



MATERIAL SAFETY DATA SHEET

Revision date: 07-Jun-2012

Version: 2.0

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Poison Control Center Phone: 1-866-531-8896
Technical Services Phone: 1-800-366-5288
Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Ceftiofur Crystalline Free Acid Sterile Suspension

Trade Name:	Excede; Naxcel
Chemical Family:	Mixture
Intended Use:	Veterinary product used as antibiotic agent.

2. HAZARDS IDENTIFICATION

Appearance:	Opaque suspension
Signal Word:	DANGER

Statement of Hazard:	May cause allergic or asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.
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Additional Hazard Information:	
Short Term:	May produce slight eye irritation. May cause slight skin irritation. (based on components) . If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects:	Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. 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. Effects on blood and blood-forming organs have also occurred.
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EU Indication of danger:	Harmful
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EU Hazard Symbols:

Xn



EU Risk Phrases:

Australian Hazard Classification (NOHSC):	R42/43 - May cause sensitization by inhalation and skin contact. Hazardous Substance. Non-Dangerous Goods.
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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ceftiofur Crystalline Free Acid	80370-57-6	Not Listed	Xn; R42/43	20

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Caprylic/Capric triglyceride	73398-61-5	277-452-2	Not Listed	*
Cottonseed Oil	8001-29-4	232-280-7	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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 and other sulfur-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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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 spill if it is safe to do so. Collect spill with absorbent material. 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:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ceftiofur Crystalline Free Acid
Pfizer OEL TWA-8 Hr:

200µg/m³, Sensitizer

Analytical Method:	Analytical method available for Ceftiofur Hydrochloride. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Suspension	Color:	Opaque
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Ceftiofur Crystalline Free Acid

Rat	Oral	LD 50	>7760 mg/kg
Rat	Sub-tenon injection (eye)	LD 50	927 mg/kg
Rat	Inhalation	LC 50	>8.3 mg/L

Caprylic/Capric triglyceride

Rat	Oral	LD50	> 5000 mg/kg
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Cottonseed Oil

Rat	Oral	LD50	> 90 ml/kg
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Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Ceftiofur Crystalline Free Acid

Eye Irritation	Rabbit	Minimal
Skin Irritation	Rabbit	Minimal
Antigenicity- Passive cutaneous anaphylaxis	Guinea Pig	Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ceftiofur Crystalline Free Acid

30 Day(s)	Rat	Oral	< 1500 mg/kg/day	NOEL	Gastrointestinal System
90 Day(s)	Rat	Oral	30 mg/kg/day	NOEL	Gastrointestinal system
51 Day(s)	Dog	Oral	300 mg/kg/day	LOAEL	Blood forming organs
90 Day(s)	Dog	Oral	30 mg/kg/day	NOEL	Blood forming organs

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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11. TOXICOLOGICAL INFORMATION

Ceftiofur Crystalline Free Acid

2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	NOEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	3200 mg/kg/day	NOAEL	Not Teratogenic, Fetotoxicity, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ceftiofur Crystalline Free Acid

In Vitro Bacterial Mutagenicity (Ames)	Salmonella , E. coli	Negative
Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
In Vitro Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
In Vivo Micronucleus	Rat	Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

EU Symbol:	Xn
EU Indication of danger:	Harmful

EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases:

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15. REGULATORY INFORMATION

S24 - Avoid contact with skin.
S37 - Wear suitable gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

OSHA Label:

DANGER

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

D2a very toxic materials

D2b toxic materials



Caprylic/Capric triglyceride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	277-452-2

Cottonseed Oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-280-7

Ceftiofur Crystalline Free Acid

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

Prepared by:

Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet