

Alpharma

AUREOMYCIN(R) 100 G

AUREOMYCIN(R) 100 G (US and Canada) Approved: 05/02/00

Alpharma Inc.
 One Executive Drive
 Fort Lee, NJ 07024
 Phone: 201-947-7774
 Fax: 201-947-3879

Chemtrec 24 Hour Emergency Telephone Numbers:
 North America: 1-800-424 9300
 International: 1-703-527 3887

 SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: AUREOMYCIN(R) 100 G and AUREOMYCIN(R) CRUMBLES.
 Product Codes: 700118 / 700127 / 700139 / 700371 (700171).
 TSCA Status: All ingredients are on the TSCA Inventory.

 SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS Number	Concentration %
Chlortetracycline	57-62-5	22
Magnesium Stearate *	557-04-0	0-5
Water *		0-2
Calcium Sulfate Dihydrate	10101-41-4	qs 100

* Note: Used only to optimize product quality

 SECTION 3. HAZARDOUS IDENTIFICATION

EMERGENCY OVERVIEW

Physical State: Granular
 Color: Gray to brown
 Odor: Mild fermentation odor
 Possible dust explosion hazard based on information on related materials.

POTENTIAL HEALTH EFFECTS

Relevant Routes of Exposure: Inhalation, skin contact, eye contact, ingestion
 Target Organs: Respiratory system, gastrointestinal system, hematopoietic / blood system, renal system, hepatic system, immune system, skeletal system.

Acute Effects

General: May cause mucous membrane irritation (inflammation). May cause hepatic (liver) system effects. Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes). May cause gastrointestinal effects such as nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite. May cause renal (kidney) system effects such as urine retention, increase or decrease in urine production, painful urination, and presence of blood in urine. May cause respiratory effects such as difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest. May cause musculoskeletal effects such as muscle weakness or pain and skeletal abnormalities. May cause allergic reactions.

Skin: May cause skin irritation.

Eye: May cause eye irritation.

Chronic Effects

General: May cause blood system effects.

Carcinogenicity: Not listed by NTP, IARC, or OSHA.

Reproductive Toxicity:

Chlortetracycline: Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. It is also advisable for nursing mothers to exercise caution regarding exposure.

Conditions Aggravated: Hypersensitivity to this material. Liver conditions and/or impaired liver function. Kidney conditions and/or impaired renal function. Respiratory system conditions.

Additional Health Hazard Information: Since this material has been shown to be excreted in breast milk, nursing mothers should exercise caution regarding exposure.

 SECTION 4. FIRST AID MEASURES

Inhalation: Remove to fresh air. If discomfort occurs or persists, get medical attention.
 Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
 Eye Contact: Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
 Ingestion: If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

 SECTION 5. FIRE FIGHTING MEASURES

Flash Point: Not applicable
 Extinguishing Media: Water, carbon dioxide, dry chemical, foam
 Unusual Fire and Explosion Hazards: Possible dust explosion hazard based on information on related materials. Toxic emissions may be given off in a fire. See "Decomposition Products" in "Section 10. Stability and Reactivity".
 Fire Fighting Instructions: Wear NIOSH/MSHA approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Remove containers of this material if it can be done safely. Use water to keep fire exposed containers cool.

 SECTION 6. ACCIDENTAL RELEASE MEASURES

Spill Clean Up Procedures: Review "Section 3. Hazards Identification", and "Section 8. Exposure Controls/Personal Protection" before proceeding with the clean up. Shut off the source of the spill or leak if it is safe to do so. Eliminate possible ignition sources. Scoop or shovel spilled material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Clean spill area thoroughly.
 Treatment and Disposal: Decontaminate all protective clothing and equipment. Dispose of in accordance with recommendations in "Section 13. Disposal Considerations".
 Reporting Requirements: The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. State and local regulations vary and may impose additional reporting requirements.

 SECTION 7. HANDLING AND STORAGE

Handling & Storage Precautions: Do not generate dust or expose to ignition sources. Ground and bond all transfer equipment. Milling/mixing/drying should be performed in devices equipped with explosion relief or suppression systems or under inert conditions. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid breathing dust. When handling, use proper personal protective equipment specified in Section 8. Wash thoroughly after handling. Keep container tightly closed when not in use. Store in a well ventilated area at room temperature.

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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS

Ventilation: General room ventilation is adequate unless the process generates airborne dust or fume.

PERSONAL PROTECTION

Respirator Type(s): Half face, negative pressure air purifying, toxic dust/mist/fume high efficiency filter.

Conditions for Use: Under normal conditions of use, respiratory protection is not expected to be necessary. Respiratory protection is recommended under excessively dusty conditions. OSHA considers effective engineering controls to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. Whenever respiratory protection is used, a complete respirator program should be developed in accordance with OSHA Subpart I (29CFR1910.134) requirements.

Glove Materials: Any plastic or rubber glove.

Conditions for Use: Gloves are recommended if there is a potential for skin contact.

Skin Protection: None required under normal and foreseeable conditions of use. Consult the protective clothing manufacturer, supplier, and/or industrial hygienist.

Eye Protection: Safety goggles recommended.

EXPOSURE LIMITS

Magnesium stearate

ACGIH TLV: 10.0 mg/m³ Time weighted average, total dust

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Granular

Color: Gray to brown

Odor: Mild fermentation odor

Pure/Mixture: Mixture

pH: 7-9

H₂O Solubility: Slightly soluble (0.1-1% by weight)

SECTION 10. STABILITY AND REACTIVITY

Stability: Normally stable even under fire exposure conditions and not water reactive

Conditions to Avoid:

Dust accumulation

Airborne dust

Sources of ignition

Incompatibility - Materials to Avoid: Unknown

Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and sulfur dioxide.

Polymerization: No

Conditions of Polymerization: Will not occur

SECTION 11. TOXICOLOGICAL INFORMATION

Chlortetracycline:

Acute Oral, Single Dose, Rat: >3000 mg/kg

Summary: Acute oral LD₅₀ (rat) is greater than 3000 mg/kg body weight in both rats and mice.

Irritation Eye, Rabbit

Summary: This material is mildly irritating to rabbit eyes.

Irritation Skin, Rabbit

Summary: This material is mildly irritating to rabbit skin.

SECTION 12. ECOLOGICAL INFORMATION

Ecological Information: No ecological data available on this material.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal Recommendations: This material is suitable for incineration. These recommendations are based on the product as shipped. Use, processing, alteration, or contamination may affect these disposal recommendations. State, local, or site restrictions affecting the available proper disposal options may vary.

RCRA Waste #: Not regulated under RCRA

Empty Containers: Empty containers must be triple rinsed prior to disposal, recycling, or reuse.

SECTION 14. TRANSPORTATION INFORMATION

Enforcement Agency: US Department of Transportation

Country/Community: USA

Proper Ship. Name: Non-regulated

Enforcement Agency: International Air Transport Association

Country/Community: International

Proper Ship. Name: Non-regulated

Enforcement Agency: International Maritime Organization

Transportation Mode: Ocean

Country/Community: International

Proper Ship. Name: Non-regulated

SECTION 15. REGULATORY INFORMATION

Law/Regulation: Hazardous Chemical Reporting: Community Right-To-Know 40CFR370

Common Name: SARA Title III Section 312 - Hazardous Chemical Inventory

Enforcement Agency: Environmental Protection Agency (EPA)

Governing Authority: USA

Criteria Met: Acute, Fire

Law/Regulation: Safe Drinking Water and Toxic Enforcement Act of 1986 Proposition 65

Common Name: Prop 65

Enforcement Agency: California Environmental Protection Agency

Governing Authority: California, USA

Criteria Met: Formulation contains a member of the tetracyclines which are known to the State to cause reproductive toxicity.

SECTION 16. OTHER INFORMATION

Additional Information: NFPA RATING: These ratings are based on NFPA Code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material.

. Health	1
. Fire	1
. Reactivity	0

APPROVAL INFORMATION

Preparer . Kathy Steiger

Approver . Regulatory Affairs

Approval Date: 05/02/00

Previous Approval Date: 01/24/96

Reason For Issue: Change in ownership and product code

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