SAFETY DATA SHEET

1. Identification

Product identifier	**Ceftiofur Sodium Sterile Powder**
Other means of identification	
Synonyms	Excenel * Naxcel * Ceftiofur sodium powder for solution * Excenel sterile powder
Recommended use	Veterinary antibiotic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917 All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx
Supplier	Not available.

2. Hazard(s) identification

Physical hazards	Combustible dusts	Category 1
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	

Label elements

Signal word	Danger
Hazard statement	May form combustible dust concentrations in air. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing dust. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves. In case of inadequate ventilation wear respiratory protection. Observe good industrial hygiene practices.
Response	IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE/doctor. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Ceftiofur Hydrochloride	Cephalosporin antibiotic; b-lactam antibiotic; b-lactamase inhibitor	103980-44-5	98
Sodium hydroxide		1310-73-2	1
Benzyl Alcohol (in the sterile diluent)		100-51-6	<1
Potassium phosphate		7778-77-0	<1
Sterile diluent for injection		7732-18-5	

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. If breathing is difficult, trained personnel should give oxygen.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause skin irritation. May cause redness and pain. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. High concentration of airborne dust may form explosive mixture with air.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air. Fine particles (such as dust and mists) may fuel fires/explosions.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation. Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ventilate the contaminated area. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Ensure adequate ventilation. Avoid the generation of dusts during clean-up. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent product from entering drains. Large Spills: Stop the flow of material, if this is without risk. Collect spill with an inert, non-combustible absorbent material and transfer to labeled container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment. Small Spills: Wipe up with a damp cloth and place in container for disposal. Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Use with adequate ventilation. Minimise dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not breathe dust. Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Store in a well-ventilated place. Before reconstitution: @ 15-30°C (59-86°F). Keep away from heat, sparks and open flame. Protect from sunlight. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components	Type	Value
Ceftiofur Hydrochloride (CAS 103980-44-5)	TWA	200 µg/m³

US. ACGIH Threshold Limit Values

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
Sodium Hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines OEL Additional Information: Sensitizer

Control banding approach Not available.

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear protective gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance Powder for reconstitution plus sterile diluent

Physical state Solid.

Form Powder. plus sterile diluent.

Colour Off-white to tan

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	>400 mg/ml
Solubility (other)	Slight (methanol, THF)
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Keep away from heat, sparks and open flame. Minimise dust generation and accumulation.
Incompatible materials	Strong oxidising agents. Strong acids. Bases.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.

Benzyl Alcohol (in the sterile diluent)	Species: Guinea Pig Severity: Moderate Species: Rabbit Severity: Minimal
Ceftiofur Hydrochloride	Species: Rabbit Severity: Minimal
Sodium hydroxide	Species: Rabbit Severity: Severe

Eye contact Causes serious eye irritation.

Ceftiofur Hydrochloride	Species: Rabbit Severity: Minimal
Benzyl Alcohol (in the sterile diluent)	Species: Rabbit Severity: Severe
Sodium hydroxide	Species: Rabbit Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
Benzyl Alcohol (in the sterile diluent) (CAS 100-51-6)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg
Inhalation		
LC50	Rat	> 4.178 mg/l
		1000 mg/l, 8 Hours
Oral		
LD50	Mouse	1580 mg/kg
	Rat	1230 mg/kg
Ceftiofur Hydrochloride (CAS 103980-44-5)		
Acute		
Inhalation		
LC50	Rat	> 8.3 mg/l
Oral		
LD50	Rat	> 7760 mg/kg
Other		
LD50	Rat	927 mg/kg [Sub-tenon injection (eye)]
Subchronic		
Oral		
NOEL	Dog	30 mg/kg/day, 90 days [Target organ(s): Blood forming organs]
Sodium hydroxide (CAS 1310-73-2)		
Acute		
Intraperitoneal		
LD50	Mouse	40 mg/kg

Skin corrosion/irritation Causes skin irritation.

Corrosivity

Ceftiofur Hydrochloride	Species: Rabbit Severity: Minimal irritation

Serious eye damage/eye irritation Causes serious eye irritation.

Eye contact

Ceftiofur Hydrochloride	Species: Rabbit Severity: Minimal

Eye contact

Benzyl Alcohol (in the sterile diluent)	Species: Rabbit Severity: Severe
Sodium hydroxide	Species: Rabbit Severity: Severe

Respiratory or skin sensitisation

Canada - Alberta OELs: Irritant

Sodium hydroxide (CAS 1310-73-2)	Irritant

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation May cause an allergic skin reaction.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Ceftiofur Hydrochloride	Bacterial Mutagenicity (Ames) Result: negative Species: Salmonella , E. coli Mammalian Cell Mutagenicity Result: negative Species: Chinese Hamster Ovary (CHO) cells Unscheduled DNA Synthesis Result: negative Species: Rat

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Developmental effects

Ceftiofur Hydrochloride	3200 mg/kg/day Embryo / Fetal Development, Not Teratogenic Result: NOAEL Species: Rat Organ: Oral

Reproductivity

Ceftiofur Hydrochloride	1000 mg/kg/day 2 Generation Reproductive Toxicity, Fetotoxicity Result: NOEL Species: Rat Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect blood and blood forming organs through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information 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.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test results
Benzyl Alcohol (in the sterile diluent) (CAS 100-51-6)		
EC50	Daphnia magna (Water Flea)	230 mg/l, 48 Hours
		66 mg/l, 21 day(s) Toxicity for reproduction

Components		Species	Test results
		Pseudokirchneriella subcapitata (Green Alga)	500 mg/l, 72 Hours
	LC50	Pimephales promelas (Fathead Minnow)	460 mg/l, 96 Hours
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	10 mg/l, 96 hours
Sodium hydroxide (CAS 1310-73-2)			
Aquatic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	34.59 - 47.13 mg/l, 48 hours
Fish	LC50	Western mosquitofish (Gambusia affinis)	125 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 05-April-2017

Version No. 01

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Revision information Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
GHS: Classification