

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Gentamycin Sulfate Cream USP, 0.1%

Synonym: 1A5

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 drug – topical antibiotic

Restrictions on use: Use only as directed.

Date of Preparation: January 10, 2015

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization Category 1 Reproductive Toxicity Category 2

Label Elements:

Warning!



Hazard statement(s)

May cause an allergic skin reaction.
 Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Avoid breathing mists.

Precautionary statement(s)

Contaminated clothing must not be allowed out of the workplace.
 Wear protective clothing and gloves.
 IF on skin: wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
 IF exposed or concerned: Get medical attention.
 Store locked up.
 Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Gentamicin Sulfate	1405-41-0	0.167%

Water	7732-18-5	Proprietary
Propylene Glycol Monostearate	1323-39-3	Proprietary
Propylene Glycol	57-55-6	Proprietary
Sorbitol	50-70-4	Proprietary
Isopropyl Myristate	110-27-0	Proprietary
Tween 40 (Polysorbate 40)	9005-66-7	Proprietary
Methylparaben	99-76-3	Proprietary
Butylparaben	94-26-8	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. If unintended contact occurs, remove contaminated clothing. Wash skin with soap and water. If irritation or rash develops, 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. May cause an allergic skin reaction in sensitized people. Ingestion may cause gastrointestinal upset.

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

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use dry chemical, carbon dioxide, foam or water spray.

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.

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 skin contact. 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:

Gentamicin Sulfate	100 ug/m ³ TWA PERRIGO OEL
Water	None Established
Propylene Glycol Monostearate	None Established
Propylene Glycol	None Established
Sorbitol	None Established
Isopropyl Myristate	None Established
Tween 40 (Polysorbate 40)	None Established
Methylparaben	500 ug/m ³ TWA PERRIGO OEL
Butylparaben	None Established

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: Impervious gloves recommended if needed to avoid unintended contact.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White cream.

Odor: Odorless

Odor threshold: Not applicable	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: No data available
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 in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not determined	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, sulfur 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 upset.

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

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

Chronic Effects: Clinical use of gentamicin sulfate has had adverse effects on the kidneys.

Sensitization: Gentamicin sulfate is a skin sensitizer in some individuals.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Aminoglycoside antibiotics have been found to be non-mutagenic.

Reproductive Toxicity: Gentamicin has been shown to depress body weights, kidney weights, and median glomerular counts in newborn rats when administered systemically to pregnant rats. Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy. Serious side effects to mother, fetus or newborn have not been reported in the treatment of pregnant women with other aminoglycosides. Animal reproduction studies conducted on rats and rabbits did not reveal evidence of impaired fertility or harm to the fetus due to gentamicin sulfate.

Carcinogenicity: No carcinogenicity studies have been performed with gentamicin sulfate. None of the components present at 0.1% or greater are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Ingredients are not acutely toxic.
Gentamicin Sulfate: Oral rat LD50 >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): Acute Health, Chronic Health

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: January 10, 2015

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).