SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tildipirosin (4%) Formulation

Manufacturer or supplier's details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 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. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Skin sensitization : Category 1
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms

Signal Word : Warning
Hazard Statements : H317 May cause an allergic skin reaction.
H361f Suspected of damaging fertility.
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.
SAFETY DATA SHEET

Tildipirosin (4%) Formulation

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.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td>Skin sensitization, Sub-category 1A, Reproductive toxicity, Category 2, Specific target organ toxicity - repeated exposure (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas), Category 2, Short-term (acute) aquatic hazard, Category 1, Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 3 &lt;= 5</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>Eye irritation, Category 2A</td>
<td>&gt;= 1 &lt;= 5</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.
**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 fire fighting | 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 fire-fighters | In the event of fire, wear self-contained breathing apparatus.  
|                             | Use personal protective equipment.  

**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 spills cannot be contained.  
| Methods and materials for containment and cleaning up | Soak up with inert absorbent material.  
| For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 vapors. 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. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage: Keep in properly labeled 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

Ingredients 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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN
**Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

**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

**Eye protection**

- Wear safety glasses with side shields or goggles.
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  - Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**

- Work uniform or laboratory coat.

**SECTION 9. 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>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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>Flammability (liquids)</td>
<td>No data available</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>
</tbody>
</table>
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : 1.0499 g/cm³
Solubility: No data available
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : 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

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 sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.
Components:

Tildipirosin:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Sensitizer

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 fetal development**
- Test Type: Embryo-fetal development
  - Species: Rabbit, females
  - Embryo-fetal 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-fetal development
  - Species: Rat, female
  - Embryo-fetal 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 fetal development**
- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

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

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

**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

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
  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:

Citric acid monohydrate:

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

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

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.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

The ingredients of this product are reported in the following inventories:
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.

BR / Z8