

SAFETY DATA SHEETS

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N/A



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 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

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

- 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

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

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**

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 (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
Silicon Dioxide 7631-86-9	-	(vacated) TWA: 6 mg/m ³ <1% Crystalline silica TWA: 20 mppcf : (80)/(%) SiO ₂ mg/m ³ TWA	IDLH: 3000 mg/m ³ TWA: 6 mg/m ³

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

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 (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	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (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) 5.7 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/NDL	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 Attapulgite							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 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