

MATERIAL SAFETY DATA SHEET

Manufacturer's Name: ALTANA INC.
Divisions: E. FOUGERA & COMPANY DIVISION
 PHARMADERM DIVISION
 SAVAGE LABORATORIES DIVISION
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SECTION 1: IDENTITY

Product Name:	Gentamicin Sulfate Ophthalmic Ointment
Synonyms:	Not applicable.
CAS #:	Not applicable.
Chemical Family:	Antibiotic.
Formula:	Gentamicin Sulfate USP, Mineral Oil USP, White Petrolatum USP.

SECTION 2: SAFETY and HAZARD RATINGS

Health (Acute-Chronic):	1-0	RATINGS Minimal 0 Slight 1 Moderate 2 Severe 3 Extreme 4
Flammability:	1	
Reactivity:	0	
Environment (Air-Water-Soil):	0-0-1	
Special Hazards:	None.	
Protective Equipment:	None required under standard usage.	

SECTION 3: EMERGENCY and FIRST AID PROCEDURES

Eyes:	Flush eyes with plenty of water for at least 15 minutes.
Skin:	Wash thoroughly with soap and water.
Ingestion:	Give plenty of water to drink and induce vomiting. Never give anything by mouth to an unconscious person.
Inhalation:	Not applicable for ointment.

**CALL A PHYSICIAN
CONTACT A POISON CONTROL CENTER**

SECTION 4: INGREDIENTS

NAME	CAS#	%	CARCINOGEN			HAZARD DATA	
			IARC	NTP	OSHA	ACGIH TLV	OSHA PEL
Gentamicin Sulfate	1405-41-0		no	no	no	not established	
Mineral Oil	8042-47-5		no	no	no	2mg/m ³ not established*	
White Petrolatum	8009-03-8		no	no	no	not established * oil mist (mineral)	

SECTION 5: FIRE and EXPLOSION HAZARD DATA

Flash Point:	Not indicated.
Auto-ignition Temperature °F:	Not indicated.
Flammable Limits in Air by Volume LEL:	Not indicated.
UEL:	Not indicated.
Extinguishing Media:	Foam, Dry chemical, Carbon dioxide.
Special Fire Fighting Procedures:	Use self-contained breathing apparatus.
Unusual Fire and Explosion Hazards:	May emit toxic fumes when burning.

SECTION 6: REACTIVITY DATA (PHYSICAL HAZARDS)

Stability:	<input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable
Conditions and Chemicals to Avoid:	Heat, light, oxidants and bases.
Hazardous Combustion or Decomposition Products:	Carbon dioxide, Carbon monoxide.
Hazardous Polymerization:	<input type="checkbox"/> May Occur <input checked="" type="checkbox"/> Will Not Occur

SECTION 7: HEALTH HAZARDS

Primary Route(s) of Entry:	Dermal, Ingestion
<u>Signs and Symptoms of Exposure</u>	
a. Overexposure Effects:	Possible allergic reaction.
b. Chronic Effects:	Possible hypersensitization.
1. Inhalation:	None expected under normal condition of use.
2. Eyes:	May cause irritation.
3. Skin:	May cause irritation.
4. Ingestion:	May cause irritation.
5. Medical Conditions Potentially Aggravated:	Hypersensitivity to any of the ingredients.

SECTION 8: SPECIAL PRECAUTIONS and SPILL/LEAK PROCEDURES

Precautions to be Taken in Handling/Storage:	Keep containers closed when not in use. Do not handle or store near heat, light, oxidants and bases. Store between 3 ⁰ and 30 ⁰ C (36 ⁰ and 86 ⁰ F).
Hygienic Practices:	Wash thoroughly after handling. Use normal hygiene to protect hands, eyes and skin. Use general ventilation to protect your lungs. Do not wear contaminated clothing until thoroughly laundered.
When Material is Released or Spilled:	Assure slippery conditions are nullified. Add sand or dirt. Scoop up and remove. Wash area with soap and water. Dispose of in accordance with federal, state and local regulations.
Waste Disposal Methods:	Assure conformity with applicable disposal regulations. Dispose of absorbed material at approved incineration or chemical landfill waste disposal site.

SECTION 9: SPECIAL PROTECTION INFORMATION

Respiratory Protection:	General ventilation.
Skin Protection:	Normal hygiene.
Eye Protection:	Normal hygiene.
Other Protective Clothing or Equipment:	As needed to prevent repeated/prolonged contact.

SECTION 10: CONTAINERS and LABELING

Special Precautions:	Keep container closed. Store away from heat, light, oxidants and bases. Store between 3⁰ and 30⁰C (36⁰ and 86⁰F).
Recommended Container:	As supplied (not sold in bulk quantity).
Protect the Container by:	Avoid physical damage and heat.
Container Should be Handled in an Area with:	Adequate general ventilation.
The Empty Container is:	Not reusable.
Precautionary Label:	Federal law prohibits dispensing without a prescription.
Warning Placard:	Keep out of the reach of children. (See package insert)
IMO Hazard Class #:	Not applicable.
UN/NA #:	Not applicable.
Hazard Classification:	Not applicable.
DOT Name:	Not applicable.
Shipping Instructions:	Keep away from heat, light, oxidants and bases.

SECTION 11: ENVIRONMENTAL RISKS

Aquatic Toxicity:	Not indicated.
Biodegradability:	Not indicated.
Partition Coefficient:	Not indicated.

SECTION 12: REGULATORY INFORMATION

Refer to the following references:	OSHA Regulations:	If respirator used, 29 CFR 1910.134
	DOT Regulations:	Not applicable.
	EPA Regulations:	Not applicable.
	Other:	FDA:
		NDC: 0168-0044

SECTION 13: PHYSICAL DATA

Appearance and Odor:	A white-to-off white ointment and essentially odorless.
Molecular Weight:	Not applicable.
pH:	Not determined.
Refractive Index @ 20°C:	Not determined.
Viscosity:	10 – 50cSt
Boiling Point:	Decomposition begins at about 185°C
Freezing/Melting Point:	Melts at ~ 42°C
Congealing Point:	Not determined.
Vapor Pressure (mm Hg @ 20°C):	Not determined.
Vapor Density (Air=1):	Not determined.
Solubility in Water:	Insoluble.
Solubility in Alcohol:	Insoluble.
Solubility in Oil:	Miscible.
Solubility in Other:	Not determined.
Specific Gravity (H ₂ O = 1):	0.87 @ 60°C
% Volatile by Volume:	0
Evaporation Rate (Ether=1):	0.01

Date of Preparation/Change:
October 14, 2002

Revision # 1

Replaces
November 24, 1998

The information presented herein relates to the specific material described and may not be valid for this material used in combination with any other materials or in any process. This information is, to the best of our knowledge, accurate and reliable on the date compiled. We make no representation, warranty or guarantee as to its accuracy, reliability or completeness.

It is the reader's responsibility to ascertain whether the information supplied is suitable and complete for that person's specific uses. This Material Safety Data Sheet was prepared for ALTANA INC. by:

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