SAFETY DATA SHEETS

This SDS packet was issued with item:

078708014

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078708063 078713450 078713468 078917124

MATERIAL SAFETY DATA SHEET
CEFTIFLEX

COMPANY AND PRODUCT INFORMATION

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MANUFACTURER: CEPHAZONE PHARMA LLC.
250 E. Bonita Ave.
Pomona California 91767

PHONE: (909) 392-8900 8:00 a.m. To 4:30 p.m. (EST) Monday thru Friday

PRODUCT:	CEFTIOFUR SODIUM STERILE POWDER
CAS NUMBER:	104010-37-9
CHEMICAL FAMILY:	Cephalosporin antibiotic
USE:	Veterinary product for the treatment of bovine respiratory disease. Not for human use.
CHEMICAL FORMULA:	N/A
MOLECULAR FORMULA:	Mixture
HAZARD RATING:	**Health:** 1 Slight **Fire:** 1 Slight **Reactivity:** 0 Negligible
SPECIAL HAZARDS:	A schedule III controlled drug.

COMPOSITION INFORMATION ON INGREDIENTS

INGREDIENT 1
COMMON NAME: **Ceftiofur** Sodium
CHEMICAL NAME: **5**-Thia-1-azabicyclo [4.2.0] Oct-2-ene-2-carboxylic acid, 7-[[(2-amino-4-thiazolyl) (methoxyimino) acetyl] amino)-3-[[(2-furanylcarbonyl)ThioJ methyl]-8-oxo-monosodium salt, [6R-[6a,-70 (Z)]]
% BY WEIGHT: 98 % to 100 %
CAS NUMBER: 104010-37-9
EXPOSURE LIMIT(S): 0.2 mg^3 (200 ug/m3)
INGREDIENT 2
COMMON NAME: Sodium Hydroxide
% BY WEIGHT: <1 % (May be added to adjust pH when necessary.)
CAS NUMBER: 1310-73-2
EXPOSURE LIMIT(S): OSHA PEL-CEILING.2mg/m3
ACGIH TLV-CEILING: 2 mg/m3
INGREDIENT 3
COMMON NAME: Monopotassium Phosphate Anhydrous
% BY WEIGHT: <1 % (Added as a buffer)
CAS NUMBER: 7778-77-0
EXPOSURE LIMIT(S):Not established.
EXPOSURE LIMIT(S) FOR THE MATERIAL: Not established.

HAZARDS IDENTIFICATION

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, ingestion, and inhalation.
EFFECTS OF OVEREXPOSURE: The primary concern with inhalation or skin exposure to this agent would be the capability to elicit very mild to severe allergic reaction in some individuals. Repeated exposure may lead to sensitization. Manifestations of an allergic response may include skin rash, fever, bronchospasm, angioedema (swelling of lips, tongue and face accompanied by asthmatic breathing and hives) and anaphylaxis.

Drug solutions of ceftiofur sodium have the potential for mild delayed-type dermal sensitization following repeated topical contact. May also cause diarrhea, nausea, vomiting and anemia.
TARGET ORGANS: Skin, respiratory tract, immune system, gastrointestinal tract and blood.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to ceftiofur sodium or to the cephalosporin group of antibiotics. Persons with known sensitivity to other beta-lactam antibiotics such as penicillin may be at increased risk of developing hypersensitivity to ceftiofur sodium.

FIRST AID MEASURES

EYES: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
SKIN: Wash off with soap and water. Take off all contaminated clothing immediately.
INHALATION: Move to fresh air.
INGESTION: Contact a physician or poison control center.
NOTES TO PHYSICIAN: Serious, acute
hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines. corticosteroids, pressor amines and airway management as clinically indicated.

FIRE FIGHTING MEASURES

FLASH POINT: Not applicable (solid)
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.
UNUSUAL FIRE OR EXPLOSION HAZARDS: As with all finely divided organic powders, it is advisable to eliminate explosion hazards by methods such as grounding mechanical equipment in contact with the material to prevent the buildup of static electricity, inciting the atmosphere or controlling dust levels.
HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Remove all sources of ignition. Control the generation of dust/vapors. Ensure adequate ventilation. Provide respiratory, skin and eye protection to prevent overexposure. Do not let product enter drains. Do not flush into surface water. Do not flush to groundwater and soil. Vacuum with HEPA filtered and explosion-proof equipment. Shovel intosuitable container for disposal.

HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid generating dust/vapors and contact with skin, eyes and clothing. Use with adequate ventilation. Wash thoroughly after handling. Launder contaminated clothing before reuse. Store at room temperature. Do not get in eyes, on skin or clothing. Avoid breathing dust or mist. Use adequate dust/vapor control. Keep out of reach of children.

EXPOSURE CONTROLS / SPECIAL PROTECTION

RESPIRATORY PROTECTION: Approved respirator if there is the opportunity for dust generation, especially with large quantities.
VENTILATION: Local exhaust.
PROTECTIVE GLOVES: Rubber. EYE
PROTECTION: Safety glasses with side shields.

OTHER PROTECTIVE EQUIPMENT: Protective covering for exposed areas of skin.

PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Off-white to tan powder.
BOILING POINT: Decomposes.
FREEZING POINT: Not applicable.
MELTING POINT: Decomposes above 190°C without melting.
MOLECULAR WEIGHT: Mixture.
PARTITION COEFFICIENT (n-TANOL/WATER)**:** 0.3(at pH5)
SOLUBILITY IN SOLVENTS: Methanol: <5 mg/mL; propylene glycol: 226 mg/mL; 2-pyrrolidonc: 302 mg/mL; THF: <5 mg/mL.
SOLUBILITY IN WATER: >400 mg/mL initially. Gels with time. No gelling or precipitation at 70 mg/mL
VAPOR DENSITY (AIR =I): Negligible.
VAPOR PRESSURE: Negligible.
VOLATILITY: Negligible.

