



**PHARMACAL**

# SAFETY DATA SHEET

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Version 1

## 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**

<b>Supplier</b>	<b>Company Name</b>
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)

Skin corrosion/irritation	Category 1 Sub-category B
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**Label elements**

**Emergency Overview**

<p><b>Danger</b></p> <p><b>Hazard statements</b> Causes severe skin burns and eye damage.</p>
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**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)**

Product is intended for consumption. Please see the product label for instructions for use and precautions.

**Other Information**

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	Weight-%	Trade Secret
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 (CO<sub>2</sub>).

**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 1310-73-2	Ceiling: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> (vacated) Ceiling: 2 mg/m <sup>3</sup>	IDLH: 10 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>

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**

<b>Physical state</b>	Liquid	<b>Odor</b>	Almond
<b>Appearance</b>	Suspension	<b>Odor threshold</b>	No information available
<b>Color</b>	Cream		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	9.5-11	
<b>Melting point/freezing point</b>	No information available	
<b>Boiling point / boiling range</b>	99 °C / 210 °F	
<b>Flash point</b>	No information available	
<b>Evaporation rate</b>	< 1	
<b>Flammability (solid, gas)</b>	No information available	
<b>Flammability Limit in Air</b>		
<b>Upper flammability limit:</b>	No information available	

<b>Lower flammability limit:</b>	No information available
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Specific Gravity</b>	1.12
<b>Water solubility</b>	Insoluble in water
<b>Solubility in other solvents</b>	No information available
<b>Partition coefficient</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Oxidizing properties</b>	No information available

**Other Information**

<b>Density</b>	No information available
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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**

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**

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

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Hydroxide 1310-73-2	-	= 1350 mg/kg ( Rabbit )	-
Benzaldehyde 100-52-7	= 800 mg/kg ( Rat )	> 1250 mg/kg ( Rabbit )	-
Carboxymethylcellulose 6000 9004-32-4	-	-	> 5800 mg/m <sup>3</sup> ( 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 Acute 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		10.6 - 11.8: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 12.69: 96 h Oncorhynchus mykiss mg/L LC50 static 0.8 - 1.44: 96 h Lepomis macrochirus mg/L LC50 flow-through 6.8 - 8.53: 96 h Pimephales promelas mg/L LC50 flow-through 7.5: 96 h Lepomis macrochirus 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**

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Listed
<b>EINECS/ELINCS</b>	Not Listed
<b>ENCS</b>	Not Listed
<b>IECSC</b>	Not Listed
<b>KECL</b>	Not Listed
<b>PICCS</b>	Listed
<b>AICS</b>	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 1310-73-2	1000 lb			X

**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 <sup>3</sup>

**16. OTHER INFORMATION**

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

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**End of Safety Data Sheet**