

Doxycycline Hyclate Tablets

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 02/20/2015 Date of issue: 02/20/2015

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Doxycycline Hyclate Tablets

1.2. Intended Use of the Product

Use of the substance/mixture: Antibiotic.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Putney, Inc.

One Monument Square, Suite 400

Portland, ME 04101

1-866-683-0660

www.putneyvet.com

1.4. Emergency Telephone Number

Emergency Number : 1-866-683-0660 (Monday-Friday: 9:00 AM–4:00PM EST)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

2.2. Label Elements

GHS-US Labeling

No labeling is required as defined in the 29 CFR 1910.1200(b)(5)(iii).

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Doxycycline hyclate	(CAS No) 24390-14-5	50 - 75	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Cellulose	(CAS No) 9004-34-6	< 45	Comb. Dust
Croscarmellose sodium	(CAS No) 74811-65-7	< 5	Not classified
Magnesium stearate	(CAS No) 557-04-0	< 1	Comb. Dust
Titanium dioxide	(CAS No) 13463-67-7	< 1	Not classified
Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	(CAS No) 85586-07-8	< 0.5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 2, H401 Aquatic Chronic 3, H412
Polyethylene glycol	(CAS No) 25322-68-3	< 0.5	STOT SE 3, H335

The exact percentage of composition has been withheld as a trade secret [29 CFR 1910.1200].

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

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First-aid Measures After Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

First-aid Measures After Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water.

First-aid Measures After Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water. If easy to do, remove contact lenses. Get medical attention if irritation persists.

First-aid Measures After Ingestion: If accidental ingestion occurs, flush mouth out with water and obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: None expected under normal conditions of use.

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use.

Symptoms/Injuries After Eye Contact: None expected under normal conditions of use.

Symptoms/Injuries After Ingestion: Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid unnecessary contact with skin, eyes, or clothing. Avoid generating dust.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Collect spillage by scooping or shoveling and transfer to a closed waste container for disposal. If dust is present: vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use explosion proof vacuum during cleanup, with appropriate filter, do not mix with other materials.

6.4. Reference to Other Sections

No additional information available

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

7.3. Specific End Use(s)

Antibiotic.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Cellulose (9004-34-6)

USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)

Titanium dioxide (13463-67-7)

USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA IDLH	US IDLH (mg/m ³)	5000 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust)

8.2. Exposure Controls

Appropriate Engineering Controls

: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment

: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Hand Protection

: Wear protective gloves.

Eye Protection

: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and Body Protection

: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory Protection

: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State

: Solid

Appearance

: Light orange

Odor

: No data available

Odor Threshold

: No data available

pH

: No data available

Evaporation Rate

: No data available

Melting Point

: 200 °C (392 °F)

Freezing Point

: No data available

Boiling Point

: No data available

Flash Point

: No data available

Auto-ignition Temperature

: No data available

Decomposition Temperature

: No data available

Flammability (solid, gas)

: No data available

Vapor Pressure

: No data available

Relative Vapor Density at 20 °C

: No data available

Relative Density

: No data available

Solubility

: No data available

Partition Coefficient: N-Octanol/Water

: No data available

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Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under normal conditions.
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.
- 10.5. Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Doxycycline hyclate (24390-14-5)	
LD50 Oral Rat	1700 mg/kg
Magnesium stearate (557-04-0)	
LD50 Oral Rat	> 2000 mg/kg
Cellulose (9004-34-6)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 5800 mg/m ³ (Exposure time: 4 h)
Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)	
LD50 Oral Rat	> 1000 mg/kg
Titanium dioxide (13463-67-7)	
LD50 Oral Rat	> 10000 mg/kg
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 ml/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Titanium dioxide (13463-67-7)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: None expected under normal conditions of use.

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use.

Symptoms/Injuries After Eye Contact: May cause minor eye irritation.

Symptoms/Injuries After Ingestion: Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)	
LC50 Fish 1	10 - 100 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 Daphnia 1	2.8 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	2.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas)

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

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Sulfuric acid, mono-C12-14-alkyl esters, sodium salts (85586-07-8)	
BCF fish 1	2.1 - 11

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Magnesium stearate (557-04-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Cellulose (9004-34-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Titanium dioxide (13463-67-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Polyethylene glycol (25322-68-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Doxycycline hyolate (24390-14-5)

U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.
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Titanium dioxide (13463-67-7)

U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer.
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Cellulose (9004-34-6)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

Titanium dioxide (13463-67-7)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 02/20/2015
Data Sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2

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STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H232	May form combustible dust concentrations in air
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)