

SAFETY DATA SHEET

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 50 mg, 60 count

Other means of identification

Product Code NDC Number

PRN FP 30030748

49427-141-48

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 Pensacola, FL 32514 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

count

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	2-4	*
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

Evelface 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 Appearance Solid Tablet

Odor

Garlic-like

Color

Dark brown

Odor threshold

No information available

<u>Property</u>

Flash point

Evaporation rate

<u>Values</u>

Not Applicable

Remarks • Method

рН

Melting point/freezing point Boiling point / boiling range

oint inge No information available
No information available

No information available No information available No information available No information available

Flammability (solid, gas) Flammability Limit in Air

Upper flammability limit:

No information available

PRN FP 30030748 PRN Pharmacal Proin 50 mg, 60 count

Lower flammability limit:

Vapor pressure Vapor density Specific Gravity No information available No information available No information available No information available

Water solubility

Solubility in other solvents Partition coefficient Autoignition temperature Decomposition temperature Partially soluble No information available No information available No information available

Oxidizing properties

No information available 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 (NOx).

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.

PRN FP 30030748 PRN Pharmacal Proin 50 mg, 60 count

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)

Not classifiable as a human carcinogen

Reproductive toxicity STOT - single exposure

No information available. No information available.

No information available.

STOT - repeated exposure 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

PRN FP 30030748 PRN Pharmacal Proin 50 mg, 60 count

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	Х	Х		Х					Х	Х
Hydrochloride					<u></u>					
Stearic acid	Х	X		X		X	Х	X	Х	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 INFORM	IATION	
<u>NFPA</u>	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