Aureomycin 50 G

AUREOMYCIN® 50 G (US)

Page:

Approved: 10/31/02

Alpharma Inc.

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MATERIAL SAFETY DATA SHEET

CHEMICAL PRODUCT AND COMPANY IDENTIFICATION SECTION 1.

Product Name AUREOMYCIN® 50 G

Product Codes...... 700135

TSCA Status All ingredients are on the TSCA Inventory.

SECTION 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS Number	Concentration %
Chlortetracycline	57-62-5	11
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.

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SECTION 3. HAZARDOUS IDENTIFICATION (Continued . . .)

Acute Effects

(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

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.

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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

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. Exposure Controls/Personal Protection".

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

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.

protective clothing manufacturer, supplier, and/or industrial hygienist.

Eye Protection: Safety goggles recommended.

EXPOSURE LIMITS

Chlortetracycline

IOEL..... 0.200 mg/m3

Magnesium stearate

ACGIH TLV: 10.0 mg/m3 8 hour 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

sulfur dioxide.

Polymerization: No

Conditions of

Polymerization Will not occur

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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 the rabbit eyes.

Irritation Skin, Rabbit

Summary: This material is mildly irritating to the 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 Dept. 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

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SECTION 15. REGULATORY INFORMATION (Continued . . .)

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

use by emergency personnel to determine the immediate hazards of a material.

......Health 1Fire 1Reactivity 0

APPROVAL INFORMATION

Preparer: Kathy Steiger Approver Regulatory Affairs

Approval Date: 10/31/02 Previous Approval Date ...: 05/10/00

Reason For Issue: To delete incorrect product code numbers.

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