

V# 2542 Greenstone Limited -CS
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MATERIAL SAFETY DATA SHEET

Revision date: 30-Sep-2005

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Greenstone Limited
100 Route 206 North
Peapack, NJ 07977

Emergency telephone number: 800-435-7095

Material Name: Azithromycin Powder for Oral Suspension

Trade Name: Not applicable
Synonyms: None
Chemical Family: Azalide
Intended Use: Antibiotic agent

2. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Azithromycin dihydrate	117772-70-0	Not listed	9.5
Sucrose	57-50-1	200-334-9	*

Ingredient	CAS Number	EU EINECS List	%
FD & C Red No. 40	25956-17-6	247-368-0	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Xanthan gum	11138-66-2	234-394-2	*
Spray dried artificial banana flavor	MIXTURE	Not listed	*
Spray dried artificial cherry flavor	MIXTURE	Not listed	*
Sodium phosphate tribasic, anhydrous	7601-54-9	231-509-8	*
Spray dried artificial creme de vanilla flavor	MIXTURE	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white powder with a cherry-vanilla-banana odor
Signal Word: None required

Statement of Hazard: • Non-hazardous in accordance with international standards for workplace safety.

Eye Contact: May cause eye irritation.
Skin Contact: May cause skin irritation.
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: Accidental ingestion may cause effects similar to those seen in clinical use. See 'Known clinical effects' and 'Other potential health effects', below.
Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.
Potential Health Effects: Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If discomfort persists, get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Spills should be handled by vacuuming or wet mopping. Avoid generating airborne dust. Close container and move it to a secure holding area.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use appropriate ventilation. Minimize dust generation and accumulation. Avoid breathing dust.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Azithromycin dihydrate

Manufacturer OEL: 0.5mg/m³

Sucrose

OSHA - Final PELs - TWAs
15 mg/m³ total dust
5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)
10 mg/m³ TWA

Analytical Method: (Contact Greenstone for additional details)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Chemical protective gloves
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder
Color: White to off-white
Odor: Cherry, vanilla and banana
Molecular Formula: Mixture
Molecular Weight: Mixture

Partition Coefficient (n-octanol/water - ELog D): 0.65 @ 20°C & pH= 7 (azithromycin)

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: Strong oxidizers

Polymerization: Will not occur

This material presents a weak to moderate dust explosion hazard has moderate sensitivity to ignition

Max. Explosion Pressure (bar): 7.7
Max. Rate of Pressure Rise (bar/sec): 433
Kst Value (bar²m/s): 118
St Class: 1
Min. Ignition Energy (mJ): 25-50
Min. Ignition Temperature (°C): 380-390
Limiting Oxygen Concentration (% vol): 9.8-11.5
Min. Explosion Concentration (g/m³): 100-110 g/m³ 4.10 x 10⁵

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Ambient Humidity: 4.0E5 See below
Ambient Humidity: 1:30 min.
Low Humidity: 1.7 hrs.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Sucrose

Rat Oral LD50 29.7 g/kg

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Azithromycin dihydrate

Mouse (F) Oral LD50 4000 mg/kg

Mouse (M) Oral LD50 3000mg/kg

Rat Oral LD50 > 2000mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Azithromycin dihydrate

Antigenicity- Passive cutaneous anaphylaxis Guinea Pig No effect

Eye Irritation / Sensitization

Azithromycin may be slightly irritating to eyes, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.

Skin Irritation / Sensitization

Azithromycin may be slightly irritating to skin, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Azithromycin dihydrate

6 Month(s) Rat Oral 10 mg/kg/day LOEL Liver

6 Month(s) Dog Oral 10 mg/kg/day LOEL Liver

1 Month(s) Rat Intravenous 5 mg/kg/day NOEL Liver

1 Month(s) Dog Intravenous 5 mg/kg/day NOEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Azithromycin dihydrate

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility

Prenatal & Postnatal Development Mouse Oral 40 mg/kg/day NOEL Not Teratogenic

Prenatal & Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Azithromycin dihydrate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Cytogenetics Mouse Lymphoma Negative

In Vitro Cytogenetics Mouse Negative

In Vitro Cytogenetics Human Lymphocytes Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12. ECOLOGICAL INFORMATION

Environmental Overview: In the environment, the active ingredient in this formulation is expected to mainly reside in the aquatic environment and slowly degrade.

Mobility, Persistence and Degradability: Azithromycin half life < 28 days (Aerobic Biodegradation - Water)

Bioaccumulation and Toxicity: The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

Partition Coefficient (n-octanol/water - ELog D): 0.65 @ 20°C & pH= 7 (azithromycin)

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Azithromycin dihydrate

Daphnia magna	EC50	48 Hours	120 mg/L
Hyallela azteca	LC50	96 Hours	> 120 mg/L
Lumbricus terrestris	LC50	28 Days	> 1000 mg/kg
Activated sludge	IC50	269 mg/L	
Aspergillus niger	MIC	> 1000 mg/L	

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Labeling: None required
EU Indication of danger: Not classified

EU EINECS List: Not Listed
EU ELINCS List: Not Listed

OSHA Label:
None required
• Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

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WHMIS hazard class:

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

FD & C Red No. 40

EU EINECS List	247-368-0
Inventory - United States TSCA - Sect. 8(b)	Listed

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
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Xanthan gum

EU EINECS List	234-394-2
Inventory - United States TSCA - Sect. 8(b)	Listed

Sucrose

EU EINECS List	200-334-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Sodium phosphate tribasic, anhydrous

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
EU EINECS List	231-509-8
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet