

# SAFETY DATA SHEET



Revision date: 06-Jan-2014

Version: 3.0

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

### Product Identifier

**Material Name:** Ceftiofur Sodium Sterile Powder

**Trade Name:** Naxcel; Excenel  
**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:** Off white to light tan powder

### Classification of the Substance or Mixture

#### GHS - Classification

Skin Corrosion/Irritation: Category 2  
Serious Eye Damage/Eye Irritation: Category 2A  
Respiratory Sensitization: Category 1  
Skin Sensitization: Category 1

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### EU Classification:

EU Indication of danger: Harmful  
Irritant

EU Symbol: Xn Xi  
EU Risk Phrases:

R36 - Irritating to eyes.  
R38 - Irritating to skin.  
R42/43 - May cause sensitization by inhalation and skin contact.

### Label Elements

**Signal Word:** Danger

NAXCEL

Rx NAXCEL

#020014

1/06/14

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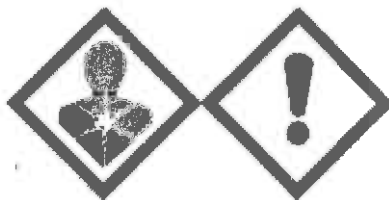
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### 2. HAZARDS IDENTIFICATION

**Hazard Statements:**  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction  
May form combustible dust concentrations in air

**Precautionary Statements:**  
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking  
P264 - Wash hands thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
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  
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  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
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  
P501 - Dispose of contents/container in accordance with all local and national regulations



#### Other Hazards

##### Short Term:

May cause eye irritation; May cause 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. Clinical use of this drug has caused effects on blood forming organs, blood cell changes.

#### 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

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Ceftiofur Sodium	104010-37-9	Not Listed	Xn; R42/43	Resp Sens. (H334) Skin Sens. (H317)	98
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Potassium phosphate	7778-77-0	231-913-4	Not Listed	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 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:** Breathing dust may worsen asthma symptoms.

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

**Notes to Physician:** None

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

**Advice for Fire-Fighters**

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Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

### 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. Avoid dust formation.

#### 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:

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

##### Additional Consideration for Large Spills:

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. 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

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. Wash thoroughly after handling. Releases to the environment should be avoided. Use appropriate personal protective equipment.

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

##### Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

##### 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 Sodium

Zoetis OEL TWA 8-hr

200 µg/m<sup>3</sup>, Sensitizer

#### Sodium hydroxide

ACGIH Ceiling Threshold Limit:

2 mg/m<sup>3</sup>

Australia PEAK

2 mg/m<sup>3</sup>

Austria OEL - MAKs

2 mg/m<sup>3</sup>

Bulgaria OEL - TWA

2.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA

1 mg/m<sup>3</sup>

Estonia OEL - TWA

1 mg/m<sup>3</sup>

France OEL - TWA

2 mg/m<sup>3</sup>

Greece OEL - TWA

2 mg/m<sup>3</sup>

Hungary OEL - TWA

2 mg/m<sup>3</sup>

Japan - OELs - Ceilings

2 mg/m<sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

#### Exposure Controls

<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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>	Powder	<b>Color:</b>	Off-white to tan
<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>	Slightly soluble: Methanol, Tetrahydrofuran
<b>Water solubility:</b>	>400 mg/ml
<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
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Polymerization:</b>	Will not occur

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Partition Coefficient  
(n-octanol/water - cLog P): 0.3 (pH 5)

### 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. Keep away from heat, spark, flames and all other sources of ignition.  
**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 active ingredient(s).

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

##### Ceftiofur Sodium

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

##### Sodium hydroxide

Mouse IP LD50 40 mg/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 Sodium

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit Minimal

##### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

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

##### Ceftiofur Sodium

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 Sodium

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### 11. TOXICOLOGICAL INFORMATION

2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	NOEL	Fetotoxicity
Embryo / Fetal Development	Rat	Oral	3200 mg/kg/day	NOAEL	Not Teratogenic

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

##### Ceftiofur Sodium

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 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.

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### 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



**Ceftiofur Sodium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Sodium hydroxide**

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	Schedule 6 215-185-5

**Potassium phosphate**

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	231-913-4

### 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  
H314 - Causes severe skin burns and eye damage

R35 - Causes severe burns.  
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.



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**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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. 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**