

Pharmacia & Upjohn

Agent ID# 55544

PIRSUE® Sterile Solution MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: PIRSUE® Sterile Solution

SYNONYMS: 400038 – EDP Number

MOLECULAR FORMULA: Mixture

USE: Treatment for mastitis in lactating cattle. Not for human use.

MANUFACTURER/SUPPLIER:

PHARMACIA & UPJOHN

7171 PORTAGE RD

KALAMAZOO, MI 49001-0199

TELEPHONE NUMBERS:

(616) 833-5122 - (24 Hours, Emergency)

(616) 833-7555 - (8:00 AM - 4:30 PM, EST Emergency)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1

COMMON NAME: Water.

% BY WEIGHT: 98% (approximately)

CAS NUMBER: 7732-18-5

EXPOSURE LIMIT(S): Not established.

INGREDIENT 2

COMMON NAME: Non-hazardous Ingredient(s).

% BY WEIGHT: 1% (approximately)

EXPOSURE LIMIT(S): Not established.

INGREDIENT 3

COMMON NAME: Pirlimycin hydrochloride

CHEMICAL NAME: Methyl(2S-cis)-7-chloro-6,7,8-trideoxy-6-[[[4-ethyl-2-piperidinyl]carbonyl]amino]-1-thio-L-threo-a-D-galacto-octopyranoside hydrochloride hydrate.

% BY WEIGHT: 0.5%

CAS NUMBER: 77495-92-2

EXPOSURE LIMIT(S): Not established.

EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

3. HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, inhalation, and ingestion.

EFFECTS OF OVEREXPOSURE: May cause skin and eye irritation or allergic skin reaction. May cause stomach irritation if swallowed or act as a laxative from repeated ingestion of greater than 10% of the diet.

MEDICAL CONDITIONS AGGRAVATED BY

EXPOSURE: Hypersensitivity to pirlimycin hydrochloride.

4. FIRST AID MEASURES

EYES: Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.

SKIN: Wash with soap and water. Remove contaminated clothing.

INHALATION: Remove from exposure.

INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable.

LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

EXTINGUISHING MEDIA: Water, carbon dioxide or dry chemical.

FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full-body protective equipment.

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides. Hydrogen chloride.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS

RELEASED OR SPILLED: Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep out of drains, prevent entry to surface water, groundwater and soil. Vacuum or scoop spilled material and place in container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING:

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothing before reuse. Store in a cool, dry place. Protect from light. Keep out of reach of children.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.
VENTILATION: Local exhaust.
PROTECTIVE GLOVES: Not required.
EYE PROTECTION: Not required.
OTHER PROTECTIVE EQUIPMENT: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Aqueous liquid.
MOLECULAR WEIGHT: Mixture.
SOLUBILITY IN WATER: Soluble.

10. STABILITY AND REACTIVITY

STABILITY: Stable.
PHYSICAL CONDITIONS TO AVOID: Exposure to light.
INCOMPATIBILITY WITH OTHER MATERIALS: None.
HAZARDOUS DECOMPOSITION PRODUCTS: None.
HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:
EYE IRRITATION (RABBIT): Severely irritating (for pirlimycin hydrochloride).
SKIN IRRITATION (RABBIT): Moderately irritating to abraded and intact skin (for pirlimycin hydrochloride).
SENSITIZATION: No information found, but may cause sensitization due to structural similarities to other antibiotics that cause sensitization (for pirlimycin hydrochloride).
ORAL LD50 (MOUSE): 2,524 mg/kg (for pirlimycin hydrochloride).
OTHER STUDIES: Oral irritation test of pirlimycin hydrochloride in the rabbit - oral administration of 500 mg/kg/day for 14 days - caused gastric irritation, while the no-observable-effect-level (NOEL) was 50 mg/kg/day. Intramuscular irritation test for pirlimycin hydrochloride in the rabbit - severely irritating.
GENOTOXICITY: Various tests (Ames, mammalian-cell mutation, micronucleus in rat and mouse, germ-cell

mutation in *Drosophila* and UDS in vitro) demonstrated that pirlimycin hydrochloride was not mutagenic.
TERATOGENICITY: Two generation rat studies using pirlimycin hydrochloride showed doses up to 400 mg/kg/day was toxic to first generation males and females, but was not embryotoxic, fetotoxic or teratogenic and did not adversely affect lactation, survival, growth or reproductive performance of first and second generation offspring.
CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE: The following data applies to pirlimycin hydrochloride.
MOBILITY: Pirlimycin hydrochloride does not bind tightly to soil.
PERSISTENCE/DEGRADABILITY: Pirlimycin hydrochloride is hydrolyzed very slowly at neutral pH has a moderate rate of photodegradability and does not readily biodegrade to carbon dioxide by soil microorganisms. The slow disappearance in the environment is offset by low usage and releases.
BIOACCUMULATIVE POTENTIAL: Pirlimycin hydrochloride does not bioaccumulate. Pirlimycin hydrochloride and its metabolites will remain in the aqueous state as the biological concentration factors are <100. About 50% of the pirlimycin hydrochloride is excreted as metabolites in urine and feces, while the other 50% is eliminated unchanged in milk from the first four milkings.
ABIOTIC POTENTIAL: Small amounts of pirlimycin hydrochloride sent to sanitary sewage will not adversely affect sewage treatment facilities.
ECOTOXICITY: LC50 (Rainbow Trout - 96 Hr): >970 ppm. No observable effect concentration = 190 ppm. LC50 (Bluegill - 96 Hr): >990 ppm. No observable effect concentration = 380 ppm. Median effective concentration (Daphnia): 190 ppm. No observable effect concentration = <130 ppm. Minimum inhibitory concentration (algae): >0.029 ppm. No observable effect concentration = 0.014 ppm.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable international, national, state and/or local waste disposal regulations.

14. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

15. OTHER INFORMATION

PREPARED BY: Environment & Safety

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16. LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.

August 12, 1998