

SAFETY DATA SHEET

Revision date: July 2018

Version: 2

Page 1 of 9

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

Product Identifier**Material Name: Oxytetracycline Hydrochloride Soluble Powder**

Trade Name: Oxytet® Soluble
Synonyms: Terramycin
Chemical Family: Tetracycline antibiotic

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

Intended Use: Veterinary product used as antibiotic agent
Restrictions on Use: Not for human use

Manufacturer/Supplier:

Huvepharma Inc.
1301 Iowa Ave.
Longmont, CO 80501

Huvepharma, Inc.
525 Westpark Drive, Suite 230
Peachtree City, GA 30269
Telephone: 1-770-486-7212

Emergency telephone number: 1-877-994-4883
Contact e-mail: customerservice@huvepharma.us

2. HAZARDS IDENTIFICATION

Appearance: Yellow powder

Classification of the Substance or Mixture**GHS - Classification**

Reproductive Toxicity: Category 1A
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 2A
Specific target organ toxicity, single exposure: Category 3 respiratory tract irritation

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements: H319- Causes serious eye damage
H360 - May damage fertility or the unborn child
May form combustible dust concentrations in air

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 2 of 9

Version: 2

Precautionary Statements: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
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

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on male reproductive system, liver, the developing fetus.

Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes (leukocytosis, atypical lymphocytes, toxic granulation of granulocytes and thrombocytopenia purpura), convulsion or shock may also occur. Clinical use of this drug has caused liver effects, kidney dysfunction.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	%
Citric Acid	77-92-9	50-70
Oxytetracycline hydrochloride	2058-46-0	30-50

Additional Information:

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.

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 3 of 9

Version: 2

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
- Ingestion:** Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
- Inhalation:** Remove to fresh air. Get 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:** Breathing dust may worsen asthma symptoms.

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, foam or water spray. Apply extinguishing media carefully to avoid creating airborne dust.

Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air. This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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. Avoid dust formation.

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:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 4 of 9

Version: 2

Additional Consideration for Large Spills: Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. 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

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. When handling, use appropriate personal protective equipment (see Section 8). 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 at room temperature in properly labeled containers. Keep away from heat, sparks, flame, and other sources of ignition. Keep away from direct sunlight.

Storage Temperature: 20-25°C with limited excursions from 15-40°C allowed

Specific end use(s): Veterinary antibiotic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Oxytetracycline hydrochloride

Huvepharma OEL TWA 8-hr

500 µg/m³

Exposure Controls

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

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

Hands: Wear impervious gloves if skin contact is possible.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory Protection: Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. It is recommended that a NIOSH approved respirator be used if needed.

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 5 of 9

Version: 2

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	Yellow
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)	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

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable at room temperature in closed containers under normal storage and handling conditions.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Keep away from heat, spark, flames and all other sources of ignition. Avoid dispersion as a dust cloud. Minimize dust generation and accumulation. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions. Avoid incompatible materials.
Incompatible Materials:	Keep away from strong oxidizers, bases
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, hydrogen chloride, chlorine, nitrogen oxides, and other toxic vapors.

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 6 of 9

Version: 2

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
Routes of exposure: eye contact, skin contact, inhalation

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

Oxytetracycline hydrochloride

Mouse	Oral	LD50	6696 mg/kg
Mouse	SC	LD50	> 600mg/kg
Rat	SC	LD50	800mg/kg
Mouse	IV	LD50	100mg/kg
Rat	IV	LD50	302mg/kg

Citric Acid

Rat	Oral	LD50	6730 mg/kg
Mouse	Oral	LD50	5040 mg/kg
Rat	Other	LD50	883 mg/kg
Mouse	Other	LD50	42 mg/kg
Rabbit	Other	LD50	330 mg/kg

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

Oxytetracycline hydrochloride

13 Week(s)	Mouse	Oral	3821 mg/kg/day	NOAEL	None identified
13 Week(s)	Rat	Oral	3352 mg/kg/day	NOAEL	Liver
12 Month(s)	Dog	Oral	125 mg/kg/day	NOAEL	Male reproductive system
24 Month(s)	Dog	Oral	250 mg/kg/day	NOAEL	None identified
14 Day(s)	Rat	Oral	108 g/kg	LOEL	Brain

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

Oxytetracycline hydrochloride

2 Generation Reproductive Toxicity	Rat	Oral	18 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	1500 mg/kg/day	NOAEL	Maternal Toxicity
Embryo / Fetal Development	Mouse	Oral	2100 mg/kg/day	NOAEL	Embryotoxicity,

Reproductive & Development Toxicity Comments:

May have the potential to produce effects on the developing fetus.

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 7 of 9

Version: 2

11. TOXICOLOGICAL INFORMATION

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Oxytetracycline hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
Micronucleus	Mouse	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive with activation

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Oxytetracycline hydrochloride

24 Month(s)	Rat	Oral, in feed	150 mg/kg/day	NOEL	Not carcinogenic
103 Week(s)	Mouse	Oral, in feed	1372 mg/kg/day	NOEL	Not carcinogenic

Carcinogen Status:

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

Chronic Effects

Prolonged inhalation may be harmful

Symptoms related to the physical, chemical and toxicological characteristics

Dust may irritate the respiratory tract, skin and eyes. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain.

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

Toxicity:

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

Oxytetracycline hydrochloride

Oncorhynchus mykiss (Rainbow Trout) ASTM EPA LC50 96 Hours > 116 mg/L

Daphnia magna (Water Flea) ASTM EPA EC50 48 Hours > 102 mg/L

Lepomis macrochirus (Bluegill Sunfish) ASTM EPA LC50 96 Hours > 94.9 mg/L

Selenastrum capricornutum (Green Alga) ISO EC50 72 Hours 4.18 mg/L

Aquatic Toxicity Comments:

A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability:

No data available

Bio-accumulative Potential:

No data available

Mobility in Soil:

No data available

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 8 of 9

Version: 2

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Should not be released into the environment. 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. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container.

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

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Citric Acid

This product is a "Hazardous Chemical" as defined by OSHA Hazard Communication Standard, 29 CFR 1910.1200

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Not Listed

Australia (AICS):

Not Listed

SARA 302 Extremely Hazardous

Not Listed

Substance

SARA Hazard Categories

Immediate Hazard- Yes
Delayed Hazard- No
Fire Hazard – Yes
Pressure Hazard- No
Reactivity Hazard- No

Oxytetracycline hydrochloride

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

developmental toxicity initial date 10/1/91 internal use

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

SAFETY DATA SHEET

Material Name: Oxytetracycline Hydrochloride Soluble Powder
Revision date: July 2018

Page 9 of 9

Version: 2

16. OTHER INFORMATION

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

Prepared by: Toxicology and Hazard Communication
Huvepharma Global Risk Management

Huvepharma Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without 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