1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tildipirosin (18%) Formulation

Manufacturer or supplier’s details
Company : MSD
Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone : +1-908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | liquid |
| Colour | No data available |
| Odour | No data available |

May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
Skin sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

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 through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.

**Storage:**

- P405 Store locked up.

**Disposal:**

- P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards:

Not classified based on available information.

Health hazards:

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

Environmental hazards:

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification:

None known.

### 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>Tildipirosin</td>
<td>328898-40-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
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.

5. FIREFIGHTING 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.

6. ACCIDENTAL RELEASE MEASURES
7. HANDLING AND STORAGE

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 assessment
  Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSOAL 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>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
Eye/face 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).

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Colour: No data available
Tildipirosin (18%) Formulation

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
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
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.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- 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:
Tildipirosin (18%) Formulation

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.

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
**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>
</tr>
</thead>
<tbody>
<tr>
<td>5.10</td>
<td>2021/08/27</td>
<td>25239-00020</td>
<td>2020/10/16</td>
<td>2014/10/24</td>
</tr>
</tbody>
</table>

**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 - As**
  - Some evidence of adverse effects on sexual function and
Tildipirosin (18%) Formulation

Assessment

fertility, based on animal experiments.

Citric acid monohydrate:

Effects on foetal development

Test Type: Embryofetal 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
Tildipirosin (18%) Formulation

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

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
Tildipirosin (18%) Formulation

Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10
M-Factor (Chronic aquatic toxicity): 100
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:

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:

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

Mobility in soil
No data available

Other adverse effects
No data available
Tildipirosin (18%) Formulation

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.

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.

National Regulations

GB 6944/12268
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Tildipirosin (18%) Formulation

Version 5.10
Revision Date: 2021/08/27
SDS Number: 25239-00020
Date of last issue: 2020/10/16
Date of first issue: 2014/10/24

Class: 9
Packing group: III
Labels: 9

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 Ships carrying Dangerous Chemicals in Bulk; ICS0 - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Tildipirosin (18%) Formulation

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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN