

SAFETY DATA SHEETS

This SDS packet was issued with item:

078941583

N/A



SAFETY DATA SHEET

Issue Date 10-Dec-2019

Revision Date 20-Dec-2019

Version 1

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

Product identifier.

Product Name Proin ER 18 mg

Other means of identification

Product Code PRN FP 30034457
Product Size 30 tablets
NDC Number 49427-344-57

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

Company Name	Manufacturer
Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514	Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514

Emergency telephone number

24 Hour Emergency Phone Number 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)

Label elements

Emergency Overview

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

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

Appearance Tablet	Physical state Solid	Odor Garlic and Liver
--------------------------	-----------------------------	------------------------------

Hazards not otherwise classified (HNOC)

Warning
Not for human use
Keep out of reach of children
Consult a physician in case of accidental ingestion by humans

Other information

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

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

Chemical name	CAS-No	Weight-%
Microcrystalline Cellulose	9004-34-6	25-30%

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

4. FIRST AID MEASURES

Description of 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. If skin irritation persists, call a physician.
Inhalation	Remove to fresh air.
Ingestion	Consult a physician in case of accidental ingestion by humans.

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 Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical In the event of fire and/or explosion do not breathe fumes. Thermal decomposition can lead to release of irritating and toxic gases and vapors.

Explosion data

Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

Special protective equipment for fire-fighters 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

Other information Refer to protective measures listed in Sections 7 and 8.

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 Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep out of the reach of children. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep product in a secured location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline Cellulose 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 5 mg/m ³ (vacated) STEL: 10 mg/m ³	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust TWA: 1 mg/m ³

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Goggles recommended for handling bulk liquid and for cleaning up spills.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable 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 Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid
Appearance Tablet
Color Dark brown
Odor Garlic and Liver
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not Applicable	

Melting point/freezing point		None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Specific Gravity	No data available	None known
Water solubility	Soluble in water	
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known

Other Information

Liquid Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

No information available.

Stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Keep out of reach of children.

Incompatible materials

None known based on information supplied.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May be harmful in contact with skin.
Ingestion	May be harmful if swallowed.

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit) > 2000 mg/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 3134 mg/kg

ATEmix (dermal) 2083 mg/kg

Unknown Toxicity

100 % of the mixture consists of ingredient(s) of unknown toxicity

59 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

69 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity No information available.

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse empty containers.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

15. REGULATORY INFORMATION

FDA Statement

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

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

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

US State Regulations

16. OTHER INFORMATION

<u>NFPA</u>	Health hazards 0	Flammability 0	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X
<i>Chronic Hazard Star Legend</i>	<i>* = Chronic Health Hazard</i>			

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