SAFETY DATA SHEETS

This SDS packet was issued with item:

078825537

N/A



SAFETY DATA SHEET

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

Product identifier

Product Name PRN Pharmacal CranMate

Other means of identification

Product Code PRN FP 30032648

Recommended use of the chemical and restrictions on use
Recommended Use Nutritional Supplements.
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 Pensacola, FL 32514 Pensacola, FL 32514 Responsacola, FL 32514

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance Tablet Physical state Solid Odor Liver

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

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

| Chemical Name | CAS No. | Weight-% | Trade Secret |
|----------------------------------|------------|----------|--------------|
| Sorbitol | 50-70-4 | 45-60 | * |
| Dicalcium Phosphate | 7757-93-9 | 10-20 | * |
| Cranberry Purified Fruit Extract | 91770-88-6 | 5-15 | * |
| Microcrystalline Cellulose | 9004-34-6 | 5-15 | * |
| Red Iron Oxide | 1309-37-1 | 0.5-2 | * |

^{*} 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

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Foam. Carbon dioxide (CO2). Dry chemical. Water spray (fog).

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 |
|----------------------------|----------------------------------|------------------------------------|---|
| Microcrystalline Cellulose | TWA: 10 mg/m ³ | TWA: 15 mg/m³ total dust | TWA: 10 mg/m ³ total dust |
| 9004-34-6 | | TWA: 5 mg/m³ respirable fraction | TWA: 5 mg/m³ respirable dust |
| | | (vacated) TWA: 15 mg/m³ total | |
| | | dust | |
| | | (vacated) TWA: 5 mg/m ³ | |
| | | respirable fraction | |
| Red Iron Oxide | TWA: 5 mg/m³ respirable fraction | TWA: 10 mg/m ³ fume | IDLH: 2500 mg/m3 Fe dust and |
| 1309-37-1 | | TWA: 15 mg/m³ total dust | fume |
| | | TWA: 5 mg/m³ respirable fraction | TWA: 5 mg/m ³ Fe dust and fume |
| | | (vacated) TWA: 10 mg/m³ fume | |
| | | and total dust | |
| | | (vacated) TWA: 5 mg/m ³ | |
| | | respirable fraction regulated | |
| | | under Rouge | |

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

Liver

Information on basic physical and chemical properties

Physical state Solid Appearance Tablet

Color Brown Odor threshold No information available

Odor

Remarks • Method

<u>Property</u> <u>Values</u>

pH Not Applicable

Melting point/freezing pointNo information availableBoiling point / boiling rangeNo information availableFlash pointNo information availableEvaporation rateNo information availableFlammability (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 No information available 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 No information available

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 Contact with eyes may cause irritation.

Skin Contact May cause irritation.

Ingestion May cause irritation.

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 | |
|---|---------------------|-----------------------|------------------------|--|
| Dicalcium Phosphate 7757-93-9 | = 10000 mg/kg (Rat) | > 7940 mg/kg (Rabbit) | - | |
| Microcrystalline Cellulose 9004-34-6 | - | - | > 5800 mg/m³ (Rat) 4 h | |
| Red Iron Oxide 1309-37-1 | > 10000 mg/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

SensitizationNo information available.Germ cell mutagenicityNo information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

| Chemical Name | ACGIH | IARC | NTP | OSHA |
|----------------|-------|---------|-----|------|
| Red Iron Oxide | | Group 3 | | |
| 1309-37-1 | | • | | |

IARC (International Agency for Research on Cancer)

Not classifiable as a human carcinogen

Reproductive toxicity
STOT - single exposure
STOT - repeated exposure
Target Organ Effects

Aspiration hazard

No information available.
No information available.
Eyes, Respiratory system, Skin.
No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 74% 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 (oral) 16811 mg/kg ATEmix (dermal) 13348 mg/kg ATEmix (inhalation-dust/mist) 15.2 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

DescriptionThe following quidelines apply for domestic ground transport. If shipping by air or ocean,

please contact our Transportation Dept.

FEED SUPPLEMENTS, NMFC #67075

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

Not Listed **TSCA DSL/NDSL** Not Listed **EINECS/ELINCS** Not Listed **ENCS** Not Listed Not Listed **IECSC** Not Listed **KECL 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 |
|-------------------------------------|------|-----|------|--------|--------|------|-------|------|-------|------|
| Sorbitol | Х | Х | | Х | | Х | Х | Х | Х | Х |
| Dicalcium Phosphate | Х | Х | | Х | | Х | Х | Х | Х | Х |
| Cranberry Purified Fruit Extract | | Х | | Х | | | | | | Х |
| Microcrystalline Cellulose | Х | Х | | Х | | Х | Х | Х | Х | Х |
| Red Iron Oxide | Х | Х | | Х | | X | Х | Х | Х | Х |

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 |
| Red Iron Oxide 1309-37-1 | X | X | Х |

International Regulations

| Chemical Name | Carcinogenicity | Exposure Limits |
|----------------------------|-----------------|-----------------------------------|
| Microcrystalline Cellulose | | Mexico: TWA 10 mg/m ³ |
| | | Mexico: STEL 20 mg/m ³ |
| Red Iron Oxide | | Mexico: TWA 5 mg/m ³ |
| | | Mexico: STEL 10 mg/m ³ |

| | 16. OTHER INFORMATION | | | | | | |
|----|-----------------------|----------------|--------------------|------------------------------------|--|--|--|
| NF | PA Health hazards 0 | Flammability 0 | Instability 0 | Physical and Chemical | | | |
| H | MIS Health hazards 0 | Flammability 0 | Physical hazards 0 | Properties - Personal protection X | | | |

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End of Safety Data Sheet