SAFETY DATA SHEET

1. Identification

Product identifier
EXCENEL® RTU EZ

Other means of identification
Synonyms
Ceftiofur Hydrochloride Sterile Suspension * EXCENEL® * EXCENEL RTU EZ * EXCENEL® RTU EZ Sterile Suspension * Ceftiofur hydrochloride sterile injectable suspension * EXCENEL® Evo * EXCENEL® Flow * EXCENEL® Fluid * EXCENEL® Fluid suspension * EXCENEL RTU EZ Antibiotic Suspension for Injection

Recommended use of the chemical and restrictions on use
Recommended use
Veterinary product used as antibiotic agent
Restrictions on use
Not for human use

Details of manufacturer or importer
Company Name (AU)
Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW  2138  AUSTRALIA

Tel
1800 814 883

Fax
(02) 8876 0444

Email
productsupport.au@zoetis.com

Emergency Phone
1800 814 883 (all hours)

Police and Fire Brigade
Dial 000

If ineffective
Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical
Physical hazards
Not classified.

Health hazards
Sensitization, respiratory
Category 1
Sensitization, skin
Category 1

Environmental hazards
Not classified.

Label elements, including precautionary statements

Hazard symbol(s)
Health hazard

Signal word
Danger

Hazard statement(s)
May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement(s)

Prevention
Avoid breathing mist or vapour. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. Wash contaminated clothing before reuse.

Storage
Store away from incompatible materials.

Disposal
Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification: 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.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Mixture</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftiofur Hydrochloride</td>
<td>103980-44-5</td>
<td>6.11</td>
</tr>
<tr>
<td>Cephalosporin antibiotic; β-lactam antibiotic; β-lactamase inhibitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miglyol 812</td>
<td>73398-61-5</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>2.5 mg/ml</td>
</tr>
</tbody>
</table>

Composition comments: * Non-hazardous Ingredients

4. First-aid measures

Description of necessary 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. Self Injection: In all instances of accidental self injection contact a doctor as soon as possible. Further information on treatment is available from Poisons Information Centre - Phone 131 126. Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. Check your tetanus immunisation status.
- **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.

Personal protection for first-aid responders:

For personal protection, see section 8 of the SDS. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call. 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

Extinguishing media:

- **Suitable extinguishing media**: Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
- **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.

Special protective equipment and precautions for fire fighters:

- **Self-contained breathing apparatus and full protective clothing must be worn in case of fire.**
- **Fire fighting equipment/instructions**: Move containers from fire area if you can do so without risk.
- **Hazchem code**: None.
- **General fire hazards**: No unusual fire or explosion hazards noted.
- **Specific methods**: Use standard firefighting procedures and consider the hazards of other involved materials.
6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel
Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders
Keep unnecessary personnel away. Ensure adequate ventilation. Use personal protection recommended in Section 8 of the SDS. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Ventilate the contaminated area. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

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.

Methods and materials for containment and cleaning up
Ensure adequate ventilation. 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.

7. Handling and storage

Precautions for safe handling
Use with adequate ventilation. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Wash contaminated clothing before reuse.

Conditions for safe storage, including any incompatibilities

8. Exposure controls and personal protection

Control parameters
Follow standard monitoring procedures.

Occupational exposure limits

<table>
<thead>
<tr>
<th>Zoetis Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Hydrochloride (CAS 103980-44-5)</td>
<td>TWA</td>
<td>200 µg/m³</td>
</tr>
</tbody>
</table>

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

Exposure guidelines
OEL Additional Information: Sensitizer

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, for example personal protective equipment (PPE)

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.

Hygiene measures: 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Suspension</td>
</tr>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Form</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Opaque</td>
</tr>
<tr>
<td>Odour</td>
<td>Not available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td></td>
</tr>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit – upper (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Other physical and chemical parameters</td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>Not oxidising</td>
</tr>
</tbody>
</table>

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. Protect from freezing.

Incompatible materials: Strong oxidising agents.
Irritating and/or toxic fumes and gases may be emitted upon the product’s decomposition.

11. Toxicological information

Information on possible 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.
Species: Rabbit
Severity: Minimal

Eye contact
Direct contact with eyes may cause temporary irritation.
Species: Rabbit
Severity: Minimal

Ingestion
Expected to be a low ingestion hazard.

Symptoms related to exposure
Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

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

Test Results

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftiofur Hydrochloride (CAS 103980-44-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>Rat</td>
<td>LC50 &gt; 8.3 mg/l</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>LD50 &gt; 7760 mg/kg</td>
</tr>
<tr>
<td>Other</td>
<td>Rat</td>
<td>LD50 927 mg/kg [Sub-tenon injection (eye)]</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Dog</td>
<td>NOEL 30 mg/kg/day, 90 days [Target organ(s): Blood forming organs]</td>
</tr>
</tbody>
</table>

Polysorbate 80 (CAS 9005-65-6)

| **Acute** | | |
| Intravenous | Rat | LD50 1790 mg/kg |
| Oral | Mouse | LD50 25 g/kg |

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

Corrosivity
Species: Rabbit
Severity: Minimal irritation

Serious eye damage/irritation
Direct contact with eyes may cause temporary irritation.

Eye contact
Species: Rabbit
Severity: Minimal

Respiratory or skin sensitisation

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
Due to partial or complete lack of data the classification is not possible.

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
Not classified.

Aspiration hazard
Not an aspiration hazard.

Chronic effects
Prolonged inhalation may be harmful.

Other 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.

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

Bioaccumulative potential
No data available.

Mobility in soil
No data available for this product.

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 methods
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.

Residual waste
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

ADG
Not regulated as dangerous goods.

RID
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 established.

15. Regulatory information

Safety, health and environmental regulations

This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA No. 82351

Poison Schedule (Product) - Schedule 4

Material name: EXCENEL® RTU EZ

797

SDS AUSTRALIA

7 / 9
Australia Medicines & Poisons Schedule 8
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9
Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)
Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

Prohibited Carcinogenic Substances
Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)
Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)
Not listed.

Restricted Carcinogenic Substances
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

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

*“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 07-February-2019

Disclaimer Zoetis Inc. believes that the information contained in this 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. The information in the sheet was written based on the best knowledge and experience currently available.
<table>
<thead>
<tr>
<th>Revision information</th>
<th>Product and Company Identification: Synonyms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Composition / Information on Ingredients: Ingredients</td>
</tr>
<tr>
<td></td>
<td>Physical &amp; Chemical Properties: Multiple Properties</td>
</tr>
</tbody>
</table>