



SAFETY DATA SHEET

Quality Affordable Healthcare Products™

1. IDENTIFICATION

Product identifier: Mupirocin Ointment USP, 2%

Synonym: 1N2, 5R2

Manufacturer Name: Perrigo Company.
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451
Technical Contact: (972)-523-667-422 (Israel)

Global Emergency phone number: 760-476-3962 Code: 333304

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

Restrictions on use: Use only as directed.

Date of Preparation: March 27, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

| Physical | Health |
|---------------|---------------|
| Not hazardous | Not Hazardous |

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| Chemical name | CAS No. | Concentration |
|---------------------|------------|---------------|
| Mupirocin | 12650-69-0 | 2% |
| Polyethylene Glycol | 25322-68-3 | Balance |

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, 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.

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 immediate medical attention.

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

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not required. For unintended exposure, seek medical advice.

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 flammable or combustible but may 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. Cool fire exposed containers with water.

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 | 5000 ug/m ³ TWA Perrigo OEL |
| Polyethylene Glycol | 10 mg/m ³ TWA AIHA WEEL |

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, a NIOSH approved particulate/organic vapor or supplied air 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

Appearance (physical state, color, etc.): White to off-white ointment.

Odor: No odor

| | |
|--|---|
| Odor threshold: Not determined | pH: 4.0 |
| Melting point/freezing point: Not determined | Boiling Point: Not determined |
| Flash point: >200°F / 93.3°C | Evaporation rate: Not determined |
| Flammability (solid, gas): Not applicable | VOC: Not determined |
| Flammable limits: LEL: Not determined | UEL: Not determined |
| Vapor pressure: Not determined | 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 | 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

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

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 up to 14 times a human topical dose (approximately 60 mg mupirocin per day) on a mg/m² basis 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 up to 22 and 43 times, respectively, the human topical dose (approximately 60 mg mupirocin per day) on a mg/m² basis 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

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is 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. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

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

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): 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.

CANADA:

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

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: March 27, 2014

Date of last revision: February 19, 2013

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).