SAFETY DATA SHEETS

This SDS packet was issued with item:

078393814

N/A

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

Veterinary antibiotic agent Recommended use

Recommended restrictions Not for human use Manufacturer/Importer/Supplier/Distributor information

Zoetis Inc. **Company Name (US)**

10 Sylvan Way

Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison

and Drug Center

1-866-531-8896

Product Support/Technical

1-800-366-5288

Services

numbers

Emergency telephone

CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Zoetis Belgium S.A. **Company Name (EU)**

> Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone

number

International CHEMTREC (24 hours): +1-703-527-3887

VMIPSrecords@zoetis.com **Contact E-Mail**

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

> Serious eye damage/eye irritation Category 2 Sensitization, respiratory Category 1 Sensitization, skin Category 1

Not classified. **Environmental hazards OSHA** defined hazards Combustible dust

Label elements



Signal word Danger

May form combustible dust concentrations in air. Causes skin irritation. May cause an allergic skin Hazard statement

reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statement

Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Avoid breathing dust.

Wash thoroughly after handling. Contaminated work clothing must 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.

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If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Response

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/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

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.

Hazard(s) not otherwise classified (HNOC)

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	

Composition comments

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or Inhalation

doctor/physician. If breathing is difficult, trained personnel should give oxygen.

Remove contaminated clothing immediately and wash skin with soap and water. Get medical Skin contact

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.

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Eye contact

Continue rinsing. Get medical attention if irritation develops and persists.

Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, Ingestion call a poison control center 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. Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. Severe eye irritation.

symptoms/effects, acute and

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 delayed

nausea, vomiting, or diarrhea.

Indication of immediate medical attention and special treatment needed

Most important

General information

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

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

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media Suitable 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 Self-contained breathing apparatus and full protective clothing must be worn in case of fire. and precautions for firefighters

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Fire fighting equipment/instructions Specific methods General fire hazards

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do

so without risk.

Use standard firefighting procedures and consider the hazards of other involved materials.

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.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. 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. Minimize 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis Components	Туре	Value	
Ceftiofur Hydrochloride (CAS 103980-44-5)	TWA	200 μg/m³	
US. OSHA Table Z-1 Limits for Air C	ontaminants (29 CFR 1910.1	000)	
Components	Туре	Value	
Sodium hydroxide (CAS 1310-73-2)	PEL	2 mg/m3	
US. ACGIH Threshold Limit Values			
Components	Туре	Value	
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3	
US. NIOSH: Pocket Guide to Chemic	al Hazards		
Components	Туре	Value	
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3	

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US. Workplace Environmental Exposure Level (WEEL) Guides

Type Benzyl Alcohol (in the TWA 44.2 mg/m3

sterile diluent) (CAS

100-51-6)

Components

10 ppm

Value

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

Not available.

Exposure guidelines OEL Additional Information: Sensitizer

Control banding approach

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

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

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.

In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection 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

vapor 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

Powder for reconstitution plus sterile diluent **Appearance**

Physical state

Powder, plus sterile diluent. **Form**

Color Off-white to tan Odor Not available. **Odor threshold** Not available. pН Not available. Not available. Melting point/freezing point Not available. Initial boiling point and boiling

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

(%)

Not available.

Flammability limit - upper

Flammability limit - lower

Not available.

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper (%)

Not available. Vapor pressure Vapor density Not available.

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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 temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive propertiesNot explosive. **Oxidizing properties**Not oxidizing.

10. Stability and reactivity

ReactivityThe 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. Minimize dust

generation and accumulation.

Incompatible materials Strong oxidizing 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.

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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

Causes skin irritation. Skin corrosion/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

Species: Rabbit Benzyl Alcohol (in the sterile diluent)

Severity: Severe

Sodium hydroxide Species: Rabbit

Severity: Severe

Respiratory or skin sensitization

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

Skin sensitization May cause an allergic skin reaction.

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

mutagenic or genotoxic.

Mutagenicity

Ceftiofur Hydrochloride Bacterial Mutagenicity (Ames)

Result: Negative

Species: Salmonella, E. coli

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Mutagenicity

Ceftiofur Hydrochloride 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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicityThis 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.

Test Results Components **Species** 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) Reproduction Pseudokirchneriella subcapitata (Green 500 mg/L, 72 Hours Alga) LC50 Pimephales promelas (Fathead 460 mg/L, 96 Hours Minnow) Aquatic LC50 Bluegill (Lepomis macrochirus) 10 mg/l, 96 hours Fish 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

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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 instructionsAvoid 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

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Sodium hydroxide (CAS 1310-73-2) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

No

SARA 313 (TRI reporting)

Not regulated.

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Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material **US** state regulations

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3,

subd. (a))

Sodium hydroxide (CAS 1310-73-2)

International Inventories

Country (a) ar region

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 *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

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Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while Disclaimer

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. The information in the sheet was written based on the best knowledge and experience currently

available.

This document has undergone significant changes and should be reviewed in its entirety. **Revision information**

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On inventory (veelne)*

No

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).