



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 ReBalance Oral Suspension

Other means of identification

Product Code PRN FP 30024711
NDC Number 49427-247-11

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	Company Name
Pegasus Laboratories, Inc. 8809 Ely Road Pensacola, FL 32514	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)

Skin Corrosion/Irritation Category	Category 1 Sub-category B
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Label elements

Emergency Overview

Danger

Hazard statements

Causes severe skin burns and eye damage.



Appearance Suspension

Physical state Liquid

Odor Almond

Precautionary Statements - Prevention

- Do not breathe dust/fume/gas/mist/vapors/spray
- Wash face, hands and any exposed skin thoroughly after handling
- Wear protective gloves/protective clothing/eye protection/face protection

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

- Wash contaminated clothing before reuse
- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

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 %
Sulfadiazine	68-35-9	15-30*
Sodium Hydroxide	1310-73-2	3-6*
Pyrimethamine	58-14-0	0.5-3*
Benzaldehyde	100-52-7	0.1-2*
Carboxymethylcellulose 6000	9004-32-4	0.1-2*

* The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures

- Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area.
- Skin Contact** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
- Inhalation** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
- Ingestion** Product is intended for consumption. Please see the product label for instructions for use and precautions.
- Self-protection of the first aider** Use personal protective equipment as required. Avoid contact with skin, eyes or clothing.

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

The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating and toxic gases and vapors. In the event of fire and/or explosion do not breathe fumes.

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 Evacuate personnel to safe areas. Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Keep people away from and upwind of spill/leak.

Environmental precautions

Environmental precautions Do not allow into any sewer, on the ground or into any body of water. Should not be released into the environment. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. 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 Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Take up mechanically, placing in appropriate containers for disposal. Clean contaminated surface thoroughly. Prevent product from entering drains. Dam up. After cleaning, flush away traces with water.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation, especially in confined areas. In case of insufficient ventilation, wear suitable respiratory equipment. Use only with adequate ventilation and in closed systems.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers.

Incompatible materials Incompatible with oxidizing agents. Bleaching agent. Incompatible with strong acids and bases.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium Hydroxide	Ceiling: 2 mg/m ³	TWA: 2 mg/m ³	IDLH: 10 mg/m ³

1310-73-2	(vacated) Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³
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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 Tight sealing safety goggles. Face protection shield.

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 When using do not eat, drink or smoke. Wash contaminated clothing before reuse. Keep away from food, drink and animal feeding stuffs. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with skin, eyes or clothing. Take off all contaminated clothing and wash it before reuse. Wear suitable gloves and eye/face protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Odor	Almond
Appearance	Suspension	Odor threshold	No information available
Color	Cream		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	9.5-11	
Melting point/freezing point	No information available	
Boiling point / boiling range	99 °C / 210 °F	
Flash point	No information available	
Evaporation rate	< 1	
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	Insoluble in water	
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

Exposure to air or moisture over prolonged periods.

Incompatible materials

Incompatible with oxidizing agents. Bleaching agent. Incompatible with strong acids and bases.

Hazardous Decomposition Products

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation May cause irritation of respiratory tract.
Eye contact Mild eye irritation.
Skin Contact Moderate skin irritation.
Ingestion May cause irritation.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Hydroxide 1310-73-2	-	= 1350 mg/kg (Rabbit)	-
Pyrimethamine 58-14-0	= 440 mg/kg (Rat)	-	-
Benzaldehyde 100-52-7	= 1292 mg/kg (Rat)	> 1250 mg/kg (Rabbit)	-
Carboxymethylcellulose 6000 9004-32-4	= 27000 mg/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 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
Pyrimethamine 58-14-0		Group 3		

*IARC (International Agency for Research on Cancer)
Not classifiable as a human carcinogen*

Reproductive toxicity No information available.

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Chronic toxicity Chronic exposure to corrosive fumes/gases may cause erosion of the teeth followed by jaw necrosis. Bronchial irritation with chronic cough and frequent attacks of pneumonia are common. Gastrointestinal disturbances may also be seen. Avoid repeated exposure. Possible risk of irreversible effects.
Target Organ Effects Eyes, Respiratory system, Skin.
Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Toxicity 27 % 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 (dermal) 24417 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

27% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Hydroxide 1310-73-2		45.4: 96 h Oncorhynchus mykiss mg/L LC50 static		
Benzaldehyde 100-52-7		0.8 - 1.44: 96 h Lepomis macrochirus mg/L LC50 flow-through 7.5: 96 h Lepomis macrochirus mg/L LC50 static 6.8 - 8.53: 96 h Pimephales promelas mg/L LC50 flow-through 10.6 - 11.8: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 12.69: 96 h Oncorhynchus mykiss mg/L LC50 static		50: 24 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.

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 Listed
EINECS/ELINCS Not Listed
ENCS Not Listed
IECSC Not Listed
KECL Not 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
Sulfadiazine	X	X		X				X	X	X
Sodium Hydroxide	X	X		X		X	X	X	X	X
Pyrimethamine		X		X		X			X	X
Benzaldehyde	X	X		X		X	X	X	X	X
Carboxymethylcellulose 6000	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 Yes
Chronic Health Hazard Yes
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)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium Hydroxide	1000 lb			X

1310-73-2			
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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)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium Hydroxide 1310-73-2	1000 lb		RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sodium Hydroxide 1310-73-2	X	X	X
Benzaldehyde 100-52-7	X	X	X

International Regulations

Chemical Name	Carcinogenicity	Exposure Limits
Sodium Hydroxide		Mexico: Ceiling 2 mg/m ³

16. OTHER INFORMATION

NFPA	Health hazards 3	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 3	Flammability 0	Physical hazards 0	Personal protection X

Disclaimer

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End of Safety Data Sheet