MATERIAL SAFETY DATA SHEET

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

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Material Name: TERRAMYCIN-343® soluble powder blend

Trade Name: Not determined
Synonyms: Oxytetracycline hydrochloride soluble powder blend
Chemical Family: Tetracycline derivative
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sucrose	57-50-1	200-334-9	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	*
Betaine hydrochloride	590-46-5	209-683-1	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Yellow powder
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. May cause skin irritation. May cause allergic reactions in susceptible individuals. Prolonged or repeated contact may cause allergic reaction.

Inhalation: May cause nose, throat and lung irritation. May cause allergic reaction.

Ingestion: Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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. 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.

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. Wipe up with a damp cloth and place in 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. Vacuum or sweep material into appropriate recovery container. Close container and move it to a secure holding area.

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. Minimize dust generation and accumulation. Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing dust.

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

Sucrose

OSHA - Final PELS - TWAs	15 mg/m³ total dust 5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Oxytetracycline hydrochloride

Pfizer OEL TWA-8 Hr:	0.5 mg/m³

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. 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:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:	Powder	**Color:**	Yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solubility: Insoluble: Water

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:	Exposure to high temperatures may cause decomposition of the active ingredient. Toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds may be emitted.
Polymerization:	Will not occur

Possible dust explosion hazard (material has not been evaluated).

11. TOXICOLOGICAL INFORMATION

NTP:	Not classified
IARC:	Not classified
OSHA:	No

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

Sucrose
Rat Oral LD50 29.7 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 acutely toxic by ingestion based on the amount of the active ingredient(s) it contains.

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.

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.

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: Not listed as a carcinogen by IARC, NTP or US OSHA.

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.

Additional Information: PREGNANCY RISK FACTOR D. Results of animal studies indicate that tetracyclines as a class cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy. Tetracyclines as a class are also known to cause tooth discoloration in young children and children exposed to the drug in utero.

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: TERRAMYCIN-343® soluble powder blend

15. REGULATORY INFORMATION

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.

Sucrose

EU EINECS List	200-334-9
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

Betaine hydrochloride

EU EINECS List	209-683-1
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet