



Quality Affordable Healthcare Products™

SAFETY DATA SHEET

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).



SAFETY DATA SHEET

Quality Affordable Healthcare Products™

1. IDENTIFICATION

Product identifier: ECONAZOLE NITRATE CREAM 1%

Synonym: 2F3

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

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human topical drug – prescription use only

Restrictions on use: Use only as directed.

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
Econazole Nitrate	24169-02-6	1%
Water	7732-18-5	Proprietary
Pegoxol-7 Stearate	9004-99-3	Proprietary
Mineral Oil	8012-95-1	<10%
Peglicol 5 oleate/oleoyl polyoxylglycerides	69071-70-1	Proprietary
Benzoic Acid	65-85-0	<1%
Butylated Hydroxyanisole	25013-16-5	<0.1%

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: Remove contaminated clothing. Wash skin with soap and water. If irritation develops and persists, get medical attention. Launder clothing 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 medical attention.

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

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not normally required.

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.

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, skin 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:

Econazole Nitrate	1000 ug/m ³ TWA PERRIGO OEL
Water	None Established
Pegoxol-7 Stearate	None Established
Mineral Oil	5 mg/m ³ (inhalable) TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL
Peglicol 5 oleate/oleoyl polyoxylglycerides	None Established
Benzoic Acid	None Established

Butylated Hydroxyanisole	None Established
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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 excessive and irritation is experienced, 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: Impervious gloves recommended if contact with the drug product is possible.

Eye protection: Chemical safety goggles recommended if contact with the drug product is possible.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Odor: Odorless

Odor threshold: Not applicable	pH: 2.0-4.0
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: Not determined	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: 10,000-75,000 cps

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 and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

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

Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea.

Skin contact: No adverse effects are expected. Minor irritation is possible

Eye contact: Contact may cause slight 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: None of the components have been shown to cause germ cell mutagenicity. Econazole nitrate was negative in the AMES assay.

Reproductive Toxicity: Econazole nitrate has not been shown to be teratogenic when administered orally to mice, rabbits or rats. Fetotoxic or embryotoxic effects were observed in Segment I oral studies with rats receiving 10 to 40 times the human dermal dose. Similar effects were observed in Segment II or Segment III studies with mice, rabbits and/or rats receiving oral doses 80 or 40 times the human dermal dose. Oral administration of econazole nitrate in rats has been reported to produce prolonged gestation. Intravaginal administration in humans has not shown prolonged gestation or other adverse reproductive effects attributable to econazole nitrate therapy.

Carcinogenicity: No carcinogenicity studies have been performed with econazole nitrate. None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 45,500 mg/kg
Econazole Nitrate: Oral rat LD50 462 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 = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: May 8, 2015

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