

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Bacitracin Ointment

Synonym: 536

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

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986

Recommended use: Human drug – prescription only.

Restrictions on use: Use only as directed.

Date of Preparation: August 3, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Aspiration Toxicity Category 1

Label Elements:

Danger!



Hazard statement(s)

May be fatal if swallowed and enters airways.

Precautionary statement(s)

IF Swallowed: Immediately call a poison center or doctor. Do NOT induce vomiting.

Store locked up.

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Bacitracin	1405-87-4	500 units/gram
Mineral Oil	8042-47-5	Proprietary
White Petrolatum	8009-03-8	Proprietary

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 or eyes. 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: This product is intended for use in the eyes. For unintended 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. 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 mild eye and skin irritation. Ingestion may cause gastrointestinal effects such as nausea or diarrhea. Occasional allergic reactions have been reported in patients. Possible aspiration hazard. May enter the lungs during swallowing or vomiting and cause severe lung damage.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray or fog, CO₂, dry chemical or foam. Do not use solid water jet as this may spread 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 unintended 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:

Bacitracin	1000 ug/m ³ TWA Perrigo OEL
Mineral Oil	5 mg/m ³ (inhalable) TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL

White Petrolatum	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
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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 organic vapor/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: None required for normal use. Impervious gloves recommended for manufacturing operations.

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.): Yellow-orange ointment.

Odor: No odor

Odor threshold: Not determined	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: >200°F / 93.3°C	Evaporation rate: Same as water
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): Soluble
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

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: This product is intended for use in the eye. Contact may cause slight irritation.

Chronic Effects: None known. Intramuscular administration of bacitracin has caused kidney damage.

Sensitization: Components are not known to be sensitizers. Rare allergic reactions have been reported with topical use of bacitracin. Rashes and allergic anaphylactoid reactions have occurred in some patients.

Anaphylactoid reactions have ranged from generalized itching, swelling of the lips and face, sweating, and tightness of the chest, to hypotension, unconsciousness, apnea, and cardiac arrest.

Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens.

Reproductive Toxicity: No adverse effects are expected. Components are not reproductive toxins.

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

Acute Toxicity Values:

Bacitracin: LD50 oral mouse >3750 mg/kg.

Mineral Oil: LD50 oral rat >5000 mg/kg

Petrolatum: LD50 oral rat >5000 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: August 3, 2014

Date of last revision: New SDS

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).