



LABORATORIES, INC.

Material Safety Data Sheet

Product Id: Bacitracin Ointment

Date prepared: April, 2011

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Supplier: G&W Laboratories, Inc.
111 Coolidge Street
South Plainfield, New Jersey 07080 – 3895

Emergency telephone: (800) 922-1038

Product name: Bacitracin Ointment.
Product Code: 0280
Synonyms: N/A
Trade name: N/A
Formula: Bacitracin, USP, White Petrolatum and Mineral oil.
EPA registry #: Not applicable.
RTECS #: Not applicable.
General use: Pharmaceutical topical ointment primarily used as first aid antibiotic to prevent infection from minor cuts, scrapes and burns. For external use only.

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Quantity	CAS Number
Bacitracin, USP	500 IU/g	1405-87-4
White Petrolatum	Proprietary	8009-03-8
Mineral Oil	Proprietary	8042-47-5

3. HAZARDS IDENTIFICATION

Emergency overview: Persons developing hypersensitivity reactions should receive medical attention.

Principal routes of exposures:

Skin contact: None expected for normal use, however, may cause irritation due to allergic reaction.

Eye contact: Flush eyes with plenty of water for 15 minutes. Seek medical assistance if any adverse effect continues after rinsing.

Ingestion: May cause indigestion, nausea and vomiting. Call Physician or Poison Control Center for most current information. Never induce vomiting if individual is unconscious or unable to swallow.

Inhalation: Not likely during normal use due to the physical state of the product.

Hazard information:

Target organs effects: May cause skin irritation.

Reproductive effects: Not reported.

Mutagenic effects: Not reported.

Carcinogenicity rating: OSHA, IARC and NTP do not list this product as carcinogen.

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4. FIRST AID MEASURES

Eye contact: Flush eyes with plenty of water for at least 15 minutes.

Ingestion: If conscious and alert, rinse mouth with water, contact Physician or Poison Control Center.

Inhalation: Remove to fresh air. If breathing is difficult, give oxygen.

Skin contact: Wash thoroughly with soap and water.

Notes to physician: Product contains Bacitracin. Treat symptomatically and supportively.

Protection of first-aiders: Follow general safety rules and take Universal Precautions.

5. FIRE FIGHTING MEASURES

Flash point (°F): Not Established.

Flash point (°C): Not Established.

Auto-ignition temperature: N/A

Flammable limits in air - lower (%): Not Reported.

Flammable limits in air - upper (%): Not Reported.

NFPA rating: Flammability 1, Health 2, Instability 0

HMIS classification: Not applicable.

Fire fighting information:

Suitable extinguishing media: Dry chemical, Water, Carbon Dioxide, Foam or Sand/earth.

Extinguishing media, which must not be used for safety reasons: Strong acids, strong bases.

Oxidizing agents e.g., Hydrogen Peroxide, Bromine, Chromic acid etc.

Special protective equipment for firefighters: Wear eye protection, self-contained breathing apparatus and full protective equipment.

Specific methods: Not known.

Hazardous combustion products: Not Known.

Explosivity: Not determined.

Explosion limits: Not available.

Lower: Not established.

Upper: Not established.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid Eye Contact.

Environmental precaution: Avoid direct heat and store at recommended Temp. (15°C -30°C), well ventilated and away from food and animal feed.

Methods for cleaning up (*Small Spills*): Absorb and wipe small spill, wash hands with water and soap.

Methods for cleaning up (*Large Spills*): Trained personnel following pre-planned procedures should handle the clean up. Place all spill residue in an appropriate sealed container.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Do not store near strong oxidizers. Do not drink, eat or smoke while handling this product. Wash hands thoroughly after handling this product.

Safe handling advice: Keep out of children and follow the general safety practices.

Storage:

Technical measures/storage conditions: Do not damage container and keep it closed, Store at room Temp. between 59°F and 86°F (15°C – 30°C).

Incompatible products: Strong Acids, Strong Bases and Oxidizers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls: Follow general safety rules and work in a well-ventilated area.

Eye Protection: Avoid direct eye contact and wear safety glasses if splashing is possible.

Hand protection: Wear appropriate gloves.

Skin protection: Practice normal hygiene. Wear appropriate gloves and clothing to prevent skin exposure.

Respiratory protection: Maintain adequate ventilation.

Other/general protection: N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: A translucent ointment.

Physical state: Semisolid.

Color: Off white.

pH: Not established.

Water solubility: Insoluble in water.

