# MATERIAL SAFETY DATA SHEET

## SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

**Pfizer Inc**
**Animal Health Group**
**812 Springdale Drive**
**Exton, PA 19341**

**Emergency telephone** 1-800-228-5635
**Hours of operation** 24 Hours
**Telephone** 1-800-877-6250

**Product name** **TERRAMYCIN® ophthalmic ointment**

**Synonyms** TERRAMYCIN® ophthalmic ointment; Oxytetracycline hydrochloride/polymyxin B sulfate ophthalmic ointment

**Chemical family** Tetracycline derivative

**Therapeutic use** Antibiotic agent

**Description** Light yellow ointment

## SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

| Hazardous Ingredient | CAS Number | Amount |
|---|---|---|
| White petrolatum | 8009-03-8 | Trade Secret |
| Mineral oil, heavy | 8042-47-5 | Trade Secret |
| Oxytetracycline hydrochloride | 2058-46-0 | Trade Secret |
| Polymyxin B sulfate | 1405-20-5 | Trade Secret |

## SECTION 3 - HAZARDS IDENTIFICATION

**CERCLA ratings (scale 0-3)** Health=1 Fire=0 Reactivity=0

**NFPA ratings (scale 0-4)** Health=1 Fire=0 Reactivity=0

**Signal word** **CAUTION!**

**Statements of hazard** INFANTS OF MOTHERS EXPOSED DURING PREGNANCY MAY DEVELOP DISCOLORATION OF THE TEETH.

**Eye**

**Short term effects** Not known or expected.

**Long term effects** Not known or expected.

**Skin**

**Short term effects** Not known or expected.

**Long term effects** Not known or expected.

**Inhalation**

**Short term effects** Not known or expected.

**Long term effects** Not known or expected.

**Ingestion**

**Short term effects** Ingestion of this material may cause effects similar to those generally seen in

## SECTION 3 - HAZARDS IDENTIFICATION continued

| | |
|---|---|
| | clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Persons sensitive to this material or other materials in its chemical class may develop allergic reactions. |
| **Long term effects** | Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, yellowing of the skin and eyes, tooth discoloration, nausea, vomiting, diarrhea, stomach pain, and chest pain. 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. |

## SECTION 4 - FIRST AID MEASURES

| | |
|---|---|
| **Eyes** | Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention. |
| **Skin** | Wash skin with soap and plenty of water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention. |
| **Inhalation** | Remove to fresh air. If discomfort persists, get medical attention. |
| **Ingestion** | If swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |

## SECTION 5 - FIRE FIGHTING MEASURES

| | |
|---|---|
| **General hazard** | Toxic or corrosive emissions may be given off in a fire. See Hazardous combustion products, below, and Hazardous decomposition products in Section 10 - STABILITY AND REACTIVITY. |
| **Fire fighting instructions** | Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. |
| **Extinguisher to use** | Use carbon dioxide, dry chemical, or water spray. |
| **Hazardous combustion products** | Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds. |
| **Flash point** | Not applicable |
| **Autoignition** | Not applicable |
| **Minimum explosive concentration for dust/vapor** | Not applicable |
| **Flammability limits** | Not applicable |

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

| | |
|---|---|
| **Occupational spill** | Contain the source of the spill or leak if it is safe to do so. Absorb spills with noncombustible material and transfer to labeled container for treatment and disposal. Clean spill area thoroughly. |
| **Clean up - large spill** | Review Sections 3, 8 and 12 before proceeding with clean up. Use appropriate containment to avoid environmental contamination. Absorb with non-combustible material. Put saturated absorbent material into a labeled container. Close container and move it to a secure holding area. |

## SECTION 7 - HANDLING AND STORAGE

| | |
|---|---|
| **General handling** | Keep away from heat. Use with adequate ventilation. Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. Avoid breathing vapor or mist. When handling, use proper personal protective equipment specified in Section 8. |
| **Storage** | Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at ambient temperature. |
| Temperature range | 15 - 25 °C |

