6	*
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		

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

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

**Other Information**

**Density** 43 lbs./ft3

**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. <i>IARC (International Agency for Research on Cancer)</i> <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**

**TSCA** Not Listed

**DSL/NDSL** 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	<b>Physical and Chemical Properties - Personal protection</b>
<b>HMIS</b>	Health hazards 0	Flammability 0	Physical hazards 0	

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**End of Safety Data Sheet**