



# SAFETY DATA SHEET

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Version 2

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

### Product identifier

**Product Name** PRN Pharmacal Endosorb Tablets

### Other means of identification

**Product Code** PRN FP 30030251  
**NDC Number** 49427-010-05

### 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

<b>Supplier</b>	<b>Company Name</b>
Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514	Pegasus Laboratories, Inc. 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 considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity	Category 2
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### Label elements

#### Emergency Overview

#### **Warning**

#### **Hazard statements**

Suspected of causing cancer.



**Appearance** Tablet

**Physical state** Solid

**Odor** Odorless

#### **Precautionary Statements - Prevention**

- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required

- IF exposed or concerned: Get medical advice/attention

**Precautionary Statements - Storage**

- Store locked up

**Precautionary Statements - Disposal**

- Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)**

Per manufacturer guidance, this product is not considered hazardous when used as intended in its manufactured form. OSHA's Globally Harmonized System (GHS), which is based on overall hazard potential and is not risk-based, may assign classifications and hazards that could conflict with this statement. Do not use product in a manner inconsistent with product label/insert instructions.

Please see the label for instructions for use and precautions.

**Other Information****3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS. Number	Weight %
Colloidal Activated Attapulgite	12174-11-7	20-25*
Microcrystalline Cellulose	9004-34-6	1-5*
Stearic acid	57-11-4	0.2-2*
Silicon Dioxide	7631-86-9	0.13

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

**4. FIRST AID MEASURES****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.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	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 (CO<sub>2</sub>).

**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

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Colloidal Activated Attapulgite 12174-11-7	TWA: 1 mg/m <sup>3</sup> respirable fraction	-	-
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>
Silicon Dioxide 7631-86-9	-	(vacated) TWA: 6 mg/m <sup>3</sup> <1% Crystalline silica TWA: 20 mppcf : (80)/(%) SiO <sub>2</sub> mg/m <sup>3</sup> TWA	IDLH: 3000 mg/m <sup>3</sup> TWA: 6 mg/m <sup>3</sup>

NIOSH IDLH *Immediately Dangerous to Life or Health*

**Other Information** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

### Appropriate engineering controls

**Engineering Controls** Showers  
Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Skin and body protection</b>	Wear protective gloves and protective clothing.
<b>Respiratory protection</b>	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.
<b>General Hygiene Considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Physical state</b>	Solid	<b>Odor</b>	Odorless
<b>Appearance</b>	Tablet	<b>Odor threshold</b>	No information available
<b>Color</b>	Light green		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	Not Applicable	
<b>Melting point/freezing point</b>	No information available	
<b>Boiling point / boiling range</b>	No information available	
<b>Flash point</b>	No information available	
<b>Evaporation rate</b>	No information available	
<b>Flammability (solid, gas)</b>	No information available	
<b>Flammability Limit in Air</b>		
<b>Upper flammability limit:</b>	No information available	
<b>Lower flammability limit:</b>	No information available	
<b>Vapor pressure</b>	No information available	
<b>Vapor density</b>	No information available	
<b>Specific Gravity</b>	No information available	
<b>Water solubility</b>	Partially soluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition coefficient</b>	No information available	
<b>Autoignition temperature</b>	No information available	
<b>Decomposition temperature</b>	No information available	
<b>Oxidizing properties</b>	No information available	

**Other Information**

<b>Density</b>	53 lbs/ft <sup>3</sup>
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**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**

Keep out of reach of children.

**Incompatible materials**

Incompatible with oxidizing agents. Bleaching agent.

**Hazardous Decomposition Products**May emit toxic fumes under fire conditions. Hydrocarbons. Carbon dioxide (CO<sub>2</sub>). Carbon monoxide.**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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose 9004-34-6	> 5 g/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
Stearic acid 57-11-4	-	> 5 g/kg ( Rabbit )	-
Silicon Dioxide 7631-86-9	> 5000 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	> 2.2 mg/L ( Rat ) 1 h

**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.

Chemical Name	ACGIH	IARC	NTP	OSHA
Colloidal Activated Attapulgite 12174-11-7		Group 2B Group 3		X
Microcrystalline Cellulose 9004-34-6		Group 1	Known	X
Silicon Dioxide 7631-86-9		Group 3		

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Not classifiable as a human carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

**Reproductive toxicity** No information available.**STOT - single exposure** No information available.**STOT - repeated exposure** No information available.**Target Organ Effects** Eyes, Respiratory system, Skin.**Aspiration hazard** No information available.**Numerical measures of toxicity - Product Information****Unknown Toxicity** 98 % of the mixture consists of ingredient(s) of unknown toxicity**The following values are calculated based on chapter 3.1 of the GHS document****ATEmix (inhalation-dust/mist)** 5.8 mg/L

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

100% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Silicon Dioxide 7631-86-9	440: 72 h Pseudokirchneriella subcapitata mg/L EC50	5000: 96 h Brachydanio rerio mg/L LC50 static		7600: 48 h Ceriodaphnia dubia mg/L EC50

### 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, unless specified by the manufacturer.

## 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	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
Colloidal Activated Attapulgate							X		X	X
Microcrystalline Cellulose	X	X		X		X	X	X	X	X
Stearic acid	X	X		X		X	X	X	X	X
Silicon Dioxide	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**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose 9004-34-6	X	X	X
Silicon Dioxide 7631-86-9	X	X	X

**International Regulations**

Chemical Name	Carcinogenicity	Exposure Limits
Microcrystalline Cellulose		Mexico: TWA 10 mg/m <sup>3</sup> Mexico: STEL 20 mg/m <sup>3</sup>

**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**