

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



SAFETY DATA SHEET

Issue Date 03-Jun-2014

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Version 2

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

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 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

- 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 | 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

| | |
|---------------------|--|
| 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 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 Attapulgit 12174-11-7 | TWA: 1 mg/m ³ 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

| | | | |
|----------------|------------|----------------|--------------------------|
| Physical state | Liquid | Odor | Licorice |
| Appearance | Suspension | Odor threshold | No information available |
| Color | 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

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 May cause irritation of respiratory tract.

Eye contact May cause slight irritation.

Skin Contact May cause irritation.

Ingestion May cause irritation.

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|--|-------------------|-------------|-----------------|
| Aluminum Magnesium Silicate 1327-43-1 | > 16 g/kg (Rat) | - | - |

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

18% 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, 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 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

| | | | | |
|--------------------|------------------|----------------|--------------------|------------------------------------|
| <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 |

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End of Safety Data Sheet