# **CURACEF DUO Suspension for Injection for Cattle**

# Virbac (Australia) Pty Limited

Chemwatch: **87-5592**Version No: **3.1.1.1** 

Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Code: 2

Issue Date: **22/11/2017**Print Date: **22/11/2017**S.GHS.AUS.EN

### SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

### **Product Identifier**

| Product name                  | CURACEF DUO Suspension for Injection for Cattle                           |  |
|-------------------------------|---|--|
| Synonyms                      | PVMA No: 83071  |  |
| Proper shipping name          | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains ketoprofen) |  |
| Other means of identification | Not Available   |  |

# Relevant identified uses of the substance or mixture and uses advised against

| Relevant identified uses For the treatment of respiratory infections in cattle associated with signs of inflammation or pyrexia. |  |
|--|--|
|--|--|

# Details of the supplier of the safety data sheet

| Registered company name | Virbac (Australia) Pty Limited               |
|-------------------------|--|
| Address                 | 361 Horsley Road Milperra NSW 2214 Australia |
| Telephone               | 1800 242 100                                 |
| Fax                     | +61 2 9772 9773                              |
| Website                 | www.virbac.com.au                            |
| Email                   | au_customerservice@virbac.com.au             |

### **Emergency telephone number**

| Association /<br>Organisation     | Poisons Information Centre |
|-----------------------------------|----------------------------|
| Emergency telephone numbers       | 13 11 26                   |
| Other emergency telephone numbers | Not Available              |

# **SECTION 2 HAZARDS IDENTIFICATION**

### Classification of the substance or mixture

HAZARDOUS CHEMICAL. DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

| Poisons Schedule              | S4   |  |  |
|-------------------------------|--|--|--|
| Classification <sup>[1]</sup> | Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Respiratory Sensitizer Category 1, Skin Sensitizer Category 1, Reproductive Toxicity Category 2, Specific target organ toxicity - repeated exposure Category 2, Acute Aquatic Hazard Category 2, Chronic Aquatic Hazard Category 2 |  |  |
| Legend:                       | 1. Classified by Chemwatch; 2. Classification drawn from HSIS; 3. Classification drawn from EC Directive 1272/2008 - Annex VI  |  |  |

### Label elements

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Hazard pictogram(s)







SIGNAL WORD

DANGER

# Hazard statement(s)

| H302 | armful if swallowed.   |  |
|------|--|--|
| H315 | Causes skin irritation.  |  |
| H319 | Causes serious eye irritation.   |  |
| H334 | y cause allergy or asthma symptoms or breathing difficulties if inhaled. |  |
| H317 | ay cause an allergic skin reaction.                                      |  |
| H361 | Suspected of damaging fertility or the unborn child.                     |  |
| H373 | May cause damage to organs through prolonged or repeated exposure.       |  |
| H411 | Toxic to aquatic life with long lasting effects.                         |  |

# Precautionary statement(s) Prevention

| P201 | Obtain special instructions before use.                                   |  |
|------|---|--|
| P260 | o not breathe dust/fume/gas/mist/vapours/spray.                           |  |
| P280 | ear protective gloves/protective clothing/eye protection/face protection. |  |
| P281 | Use personal protective equipment as required.                            |  |
| P285 | In case of inadequate ventilation wear respiratory protection.            |  |
| P270 | Do not eat, drink or smoke when using this product.                       |  |

# Precautionary statement(s) Response

| P304+P340      | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.                                 |  |
|----------------|--|--|
| P308+P313      | F exposed or concerned: Get medical advice/attention.  |  |
| P342+P311      | experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.   |  |
| P362           | Take off contaminated clothing and wash before reuse.  |  |
| P302+P352      | IF ON SKIN: Wash with plenty of soap and water.  |  |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |  |

# Precautionary statement(s) Storage

| P/05 | Store locked up |
|------|-----------------|

# Precautionary statement(s) Disposal

**P501** Dispose of contents/container in accordance with local regulations.

# SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

# **Substances**

See section below for composition of Mixtures

### **Mixtures**

| CAS No        | %[weight] | Name                                       |
|---------------|-----------|--|
| 22071-15-4    | 10-20     | ketoprofen                                 |
| 103980-44-5   | 1-10      | ceftiofur hydrochloride                    |
| Not Available | >60       | Ingredients determined not to be hazardous |

# **SECTION 4 FIRST AID MEASURES**

# Description of first aid measures

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| Eye Contact  | If this product comes in contact with the eyes:  • Wash out immediately with fresh running water.  • Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.  • Seek medical attention without delay; if pain persists or recurs seek medical attention.  • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.   |
|--------------|---|
| Skin Contact | If skin contact occurs:  ► Immediately remove all contaminated clothing, including footwear.  ► Flush skin and hair with running water (and soap if available).  ► Seek medical attention in event of irritation.   |
| Inhalation   | <ul> <li>If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>Other measures are usually unnecessary.</li> </ul>   |
| Ingestion    | <ul> <li>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</li> <li>For advice, contact a Poisons Information Centre or a doctor.</li> <li>Urgent hospital treatment is likely to be needed.</li> <li>In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.</li> <li>If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.</li> <li>If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.</li> <li>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</li> <li>INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>NOTE: Wear a protective glove when inducing vomiting by mechanical means.</li> </ul> |

# Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

for non-steroidal anti-inflammatories (NSAIDs)

- > Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.
- ▶ Patients should be managed by symptomatic and supportive care following a NSAIDs overdose.
- There are no specific antidotes.
- Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children), and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose).
- Forced diuresis, alkalinisation of urine, hemodialysis, or haemoperfusion may not be useful due to high protein binding.

### **SECTION 5 FIREFIGHTING MEASURES**

# **Extinguishing media**

- ▶ Foam
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog Large fires only.

Fire Fighting

### Special hazards arising from the substrate or mixture

Fire Incompatibility

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

# Advice for firefighters

# • Alert Fire Brigade and tell them location and nature of hazard.

- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Use water delivered as a fine spray to control fire and cool adjacent area.
- Avoid spraying water onto liquid pools.
- ▶ DO NOT approach containers suspected to be hot.

# Fire/Explosion Hazard

- ▶ Combustible. • Slight fire hazard when exposed to heat or flame.
- ▶ Heating may cause expansion or decomposition leading to violent rupture of containers.
- On combustion, may emit toxic fumes of carbon monoxide (CO).
- ▶ May emit acrid smoke.

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▶ Mists containing combustible materials may be explosive. Combustion products include:

carbon dioxide (CO2)

acrolein

other pyrolysis products typical of burning organic material.

CARE: Water in contact with hot liquid may cause foaming and a steam explosion with wide scattering of hot oil and possible severe burns. Foaming may cause overflow of containers and may result in possible fire.

**HAZCHEM** 

### **SECTION 6 ACCIDENTAL RELEASE MEASURES**

### Personal precautions, protective equipment and emergency procedures

See section 8

### **Environmental precautions**

See section 12

### Methods and material for containment and cleaning up

| Methous and material to | r containment and cleaning up   |  |
|-------------------------|---|--|
| Minor Spills            | Environmental hazard - contain spillage.  Slippery when spilt.  Clean up all spills immediately.  Avoid breathing vapours and contact with skin and eyes.  Control personal contact with the substance, by using protective equipment.  Contain and absorb spill with sand, earth, inert material or vermiculite.  Wipe up.  Place in a suitable, labelled container for waste disposal.  |  |
| Major Spills            | Environmental hazard - contain spillage.  CARE: Absorbent materials wetted with occluded oil must be moistened with water as they may auto-oxidize, become self heating and ignite.  Some oils slowly oxidise when spread in a film and oil on cloths, mops, absorbents may autoxidise and generate heat, smoulder, ignite and burn. In the workplace oily rags should be collected and immersed in water.  Slippery when spilt.  Moderate hazard.  Clear area of personnel and move upwind.  Alert Fire Brigade and tell them location and nature of hazard.  Wear breathing apparatus plus protective gloves.  Prevent, by any means available, spillage from entering drains or water course.  No smoking, naked lights or ignition sources. |  |

Personal Protective Equipment advice is contained in Section 8 of the SDS.

# **SECTION 7 HANDLING AND STORAGE**

# Precautions for safe handling

Rags wet / soaked with unsaturated hydrocarbons / drying oils may auto-oxidise; generate heat and, in-time, smoulder and ignite. This is especially the case where oil-soaked materials are folded, bunched, compressed, or piled together - this allows the heat to accumulate or even accelerate the reaction

Oily cleaning rags should be collected regularly and immersed in water, or spread to dry in safe-place away from direct

### Safe handling

sunlight or stored, immersed, in solvents in suitably closed containers. ▶ DO NOT allow clothing wet with material to stay in contact with skin

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- ▶ Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- ▶ DO NOT enter confined spaces until atmosphere has been checked.
- ▶ Avoid smoking, naked lights or ignition sources.

Other information

- Store in original containers.
- ▶ Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

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### Conditions for safe storage, including any incompatibilities

### Suitable container

Storage incompatibility

- ▶ Glass container is suitable for laboratory quantities
- ▶ **DO NOT** use aluminium or galvanised containers
- Metal can or drum
- Packaging as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

Polyol esters of fatty acids become unstable with water and high temperatures, and the instability is enhanced in the presence of alkaline substances. The presence of an alkali or acid results in the partial hydrolysis of fatty acids and the formation of free polyglycerol.

#### **HAZARD**

- Although anti-oxidants may be present, in the original formulation, these may deplete over time as they come into contact with air.
- Rags wet / soaked with unsaturated hydrocarbons / drying oils may auto-oxidise; generate heat and, in-time, smoulder and ignite. This is especially the case where oil-soaked materials are folded, bunched, compressed, or piled together this allows the heat to accumulate or even accelerate the reaction
- Oily cleaning rags should be collected regularly and immersed in water, or spread to dry in safe-place away from direct sunlight.or stored, immersed, in solvents in suitably closed containers.
- Avoid reaction with oxidising agents
  - $\cdot$  Materials soaked with plant/ vegetable derived (and rarely, animal) oils may undergo spontaneous combustion
  - Many vegetable and animal oils absorb oxygen from the air to form oxidation products. This oxidation process produces heat and the resultant increase in temperature accelerates the oxidation process.
  - Drying oils such as linseed, tung, poppy and sunflower oils and semi-drying oils such as soya bean, tall oil, corn, cotton and castor oils all absorb oxygen readily and thus experience the self-heating process.
  - · Cotton fibres are readily ignited and if contaminated with an oxidisable oil, may ignite unless heat can be dissipated

### SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### **Control parameters**

### OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

Ingradiant

# EMERGENCY LIMITS

| ingredient  | Wateriai fiame | ICCL-I        | IEEL-Z        | TEEL-3        |
|---|----------------|---------------|---------------|---------------|
| CURACEF DUO<br>Suspension for Injection for<br>Cattle | Not Available  | Not Available | Not Available | Not Available |
| Ingredient  | Original IDLH  |               | Revised IDLH  |               |
| ketoprofen  | Not Available  |               | Not Available |               |

| Ingredient                                 | Original IDLH | Revised IDLH  |
|--|---------------|---------------|
| ketoprofen                                 | Not Available | Not Available |
| ceftiofur hydrochloride                    | Not Available | Not Available |
| Ingredients determined not to be hazardous | Not Available | Not Available |

# **Exposure controls**

**Care**: Atmospheres in bulk storages and even apparently empty tanks may be hazardous by oxygen depletion. Atmosphere must be checked before entry.

Requirements of State Authorities concerning conditions for tank entry must be met. Particularly with regard to training of crews for tank entry; work permits; sampling of atmosphere; provision of rescue harness and protective gear as needed Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

# Appropriate engineering controls

 $\label{point} \mbox{HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.}$ 

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.

When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures.

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Personal protection When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: · Chemical goggles. Eye and face protection ▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. ► Contact lenses may pose a special hazard: soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. Skin protection See Hand protection below NOTE: ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Hands/feet protection Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. ▶ PVC gloves. ▶ Change gloves frequently and when contaminated, punctured or torn. Wash hands immediately after removing gloves. Neoprene rubber gloves **Body protection** See Other protection below • For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and Other protection disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. ▶ Eye wash unit. Thermal hazards Not Available

### Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

# **SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES**

### Information on basic physical and chemical properties

| Appearance                          | Off white to pink oily liquid; does not mix with water. |   |               |
|-------------------------------------|---|---|---------------|
| Physical state                      | Liquid  | Relative density (Water = 1)            | Not Available |
| Odour                               | Not Available   | Partition coefficient n-octanol / water | Not Available |
| Odour threshold                     | Not Available   | Auto-ignition temperature (°C)          | Not Available |
| pH (as supplied)                    | Not Available   | Decomposition temperature               | Not Available |
| Melting point / freezing point (°C) | Not Available   | Viscosity (cSt)                         | Not Available |

