

## 1. Identification

|   |   |  |
|---|---|--|
| <b>Product identifier</b>                                     | <b>EXCENEL® RTU EZ</b>  |  |
| <b>Other means of identification</b>                          |   |  |
| <b>Synonyms</b>   | 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 |  |
| <b>Recommended use</b>  | Veterinary product used as antibiotic agent   |  |
| <b>Recommended restrictions</b>                               | Not for human use   |  |
| <b>Manufacturer/Importer/Supplier/Distributor information</b> |   |  |
| <b>Company Name (US)</b>                                      | Zoetis Inc.<br>10 Sylvan Way<br>Parsippany, New Jersey 07054 (USA)  |  |
| <b>Rocky Mountain Poison and Drug Center</b>                  | 1-866-531-8896  |  |
| <b>Product Support/Technical Services</b>                     | 1-800-366-5288  |  |
| <b>Emergency telephone numbers</b>                            | CHEMTREC (24 hours): 1-800-424-9300<br><br>International CHEMTREC (24 hours): +1-703-527-3887   |  |
| <b>Company Name (EU)</b>                                      | Zoetis Belgium S.A.<br>Mercuriusstraat 20<br>1930 Zaventem<br>Belgium   |  |
| <b>Emergency telephone number</b>                             | International CHEMTREC (24 hours): +1-703-527-3887  |  |
| <b>Contact E-Mail</b>   | VMIPSrecords@zoetis.com   |  |

## 2. Hazard(s) identification

|                              |                            |            |
|------------------------------|----------------------------|------------|
| <b>Physical hazards</b>      | Not classified.            |            |
| <b>Health hazards</b>        | Sensitization, respiratory | Category 1 |
|                              | Sensitization, skin        | Category 1 |
| <b>Environmental hazards</b> | Not classified.            |            |
| <b>OSHA defined hazards</b>  | Not classified.            |            |

### Label elements



|                                |   |  |
|--------------------------------|---|--|
| <b>Signal word</b>             | Danger  |  |
| <b>Hazard statement</b>        | May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.   |  |
| <b>Precautionary statement</b> |   |  |
| <b>Prevention</b>              | 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.  |  |
| <b>Response</b>                | If 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. |  |
| <b>Storage</b>                 | Store away from incompatible materials.   |  |
| <b>Disposal</b>                | 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.

### 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 | 6.11      |
| Miglyol 812             |  | 73398-61-5  | *         |
| Polysorbate 80          |  | 9005-65-6   | 2.5 mg/ml |

**Composition comments** \* Non-hazardous Ingredients  
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.

#### 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 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.

#### Most important symptoms/effects, acute and delayed

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

#### 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 (CO<sub>2</sub>).

#### 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 firefighters

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.

#### Specific methods

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

#### General fire hazards

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. 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**

Use with adequate ventilation. Do not breathe mist or vapor. 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**

Store in a well-ventilated place. Protect from sunlight. Keep away from heat, sparks and open flame. Store in original tightly closed container. @ 15-30°C (59-86°F). Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep away from food, drink and animal feedings. 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****Type****Value**

Ceftiofur Hydrochloride  
(CAS 103980-44-5)

TWA

200 µg/m<sup>3</sup>

**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 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

|   |                 |
|---|-----------------|
| <b>Appearance</b>                                   | Suspension      |
| <b>Physical state</b>                               | Liquid.         |
| <b>Form</b>   | Liquid.         |
| <b>Color</b>  | Opaque.         |
| <b>Odor</b>   | Not available.  |
| <b>Odor threshold</b>                               | Not available.  |
| <b>pH</b>   | Not available.  |
| <b>Melting point/freezing point</b>                 | Not available.  |
| <b>Initial boiling point and boiling range</b>      | Not available.  |
| <b>Flash point</b>                                  | Not available.  |
| <b>Evaporation rate</b>                             | Not available.  |
| <b>Flammability (solid, gas)</b>                    | Not applicable. |
| <b>Upper/lower flammability or explosive limits</b> |                 |
| <b>Flammability limit - lower (%)</b>               | Not available.  |
| <b>Flammability limit - upper (%)</b>               | Not available.  |
| <b>Explosive limit - lower (%)</b>                  | Not available.  |
| <b>Explosive limit - upper (%)</b>                  | Not available.  |
| <b>Vapor pressure</b>                               | Not available.  |
| <b>Vapor density</b>                                | Not available.  |
| <b>Relative density</b>                             | Not available.  |
| <b>Solubility(ies)</b>                              |                 |
| <b>Solubility (water)</b>                           | Not available.  |
| <b>Partition coefficient (n-octanol/water)</b>      | Not available.  |
| <b>Auto-ignition temperature</b>                    | Not available.  |
| <b>Decomposition temperature</b>                    | Not available.  |
| <b>Viscosity</b>                                    | Not available.  |
| <b>Other information</b>                            |                 |
| <b>Explosive properties</b>                         | Not explosive.  |
| <b>Oxidizing properties</b>                         | Not oxidizing.  |

## 10. Stability and reactivity

|   |   |
|---|---|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.   |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                   |
| <b>Conditions to avoid</b>                | Contact with incompatible materials. Protect from freezing.                                   |
| <b>Incompatible materials</b>             | Strong oxidizing agents.  |
| <b>Hazardous decomposition products</b>   | Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.      |

## 11. Toxicological information

### Information on likely routes of exposure

|                         |   |
|-------------------------|---|
| <b>Inhalation</b>       | May cause allergy or asthma symptoms or breathing difficulties if inhaled. Prolonged inhalation may be harmful. |
| <b>Skin contact</b>     | May cause an allergic skin reaction.  |
| Ceftiofur Hydrochloride | Species: Rabbit<br>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 the physical, chemical and toxicological characteristics** Difficulty in breathing. May cause an allergic skin reaction. Dermatitis. Rash.

**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  |
|---|---------|---|
| Ceftiofur Hydrochloride (CAS 103980-44-5) |         |   |
| <b>Acute</b>                              |         |   |
| <b>Inhalation</b>                         |         |   |
| LC50                                      | Rat     | > 8.3 mg/L  |
| <b>Oral</b>                               |         |   |
| LD50                                      | Rat     | > 7760 mg/kg  |
| <b>Other</b>                              |         |   |
| LD50                                      | Rat     | 927 mg/kg [Sub-tenon injection (eye)]                         |
| <b>Subchronic</b>                         |         |   |
| <b>Oral</b>                               |         |   |
| NOEL                                      | Dog     | 30 mg/kg/day, 90 days [Target organ(s): Blood forming organs] |

Polysorbate 80 (CAS 9005-65-6)

**Acute**

**Intravenous**

LD50 Rat 1790 mg/kg

**Oral**

LD50 Mouse 25 g/kg

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

**Corrosivity**

Ceftiofur Hydrochloride Species: Rabbit  
Severity: Minimal irritation

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

**Eye Contact**

Ceftiofur Hydrochloride 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.

**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

**Mutagenicity**  
Ceftiofur Hydrochloride

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 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.

**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.

**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

### DOT

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

**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)

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 chemical** No

**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 (SDWA)** Not regulated.

**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

| 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                     |

| <b>Country(s) or region</b> | <b>Inventory name</b>   | <b>On inventory (yes/no)*</b> |
|-----------------------------|---|-------------------------------|
| 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, including date of preparation or last revision

**Issue date** 04-05-2017

**Version #** 01

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