

# SAFETY DATA SHEET



Revision date: 06-Jan-2014

Version: 3.0

Page 1 of 8

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Ceftiofur Crystalline Free Acid Sterile Suspension

**Trade Name:** Excede; Naxcel  
**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Veterinary product used as antibiotic agent.

### Details of the Supplier of the Safety Data Sheet

Zoetis Inc.  
100 Campus Drive, P.O. Box 651  
Florham Park, New Jersey 07932 (USA)  
Rocky Mountain Poison Control Center Phone: 1-866-531-8896  
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.  
Mercuriusstraat 20  
1930 Zaventem  
Belgium

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**  
**Contact E-Mail:** VMIPSrecords@zoetis.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

## 2. HAZARDS IDENTIFICATION

**Appearance:** Opaque suspension

### Classification of the Substance or Mixture

#### GHS - Classification

Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1

#### EU Classification:

EU Indication of danger: Harmful

EU Symbol: Xn  
EU Risk Phrases:

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

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 2 of 8

Version: 3.0

**Precautionary Statements:**

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P284 - Wear respiratory protection
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
- P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P501 - Dispose of contents/container in accordance with all local and national regulations



### Other Hazards

#### 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.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Ceftiofur Crystalline Free Acid	80370-57-6	Not Listed	Xn; R42/43	Resp Sens 1 (H334) Skin Sens 1 (H317)	20

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

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 3 of 8

Version: 3.0

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

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of 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.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**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.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

#### Advice for Fire-Fighters

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

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**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.

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 4 of 8

Version: 3.0

**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

#### Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Releases to the environment should be avoided. Use appropriate personal protective equipment. Avoid accidental injection.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Ceftiofur Crystalline Free Acid  
Zoetis OEL TWA 8-hr

200µg/m<sup>3</sup>, Sensitizer

#### Exposure Controls

**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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Suspension	<b>Color:</b>	Opaque
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 5 of 8

Version: 3.0

Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
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  
Hazardous Decomposition Products: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. 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 927mg/kg  
Rat Inhalation LC 50 >8.3mg/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

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 6 of 8

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

#### 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))

##### **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**

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

<b>Environmental Overview:</b>	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 7 of 8

Version: 3.0

### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A  
Class D, Division 2, Subdivision B



**Caprylic/Capric triglyceride**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	277-452-2

**Cottonseed Oil**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-280-7

**Ceftiofur Crystalline Free Acid**

## SAFETY DATA SHEET

Material Name: Ceftiofur Crystalline Free Acid Sterile  
Suspension  
Revision date: 06-Jan-2014

Page 8 of 8

Version: 3.0

### 15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction

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

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

Zoetis 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**