

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Pfizer Inc Pfizer Animal Health

Pfizer Animal Health 235 East 42nd Street New York, NY 10017 **Emergency** telephone

Hours of operation

Telephone

1-866-531-8896

24 Hours

1-800-366-5288

Trade names

Agrimycin Wettable Powder

Product name

Streptomycin, Oxytetracycline Wettable Powder

Chemical family

Aminoglycoside, Tetracycline derivative

Description

Gray Powder with a characteristic odor

SECTION 2 - COMPOSITION

Ingredient CAS Number Amount

Oxytetracycline hydrochloride* 2058-46-0 Proprietary Streptomycin sulfate* 3810-74-0 Proprietary

Citric acid, anhydrous* 77-92-9 Proprietary

Drewfax 345 (sodium alkyl sulfosuccinate Not assigned Proprietary

derivative)

Diatomaceous earth (uncalcined)* 61790-53-2 Proprietary

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards

for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

Signal word WARNING!

Statements of hazard MAY CAUSE EYE, SKIN, AND RESPIRATORY TRACT

IRRITATION.

MAY CAUSE ALLERGIC SKIN REACTION.

MAY CAUSE LIVER EFFECTS.

MAY CAUSE OTOTOXICITY (HARMFUL EFFECTS ON THE

EAR).

INFANTS OF MOTHERS EXPOSED DURING PREGNANCY MAY

DEVELOP DISCOLORATION OF THE TEETH AND/OR

OTOTOXICITY.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Eye effects May cause irritation

Skin effects May cause skin irritation. May cause allergic skin reaction. Exposure to

sunlight following contact may result in skin reactions in rare instances.

Inhalation effects May cause respiratory tract irritation. An Occupational Exposure Limit

has been established for one or more of the ingredients (see Section 8).

Ingestion effects See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential

health effects' in this section.

Known clinical effects Adverse reactions associated with the clinial use of streptomycin include

vestibular ototoxicity (nausea, vomiting, and vertigo); numbness; rash; fever; swelling; and blood system changes. 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.

Other potential health

effects

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. High doses of tetracyclines can cause a

liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists

(based on animal data).

NOTE: This document has been prepared in accordance with standards for

workplace safety, which require the inclusion of all known hazards of the

product or its ingredients 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.

SECTION 4 - FIRST AID MEASURES

Skin Wash skin with soap and water. Remove contaminated clothing and shoes.

Wash clothing and thoroughly clean shoes before reuse. If irritation occurs

or persists, get medical attention.

Eyes Immediately flush eyes with water for at least 15 minutes. If irritation

occurs or persists, get medical attention.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get

medical attention immediately.

Ingestion 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

Fire fighting instructions Wear approved positive pressure, self-contained breathing apparatus and

full protective turn out gear. Evacuate area and fight fire from a safe

distance.

Extinguishing media

Use carbon dioxide, dry chemical, or water spray.

Flash point

Not applicable

Hazardous combustion

products

Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen,

oxides of sulfur, hydrogen chloride and other chlorine- and sulfur-

containing compounds

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General Review Sections 3, 8 and 12 before proceeding with clean up.

Small spill Vacuum or sweep material into appropriate recovery container. Avoid

generating airborne dust. Clean spill area thoroughly.

Large spill Vacuum or sweep material into appropriate recovery container. Avoid

generating airborne dust. Close container and move it to a secure holding

area.

SECTION 7 - HANDLING AND STORAGE

General handling Minimize dust generation and accumulation. Use with adequate ventilation.

Avoid contact with eyes, skin and clothing. Avoid breathing dust.

Storage conditions Store in light-resistant containers in a cool, dry, well-ventilated area. Keep

container tightly closed when not in use.

Temperature range

for storage

<37°C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

| osui C minito | | | |
|-----------------|---------------|----------|---------------------|
| Compound | <u>Issuer</u> | Type | <u>OEL</u> |
| Oxytetracycline | Pfizer | TWA-8 Hr | 0.5mg/m^3 |
| hydrochloride | | | |

Diatomaceous earth OSHA TWA-8 Hr 6 mg/m³ (<1% crystalline silica) (uncalcined)

ACGIH TWA-8 Hr 3 mg/m³ (Respirable particulate; <1% crystalline silica)

ACGIH TWA-8 Hr 10 mg/m³ (Inhalable particulate; <1% crystalline silica)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Measurement method Oxytetracycline: CAM-KAS-99-003 (contact Pfizer for additional

details); STP O 12.93 (contact Pfizer for additional details)

Streptomycin: CAM-KAS-00-016 (contact Pfizer for additional details);

STP 17.93 (contact Pfizer for additional details)

Ventilation Keep airborne contamination levels below the exposure limits listed above

in this section. Good general ventilation should be sufficient to control

airborne levels.

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.

Eye protection Safety glasses or goggles

Skin protection Protective coveralls should be worn. The sleeves should either be taped or

have gloves worn over them to prevent material from contacting the skin.

Hand protection Wear two layers of disposable gloves.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form Powder

Color Gray

Odor Characteristic

Molecular weight Mixture

Molecular formula Mixture

pH 3.0 - 4.0 (700mg/100mL aqueous suspension)

Boiling point Not applicable

Melting point No data available

Density 4.7 cc/g

Vapor pressure Not applicable
Water solubility No data available

Solvent solubility No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity Stable

Conditions to avoid Humidity, direct sunlight, excessive heat, sparks or open flame

Incompatibilities Bases, strong oxidizers

SECTION 10 - STABILITY AND REACTIVITY ... continued

Hazardous decomposition products No data available; See Section 5 - under Hazardous combustion products.

products

Hazardous Will not occur

polymerization

SECTION 11 - TOXICOLOGY INFORMATION

| 7377 1 1 | | | |
|----------|-----|---------|---|
| Loxicol | Ogv | summary | 1 |

There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Acute toxicity

| Compound | Type | Route | Species | Dosage |
|-------------------------------|------------|--------------|---------|----------------|
| Oxytetracycline hydrochloride | LD_{50} | IV | Rat | 302 mg/kg |
| | LD_{50} | Subcutaneous | Rat | 800 mg/kg |
| | LD_{50} | Oral | Mouse | 6696 mg/kg |
| | LD_{50} | Subcutaneous | Mouse | 600 mg/kg |
| | LD_{50} | IV | Mouse | 100 mg/kg |
| Citric acid, anhydrous | Irritation | Ocular | Rabbit | 750ug/24hr:Sev |
| | Irritation | Dermal | Rabbit | 500mg/24h:Mld |
| | LD50 | Oral | Rat | 3000 mg/kg |

EyeSee Acute toxicity table.SkinSee Acute toxicity table.InhalationDust may cause irritation.

Ingestion See Acute toxicity table.

Mutagenicity Oxytetracycline was not mutagenic i

Oxytetracycline was not mutagenic in microbial cell assays, but was weakly positive in *in vitro* mammalian cells. Overall, it was judged not to

be genotoxic.

Sensitization Hypersensitivity reactions can occur in individuals sensitive to

streptomycin and/or other aminoglycosides. Skin sensitization and/or photosensitization (allergic response after UV exposure) have been

demonstrated with clinical usage of oxytetracycline.

Subchronic effects In 13-week studies in mice and rats fed oxytetracycline, no dose-related

effects were observed on mortality, food consumption, macroscopic or histopathologic evaluation. In mice, a decrease in body weight gain was seen at 50,000 ppm. The NOAEL was 25,000 ppm. In male rats, mild fatty metamorphosis was observed in the liver of all treated animals. The NOAEL in rats was 50,000 ppm, equivalent to 3352 (males) mg/kg/day or

3494 (females) mg/kg/day.

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Chronic effects/ carcinogenicity

In a 12-month study in dogs, a degenerating epithelium in the testicular tubules was observed in males fed diets containing 10,000 ppm (equivalent to 250 mg/kg/day) oxytetracycline hydrochloride. However, in a subsequent 24-month study in dogs, this effect was observed in the control animals at a higher frequency than in the treated animals and no adverse effects were reported at 250 mg/kg/day, the highest dose tested. In studies conducted by the US National Toxicology Program (NTP), no evidence of carcinogenicity was seen in mice given oxytetracycline hydrochloride at doses up to 1400 mg/kg/day. In rats, adrenal lesions in males and in the pituitary in females were observed at doses up to 2000 mg/kg/day. Based on these results the NTP was unable to classify for carcinogenicity.

Carcinogen status

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

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

In a rat teratology study with oxytetracycline, decreased ossification in the anterior extremities of fetuses and increased fetal resorptions were reported at 480 mg/kg/day, the NOAEL was 240 mg/kg/day. 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. Teratogenicity studies in mice, rats, rabbits, and guinea pigs have not shown adverse effects due to streptomycin administration during pregnancy, with the possible exception of ototoxicity.

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 information

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 The environmental characteristics of this material have not been fully

evaluated. Releases to the environment should be avoided. See aquatic

toxicity data, below:

Aquatic toxicity

<u>Compound</u> <u>Type</u> Oxytetracycline hydrochloride LC50 Species
Rainbow Trout

Dosage >116 mg/L

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure Incineration is the recommended method of disposal for this material.

Observe all local and national regulations when disposing of this mixture.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

EU Classification Substance toxic to reproduction; category 1; Irritant

EU Labelling T; Xi

EU Label Pictogram(s)





Risk phrases R43 - May cause sensitization by skin contact.

R61 - May cause harm to the unborn child.

Safety phrases S22 - Do not breathe dust.

S37 - Wear suitable gloves.

S53 - Avoid exposure - obtain special instructions before use.

California Proposition 65 Oxytetracycline hydrochlor

Oxytetracycline hydrochloride; Aminoglycosides (streptomycin sulfate)

Canadian WHMIS Class D, Division 2, Subdivision A

Class D, Division 2, Subdivision B