



MATERIAL SAFETY DATA SHEET

Revision date: 09-Mar-2011

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:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Ceftiofur Sodium Sterile Powder

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

2. HAZARDS IDENTIFICATION

Appearance: Off white to light tan powder
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 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.

EU Indication of danger: Harmful

EU Hazard Symbols:

Xn



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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 Sodium	104010-37-9	Not Listed	Xn; R42/43	98
Sodium hydroxide	1310-73-2	215-185-5	C;R35	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Potassium phosphate	7778-77-0	231-913-4	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: Formation of toxic gases is possible during heating or fire.

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 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.
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:	Minimize dust generation and accumulation. Avoid breathing dust. 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

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

Ceftiofur Sodium

Pfizer OEL TWA-8 Hr:	200µg/m ³ , Sensitizer
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Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	2 mg/m ³
Poland OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Analytical Method:	Analytical method available for Ceftiofur. 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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Physical State:	Powder	Color:	Off-white to tan
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	Slightly soluble: Methanol, Tetrahydrofuran		
Water solubility:	>400 mg/ml		
Polymerization:	Will not occur		
Partition Coefficient (n-octanol/water - cLog P):	0.3 (pH 5)		

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 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	927 mg/kg
Rat	Inhalation	LC 50	>8.3 mg/L

Sodium hydroxide

Mouse	IP	LD50	40 mg/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 Sodium

Eye Irritation	Rabbit	Minimal
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11. TOXICOLOGICAL INFORMATION

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

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) *Salmonella*, *E. coli* 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.

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

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

EU Symbol: Xn
EU Indication of danger: Harmful

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

EU Safety Phrases:
S22 - Do not breathe dust.
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



Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	454 kg final RQ
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Listed
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	215-185-5

Potassium phosphate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-913-4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R35 - Causes severe burns.
R42/43 - May cause sensitization by inhalation and skin contact.

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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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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