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| Initial boiling point and boiling range (°C) | Not Available | Molecular weight (g/mol)         | Not Applicable |
|--|---------------|----------------------------------|----------------|
| Flash point (°C)                             | Not Available | Taste                            | Not Available  |
| Evaporation rate                             | Not Available | Explosive properties             | Not Available  |
| Flammability                                 | Not Available | Oxidising properties             | Not Available  |
| Upper Explosive Limit (%)                    | Not Available | Surface Tension (dyn/cm or mN/m) | Not Available  |
| Lower Explosive Limit (%)                    | Not Available | Volatile Component<br>(%vol)     | Not Available  |
| Vapour pressure (kPa)                        | Not Available | Gas group                        | Not Available  |
| Solubility in water (g/L)                    | Not Available | pH as a solution (1%)            | Not Available  |
| Vapour density (Air = 1)                     | Not Available | VOC g/L                          | Not Available  |

# **SECTION 10 STABILITY AND REACTIVITY**

| Reactivity                         | See section 7  |
|------------------------------------|--|
| Chemical stability                 | <ul> <li>Unstable in the presence of incompatible materials.</li> <li>Product is considered stable.</li> <li>Hazardous polymerisation will not occur.</li> </ul> |
| Possibility of hazardous reactions | See section 7  |
| Conditions to avoid                | See section 7  |
| Incompatible materials             | See section 7  |
| Hazardous decomposition products   | See section 5  |

# **SECTION 11 TOXICOLOGICAL INFORMATION**

# Information on toxicological effects

| Inhaled      | The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.  Inhalation hazard is increased at higher temperatures.  Not normally a hazard due to non-volatile nature of product  Inhalation of oil droplets or aerosols may cause discomfort and may produce chemical inflammation of the lungs.  Fine mists generated from plant/ vegetable (or more rarely from animal) oils may be hazardous. Extreme heating for prolonged periods, at high temperatures, may generate breakdown products which include acrolein and acrolein-like substances.   |
|--------------|---|
| Ingestion    | Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.  Fatty acid esters have fairly low toxicity.  The most common side effects of cephalosporins include acute, life-threatening kidney failure. Neurological symptoms may occur.  JECFA established an acceptable daily intake (ADI) of 0-25 mg/kg bw for polyglyceryl esters of fatty acids having an average chain length of up to 3 glycerol units and an ADI of 0-7.5 mg/kg bw for polyglyceryl esters of interesterified ricinoleic acid.  In the EU, the esters are listed as food additives at concentrations between 5000 and 10,000 mg/kg in certain foods, and up to 7% free glycerol/polyglycerol is allowed (i.e., 700 mg/kg).  Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain. Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma. |
| Skin Contact | The material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.  |
| Eye          | Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn).   |
| Chronic      | Substance accumulation, in the human body, is likely and may cause some concern following repeated or long-term occupational exposure.  Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.  |

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Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general

Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment

Prolonged use of cephalosporins may result in resistance and super-infection of non-susceptible organisms, rarely resulting in intestinal inflammation. Loss of white blood cells and platelets have been reported; side effects are more common in those with pre-existing liver and kidney damage.

Glyceryl triesters (triglycerides) undergo metabolism to become free fatty acids and glycerol. Animal studies show that there is no toxicity when given by mouth unless the material takes up a large proportion of energy intake.

Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e.

Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools. Common side effects of treatment with HIV-I protease inhibitors (PI) include diarrhoea, nausea, vomiting, gastrointestinal discomfort, headache, weakness, fatigue and taste disturbances. Renal stones are seen occasionally.

Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.

| CURACEF DUO              | TOXICITY  | IRRITATION                          |
|--------------------------|---|-------------------------------------|
| Suspension for Injection | Inhalation (Rat) LC50: 8.3 mg/l*(ceftiofur HCI) <sup>[2]</sup>  | Not Available                       |
| for Cattle               | Oral (Rat) LD50: 7760* mg/kg*(ceftiofurHCl) <sup>[2]</sup>  |                                     |
| ketoprofen               | TOXICITY  | IRRITATION                          |
|                          | Oral (rat) LD50: 62.4 mg/kg <sup>[2]</sup>  | Not Available                       |
|                          | TOXICITY  | IRRITATION                          |
| ceftiofur hydrochloride  | Not Available   | Eye(rabbit) : minimally irritating* |
| Legend:                  | Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS.     Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances |                                     |

# **KETOPROFEN**

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases.

Oral (woman) TDLo: 80 mg/kg/10d-I Zonal hepatitis (hepatocellular necrosis), jaundice, peritonitis, body temperature increase, nausea, vomiting, changes in bladder tubules, degenerative brain changes, headache, ulceration/ bleeding from the small intestine, changes in spleen weight, gastrointestinal changes, reproductive system tumours, pigmented/ nucleated red blood cells, ulceration/ bleeding from the duodenum, specific developmental abnormalities (cardiovascular system) recorded.

# **CEFTIOFUR HYDROCHLORIDE**

The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact.

Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and

Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following

ADI: 0.03 mg/kg/day NOEL: 30 mg/kg/day Target Organs: skin, respiratory tract, immune system, gastrointestinal tract,

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blood \* Oral (dog) NOEL 30 mg/kg/d-90D for effects blood forming organs Reproductive toxicity Oral (rat) NOEL 1000 mg/kg/day for foetotoxicity \* Developmental toxicity Oral (rat) NOEL 3200 mg/kg/d for embryo/ foetal developmental effects 8 Mutagenicity: Salmonella/ E. coli - Ames: negative \* Micronucleus: negative V79 cells mammalian cell mutation assay: negative DNA (unscheduled synthesis): negative CHO cellss (in absence of S9 metabolic activation: positive (chromosome aberration assay Teratogenicity May cause hypersensitivity reactions \* Zhejiang Hisun Pharmaceuticl Company SDS

| Acute Toxicity                    | <b>✓</b> | Carcinogenicity             | 0        |
|-----------------------------------|----------|-----------------------------|----------|
| Skin Irritation/Corrosion         | ✓        | Reproductivity              | <b>~</b> |
| Serious Eye<br>Damage/Irritation  | <b>~</b> | STOT - Single Exposure      | 0        |
| Respiratory or Skin sensitisation | <b>~</b> | STOT - Repeated<br>Exposure | <b>✓</b> |
| Mutagenicity                      | 0        | Aspiration Hazard           | 0        |

Legend:

🗶 – Data available but does not fill the criteria for classification

✓ – Data available to make classification

Data Not Available to make classification

### **SECTION 12 ECOLOGICAL INFORMATION**

### **Toxicity**

| CURACEF DUO                         | ENDPOINT                       | TEST DURATION (HR)              | SPECIES  | VALUE                 | SOURCE           |
|-------------------------------------|--------------------------------|---------------------------------|--|-----------------------|------------------|
| Suspension for Injection for Cattle | Not<br>Available               | Not Available                   | Not Available  | Not<br>Available      | Not<br>Available |
|                                     | ENDPOINT                       | TEST DURATION (HR)              | SPECIES  | VALUE                 | SOURCE           |
|                                     | LC50                           | 96                              | Fish   | 77.544mg/L            | 3                |
| ketoprofen                          | EC50                           | 96                              | Algae or other aquatic plants  | 158.690mg/L           | 3                |
|                                     | EC50                           | 384                             | Crustacea  | 19.035mg/L            | 3                |
|                                     | ENDPOINT                       | TEST DURATION (HR)              | SPECIES  | VALUE                 | SOURCE           |
| ceftiofur hydrochloride             | Not<br>Available               | Not Available                   | Not Available  | Not<br>Available      | Not<br>Available |
| Legend:                             | Toxicity 3. EF<br>Data 5. ECET | PIWIN Suite V3.12 (QSAR) - Aqua | pe ECHA Registered Substances - Ecotoxi<br>tic Toxicity Data (Estimated) 4. US EPA, Ed<br>Data 6. NITE (Japan) - Bioconcentration Da | cotox database - Aqua | •                |

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

DO NOT discharge into sewer or waterways.

# Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|-------------------------|------------------|
| ketoprofen | HIGH                    | HIGH             |

# **Bioaccumulative potential**

| Ingredient | Bioaccumulation       |
|------------|-----------------------|
| ketoprofen | LOW (LogKOW = 3.0001) |

# Mobility in soil

| Ingredient | Mobility          |
|------------|-------------------|
| ketoprofen | LOW (KOC = 287.8) |

### **SECTION 13 DISPOSAL CONSIDERATIONS**

### Waste treatment methods

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- ▶ Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

### Otherwise:

- ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- ▶ Recycling **Product / Packaging** 
  - ▶ Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type.

