

Doxycycline Hyclate Tablets

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations (According to HCS-2012 APPENDIX D TO §1910.1200)

Date of issue: 03/07/2020

Revision date: 03/07/2020

Version: 1.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Trade name : Doxycycline Hyclate Tablets

1.2. Recommended use and restrictions on use

Recommended use : Antibiotic medicine
Restrictions on use : No information available

1.3. Supplier

Supplier : CHANGZHOU PHARMACEUTICAL FACTORY
Address: No.518 LAODONG EAST ROAD, CHANGZHOU, JIANGSU PROVINCE, CHINA
E-mail: chengyayun@czpharma.com
Telephone: 0519-68010600
Fax: 0519-88256855

Importer name
Address:
E-mail:
Telephone:
Fax:

1.4. Emergency telephone number

Emergency number : 0519-68010600

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS-US labelling

No labelling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

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Name	Product identifier	%
Doxycycline Hyclate	(CAS-No.) 24390-14-5	92
MCC PH112	(CAS-No.) 9004-34-6	2
Croscarmellose sodium	(CAS-No.) 74811-65-7	2
Colloidal silicon dioxide	(CAS-No.) 112945-52-5	2
Magnesium stearate	(CAS-No.) 557-04-0	2

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
- First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. Get medical advice if necessary.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects (acute and delayed)

- Potential adverse human health effects and symptoms : No data available.
- Symptoms/effects : No information available.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide (CO2).
- Unsuitable extinguishing media : No additional information available.

5.2. Specific hazards arising from the chemical

- Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Special protective equipment and precautions for fire-fighters

- Firefighting instructions : DO NOT fight fire when fire reaches explosives. Eliminate all ignition sources if safe to do so. Do not enter fire area without proper protective equipment, including respiratory protection. Keep upwind.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Remove ignition sources. Stop leak if safe to do so. Notify authorities if product enters sewers or public waters. Evacuate personnel to a safe area. Do not breathe gas/fumes/vapour/spray. Ensure adequate ventilation. Wear personal protective equipment.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage. Do not touch or walk on the spilled product. Sweep or shovel spills into appropriate container for disposal.

Methods for cleaning up : Mechanically recover the product.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Containers which are opened should be properly resealed and kept upright to prevent leakage. Keep away from heat and direct sunlight. Keep in a cool, well-ventilated place away from heat.

Storage conditions : Keep cool. Keep container tightly closed and in well ventilated place.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Doxycycline hyclate (24390-14-5)
Not applicable
MCC PH112(9004-34-6)
Not applicable
Croscarmellose Sodium(74811-65-7)
Not applicable
Colloidal Silicon Dioxide(112945-52-5)
Not applicable

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Magnesium stearate (557-04-0)

ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³ (inhalable particulate matter) 3 mg/m ³ (respirable particulate matter)
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8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation,
wear suitable respiratory equipment

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Yellow brown
Odour	: Weak odour
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: Not applicable

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Density	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive limits	: Not applicable
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

MCC PH112(9004-34-6)

LD50 oral rat	> 10 g/kg
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Croscarmellose Sodium(74811-65-7)

LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 7940 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: No data available.
Symptoms/effects	: No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming	: No known effects from this product.
GWPmix comment	: No known effects from this product.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

Not applicable

Transportation of Dangerous Goods

Not applicable

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Transport by sea

Not applicable

Air transport

Not applicable

SECTION 15 : Regulatory information

15.1 . US Federal regulations

MCC PH112 (9004-34-6)

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

Magnesium stearate (557-04-0)

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

15.2. International regulations

CANADA

No additional information available

MCC PH112 (9004-34-6)

Listed on the Canadian DSL (Domestic Substances List)

Magnesium stearate (557-04-0)

Listed on the Canadian DSL (Domestic Substances List)

EU- Regulations

No additional information available

MCC PH112 (9004-34-6)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Magnesium stearate (557-04-0)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

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15.3. US State regulations

No additional information available

SECTION 16 : Other information

Revision date : 03/07/2020

Abbreviations and acronyms:

IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose

SDS US (GHS HazCom 2012) 20220119

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