



PHARMACAL

SAFETY DATA SHEET

Issue Date 19-May-2014

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Version 1

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

Product identifier

Product Name PRN Pharmacal Endosorb Bolus

Other means of identification

Product Code PRN FP 30001347
NDC Number 49427-006-47

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products.
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	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

Warning
Hazard statements

**Appearance** Bolus**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

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

98% of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%	Trade Secret
Colloidal Activated Attapulgite	12174-11-7	20-25	*
Microcrystalline Cellulose	9004-34-6	1-5	*
Stearic acid	57-11-4	0.2-2	*

* 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**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Colloidal Activated Attapulgite 12174-11-7	TWA: 1 mg/m ³ respirable fraction	-	-

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	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
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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** No special technical protective measures are necessary.
- Skin and body protection** No special technical protective measures are necessary.
- 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 state	Solid	Odor	Odorless
Appearance	Bolus	Odor threshold	No information available
Color	Light green		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not Applicable	
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	No information available	
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 53 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 ProductsMay emit toxic fumes under fire conditions. Hydrocarbons. Carbon dioxide (CO₂). Carbon monoxide.

11. TOXICOLOGICAL INFORMATION

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

Inhalation	No data available.
Eye contact	No data available.
Skin Contact	No data available.
Ingestion	No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose 9004-34-6	-	-	> 5800 mg/m ³ (Rat) 4 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

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 Acute 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) 5.7 mg/L

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
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

KECL - China Inventory of Existing Chemical Substances

KECL - Korea 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 Attapulgite							X		X	X
Microcrystalline Cellulose	X	X		X		X	X	X	X	X
Stearic acid	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

International Regulations

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

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

Disclaimer

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End of Safety Data Sheet