- ▶ DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible or consult manufacturer for recycling options.
- ▶ Consult State Land Waste Authority for disposal.
- Bury or incinerate residue at an approved site.
- Recycle containers if possible, or dispose of in an authorised landfill.

### **SECTION 14 TRANSPORT INFORMATION**

disposal

### Labels Required



### **Marine Pollutant**



**HAZCHEM** 

•3Z

# Land transport (ADG)

| UN number                    | 3082  |  |
|------------------------------|---|--|
| UN proper shipping name      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains ketoprofen) |  |
| Transport hazard class(es)   | Class 9 Subrisk Not Applicable  |  |
| Packing group                | III   |  |
| Environmental hazard         | #env_haz  |  |
| Special precautions for user | Special provisions 274 331 335 375 AU01  Limited quantity 5 L             |  |

Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 are not subject to this Code when transported by road or rail in;

- (a) packagings;
- (b) IBCs; or
- (c) any other receptacle not exceeding 500 kg(L).
- Australian Special Provisions (SP AU01) ADG Code 7th Ed.

# Air transport (ICAO-IATA / DGR)

| UN number          | 3082  |
|--------------------|---|
| UN proper shipping | Environmentally hazardous substance, liquid, n.o.s. * (contains ketoprofen) |
| name               | Environmentally hazardous substance, liquid, in.o.s. (contains ketoprofer)  |

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| Transport hazard<br>class(es) | ICAO/IATA Class ICAO / IATA Subrisk ERG Code  | 9 Not Applicable 9L |  |  |
|-------------------------------|---|---------------------|--|--|
| Packing group                 | III   |                     |  |  |
| Environmental hazard          | #env_haz  |                     |  |  |
| Special precautions for user  | Special provisions Cargo Only Packing Instructions Cargo Only Maximum Qty / Pack Passenger and Cargo Packing Instructions Passenger and Cargo Maximum Qty / Pack Passenger and Cargo Limited Quantity Packing Instructions Passenger and Cargo Limited Maximum Qty / Pack |                     | A97 A158 A197 964 450 L 964 450 L Y964 30 kg G |  |

# Sea transport (IMDG-Code / GGVSee)

| UN number                    | 3082  |  |  |
|------------------------------|---|--|--|
| UN proper shipping name      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (contains ketoprofen) |  |  |
| Transport hazard class(es)   | IMDG Class 9 IMDG Subrisk Not Applicable                                  |  |  |
| Packing group                | III   |  |  |
| Environmental hazard         | Marine Pollutant  |  |  |
| Special precautions for user | EMS Number F-A, S-F Special provisions 274 335 969 Limited Quantities 5 L |  |  |

# Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

# **SECTION 15 REGULATORY INFORMATION**

# Safety, health and environmental regulations / legislation specific for the substance or mixture

# KETOPROFEN(22071-15-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

# CEFTIOFUR HYDROCHLORIDE(103980-44-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists

| National Inventory               | Status  |
|----------------------------------|---|
| Australia - AICS                 | N (ceftiofur hydrochloride)   |
| Canada - DSL                     | N (ceftiofur hydrochloride; ketoprofen)   |
| Canada - NDSL                    | N (ceftiofur hydrochloride)   |
| China - IECSC                    | N (ceftiofur hydrochloride; ketoprofen)   |
| Europe - EINEC / ELINCS /<br>NLP | N (ceftiofur hydrochloride)   |
| Japan - ENCS                     | N (ceftiofur hydrochloride; ketoprofen)   |
| Korea - KECI                     | N (ceftiofur hydrochloride)   |
| New Zealand - NZIoC              | N (ceftiofur hydrochloride)   |
| Philippines - PICCS              | N (ceftiofur hydrochloride)   |
| USA - TSCA                       | N (ceftiofur hydrochloride)   |
| Legend:                          | Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets) |

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### **SECTION 16 OTHER INFORMATION**

### Other information

### Ingredients with multiple cas numbers

| Name       | CAS No                 |
|------------|------------------------|
| ketoprofen | 22071-15-4, 22161-81-5 |

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

### **Definitions and abbreviations**

PC-TWA: Permissible Concentration-Time Weighted Average PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit。

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value **BCF**: BioConcentration Factors BEI: Biological Exposure Index

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