



SAFETY DATA SHEET

Mupirocin Ointment USP, 2%

1. IDENTIFICATION

Product identifier: Propranolol Hydrochloride Oral Solution (20 mg/5 mL)

Product Codes:

- 50ct Carton = 0121-1076-50
- 100ct Carton = 0121-1076-00

Supplier Name and Address:

PAI Pharma
1700 Perimeter Road
Greenville, SC 29605
(864) 277-7282

Telephone number:

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug for treatment of impetigo– prescription only.

Restrictions on use: Use only as directed

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2024.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Mupirocin	12650-69-0	2%
Polyethylene Glycol	25322-68-3	Proprietary

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or other symptoms occur, get medical attention.

Skin contact: This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

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Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Mupirocin	None Established
Polyethylene Glycol	10 mg/m ³ TWA AIHA & OARS WEEL

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Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid (cream-like ointment)	pH: Not determined
Odor: No odor	Color: White
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: Not applicable
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Not determined	Relative vapor density: Not determined
Relative density: Not determined	Solubility(ies): Not determined
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract

Ingestion: Swallowing may cause effects as seen in clinical use including hypotension, nausea, diarrhea, constipation, rash, hypersensitivity reactions, light-headedness, mental depression, fatigue, visual disturbances and disorientation.

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Ingestion: Swallowing may cause gastrointestinal irritation. No serious adverse effects are expected.

Skin contact: No adverse effects are expected. Some users have reported skin irritation with burning, stinging or pain.

Eye contact: Contact may cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

Germ Cell Mutagenicity: Results of the following studies performed with mupirocin calcium or mupirocin sodium *in vitro* and *in vivo* did not indicate a potential for genotoxicity: Rat primary hepatocyte unscheduled DNA synthesis, sediment analysis for DNA strand breaks, *Salmonella* reversion test (Ames), *Escherichia coli* mutation assay, metaphase analysis of human lymphocytes, mouse lymphoma assay, and bone marrow micronuclei assay in mice.

Reproductive Toxicity: Reproduction studies were performed in male and female rats with mupirocin administered subcutaneously at doses approximately 60 mg mupirocin per day and revealed no evidence of impaired fertility and reproductive performance from mupirocin. Developmental studies have been performed in rats and rabbits with mupirocin administered subcutaneously at doses approximately 60 mg mupirocin per day and revealed no evidence of harm to the fetus due to mupirocin.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values:

Mupirocin: LD50 oral rat 5000 mg/kg

Polyethylene Glycol: LD50 oral rat 20,000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			

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Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: New SDS

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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