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure limits**

| Hazardous Ingredient | OEL | Type | Value |
|---|---|---|---|
| Mineral oil, heavy | ACGIH | TWA-8 | 10 mg/m³ (Oil Mist, mineral) |
| | ACGIH | TWA-8 | 5 mg/m³ (Oil Mist, mineral) |
| | OSHA | TWA-8 | 5 mg/m³ (Oil Mist, mineral) |
| Oxytetracycline hydrochloride | Pfizer | TWA-8 | 0.5 mg/m³ |
| Polymyxin B sulfate | Pfizer | TWA-8 | Not established |

| | |
|---|---|
| **Exposure information** | See exposure limits for components listed above. |
| **Measurement method** | Oxytetracycline: CAM-KAS-99-003 (contact Pfizer for additional details). |
| **Ventilation** | General room ventilation is adequate unless the process generates airborne mist or vapor. |
| **Eye protection** | None required under normal and foreseeable conditions of use. |
| **Skin protection** | None required under normal and foreseeable conditions of use. Wash hands and arms thoroughly after handling this material. |
| **Hand protection** | None required under normal and foreseeable conditions of use. Wear rubber gloves if there is a potential for skin contact. |
| **Respiratory protection** | Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. |

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Physical form** | Ointment |
| **Color** | Light yellow |
| **Molecular weight** | Not applicable |
| **Molecular formula** | Not applicable |
| **pH** | Not applicable |
| **Melting point** | Not applicable |
| **Pour point** | Not applicable |
| **Vapor pressure** | Not applicable |
| **Water solubility** | No data available |
| **Solvent solubility** | No data available |

## SECTION 10 - STABILITY AND REACTIVITY

| | |
|---|---|
| **Reactivity** | Stable |
| **Conditions to avoid** | Contact with moist air causes darkening of this material. Avoid direct sunlight, excessive heat, sparks or open flame |
| **Incompatibilities** | Alkalies, strong oxidizers |
| **Hazardous decomposition products** | No data available, see Section 5 - under Hazardous combustion products |
| **Hazardous polymerization** | Will not occur |
| **Oxidizing properties** | No data available |
| **Explosive properties** | None known or expected |

## SECTION 11 - TOXICOLOGY INFORMATION

| | |
|---|---|
| **Eye** | No data available, see Section 3 - HAZARD IDENTIFICATION, above. |
| **Skin** | No data available, see Section 3 - HAZARD IDENTIFICATION, above. |
| **Inhalation** | No data available, see Section 3 - HAZARD IDENTIFICATION, above. |
| **Ingestion** | 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) in the mixture. |
| **Mutagenicity** | No evidence of mutagenicity was observed in the Ames test using Salmonella 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. |
| **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 toxicity** | See Chronic effects/Carcinogenicity below. |
| **Chronic effects/ Carcinogenicity** | Long-term oral chronic and carcinogenicity studies of oxytetracycline hydrochloride toxicity were conducted by the US National Toxicology Program (NTP) in mice at dose levels of 650 or 1400 mg/kg/day and in rats at dose levels of 1000 or 2000 mg/kg/day for 2 years. In mice, no compound-related increases in nonneoplastic 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.<br>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. |
| **OSHA carcinogen** | No |
| **NTP carcinogen** | Not classified |
| **IARC carcinogen** | Not classified |

## SECTION 11 - TOXICOLOGY INFORMATION continued

| | |
|---|---|
| **Reproductive effects** | Effects on fertility (litter size) and embryo- or fetotoxicity were observed in rats at subcutaneous dose of oxytetracycline at 1000 mg/kg, rabbits at intramuscular dose of 789 mg/kg, and dogs (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. |
| **At increased 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. |
| **Additional data** | PREGNANCY RISK CATEGORY 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. |

## SECTION 12 - ECOLOGICAL INFORMATION

| | |
|---|---|
| **Environmental overview** | No environmental effects data are available. |

## SECTION 13 - DISPOSAL INFORMATION

| | |
|---|---|
| **Disposal procedure** | Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State and Local environmental regulations and Site conditions may affect proper disposal options. |

## SECTION 14 - TRANSPORTATION INFORMATION

| | |
|---|---|
| **Proper shipping name** | TERRAMYCIN® ophthalmic ointment |
| **General shipping instructions** | Non-regulated |

## SECTION 15 - REGULATORY INFORMATION

| | |
|---|---|
| **EEC Classification/Labelling** | |
| | TOXIC; T<br>Substance Toxic to Reproduction; Category 1 (T) |
| **Risk phrases** | R61 - May cause harm to the unborn child. |
| **Safety phrases** | S53 - Avoid exposure - obtain special instructions before use. |

## SECTION 15 - REGULATORY INFORMATION continued

| | |
|---|---|
| **TSCA status** | No |
| **SARA section 302** | No |
| **SARA section 313** | No |
| **California proposition 65** | Y (see below) |

## SECTION 16 - OTHER

| | |
|---|---|
| **Summary** | THIS PRODUCT IS OR CONTAINS CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE DEVELOPMENTAL TOXICITY. |
| **Disclaimer** | **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.** |