

## **SAFETY DATA SHEETS**

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

078066980

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

078066972 078944996



**PHARMACAL**

# SAFETY DATA SHEET

Issue Date 03-Jun-2014

Revision Date 09-Jul-2014

Version 1

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

**Product identifier**

**Product Name** PRN Pharmacal Endosorb Suspension

**Other means of identification**

**Product Code** PRN FP 30021704

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

**Emergency telephone number**

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. HAZARDS IDENTIFICATION

**Classification**

**Classification of the substance or mixture**

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.

**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**

<p><b>Warning</b></p> <p><b>Hazard statements</b> Suspected of causing cancer.</p>
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**Appearance** Suspension

**Physical state** Liquid

**Odor** Licorice

**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

**Precautionary Statements - Response**

- 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)**

Product is intended for consumption. Please see the product label for instructions for use and precautions.

**Other Information**

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	Weight-%	Trade Secret
Colloidal Activated Attapulgite	12174-11-7	15-20	*
Aluminum Magnesium Silicate	1327-43-1	0.5-5	*

\* 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** 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.

### 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	-	-

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**

**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**      Do not eat, drink or smoke when using this product.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	Liquid	<b>Odor</b>	Licorice
<b>Appearance</b>	Suspension	<b>Odor threshold</b>	No information available
<b>Color</b>	Pink		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6.3	
Melting point/freezing point	No information available	
Boiling point / boiling range	No information available	
Flash point	No information available	
Evaporation rate	No information available	
Flammability (solid, gas)	No information available	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Specific Gravity	1.12	
Water solubility	Partially soluble	
Solubility in other solvents	No information available	
Partition coefficient	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Oxidizing properties	No information available	

**Other Information**

**Density**    9.3 lbs/gal.

**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 dioxide (CO2). Carbon monoxide.

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Product Information**

**Inhalation** May cause irritation of respiratory tract.  
**Eye contact** May cause slight 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.

Chemical Name	ACGIH	IARC	NTP	OSHA
Colloidal Activated Attapulgate 12174-11-7		Group 2B Group 3		X

*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.  
**Aspiration hazard** No information available.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 38% of the mixture consists of ingredient(s) of unknown toxicity

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

18% of the mixture consists of component(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**

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	Not Listed
<b>ENCS</b>	Not Listed
<b>IECSC</b>	Listed
<b>KECL</b>	Not Listed
<b>PICCS</b>	Not Listed
<b>AICS</b>	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
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Colloidal Activated Attapulgite							X		X	X
Aluminum Magnesium Silicate	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 contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

**US State Regulations**

**U.S. State Right-to-Know Regulations**

**International 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

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End of Safety Data Sheet