

SAFETY DATA SHEET



Tildipirosin (4%) Formulation

Version 2.9 Revision Date: 30.09.2023 SDS Number: 1071842-00014 Date of last issue: 04.04.2023 Date of first issue: 18.11.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tildipirosin (4%) Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitization : 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 vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.

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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.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-------------------------|-------------|-----------------------|
| Tildipirosin | 328898-40-4 | >= 1 - < 5 |
| Citric acid monohydrate | 5949-29-1 | >= 1 - < 5 |

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.

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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 spillages 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.

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| 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 Gases |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--------------|---------------------------|-------------------------------------|--|----------|
| Tildipirosin | 328898-40-4 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| | Further information: DSEN | | | |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

| | |
|----------------------|---|
| Engineering measures | : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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

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| 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 |

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| 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

| | |
|--|----------------------------|
| Appearance | : liquid |
| Color | : No data available |
| Odor | : No data available |
| Odor 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 |
| Vapor pressure | : No data available |
| Relative vapor density | : No data available |
| Relative density | : No data available |
| Density | : 1.0499 g/cm ³ |
| Solubility(ies) | |
| Water solubility | : No data available |
| Partition coefficient: n-octanol/water | : No data available |

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|---------------------------|--|
| Autoignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity | |
| 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

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 |
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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.

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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.

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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.

Components:

Citric acid monohydrate:

Assessment : May cause respiratory irritation.

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:

Tildipirosin:

Species : Rat
NOAEL : 20 mg/kg
LOAEL : 60 mg/kg

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| 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:

Tildipirosin:

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

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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

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.

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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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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
Environmentally hazardous : yes

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

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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

NOM-002-SCT

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

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Full text of other abbreviations

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AIIC - 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; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8