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SAFETY DATA SHEET

PHARMACAL

Issue Date 02-Jun-2014

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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

Supplier	Company Name
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

Appearance Tablet	Physical state Solid	Odor Garlic-like
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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

Physical state	Solid	Odor	Garlic-like
Appearance	Tablet	Odor threshold	No information available
Color	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./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 (CO₂). Thermal decomposition can lead to release of toxic/corrosive gases and vapors. Hydrogen chloride. Nitrogen oxides (NO_x).

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.

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

NFPA	Health hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Disclaimer

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End of Safety Data Sheet