

SAFETY DATA SHEETS

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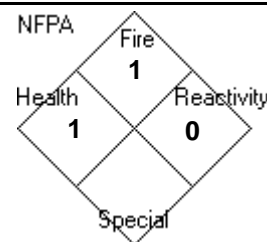
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MSDS - Material Safety Data Sheet

Product Name: Endosorb Tablet

MSDS No.: 0033

I. Basic Information:

Manufacturer: Pegasus Laboratories, Inc.**Address:** 8809 Ely Road**City, ST Zip:** Pensacola, FL 32514**Emergency Contact:** Chemtrec**Emergency Telephone Number:** 800-424-9300**Contact:** Carl Causey**Information Telephone Number:** 850-478-2770**Last Update:** 02/25/2002**Chemical State:** ☐ Liquid ☐ Gas ☒ Solid**Chemical Type:** ☐ Pure ☒ Mixture

1	Health
1	Flammability
0	Reactivity
	Pers. Protection

II. Ingredients:

☐ Trade Secret

CAS No.	Chemical Name	% Range	EHS	IARC	SARA	OSHA PEL	ACGIH TLV	Other Limits
			NTP	SUB Z	313			
12174117	Attapulgit	20-25				NI	NI	NI
9004346	Cellulose (paper fiber)	1-5			X	15 mg/m3	10 mg/m3	NI
14808607	Silica (quartz)	0.5-5		X	X	0.3mg/m3	0.05mg/m3	NI
57114	Stearic acid	0.2-2				NI	NI	NI

III. Hazardous Identification:

Hazard Category:☒ Acute☒ Chronic☐ Fire☐ Pressure☐ Reactive

Hazardous Identification Information:

Crystalline silica (quartz) is classified as group IARC-1, a category used when there is sufficient evidence of carcinogenicity in humans"; also a NTP-K classification - " known to be a human carcinogen " exists. It is also a California Proposition 65 carcinogen.

Large oral doses of stearic acid may cause irritation to the gastrointestinal tract and may also cause intestinal obstruction.

IV. First Aid Measures:

Route(s) of Entry:

Contact, Inhalation, and Ingestion

Health Hazards (Acute and Chronic):

Eyes: Eye contact with product may cause irritation and redness.

Skin: Contact with skin may cause irritation.

Inhalation: Inhalation may cause irritation, headache, nausea, and drowsiness.

Ingestion: Ingestion may cause irritation and nausea if administered in dosages other than prescribed.

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Signs and Symptoms:

NI

Medical Conditions Generally Aggravated by Exposure:

NI

Emergency and First Aid Procedures:

Eyes: Immediately flush eyes with large quantity of water for 10-15 minutes. Get medical attention.

Skin: Flush skin with plenty of water for at least 15 minutes, while removing contaminated clothing. Thoroughly clean clothing and shoes before reuse.

Inhalation: Immediately move victim to fresh air.

Ingestion: For an overdose, have victim drink water or milk to dilute. Call a physician immediately. Induce vomiting only if advised by a physician.

Other Health Warnings:

NI

V. Fire Fighting Measures:

Flash Point: NI

Lower Explosive Limit: NI

Upper Explosive Limit: NI

F.P. Method: NI

Fire Extinguishing Media:

Dry chemical, water spray/fog, foam and carbon dioxide.

Special Fire Fighting Procedures:

Prevent human exposure to fire, fumes, smoke, and products of combustion. Evacuate non-essential personnel. Firefighters should wear full-face, self-contained breathing apparatuses and protective clothing. Prevent pollution of ground water from fire control run-off.

Unusual Fire and Explosion:

NI

VI. Accidental Release Measures:

Steps to be Taken in Case Material is Released or Spilled:

In case of spills, contain and dispose of in accordance with federal, state, and local regulations. Ventilate spill area and flush area with water.

VII. Handling and Storage:

Precautions to be Taken:

Protect container against physical damage. Store in cool dry area, inaccessible to children and pets.

Other Precautions:

NI

VIII. Exposure Controls/Personal Protection:

Ventilation Requirements:

Handle in well-ventilated area. Where excessive exposure is likely, use NIOSH/MSHA approved protection equipment.

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Personal Protective Equipment:

Wear gloves and protective clothing if there is potential for prolonged/repeated skin contact. Wear safety glasses and chemical safety goggles whenever there is the possibility of contact with the eye.

IX. Physical and Chemical Properties:

Boiling Point: NI

Melting Point: NI

Evaporation Rate (Butyl Acetate = 1): NI

Vapor Pressure (mm Hg.): NI

Specific Gravity (H2O = 1):

Vapor Density (AIR = 1): NI

Solubility In Water: Partially soluble.

Appearance and Odor: Light green bolus; odorless

Other Information:

Bulk density = 53 lbs./ft³.

X. Stability and Reactivity:

Stability:

Stable

Incompatibility (Materials to Avoid):

Avoid contact with bleaching agents and oxidizers.

Decomposition/By Products:

If product is burned, carbon monoxide, carbon dioxide, and miscellaneous organic compounds are produced (some potentially toxic).

Hazardous Polymerization:

Will Not Occur.

XI. Toxicological Information:

NI

XII. Ecological Information:

NI

XIII. Disposal Considerations:

Dispose of at an approved facility in accordance with applicable regulations under RCRA and in accordance with all federal, state, and local regulations.

XIV. Transport Information:

NI

XV. Regulatory Information:

MSDS - Material Safety Data Sheet

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OSHA STATUS: This product is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

TSCA STATUS: The ingredients of this product are on the TSCA inventory.

CERCLA REPORTABLE QUANTITY: None

SARA TITLE III:

SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES: None

SECTION 311/312 HAZARD CATEGORIES: Immediate and delayed health hazards.

SECTION 313 TOXIC CHEMICALS: None

RCRA STATUS: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

XVI. Other Information:

Reason for Issue: New MSDS in the ANSI Z 400.1-1998 format.

NI=Not Indicated.

>=Greater Than.

The information and statements in this Material Safety Data Sheet are believed to accurately reflect the scientific evidence used in making the hazard identification but is not to be construed as a warranty or representation for which we assume legal responsibility. Additional information may be necessary or desirable depending on particular, exceptional, or variable conditions or circumstances of use or storage or because of locally applicable laws or government regulations. Therefore, you should use this information only as a supplement to other information available to you and must make independent determinations of the suitability of the information for your particular circumstance or conditions and of the completeness of the information available from all sources to assure both the proper use of the material described herein and the safety and health of employees.



SAFETY DATA SHEET

Issue Date 28-May-2014

Revision Date 17-Nov-2017

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

Supplier

Pegasus Laboratories, Inc.

8809 Ely Road

Pensacola, FL 32514

Company Name

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

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 Attapulgit	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	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	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	Tablet	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/ft ³
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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 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** 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 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) 5.8 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/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/NDL - 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

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