



SAFETY DATA SHEET

Revision date: 18-Jan-2019

Version: 2.1

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

Product Identifier

Material Name: Azithromycin Film-Coated Tablets (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

Label Elements

Signal Word: Not required

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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	GHS Classification	%
Azithromycin dihydrate	117772-70-0	Not Listed	Not Listed	56
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

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

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

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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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Minimize dust generation and accumulation. Use appropriate ventilation. 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.

Azithromycin dihydrate	
Manufacturer OEL:	500ug/m ³
Calcium phosphate dibasic, anhydrous	
Latvia OEL - TWA	10 mg/m ³
Starch, pregelatinized	
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
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³
Portugal OEL - TWA	4 mg/m ³
Slovakia OEL - TWA	15 mg/m ³
Spain OEL - TWA	10 mg/m ³
Magnesium stearate	
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Film-coated tablets	Color:	Pink
Odor:	No data available.	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)

Croscarmellose sodium

No data available

Calcium phosphate dibasic, anhydrous

No data available

Starch, pregelatinized

No data available

Magnesium stearate

No data available

Sodium lauryl sulfate

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

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

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10. STABILITY AND REACTIVITY

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
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:	Dust may cause irritation if tablets are crushed or broken. 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)

Magnesium stearate

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m ³

Sodium lauryl sulfate

Rat	Oral	LD50	1288 mg/kg
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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)

Sodium lauryl sulfate

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild Moderate
Skin Sensitization - GPMT	Guinea Pig	Negative
Skin Sensitization - LLNA	Mouse	Negative

Azithromycin dihydrate

Antigenicity- Active anaphylaxis	Guinea Pig	Negative
Antigenicity- Passive cutaneous anaphylaxis	Rabbit	Negative
Antigenicity- Passive cutaneous anaphylaxis	Mouse	Negative

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

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11. TOXICOLOGICAL INFORMATION

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)

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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Azithromycin dihydrate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Cytogenetics	Mouse Lymphoma	Negative
<i>In Vitro</i> Cytogenetics	Mouse	Negative
<i>In Vitro</i> 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)

Sodium lauryl sulfate

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	3.6 mg/L
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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

Azithromycin dihydrate

<i>Eisenia foetida</i> (Earthworm)	TAD	NOEC	28 Days	1000 mg/kg
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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: No data available

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:

Non-controlled

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.

Azithromycin dihydrate

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

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15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
Croscarmellose sodium	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Calcium phosphate dibasic, anhydrous	
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	231-826-1
Starch, pregelatinized	
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	232-679-6
Magnesium stearate	
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	209-150-3

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 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	18-Jan-2019 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