MATERIAL SAFETY DATA SHEET

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

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Material Name: Oxytetracycline hydrochloride liquid concentrate

Trade Name: Not determined
Synonyms: TERRAMYCIN® liquid concentrate
Chemical Family: Tetracycline derivative
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sodium hydroxide	1310-73-2	215-185-5	*
Magnesium chloride hexahydrate	7791-18-6	Not listed	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	*
Sodium formaldehyde sulfoxylate - NF	149-44-0	205-739-4	*

Ingredient	CAS Number	EU EINECS List	%
Propylene glycol	57-55-6	200-338-0	*
Povidone	9003-39-8	Not listed	*
Water, purified	7732-18-5	231-791-2	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Yellow liquid
Signal Word: CAUTION

Statement of Hazard: May cause eye, skin and respiratory tract irritation Infants of mothers exposed during pregnancy may develop discoloration of the teeth

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.

Skin Contact: Prolonged or repeated contact may cause defatting and drying of the skin.

Inhalation: May cause nose, throat and lung irritation.

Ingestion: None known

Known Clinical Effects: 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. May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal 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.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Review Sections 3, 8 and 12 before proceeding with clean up. Contain the source of the spill or leak if it is safe to do so. Dike, pump, or use non-combustible material to absorb spill; then place in a suitable, labeled recovery container. Transfer all waste to a labeled container and move it to a secure holding area. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash water with a non-combustible absorbant material and transfer to labeled container for treatment and disposal.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use only in a well-ventilated area. Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature 15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sodium hydroxide

OSHA - Final PELS - TWAs 2 mg/m³

Oxytetracycline hydrochloride

Pfizer OEL TWA-8 Hr: 0.5 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method: Oxytetracycline: CAM-KAS-99-003; STP O 12.93 (contact Pfizer for additional details).

Engineering Controls: Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Rubber gloves
Eyes: Safety glasses or goggles
Skin: None required under normal and foreseeable conditions of use. Wash hands and arms thoroughly after handling this material.
Respiratory protection: None required under normal conditions of use. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid	**Color:**	Yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Contact with moist air causes darkening of this material. Direct sunlight, excessive heat, sparks or open flame

Incompatible Materials: Bases

Hazardous Decomposition Products: No data available See Section 5 - under Hazardous combustion products.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

Carcinogenicity: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
NTP: Not classified
IARC: Not classified
OSHA: No

Magnesium chloride hexahydrate
Rat Oral LD 50 8100 mg/kg
Mouse Oral LD 50 7600mg/kg

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

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Propylene glycol
Mouse Oral LD50 22 g/kg
Rat Oral LD50 20 g/kg
Rabbit Dermal LD50 20.8 g/kg

Povidone
Rat Oral LD50 100 g/kg

Ingestion Acute Toxicity The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient it contains.

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Magnesium chloride hexahydrate
13 Week(s) Mouse Oral273 g/kg LOEL Kidney, Ureter, Bladder

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

Subchronic Effects

Subacute and subchronic toxicity studies of oxytetracycline hydrochloride were performed in mice and rats for 14 days and 13 weeks. In the 14-day studies, no compound-related gross pathologic effects were seen in mice or rats given up to 100,000 ppm in their feed. In the 13-week studies, no compound-related gross or histopathologic effects were observed in male or female mice or in female rats given up 50,000 ppm in their diet. In male rats, fatty metamorphosis of minimal severity was observed in the liver in all treated animals.

Chronic Effects/Carcinogenicity

Long-term studies of oxytetracycline hydrochloride toxicity were conducted by the US National Toxicology Program (NTP) in mice at doses up to 1400 mg/kg/day and in rats at doses up to 2000 mg/kg/day. In mice, no compound-related increases in non-neoplastic or neoplastic lesions were observed in males or females. In rats, increased incidences of pheochromocytomas of the adrenal gland in males and adenomas of the pituitary gland in females were observed. Under the conditions of these 2-year studies, the US National Toxicology Program concluded that there was equivocal evidence of carcinogenicity in male and female rats but no evidence of carcinogenicity in male or female mice.

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 Effects

Effects on fertility (litter size) and embryo- or fetotoxicity were observed in rats at subcutaneous dose of oxytetracycline at 1000 mg/kg, in rabbits at intramuscular dose of 789 mg/kg, and in dogs at 643 mg/kg (no other details reported). Tetracyclines as a class are capable of crossing the placenta and causing staining of the primary teeth.

Teratogenicity

No increase in congenital defects was found in mice and rats treated with oxytetracycline at oral doses of 1500 and 2100 mg/kg on days 6 - 15 of gestation, respectively. In rabbits, oxytetracycline was administered intramuscularly at 41.5 mg/kg/day from days 10 to 28 of gestation. The number and percentage of partial and total resorptions were significantly increased; no effects on fetal body weight were observed. No abnormalities were found at necropsy. Liver Reproductive system

Mutagenicity

No evidence of mutagenicity was observed in the Ames test using S. typhimurium strains in the presence or absence of metabolic activation. Oxytetracylcine hydrochloride was mutagenic in mouse lymphoma cells L5178Y/TK in the presence but not in the absence of metabolic activation. It was weakly positive in inducing sister chromatid exchanges in cultured Chinese hamster ovary cells with and without metabolic activation but did not induce chromosomal aberrations.

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.

Povidone

IARC: Group 3

At increase risk from exposure:

Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure. Individuals with alcoholic liver disease and also individuals with hyperlipidemia, especially hypertriglyceridemia, may be more likely to exhibit fatty changes from tetracycline.

12. ECOLOGICAL INFORMATION

Environmental Overview: See Aquatic toxicity data of the active ingredient, below:

Oxytetracycline hydrochloride
Rainbow Trout LC50 > 116 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Oxytetracycline hydrochloride liquid concentrate

15. REGULATORY INFORMATION

EU Labeling: None required
EU Indication of danger: Not classified

OSHA Label:
CAUTION
May cause eye, skin and respiratory tract irritation Infants of mothers exposed during pregnancy may develop discoloration of the teeth

Canada - WHMIS: Classifications

WHMIS hazard class:
EU Classification/Labelling: Not classified.

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ 454 kg final RQ
EU EINECS List	215-185-5
Inventory - United States TSCA - Sect. 8(b)	Listed

Propylene glycol

EU EINECS List	200-338-0
Inventory - United States TSCA - Sect. 8(b)	Listed

Povidone

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

Oxytetracycline hydrochloride

California Proposition 65	developmental toxicity, initial date 10/1/91 (internal use)
EU EINECS List	218-161-2
Inventory - United States TSCA - Sect. 8(b)	Listed

Water, purified

EU EINECS List	231-791-2
Inventory - United States TSCA - Sect. 8(b)	Listed

Sodium formaldehyde sulfoxylate - NF

EU EINECS List	205-739-4
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet