SAFETY DATA SHEET

Tildipirosin (18%) Formulation

Version 3.5   Revision Date: 27.08.2021   SDS Number: 25262-00021   Date of last issue: 09.04.2021
Date of first issue: 24.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Tildipirosin (18%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
20 Spartan Road
1619 Spartan, South Africa
Telephone : +27119239300
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

- Skin sensitisation, Category 1
  H317: May cause an allergic skin reaction.

- Reproductive toxicity, Category 2
  H361f: Suspected of damaging fertility.

- Specific target organ toxicity - repeated exposure, Category 2
  H373: May cause damage to organs through prolonged or repeated exposure.

- Short-term (acute) aquatic hazard, Category 1
  H400: Very toxic to aquatic life.

- Long-term (chronic) aquatic hazard, Category 1
  H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

- Hazard pictograms : [Warning]
- Signal word : Warning
- Hazard statements : H317 May cause an allergic skin reaction.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:
- Tildipirosin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td></td>
<td></td>
<td>Skin Sens. 1A; H317 Repr. 2; H361f STOT RE 2; H373 (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 100</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>
For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

5.2 Special hazards arising from the substance or mixture
Specific hazards during fire-fighting
Unsuitable extinguishing media: None known.
Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters
Specific extinguishing methods:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up:
Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
    Technical measures : See Engineering measures under EXPOSURE
                        CONTROLS/PERSONAL PROTECTION section.
    Local/Total ventilation : Use only with adequate ventilation.
    Advice on safe handling : Do not get on skin or clothing.
                            Do not breathe mist or vapours.
                            Do not swallow.
                            Avoid contact with eyes.
                            Handle in accordance with good industrial hygiene and safety
                            practice, based on the results of the workplace exposure as-
                            sessment
                            Take care to prevent spills, waste and minimize release to the
                            environment.
    Hygiene measures : If exposure to chemical is likely during typical use, provide eye
                       flushing systems and safety showers close to the working
                       place. When using do not eat, drink or smoke.
                       Contaminated work clothing should not be allowed out of the workplace.
                       Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities
    Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in
                                                 accordance with the particular national regulations.
    Advice on common storage : Do not store with the following product types:
                              Strong oxidizing agents

7.3 Specific end use(s)
    Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA OEL-RL (particulate)</td>
<td>10 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
|                 |           | TWA OEL-RL (Vapour + particu-
|                 |           | lates)                         | 150 ppm 470 mg/m3  | ZA OEL     |
|                 |           | Further information: Recommended Limit |
| Tildipirosin    | 328898-40-4 | TWA                           | 100 µg/m3 (OEB 2)  | Internal   |
|                 |           | Further information: DSEN     |                    |            |
Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>33.1 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipment

Eye protection: Wear the following personal protective equipment: Safety glasses
Hand protection: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not
determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Skin and body protection**
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**Respiratory protection**
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**
Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: soluble</td>
</tr>
<tr>
<td></td>
<td>Partition coefficient: n-octanol/water: No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
  Flammability (liquids) : No data available
  Molecular weight : No data available
  Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : None known.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
  Information on likely routes of exposure
    Inhalation
    Skin contact
    Ingestion
    Eye contact

Acute toxicity
  Not classified based on available information.

Components:
  Tildipirosin:
Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 2.000 mg/kg

Acute dermal toxicity: Remarks: No data available

Acute toxicity (other routes of administration): LD50 (Mouse): 6.25 - 12.5 mg/kg
Application Route: Intravenous

**Citric acid monohydrate:**

Acute oral toxicity: LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation:**
Not classified based on available information.

**Components:**

**Tildipirosin:**
Species: Rabbit
Result: No skin irritation

**Citric acid monohydrate:**
Species: Rabbit
Result: No skin irritation

**Serious eye damage/eye irritation:**
Not classified based on available information.

**Components:**

**Tildipirosin:**
Species: Rabbit
Result: No eye irritation

**Citric acid monohydrate:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

**Respiratory or skin sensitisation**

**Skin sensitisation:**
May cause an allergic skin reaction.

**Respiratory sensitisation:**
Not classified based on available information.
SAFETY DATA SHEET

Tildipirosin (18%) Formulation

Components:

Tildipirosin:
- Test Type: Maximisation Test
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Sensitiser

Germ cell mutagenicity
Not classified based on available information.

Components:

Tildipirosin:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Metabolic activation: with and without metabolic activation
  Result: negative
  Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Metabolic activation: with and without metabolic activation
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Test system: mouse lymphoma cells
  Metabolic activation: with and without metabolic activation
  Result: negative
- Genotoxicity in vivo: Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative

Citric acid monohydrate:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: in vitro micronucleus test
  Result: positive
  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  Species: Rat
  Application Route: Ingestion
  Result: negative

Carcinogenicity
Not classified based on available information.
Reproductive toxicity
Suspected of damaging fertility.

**Components:**

**Tildipirosin:**
Effects on fertility:
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - General Toxicity F1: LOAEL: 80 mg/kg body weight
  - Symptoms: Effects on F1 offspring
  - Result: Effects on reproduction parameters

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rabbit, females
  - Embryo-foetal toxicity: NOAEL: 30 mg/kg body weight
  - Symptoms: Reduced body weight
  - Result: No teratogenic potential
  - Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-foetal development
- Species: Rat, female
- Embryo-foetal toxicity: NOAEL: 30 mg/kg body weight
- Symptoms: Reduced body weight
- Result: No teratogenic potential
- Remarks: The effects were seen only at maternally toxic doses.

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

**Citric acid monohydrate:**
Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**Components:**

**Tildipirosin:**
Target Organs:
- Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas

Assessment:
- May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Tildipirosin:
Species : Rat
NOAEL : 20 mg/kg
LOAEL : 60 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : spleen, thymus gland
Symptoms : Salivation

Species : Dog
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Heart, Central nervous system, Blood
Symptoms : Tremors

Species : Dog
NOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : Heart, Cardio-vascular system
Symptoms : Irritability

Species : Dog
NOAEL : 10 mg/kg
LOAEL : 50 mg/kg
Application Route : Oral
Exposure time : 55 Weeks
Target Organs : Nervous system, eye - retina, Heart, Thyroid, spleen, thymus gland, Pancreas

Citric acid monohydrate:
Species : Rat
NOAEL : 4.000 mg/kg
LOAEL : 8.000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Tildipirosin:
General Information : No human information is available.
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Tildipirosin:**
- **Toxicity to fish:**  
  LC50 (Pimephales promelas (fathead minnow)): > 138 mg/l  
  Exposure time: 96 h  
  Method: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates:**  
  EC50 (Daphnia magna (Water flea)): 32 mg/l  
  Exposure time: 48 h  
  Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants:**  
  EC50 (Pseudokirchneriella subcapitata (green algae)): 0,12 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 0,047 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

  EC50 (Anabaena flos-aquae (cyanobacterium)): 0,027 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

  NOEC (Anabaena flos-aquae (cyanobacterium)): 0,00011 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity):**  
  10

- **Toxicity to microorganisms:**  
  EC50: 112,4 mg/l  
  Exposure time: 3 h  
  Test Type: Respiration inhibition  
  Method: OECD Test Guideline 209

  NOEC: 0,23 mg/l  
  Exposure time: 3 h  
  Test Type: Respiration inhibition  
  Method: OECD Test Guideline 209

- **M-Factor (Chronic aquatic toxicity):**  
  100

**Citric acid monohydrate:**
- **Toxicity to fish:**  
  LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
  Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates:**  
  EC50 (Daphnia magna (Water flea)): 1.535 mg/l
12.2 Persistence and degradability

**Components:**

**Tildipirosin:**
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 14.7%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B

**Citric acid monohydrate:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 97%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

**Components:**

**Citric acid monohydrate:**
- Partition coefficient: n-octanol/water: log Pow: -1.72

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**
- Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
- Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**SECTION 13: Disposal considerations**

13.1 Waste treatment methods

**Product:** Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

| ADN | UN 3082 |
| ADR | UN 3082 |
| RID | UN 3082 |
| IMDG | UN 3082 |
| IATA | UN 3082 |

14.2 UN proper shipping name

| ADN | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin) |
| ADR | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin) |
| RID | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin) |
| IATA | Environmentally hazardous substance, liquid, n.o.s. (Tildipirosin) |

14.3 Transport hazard class(es)

| ADN | 9 |
| ADR | 9 |
| RID | 9 |
| IMDG | 9 |
| IATA | 9 |

14.4 Packing group

| ADN | Packing group: III |
| ADR | Classification Code: M6 |
|     | Hazard Identification Number: 90 |
|     | Labels: 9 |
| ADR | Packing group: III |
Tildipirosin (18%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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</thead>
<tbody>
<tr>
<td>3.5</td>
<td>27.08.2021</td>
<td>25262-00021</td>
<td>09.04.2021</td>
<td>24.10.2014</td>
</tr>
</tbody>
</table>

- **Classification Code**: M6
- **Hazard Identification Number**: 90
- **Labels**: 9
- **Tunnel restriction code**: (-)

**RID**
- **Packing group**: III
- **Classification Code**: M6
- **Hazard Identification Number**: 90
- **Labels**: 9

**IMDG**
- **Packing group**: III
- **Labels**: 9
- **EmS Code**: F-A, S-F

**IATA (Cargo)**
- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (LQ)**: Y964
- **Packing group**: III
- **Labels**: Miscellaneous

**IATA (Passenger)**
- **Packing instruction (passenger aircraft)**: 964
- **Packing instruction (LQ)**: Y964
- **Packing group**: III
- **Labels**: Miscellaneous

### 14.5 Environmental hazards

- **ADN**
  - Environmentally hazardous: yes

- **ADR**
  - Environmentally hazardous: yes

- **RID**
  - Environmentally hazardous: yes

- **IMDG**
  - Marine pollutant: yes

- **IATA (Passenger)**
  - Environmentally hazardous: yes

- **IATA (Cargo)**
  - Environmentally hazardous: yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- **Remarks**: Not applicable for product as supplied.
SAFETY DATA SHEET

Tildipirosin (18%) Formulation

Version 3.5  Revision Date: 27.08.2021  SDS Number: 25262-00021  Date of last issue: 09.04.2021
Date of first issue: 24.10.2014

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H361f : Suspected of damaging fertility.
H373 : May cause damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RP : Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of
SAFETY DATA SHEET

Tildipirosin (18%) Formulation

version 3.5

Revision Date: 27.08.2021
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Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361f</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN