SAFETY DATA SHEET

1. Identification

Product identifier Excenel RTU Sterile Suspension
Other means of identification
Synonyms Excenel RTU * EXCENEL® RTU Antibiotic Suspension for Injection * Ceftioufur Hydrochloride Sterile Suspension

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

Details of manufacturer or importer
Manufacturer
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 Poison 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)

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 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. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. 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

Mixtures

<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Hydrochloride</td>
<td>103980-44-5</td>
<td>5</td>
</tr>
<tr>
<td>Cephalosporin antibiotic; b-lactam antibiotic; b-lactamase inhibitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water and other non-hazardous components</td>
<td>7732-18-5</td>
<td></td>
</tr>
</tbody>
</table>

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.

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. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

Symptoms caused by exposure

Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

Medical attention and special treatment

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

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

Ensure adequate ventilation. Keep unnecessary personnel away. Do not breathe mist or vapour. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders

Use personal protection recommended in Section 8 of the SDS. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. 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

Avoid release to the environment. Ensure adequate ventilation. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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
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 vapour. 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 locked up. Store in a well-ventilated place. Protect from sunlight. Keep away from heat, sparks and open flame. Store below 25°C. Do not freeze. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters
Follow standard monitoring procedures.

Occupational exposure limits
Zoetis Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefitiofur Hydrochloride</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
Provide adequate ventilation. 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.

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 appropriate chemical resistant gloves.

Other
Wear appropriate chemical resistant 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. 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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

Appearance
Suspension

Physical state
Liquid.

Form
Liquid.

Colour
Off-white to pale buff-colored
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 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.
Vapour pressure Not available.
Vapour density Not available.
Relative density Not available.
Solubility(ies)
   Solubility (water) Not available.
Partition coefficient (n-octanol/water) Not available.
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.
Other physical and chemical parameters
   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.
Incompatible materials Strong oxidising agents.
Hazardous decomposition products No hazardous decomposition products are known.

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.
      Ceftiofur Hydrochloride Species: Rabbit
      Severity: Minimal
   Eye contact Direct contact with eyes may cause temporary irritation.
      Ceftiofur Hydrochloride 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
May cause an allergic skin reaction.

### Components

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone 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>&gt; 8.3 mg/l</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 7760 mg/kg</td>
</tr>
<tr>
<td>Other</td>
<td>Rat</td>
<td>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>30 mg/kg/day, 90 days [Target organ(s): Blood forming organs]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Corrosivity</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Hydrochloride</td>
<td>Rabbit</td>
<td>Minimal irritation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Eye contact</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Hydrochloride</td>
<td>Rabbit</td>
<td>Minimal</td>
</tr>
</tbody>
</table>

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

### Respiratory sensitisation
May cause an allergic skin reaction.

### Skin sensitisation
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

### Germ cell mutagenicity

<table>
<thead>
<tr>
<th>Mutagenicity</th>
<th>Bacterial Mutagenicity (Ames)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Salmonella, E. coli</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mammalian Cell Mutagenicity</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Chinese Hamster Ovary (CHO) cells</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unscheduled DNA Synthesis</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Developmental effects</th>
<th>3200 mg/kg/day Embryo / Fetal Development, Not Teratogenic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Result: NOAEL</td>
</tr>
<tr>
<td>Organ: Oral</td>
<td></td>
</tr>
</tbody>
</table>
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.

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. Contract with a disposal operator licensed by the Law on Disposal and Cleaning.

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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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
National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 50507

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued 24 October 2016

**Australia Medicines & Poisons Appendix A**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix B**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix C**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix D**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix E**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix F**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix G**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix H**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix I**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix J**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Appendix K**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 2**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 3**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 4**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 5**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 6**

Poisons schedule number not allocated.

**Australia Medicines & Poisons Schedule 7**

Poisons schedule number not allocated.

**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.


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>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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            24-October-2016
Revision date         14-October-2021
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.

Revision information    Periodical revision