MATERIAL SAFETY DATA SHEET

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

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Material Name: Oxytetracycline hydrochloride/sulfamethizole/phenazopyridine hydrochloride capsules

Trade Name: Not determined
Synonyms: UROBIOTIC®-250 capsules
Chemical Family: Tetracycline derivative/Sulfonamide/Diaminopyridine derivative
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Phenazopyridine hydrochloride	136-40-3	205-243-8	*
Starch	9005-25-8	232-679-6	*
Sodium lauryl sulfate	151-21-3	205-788-1	*
Magnesium stearate	557-04-0	209-150-3	*
Oxytetracycline hydrochloride	2058-46-0	218-161-2	*
Sulfamethizole	144-82-1	205-641-1	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Yellow opaque top, light green opaque body hard gelatin lock-type capsule, imprinted in dark green with "PFIZER 092" top and bottom
Signal Word: CAUTION

Statement of Hazard: Infants of mothers exposed during pregnancy may develop discoloration of the teeth
Eye Contact: None known
Skin Contact: None known
Inhalation: None known
Ingestion: None known

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including inflammation of the tongue, soft tissues of the mouth, rectum and vagina, nausea, diarrhea and dermatitis, as well as reactions of an allergic nature, may occur during oxytetracline HCl therapy, but are rare. 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. As in all sulfonamide therapy, the following reactions may occur including nausea, vomiting, diarrhea, inflammation of the liver and pancreas, blood disorder, drug fever, skin rash, infection of the conjunctiva and sclera, blood in the urine and crystalluria. 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. If irritation occurs or persists, 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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-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. IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING.

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

Phenazopyridine hydrochloride
Pfizer OEL TWA-8 Hr: 0.3 mg/m³, Skin

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

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³
Pfizer STEL 0.75 mg/m³

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: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands: None required under normal and foreseeable conditions of use.
Eyes: Not required under normal conditions of use.
Skin: None required under normal and foreseeable conditions of use.
Respiratory protection: None required under normal conditions of use. Use dust mask for dusty conditions.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Capsule
Odor: Odorless
Molecular Weight: Mixture
Color: Yellow/light green
Molecular Formula: 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, strong oxidizers

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

11. TOXICOLOGICAL INFORMATION

NTP: Not classified
IARC: 2B
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

Phenazopyridine hydrochloride
Rat Oral LD50 472 mg/kg
Mouse Intravenous LD 50 180 mg/kg

Starch
Mouse IP LD50 6600 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg

Sulfamethizole
Mouse Oral LD50 > 10 g/kg
Rat Oral LD50 3500mg/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.

Sodium lauryl sulfate
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Although long-term studies in animals have not been conducted with oxytetracycline hydrochloride/sulfamethizole/phenazopyridine hydrochloride, rodent studies have shown that phenazopyridine HCl alone is an animal tumorigen. Oral administration of phenazopyridine HCl significantly increased the incidence of liver adenomas and carcinomas in female mice. In male and female rats, it induced tumors of the colon and rectum. The IARC Working Group concluded that there is sufficient evidence for the carcinogenicity of phenazopyridine HCl in experimental animals (Group 2B). 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

Phenazopyridine hydrochloride

Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	NOEL	Not teratogenic

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

Phenazopyridine hydrochloride

Bacterial Mutagenicity (Ames)	*Salmonella*	Positive
Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive
In Vivo	Drosophila	Equivocal

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

Phenazopyridine hydrochloride
78 Week(s) Rat Oral, in feed 3700 ppm LOEL Tumors, Gastrointestinal system
80 Week(s) Female Mouse Oral, in feed 600 ppm LOEL Tumors, Liver
80 Week(s) Male Mouse Oral, in feed 1200 ppm NOEL Not carcinogenic

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

Phenazopyridine hydrochloride
IARC: Group 2B
NTP: Listed
OSHA: Present

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.

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/sulfamethizole/phenazopyridine hydrochloride capsules

15. REGULATORY INFORMATION

OSHA Label:
CAUTION
Infants of mothers exposed during pregnancy may develop discoloration of the teeth

Canada - WHMIS: Classifications

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

Phenazopyridine hydrochloride

California Proposition 65	carcinogen, initial date 1/1/88
EU EINECS List	205-243-8

Starch

EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Sodium lauryl sulfate

EU EINECS List	205-788-1
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
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

Sulfamethizole

EU EINECS List	205-641-1
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