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

**Product Identifier** 

Material Name: TET-SOL 324

TET-SOL® 324 **Trade Name:** 

Tetracycline Hydrochloride Soluble Powder Synonyms:

**Chemical Family:** Tetracycline derivative

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

Intended Use: Veterinary antibiotic agent

Restrictions on Use: Not for human use

**Details of the Supplier of the Safety Data Sheet** 

Zoetis Belgium S.A. Zoetis Inc. 100 Campus Drive, P.O. Box 651 Mercuriusstraat 20 Florham Park, New Jersey 07932 (USA) 1930 Zaventem Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896 **Belgium** 

Product Support/Technical Services Phone: 1-800-366-5288

**Emergency telephone number: Emergency telephone number:** 

CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: VMIPSrecords@zoetis.com

# 2. HAZARDS IDENTIFICATION

Appearance: Yellow crystalline powder

Classification of the Substance or Mixture

Reproductive Toxicity: Category 1A

**US OSHA Specific - Classification** 

Physical Hazard: Combustible Dust

**EU Classification:** 

EU Indication of danger: Toxic to reproduction: Category 1

EU Symbol:

EU Risk Phrases:

R61 - May cause harm to the unborn child.

**Label Elements** 

Signal Word:

Danger

**Hazard Statements:** H360D - May damage the unborn child

May form combustible dust concentrations in air

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**Precautionary Statements:** P201 - Obtain special instructions before use

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

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

P240 - Ground/Bond container and receiving equipment

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 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. Drugs of this class may cause liver and kidney effects

**Australian Hazard Classification** 

(NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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

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Ingredient	CAS Number	EU	<b>EU Classification</b>	GHS	%
		EINECS/ELINCS		Classification	
		List			
Tetracycline Hydrochloride	64-75-5	200-593-8	Repr.Cat.1;R61	Repro. 1A (H360)	324 g/lb

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

safety. For one or more ingredients, the chemical identity has been withheld as a trade secret.

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.

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**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 For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

**Medical Conditions** Breathing dust may worsen asthma symptoms.

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

### 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 Formation of toxic

**Products:** 

Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Dust can form an explosive mixture in air. 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

Avoid dust formation. 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 the spill if it is safe to do so. Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spilled material by a method that controls dust generation. Use non-combustible absorbent material to wipe up spill and place in a sealed

container for disposal. Clean contaminated surface 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**

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### 7. HANDLING AND STORAGE

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. Avoid open handling. Use local exhaust ventilation or perform work under fume hood/fume cupboard. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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 and

flames. Protect from light . Protect from moisture.

**Storage Temperature:** At or below 25°C (77°F)

**Incompatible Materials:** Strong oxidizing agents; moisture, alkalis

Veterinary antibiotic agent Specific end use(s):

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters** 

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

**Tetracycline Hydrochloride** 

**Zoetis OEL TWA 8-hr** 500 µg/m<sup>3</sup>

**Exposure Controls** 

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process

containment, local exhaust ventilation, or other engineering controls to maintain airborne levels

below recommended exposure limits.

Refer to applicable national standards and regulations in the selection and use of personal **Personal Protective** 

protective equipment (PPE). **Equipment:** 

Wear impervious gloves as minimum protection. Hands: Wear safety glasses as minimum protection. Eves:

Wear impervious protective clothing when handling this compound. Skin:

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:** Crystalline powder Color: Yellow

Odorless Odor. **Odor Threshold:** No data available. Molecular Formula: C22 H24 N2 O8 \* HCI (active) **Molecular Weight:** 480.90 (active)

Slightly soluble: Alcohol Insoluble: Acetone **Solvent Solubility:** 

No data available Water Solubility: Solubility: Soluble: Water pH: No data available.

**Melting/Freezing Point (°C):** 223

**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

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No data available Vapor Pressure (kPa): No data available Vapor Density (g/ml): **Relative Density:** No data available Viscosity: No data available

Flammablity:

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 under normal conditions of use.

**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. Dust may form explosive mixture in air. Fine particles (such as dust and mists)

may fuel fires/explosions.

Strong oxidizing agents; moisture, alkalis **Incompatible Materials:** 

**Hazardous Decomposition** Toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and

**Products:** other chlorine-containing compounds may be emitted.

### 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)

**Tetracycline Hydrochloride** 

Rat Oral LD50 6443 mg/kg Mouse Oral LD50 2759mg/kg Rat Intravenous LD50 128mg/kg Mouse Intravenous LD50 157mg/kg

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

**Tetracycline Hydrochloride** 

14 Day(s) Rat Oral 50,000 ppm NOAEL No effects at maximum dose

13 Week(s) Rat Oral 12,500 ppm **NOAEL** Liver, Bone

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Tetracycline Hydrochloride** 

LOAEL Fertility and Embryonic Development Rat Subcutaneous 240 mg/kg/day Embryotoxicity Fertility and Embryonic Development Rat 240 mg/kg/day Fetotoxicity Intramuscular LOAEL

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#### 11. TOXICOLOGICAL INFORMATION

Fertility and Embryonic Development Mouse Intraperitoneal 150 mg/kg/day LOAEL Developmental toxicity,

Reproductive & Development

**Toxicity Comments:** 

Product may have the potential to produce effects on the developing fetus.

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

**Tetracycline Hydrochloride** 

Bacterial Mutagenicity (Ames) Salmonella Negative

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

Sex-Linked Recessive Lethal Test Drosophila Negative

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

**Tetracycline Hydrochloride** 

2 Year(s) Rat Oral, in feed 25,000 ppm NOAEL Not carcinogenic 2 Year(s) Mouse Oral, in feed 25,000 ppm NOAEL Not carcinogenic

<u>Carcinogen Status:</u> Not listed as a carcinogen by IARC, NTP or US OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. 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.

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## 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.



**Tetracycline Hydrochloride** 

**EU EINECS/ELINCS List** 

CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):

1.0 %

developmental toxicity initial date 1/1/91 internal use

Present Present 200-593-8

## **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:**The data contained in this SDS 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 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated

Section 15 - Regulatory Information.

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**Prepared by:**Toxicology and Hazard Communication
Zoetis Global Risk Management

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**End of Safety Data Sheet** 

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