SAFETY DATA SHEETS

This SDS packet was issued with item: 078936533

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078416709 078944712



SAFETY DATA SHEET

Issue Date 21-May-2014

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Version 1

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

<u>Product identifier</u> Product Name	PRN Pharmacal Pet-Ema
Other means of identification Product Code NDC Number	PRN FP 30022835 49427-418-25
Recommended use of the chemical	
Recommended Use	Pharmaceutical.
Uses advised against	No information available.
Details of the supplier of the safety	
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)

Acute toxicity - Inhalation (Dusts/Mists)	Category 2

Label elements

Emergency Overview		
Danger		
Hazard statements Fatal if inhaled.		
Appearance Liquid	Physical state Liquid	Odor Odorless

Precautionary Statements - Prevention

• Do not breathe dust/fume/gas/mist/vapors/spray

- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- Immediately call a POISON CENTER or doctor/physician

Precautionary Statements - Storage

- · Store in a well-ventilated place. Keep container tightly closed
- Store locked up

Precautionary Statements - Disposal

· Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC) Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%
Glycerine	56-81-5	80-99*
Docusate Sodium	577-11-7	1-5*
* =		

* 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 Clean mouth with water and drink afterwards plenty of water.

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 ec	uipment 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 containm	ent 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. Dam up. Cover liquid spill with sand, earth or other non-combustible absorbent material. Take up mechanically, placing in appropriate containers for disposal. 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 Bleaching agent. Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Glycerine	-	TWA: 15 mg/m ³ mist, total	-
56-81-5		particulate	
		TWA: 5 mg/m ³ mist, respirable	
		fraction	
		(vacated) TWA: 10 mg/m ³ mist,	
		total particulate	
		(vacated) TWA: 5 mg/m ³ mist,	
		respirable fraction	

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, suc	ch 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.

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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	l industrial hygiene and safet	y practice.
	9. PHYSICAL AND CHEMIC	CAL PROPERTIES	
Information on basic physical and	chemical properties		
Physical state	Liquid		
Appearance	Liquid	Odor	Odorless
Color	Blue	Odor threshold	No information available
Property_	Values_	Remarks • Method	_
pH	Not Available		
Melting point/freezing point	No information available		
Boiling point / boiling range	No information available		
Flash point	> 177 °C / > 350 °F	Pensky-Martens Clos	sed Cup (PMCC)

Other Information

Evaporation rate

Vapor pressure

Specific Gravity

Water solubility

Partition coefficient

Oxidizing properties

Vapor density

Flammability (solid, gas)

Flammability Limit in Air Upper flammability limit:

Lower flammability limit:

Solubility in other solvents

Autoignition temperature

Decomposition temperature

Density

11 lbs./gal.

> 1

1.28

No information available

No information available No information available

Soluble in water

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

Bleaching agent. Oxidizing agents.

Hazardous Decomposition Products

May emit toxic fumes under fire conditions. Hydrocarbons. Carbon monoxide. Carbon dioxide (CO2). Acrolein.

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
Glycerine 56-81-5	-	> 10 g/kg (Rabbit)	> 570 mg/m³(Rat)1 h
Docusate Sodium 577-11-7	-	= 10000 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms

No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization Germ cell mutagenicity Carcinogenicity	No information available. No information available. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Target Organ Effects	Eyes, kidney, Respiratory system, Skin.
Aspiration hazard	No information available.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS documentATEmix (dermal)10030 mg/kgATEmix (inhalation-dust/mist)0.2 mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity

0% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerine 56-81-5		51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static		500: 24 h Daphnia magna mg/L EC50
Docusate Sodium 577-11-7		20 - 40: 96 h Oncorhynchus mykiss mg/L LC50 semi-static 24: 96 h Oncorhynchus mykiss mg/L LC50 static 37: 96 h Lepomis macrochirus mg/L LC50 static		36: 48 h Daphnia magna 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,

MEDICINES, NOI NMFC 58770, SUB 2

please contact our Transportation Dept.

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	Listed
DSL/NDSL	Listed
EINECS/ELINCS	Listed
ENCS	Listed
IECSC	Listed
KECL	Listed
PICCS	Listed
AICS	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
Glycerine	Х	Х		Х		Х	Х	Х	Х	Х
Docusate Sodium	Х	Х		Х		Х	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
Glycerine	Х	Х	Х
56-81-5			

International Regulations

Mexico - Grade

Slight risk, Grade 1

Chemical Name	Carcinogenicity	Exposure Limits
Glycerine		Mexico: TWA 10 mg/m ³

16. OTHER INFORMATION

<u>NFPA</u>	Health hazards 0	Flammability 1	Instability 0	Physical and Chemical
HMIS	Health hazards 0	Flammability 1	Physical hazards 0	Properties - Personal protection X

Disclaimer

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End of Safety Data Sheet