



SAFETY DATA SHEET

Revision date: 25-Sep-2014

Version: 2.0

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

Product Identifier

Material Name: Azithromycin Powder for Oral Suspension (Greenstone LLC)

Trade Name: Not applicable

Chemical Family: Azalide

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Greenstone LLC

100 Route 206 North

Peapack, NJ 07977

800-435-7095

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: May form combustible dust concentrations in air

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Azithromycin dihydrate	117772-70-0	Not Listed	Not Listed	Not Listed	9.5

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

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

Azithromycin dihydrate

Manufacturer OEL:	500ug/m ³
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Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

FD & C Red No. 40

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Hydroxypropyl cellulose

No data available

Sucrose

No data available

Xanthan gum

No data available

Spray dried artificial banana flavor

No data available

Spray dried artificial creme de vanilla flavor

No data available

Spray dried artificial cherry flavor

No data available

Sodium phosphate tribasic, anhydrous

No data available

Azithromycin dihydrate

Measured 7 Log P 0.67

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available. 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 (bar*m/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 See below

Polymerization: Will not occur

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

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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10. STABILITY AND REACTIVITY

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

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

Short Term:

May cause irritation (based on animal data) .

Long Term:

Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.

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.

Irritation / Sensitization: (Study Type, Species, Severity)

Azithromycin dihydrate

Antigenicity- Active anaphylaxis Guinea Pig Negative

Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative

Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

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))

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11. TOXICOLOGICAL INFORMATION

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)

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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.

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.

Toxicity:

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

Azithromycin dihydrate

<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	120 mg/L
<i>Hyallela azteca</i> (Freshwater Amphipod)	OECD	LC50	96 Hours	> 120 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	> 84 mg/L
Green Algae	OECD	EC50	72 Hours	0.0037 mg/L
<i>Microcystis aeruginosa</i> (Blue-green Alga)	OECD	ErC50	96 Hours	0.0018 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Azithromycin dihydrate

<i>Aspergillus niger</i> (Fungus)	OECD	MIC	> 1000 mg/L
<i>Trichoderma viride</i> (Fungus)	OECD	MIC	> 1000 mg/L
<i>Clostridium perfringens</i> (Bacterium)	OECD	MIC	2.0 mg/L
<i>Bacillus subtilis</i> (Bacterium)	OECD	MIC	2.0 mg/L

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

Azithromycin dihydrate

Eisenia foetida (Earthworm) TAD NOEC 28 Days 1000 mg/kg

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

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Azithromycin dihydrate

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 4.6 mg/L Survival
Ceriodaphnia dubia (Daphnids) OPPTS 7 Day(s) NOEC 0.0044 mg/L Reproduction

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Azithromycin dihydrate

Measured 7 Log P 0.67

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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.

Spray dried artificial creme de vanilla flavor

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

Not Listed

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15. REGULATORY INFORMATION

Spray dried artificial banana flavor	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Spray dried artificial cherry flavor	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Sodium phosphate tribasic, anhydrous	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-509-8
FD & C Red No. 40	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-368-0
Hydroxypropyl cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Xanthan gum	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	234-394-2
Sucrose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9
Azithromycin dihydrate	
CERCLA/SARA 313 Emission reporting	Not Listed

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15. REGULATORY INFORMATION

California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

16. OTHER INFORMATION

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date: 25-Sep-2014
Product Stewardship Hazard Communication

Prepared by: Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet