SAFETY DATA SHEETS

This SDS packet was issued with item:

078914616

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

078058973 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



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 Company Name

Pegasus Laboratories, Inc. Pegasus Laboratories, Inc.

8809 Ely Road Pensacola, FL 32514 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

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

Physical stateSolidAppearanceTabletOdorGarlic-like

Color Dark brown Odor threshold No information available

Property Values Remarks • Method

pH Not Applicable

Melting point/freezing point

No information available

No information available

Flash point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No information available
No information available

Flammability Limit in Air

Upper flammability limit:No information available

Lower flammability limit:

Vapor pressure

Vapor density

Specific Gravity

No information available
No information available
No information available

Water solubility Partially soluble

Solubility in other solvents
Partition coefficient
Autoignition temperature
Decomposition temperature
Oxidizing properties

No information available
No information available
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.

Revision Date 03-Jul-2014

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
STOT - repeated exposure
Aspiration hazard
No information available.
No information available.
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 30031548 PRN Pharmacal Proin 75 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 Hydrochloride | Х | Х | | Х | | | | | Х | Х |
| Stearic acid | Х | Х | | Х | | Х | Х | Х | Х | Х |

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 | | | | | | | |
|-----------------------|------------------|----------------|--------------------|------------------------------------|--|--|--|
| <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

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



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, 180 count

Other means of identification

 Product Code
 PRN FP 30031550

 NDC Number
 49427-316-50

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 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

Physical stateSolidAppearanceTabletOdorGarlic-like

Color Dark brown Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH Not Applicable

Melting point/freezing point

Boiling point / boiling range

No information available
No information available

Flash point

Evaporation rate

Flammability (solid, gas)

No information available
No information available
No information available

Flammability Limit in Air

Upper flammability limit:No information available

Lower flammability limit:No information availableVapor pressureNo information availableVapor densityNo information availableSpecific GravityNo information available

Water solubility Partially soluble

Solubility in other solvents
Partition coefficient
Autoignition temperature
Decomposition temperature
Oxidizing properties

No information available
No information available
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.

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
STOT - repeated exposure
Aspiration hazard
No information available.
No information available.
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

DescriptionThe following quidelines 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 | Х | Х | | Х | | | | | Х | Х |
| Stearic acid | X | X | | X | | X | X | X | X | X |
| Stearic acid | _ ^ | ^ | | ^ | | ^ | ^ | ^ | _ ^ | _ ^ |

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

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