STABILITY AND REACTIVITY

STABILITY: Stable at normal conditions.
PHYSICAL CONDITIONS TO AVOID: Slowly degrades on exposure to UV or fluorescent light, water exposure or increases in temperatures.
INCOMPATIBILITY WITH OTHER MATERIALS: Alkaline pH, oxidizing agents, and heavy metal ions.
HAZARDOUS DECOMPOSITION PRODUCTS: None.
HAZARDOUS POLYMERIZATION: Does not occur.

TOXICOLIGICAL INFORMATION

ACUTE STUDIES: Not acutely toxic. The following data applies to ceftiofur sodium, the active ingredient in CEFTIOFUR SODIUM STERILE POWDER
EYE IRRITATION (RABBIT): Minimally irritating, but absorption via the ocular route may occur.
SKIN IRRITATION (RABBIT): Practically nonirritating to intact skin.
SENSITIZATION: May cause hypersensitivity reactions.
INHALATION LD50 (RAT): >8.3 mg/mL
ORAL TOXICITY (DOG): The no observable effect level (NOEL) of 30 mg/kg/day was established in the **dog**: as a result of a 90-day oral toxicity study.
ORAL LD50 (RAT): >7,760 mg/kg
INTRAPERITONEAL LD50 (RAT): 927 mg/kg
OTHER STUDIES:
GENOTOXICITY: Ceftiofur was negative in the Ames assay, micronucleus **test**, V7 mammalian cell mutation assay, and unscheduled DNA synthesis assay. In the in vitro chromosome aberration assay using CHO cells (in the absence of S9 metabolic activation), lengthy treatment with high doses of ceftiofur sodium resulted in increased frequency of aberrations. Aberrations were in the categories of chromatid breaks and gaps and isochromatid gaps. No evidence of the formation of rearrangements could be seen in these cells.

ECOLOGICAL INFORMATION

REPRODUCTION/FERTILITY: The reproduction NOEL in the rat is 1,000 mg/kg/day orally. Oral administration at this level did not cause adverse effects upon fertility or reproductive performance of F0 and Fl generation animals. Likewise, no adverse effects were observed in the growth and viability of the F2 litter through to the weaning period.
TERATOGENICITY: Not teratogenic in rats at oral doses up to 3,200 mg/kg/day.
CARCINOGENICITY: Negative genetox tests would suggest that ceftiofur sodium is not carcinogenic.

Ingredient (s) are not listed as carcinogenic by IARC, NTP or OSHA.

ENVIRONMENTAL FATE:

MOBILITY: Ceftiofur sodium is very soluble in water, therefore, it is expected to be relatively mobile and migrate toward the aquatic compartment Since cefliofur sodium decomposes above 190°C without melting and has no measurable vapor pressure, it is not expected to enter the air.

PERSISTENCE/DEGRADABILITY: In the aqueous environment, ceftiofur or its metabolites are subject to degradation by hydrolysis. At pH 7 and 22◦C, ceftiofur is 50% destroyed in 8 days and is completely destroyed in 80 days or less. Increases in temperature or pH, accelerate the rate of hydrolysis and destruction of antibacterial activity of ceftiofur and its metabolites. Degradation rate is also accelerated upon exposure to light or oxidizers. Ceftiofur sodium and its metabolites rapidly degrade in manure to 0 PPM bioactivity within 72 hours at ambient temperatures. Furthermore, a study of aerobic biodegradation in several soils showed that ceftiofur had no inhibitory effects on the soil organisms and readily biodegrades to carbon dioxide. It can be concluded that ceftiofur will not reach concentrations in soil at which adverse effects would occur.

BIOACCUMULATTVE POTENTIAL: Ceftiofur sodium has an octanol/water partition coefficient of 0.3 at pH 5**.** Based on this value, it would be expected to migrate to the aqueous environment but it should not bioaccumulate in aquatic organisms. The biological concentration factor (BCF) is 0.235. Since all the metabolites are more polar and water soluble than ceftiofur, these compounds should also remain in the aqueous environment with no bioaccumulation.

ABIOTIC POTENTIAL: Based on its anticipated use and fate in the environment, and its decomposition rate in water, manure and soils, the concentration of ceftiofur and related metabolites in soil is expected to be below the minimal inhibitory concentration of most bacteria and soil fungi. Therefore, no detrimental effects to these classes of organisms are expected. Small amounts released to sanitary sewerage should not adversely affect the biotic flora of sewerage treatment facilities.

ECOTOXICITY: No information found.

DISPOSAL CONSIDERATIONS

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

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.

OTHER INFORMATION

REVIEWED BY: Environment & Safety.

DISCLAIMER: The information contained in the MSDS is believed to be correct as of its date of issuance. BY MAKING THE MSDS AVAILABLE, PHARMACIA & UPJOHN CO. DOES NOT MAKE ANY EXPRESS OR IMPLIED WARRANTY (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) REGARDING THE MSDS, ITS ACCURACY OR THE PRODUCT TO WHICH IT RELATES. Anyone using this information agrees that Pharmacia & Upjohn shall not be held liable (based on its negligence or otherwise) for any personal injury or other damage relating to, or arising from such use, including direct, incidental, or consequential damage and such user agrees to indemnify Pharmacia & Upjohn for any claims arising out of its use.

LABELING

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