

----- MATERIAL SAFETY DATA SHEET -----
EXCENEL(R) RTU STERILE SUSPENSION
Pharmacia & Upjohn

Revision Date: July 31, 2001
Agent Id#: 40398

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: EXCENEL(R) RTU STERILE SUSPENSION
SYNONYMS: Ceftiofur Hydrochloride Sterile Suspension
MOLECULAR FORMULA: MIXTURE
CHEMICAL FAMILY: Cephalosporin antibiotic
USE: Veterinary product. Not for human use.
MANUFACTURER/SUPPLIER:

PHARMACIA & UPJOHN
7171 PORTAGE RD.,
KALAMAZOO, MICHIGAN U.S.A. 49001-0199

IN CANADA:

PHARMACIA ANIMAL HEALTH
40 CENTENNIAL RD.,
ORANGEVILLE, ONTARIO. L9W 3T3

TELEPHONE NUMBERS:

(USA): (616) 833-7555 - (8:00 AM TO 4:30 PM)

(CANADA): (519) 941-1030 - (8:00 AM TO 5:00 PM)

24 HOUR CONTACT NUMBER (CANADA & USA): (616) 833-5122

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1

COMMON NAME: Cottonseed oil
% BY WEIGHT: 94.55 %
CAS NUMBER: 8001-29-4
EXPOSURE LIMIT(S): Not established.

INGREDIENT 2

COMMON NAME: Ceftiofur Hydrochloride
CHEMICAL NAME: 5-thia-1-azabicyclo{4.2.0}oct-2-ene-2-
carboxylic acid, 7-{{2-(2-amino-4-thiazolyl)-2-
(methoxyimino)acetyl}amino}-3-{{(2-
furanylcarbonyl)thio}methyl}}-8-oxo-, monohydrochloride

% BY WEIGHT: 5.25 %

CAS NUMBER: 103980-44-5

EXPOSURE LIMIT(S):

PHARMACIA & UPJOHN EXPOSURE LIMIT-TWA: 0.2 MG/M3

INGREDIENT 3

COMMON NAME: Sorbitan monooleate
% BY WEIGHT: 0.15 %
CAS NUMBER: 1338-43-8
EXPOSURE LIMIT(S): Not established.

INGREDIENT 4

COMMON NAME: Phospholipon 90 h
CHEMICAL NAME: Soy phospholipid concentrate;
phosphatidylcholine

% BY WEIGHT: 0.05 %

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, ingestion and inhalation.

EFFECTS OF OVEREXPOSURE: The primary concern with inhalation or skin exposure to ceftiofur hydrochloride would be the capability to elicit very mild to severe allergic reactions 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. Oral ingestion of large quantities of ceftiofur hydrochloride may also cause diarrhea, nausea, vomiting and anemia. Cottonseed oil is considered practically nontoxic. Ingestion of large amounts may have a laxative effect.

TARGET ORGANS: Skin, respiratory tract, immune system, gastrointestinal tract, and blood.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to ceftiofur hydrochloride or 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 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: Move from exposure.

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.

5. FIRE FIGHTING MEASURES

FLASH POINT: 252 deg C (486 deg F)

LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

AUTOIGNITION TEMPERATURE: 343 deg C (649 deg F)

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: None.

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 adequate ventilation and respiratory, skin and eye protection to prevent overexposure. For large spills, absorb on sand, vermiculite, spill pillows, or other appropriate absorbent material and place in container. Clean surfaces with an oil cutting cleaning agent. Rinse affected surface with household ammonia. Allow solution to stand for 5 minutes. Place all wipes and rags used for cleaning in waste containers. The liquid generated from cleaning can be disposed in the sanitary sewer. For small spills, place broken material in a container. Absorb spill with paper towels and place in a container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in a cool, dry place and protect from light. Keep out of the 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.
Persons with known sensitivities to penicillin or to the cephalosporin group of antibiotics should avoid direct contact with this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Off-white to buff colored suspension.
BOILING POINT: > 232 deg C (> 450 deg F)
FREEZING POINT: -5 - 0 deg C (23 - 32 deg F) (solidifies)
ODOR: Musty odor.
SOLUBILITY IN SOLVENTS: Soluble in non-polar solvents such as hydrocarbons.
SOLUBILITY IN WATER: Insoluble.
SPECIFIC GRAVITY (WATER=1): 0.935 - 0.942
VAPOR PRESSURE: < 1 MMHG

10. STABILITY AND REACTIVITY

STABILITY: Stable.
PHYSICAL CONDITIONS TO AVOID: Slowly degrades on exposure to UV light.
INCOMPATIBILITY WITH OTHER MATERIALS: Heat, alkaline pH, oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: None.
HAZARDOUS POLYMERIZATION: Does not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE STUDIES:

SENSITIZATION: May cause hypersensitivity reactions.

ACUTE TOXICITY: IP LD50 (rat): 881 mg/kg (for ceftiofur hydrochloride)

ORAL TOXICITY (PIG): Administration of up to 150 mg/kg/day of ceftiofur hydrochloride orally for five days was well tolerated and free of toxic effects in baby pigs.

OTHER STUDIES:

GENOTOXICITY:

Ceftiofur was negative in the:

Ames Assay

Micronucleus test

V79 mammalian cell mutation assay

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.

REPRODUCTION/FERTILITY: The NOEL for reproductive effects in the rat for ceftiofur sodium is 1000 mg/kg/day orally. Oral administration at this level did not cause adverse effects upon fertility or reproductive performance of F0 and F1 generation animals. Likewise, no adverse effects were observed in the growth and viability of the F2 litter through the weaning period.

TERATOGENICITY: Ceftiofur sodium was not teratogenic in rats at oral doses up to 3200 mg/kg/day.

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

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:

MOBILITY: This material has low solubility in water and is not expected to be mobile or migrate toward the aquatic compartment.

PERSISTENCE/DEGRADABILITY: In the aqueous environment, ceftiofur or its metabolites are subject to degradation by hydrolysis. At pH 7 and room temperature, ceftiofur hydrochloride is 50% destroyed in 9 days (50% ethanol/water solution). Increases in temperature or pH accelerate the rate of hydrolysis and destruction of antibacterial activity of ceftiofur and its metabolites.

The degradation rate is also accelerated upon exposure to light or oxidizers. Ceftiofur hydrochloride 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 sodium had no inhibitory effects on the soil organisms and readily biodegrades to carbon dioxide. It is expected that ceftiofur hydrochloride will not reach concentrations in soil at which adverse effects would occur.

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 MIC (minimal inhibitory concentration) of most bacteria and soil fungi. Therefore, no detrimental effects to these classes of organisms are expected. Small amounts released to the sanitary sewer should not adversely effect the biotic flora of sewage treatment facilities.

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

REVIEWED BY: Environment and 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.

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