



# 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.

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.

EU Indication of danger: Harmful

EU Hazard Symbols:

Xn



EU Risk Phrases:

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

Australian Hazard Classification (NOHSC): 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/m<sup>3</sup>, 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  
Molecular Formula: Mixture  
Color: Opaque  
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

##### **Cottonseed Oil**

Rat Oral LD50 > 90 ml/kg

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**