SAFETY DATA SHEET



1. Identification

Product identifier Excede Sterile Suspension

Other means of identification

Synonyms Excede * Naxcel * Ceftiofur Crystalline Free Acid Sterile Suspension * Excede 100 * Excede 200

Recommended use Veterinary antibiotic agent

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

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

Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone

number

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

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1

Sensitization, skin Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary statement

Prevention Avoid breathing mist or vapor. Contaminated work clothing must not be allowed out of the

workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

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

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. Wash contaminated clothing

before reuse.

Storage Store away from incompatible materials.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise None known.

classified (HNOC)

Supplemental information

May cause eye irritation. May cause skin irritation. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. 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. Effects on blood and blood-forming organs have also occurred.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Cottonseed Oil		8001-29-4	17.5
Ceftiofur Crystalline Free Acid		80370-57-6	100 or 200 mg/ml
Non-hazardous ingredients		Proprietary	*

Composition comments

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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

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

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.

Ingestion Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur,

call a poison control center immediately. Never give anything by mouth to a victim who is

unconscious or is having convulsions.

Most important

symptoms/effects, acute and

delayed Indication of immediate medical attention and special

treatment needed

General information

Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. May cause eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort. May cause skin irritation. May cause redness and pain.

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

IF exposed or concerned: Get medical advice/attention. 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

Unsuitable extinguishing media

Specific hazards arising from the chemical

Special protective equipment

and precautions for firefighters

Fire fighting equipment/instructions

Specific methods General fire hazards Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

During fire, gases hazardous to health may be formed.

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

Move containers from fire area if you can do so without risk.

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

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Ventilate closed spaces before entering them. 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. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Avoid release to the environment. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). 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

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Observe good industrial hygiene practices. Provide adequate ventilation. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Avoid accidental injection. Avoid release to the environment. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Protect from sunlight. Keep away from heat, sparks and open flame. Store in original tightly closed container. @ 15 - 25°C (59 - 77°F). Do not allow material to freeze. Keep away from food, drink and animal feedingstuffs. 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	Туре	Value	
Ceftiofur Crystalline Free Acid (CAS 80370-57-6)	TWA	200 μg/m³	
US. OSHA Table Z-1 Limit	s for Air Contaminants (29 CFR 1910.100	0)	
Components	Туре	Value	Form
Cottonseed Oil (CAS 8001-29-4)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
US. NIOSH: Pocket Guide	to Chemical Hazards		
Components	Туре	Value	Form
Cottonseed Oil (CAS 8001-29-4)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Mist.
logical limit values	No biological exposure limits noted for the ingredient(s).		
oosure guidelines	OEL Additional Information: Sensitizer		
ntrol banding approach	Not available.		
propriate engineering ntrols	Ensure adequate ventilation, especially changes per hour) should be used. Ven applicable, use process enclosures, loc maintain airborne levels below recomme	tilation rates should be mate al exhaust ventilation, or oth	ched to conditions. If ner engineering controls to

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 appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove

supplier.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable

established, maintain airborne levels to an acceptable level.

coveralls, etc.) in both production and laboratory areas.

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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 engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapor cartridge, full facepiece, dust and mist filter.

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Thermal hazards

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 Suspension Physical state Liquid. Liquid. **Form** Color Opaque. Odor Not available. **Odor threshold** Not available. Not available. Ha Melting point/freezing point Not available. Initial boiling point and boiling

range

Not available.

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

Not available. Vapor density Not available. Relative density

Solubility(ies)

Solubility (water) Not available. Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available. Not available. **Decomposition temperature Viscosity** Not available.

Other information

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

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

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.

Strong oxidizing agents. Incompatible materials

Hazardous decomposition products

No dangerous reaction known under conditions of normal use.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation

may be harmful.

Skin contact May cause an allergic skin reaction.

Ceftiofur Crystalline Free Acid Species: Rabbit

Severity: Minimal

Eye contact Direct contact with eyes may cause temporary irritation.

Ceftiofur Crystalline Free Acid Species: Rabbit

Severity: Minimal

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash. May cause eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin

irritation. May cause redness and pain.

Information on toxicological effects

Acute toxicity May cause an allergic skin reaction.

Components Species Test Results

Ceftiofur Crystalline Free Acid (CAS 80370-57-6)

<u>Acute</u>

Inhalation

LC50 Rat > 8.3 mg/l, 4 Hours

Oral

LD50 Rat > 7760 mg/kg

Other

LD50 Rat 927 mg/kg [Sub-tenon injection (eye)]

<u>Subacute</u>

Oral

NOEL Rat < 1500 mg/kg/day, 30 days [Target

organ(s): Gastrointestinal System]

Subchronic

Oral

LOAEL Dog 300 mg/kg/day, 51 days [Target organ(s):

Blood forming organs]

NOEL Dog 30 mg/kg/day, 90 days [Target organ(s):

Blood forming organs]

Rat 30 mg/kg/day, 90 days [Target organ(s):

Gastrointestinal system]

Cottonseed Oil (CAS 8001-29-4)

Acute

Oral

LD50 Rat > 90 ml/kg

Non-hazardous ingredients

Acute

Oral

LD50 Rat > 5000 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Ceftiofur Crystalline Free Acid Species: Rabbit

Severity: Minimal

Serious eve damage/eve

irritation

Direct contact with eyes may cause temporary irritation.

Eve Contact

Ceftiofur Crystalline Free Acid Species: Rabbit Severity: Minimal

Respiratory or skin sensitization

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

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 Crystalline Free Acid In Vitro Bacterial Mutagenicity (Ames)

Result: Negative

Species: Salmonella, E. coli

In Vitro Mammalian Cell Mutagenicity

Result: Negative

Species: Chinese Hamster Ovary (CHO) cells

In Vivo Micronucleus Result: Negative Species: Rat

Unscheduled DNA Synthesis

Result: Negative

Species: Rat Hepatocyte

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

IARC Monographs. Overall Evaluation of Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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

Developmental effects

Ceftiofur Crystalline Free Acid 3200 mg/kg/day Embryo / Fetal Development, Not

Teratogenic, Fetotoxicity, Maternal Toxicity

Result: NOAEL Species: Rat Organ: Oral

Reproductivity

1000 mg/kg/day 2 Generation Reproductive Toxicity, No Ceftiofur Crystalline Free Acid

effects at maximum dose

Result: NOEL Species: Rat Organ: Oral

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Avoid release to the environment.

Material name: Excede Sterile Suspension 387 Version #: 01 Issue date: 04-05-2017 Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available. Partition coefficient n-octanol / water (log Kow)

Ceftiofur Crystalline Free Acid 0.1

Mobility in soil No data available.

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation Other adverse effects

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. Dispose in accordance with all applicable regulations. Local disposal regulations

Hazardous waste code None known.

products

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

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

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 established. Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

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

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)

Not 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 - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No

chemical

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SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

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

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

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Australia Australian Inventory of Chemical Substa	inces (AICS) No
Canada Domestic Substances List (DSL)	No
Canada Non-Domestic Substances List (NDSL)	No
China Inventory of Existing Chemical Substan	ces in China (IECSC) No
Europe European Inventory of Existing Comme Substances (EINECS)	cial Chemical No
European List of Notified Chemical Sub	stances (ELINCS) No
Japan Inventory of Existing and New Chemica	Substances (ENCS) No
Korea Existing Chemicals List (ECL)	No
New Zealand Inventory	Yes
Philippines Philippine Inventory of Chemicals and C (PICCS)	hemical Substances 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).

Toxic Substances Control Act (TSCA) Inventory

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

04-05-2017 Issue date

Version # 01

United States & Puerto Rico

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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**

387 Version #: 01 Issue date: 04-05-2017

No