Odor: Slight characteristic odor of petrolatum.

Boiling point: > 200°C (392°F)

Melting point: > 50°C

Flash point: Not established.

Explosive properties: Not known.

Vapor pressure: N/A

Relative density: Less than 1 (water = 1).

10. STABILITY AND REACTIVITY

Chemical stability: Stable at normal conditions.

Hazard polymerization: No report of polymerization.

Hazardous decomposition products: If exposed to very high temperature, thermal decomposition may generate toxic gasses and irritant fumes e.g., carbon oxide, sulfur oxide etc.

Materials to avoid: Strong Acids, Strong Bases and Oxidizers.

Conditions to avoid: Strong source of heat.

11. TOXICOLOGICAL INFORMATION

Acute toxicity:

Oral: Not intended for oral ingestion, however, a large amount of ingested product may cause stomach irritation, nausea, diarrhea and vomiting.

Eye: May cause eye irritation and temporary blurred vision.

Skin: May cause irritation if someone is sensitive to any of the ingredients listed.

Experimental Data: Some of the toxicity data available for the similar drug Bacitracin Zinc are presented below:

LD₅₀ (Oral Mouse): > 3750 mg/kg

LD₅₀ (Intravenous Mouse): 360 mg/kg

LD₅₀ (Oral Guinea Pig): > 2000 mg/kg

LD₅₀ (Subcutaneous Mouse): 1300 mg/kg

Chronic toxicity:

Oral: Not established

Dermal: Bacitracin has low order of toxicity, but rashes and allergic reaction may have occur to some patients those who are sensitive to any of the chemicals listed.

Inhalation: Not established.

Sub-chronic toxicity: Not determined.

Corrosivity: Not established.

Sensitization: TCLo (Skin Human) 20 pph/48 hours continuous: dermatitis and allergic reaction.
Target organs effects: Not known
Carcinogenic effects: The ingredients of this product are not listed as carcinogen in the U.S. EPA, U.S. NTP, U.S. OSHA and U.S. NIOSH.
Mutagenic effects: The ingredients of the product are not reported to cause mutagenic effects on humans.
Reproductive effects: Not determined on humans.
Developmental effects: Not determined on humans.
General notes: N/A

12. ECOLOGICAL INFORMATION

Mobility: Not determined.
Bioaccumulation: Data not available.
Degradation: Not known.
Eco-toxicity effects: No ingredient of this product is known to have ozone depletion potential.
Aquatic toxicity effects: Release of large volume of this product into aquatic environment may be harmful to aquatic plant and animal life.
General notes: All work practices should be aimed at eliminating environmental contamination.

13. DISPOSAL CONSIDERATIONS

Waste from residue / unused products: Follow appropriate federal, state and local regulations, and dispose in compliance with these regulation(s):

Contaminated packaging: Waste or contaminated materials must be placed in and shipped in appropriate poly or metal containers. Permeable cardboard containers are not recommended and should not be used. Ensure that all the containers have the required labeling according to all applicable regulations.

14. TRANSPORT INFORMATION

DOT:

DOT UN-No: Not applicable
DOT shipping name: N/A
Hazard class: This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101
Subsidiary risk (hazard class): Not applicable
Packing group: Not applicable
DOT reportable quantity (lbs): There are no specific threshold quantities listed for this product. The default federal MSDS submission and inventory requirement filing threshold of 10,000 lb can be applied, per 40 CFR 370.20.

TDG (Canada):

Status: This product is not classified as hazardous goods, per regulation of Transport Canada.
Packing group: Not applicable

15. REGULATORY INFORMATION

SARA hazard class: The ingredients of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title III of the Superfund Amendments & Reauthorization Act.

Immediate health: Not listed.
Delayed health: Not listed.
Fire: Not listed.
Sudden pressure: Not applicable.
Reactivity: Not applicable.

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TSCA inventory list: This product is regulated by U.S. FDA and hence, it is not subject to requirements under TSCA.

WHMIS:

WHMIS trade secret: Not Applicable

WHMIS hazard class: Not Applicable

Canada DSL inventory list: Not Listed

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensations and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substance Control Act.
5. WHMIS = Canadian Workplace Hazardous Materials Information System.
6. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. OTHER INFORMATION

This data sheet contains changes from previous version in section (s): N/A

Additional advice: N/A

References: N/A

MSDS format:

North American Format – U.S. and Canada
This Material Safety data Sheet was prepared in
accordance with OSHA 29 CFR 1910.1200.

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End of safety data sheet