

## **SAFETY DATA SHEETS**

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

078937043

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

078944886



# 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

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

#### Manufacturer

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**

<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water. If skin irritation persists, call a physician.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician in case of accidental ingestion by humans.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	No information available
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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**5. FIRE-FIGHTING MEASURES**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	No information available.
<b>Specific hazards arising from the chemical</b>	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.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	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**

<b>Personal precautions</b>	Ensure adequate ventilation, especially in confined areas.
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**Environmental precautions**

<b>Environmental precautions</b>	See Section 12 for additional ecological information
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<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.
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**Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
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**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 <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 5 mg/m <sup>3</sup> (vacated) STEL: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust TWA: 1 mg/m <sup>3</sup>

### 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 <sup>3</sup> ( 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

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

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**End of Safety Data Sheet**