Section 1: Identification

Product name : Tildipirosin (18%) Formulation

Manufacturer or supplier's details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification
Skin sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas)

GHS label elements
Hazard pictograms : 
Signal word : Warning
Hazard statements : H317 May cause an allergic skin reaction. H361f Suspected of damaging fertility. H373 May cause damage to organs (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas) through prolonged or repeated exposure.

Precautionary statements : Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapours. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/ protective clothing/ eye protec-
SAFETY DATA SHEET

Tildipirosin (18%) Formulation

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

Section 4: 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.

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.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.

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).

Notes to physician: Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code: 3Z

Section 6: Accidental release measures

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

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.

Methods and materials for containment and 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.

Section 7: Handling and storage
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 assessment.
- 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.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

| Wipe limit | 100 µg/100 cm² | Internal |

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

#### Personal protective equipment

**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

**Hand protection**
Material: 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.
Eye protection: Wear the following personal protective equipment: Safety glasses
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).

Section 9: Physical and chemical properties
Appearance: liquid
Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
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Solubility(ies)
  Water solubility : soluble

Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available

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.

Molecular weight : No data available
Particle size : No data available

Section 10: Stability and reactivity
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information
Exposure routes : Inhalation
                 Skin contact
                 Ingestion
                 Eye contact

Acute toxicity
Not classified based on available information.

Components:

Propylene glycol:
Acute oral toxicity : LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal...
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:

Propylene glycol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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:

Propylene glycol:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Metabolic activation: with and without metabolic activation
Result: negative
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Tildipirosin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Metabolic activation: with and without metabolic activation
Result: negative
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Version: 6.11  Revision Date: 27.08.2021  SDS Number: 25257-00020  Date of last issue: 16.10.2020

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.

Components:

Propylene glycol:
Species:
Application Route:
Exposure time:
Result:

Reproductive toxicity
Suspected of damaging fertility.

Components:

Propylene glycol:
Effects on fertility
Species:
Application Route:
Result:

Effects on foetal development
Species:
Application Route:
Result:
Tildipirosin (18%) Formulation

Species: Mouse
Application Route: Ingestion
Result: negative

**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 (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas) 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:

Propylene glycol:
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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
LOAEL: 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

#### Ecotoxicity

**Components:**

**Propylene glycol:**

- **Toxicity to fish** : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates** : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants** : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d
- **Toxicity to microorganisms** : NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

**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
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

**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
Exposure time: 24 h

**Persistence and degradability**

**Components:**

**Propylene glycol:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

**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

**Bioaccumulative potential**

**Components:**

**Propylene glycol:**
Partition coefficient: n-octanol/water: log Pow: -1.07

**Citric acid monohydrate:**
**Section 13: Disposal considerations**

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.
- 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**

**International Regulations**

**UNRTDG**
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
  - Class: 9
  - Packing group: III
  - Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3082
- Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Tildipirosin)
  - Class: 9
  - Packing group: III
  - Labels: Miscellaneous
  - Packing instruction (cargo aircraft): 964
  - Packing instruction (passenger aircraft): 964
  - Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
  - Class: 9
  - Packing group: III
  - Labels: 9
  - EmS Code: F-A, S-F
  - Marine pollutant: yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.
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Tildipirosin (18%) Formulation

National Regulations

NZS 5433
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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.

Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
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.

NZ / EN