

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**Product Identifier****Material Name:** Doxycycline Hyclate Capsules (Greenstone LLC)**Trade Name:** Not established**Chemical Family:** Mixture**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**

Reproductive Toxicity: Category 1A

EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:

R61 - May cause harm to the unborn child.

Label Elements**Signal Word:** Danger**Hazard Statements:** H360D - May damage the unborn child**Precautionary Statements:**

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations

**Other Hazards****Australian Hazard Classification (NOHSC):**

No data available

Hazardous Substance. Non-Dangerous Goods.

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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 | % |
|--|------------|-----------------------|-------------------|--------------------|-------|
| Doxycycline hyclate | 24390-14-5 | Not Listed | Repr.Cat 1;R61 | Repr. 1A (H360D) | 35-40 |
| Maize starch | 9005-25-8 | 232-679-6 | Not Listed | Not Listed | * |
| Magnesium stearate/sodium lauryl sulfate blend | MIXTURE | Not Listed | Not Listed | Not Listed | * |
| Sodium Lauryl Sulfate | 151-21-3 | 205-788-1 | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|-------------------------|------------|-----------------------|-------------------|--------------------|---|
| Lactose NF, monohydrate | 64044-51-5 | Not Listed | Not Listed | Not Listed | * |
| Hard gelatin capsules | MIXTURE | Not Listed | Not Listed | Not Listed | * |
| Alginic acid | 9005-32-7 | 232-680-1 | Not Listed | Not Listed | * |

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

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

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

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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.

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. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

Doxycycline hyclate

Manufacturer OEL: 250ug/m³

Maize starch

| | |
|-----------------------------------|------------------------|
| 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 |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 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.

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:

Capsule

Color:

Light blue

Odor:

Odorless

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)

Microcrystalline cellulose

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Magnesium stearate/sodium lauryl sulfate blend

No data available

Lactose NF, monohydrate

No data available

Sodium Lauryl Sulfate

No data available

Alginic acid

No data available

Maize starch

No data available

Doxycycline hyclate

No data available

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

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

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 allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver

Known Clinical Effects: May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

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11. TOXICOLOGICAL INFORMATION

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

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Sub-tenon injection (eye) LD 50 210mg/kg

Alginic acid

Rat Oral LD 50 >5 gm/kg

Doxycycline hyclate

Mouse Oral LD50 1900 mg/kg (hydrochloride)
Rat Oral LD50 > 2000mg/kg (hydrochloride)
Rat Intravenous LD50 228mg/kg (hydrochloride)
Rat (weanling) Intraperitoneal LD50 262mg/kg (hydrochloride)

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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

Skin Irritation / Sensitization Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Doxycycline hyclate

30 Day(s) Rat Oral 500 mg/kg NOEL None identified
18 Month(s) Rat Oral 50 mg/kg/day NOEL Thyroid, Bone
1 Year(s) Dog Oral < 10 mg/kg/day NOEL Liver

Subchronic Effects Rats administered doses of doxycycline hydrochloride up to 500 mg/kg/day for 30 days showed no toxic effects.

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

Doxycycline hyclate

Reproductive & Fertility-Females Rat Oral 250 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Monkey Oral 50 mg/kg/day NOEL No effects at maximum dose

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

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11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

| | |
|---------------------------------------|--|
| Environmental Overview: | The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided. |
| Toxicity: | No data available |
| Persistence and Degradability: | No data available |
| Bio-accumulative Potential: | No data available |
| 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:

Class D, Division 2, Subdivision A



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15. REGULATORY INFORMATION

Doxycycline hyclate

| | |
|------------------------------------|--|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | developmental toxicity initial date 10/1/91 internal use |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

Maize starch

| | |
|---|------------|
| 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 |

Lactose NF, monohydrate

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | Not Listed |

Magnesium stearate/sodium lauryl sulfate blend

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Sodium Lauryl Sulfate

| | |
|--|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 6 |
| EU EINECS/ELINCS List | 205-788-1 |

Hard gelatin capsules

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Alginic acid

| | |
|---|------------|
| 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 | 232-680-1 |

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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Revision date: 12-Mar-2015

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