

Tildipirosin (18%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 25224-00025 Date of first issue: 24.10.2014 5.9

SECTION 1. IDENTIFICATION

Product name Tildipirosin (18%) Formulation

Manufacturer or supplier's details

MSD Company

Address Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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

repeated exposure

Specific target organ toxicity - : Category 2 (Heart, Cardio-vascular system, Nervous system,

eye - retina, Thyroid, thymus gland, spleen, Pancreas)

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 (Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland,



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spleen, Pancreas) 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 vapors.

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 protec-

tion/ 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 ad-

vice/ 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.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Tildipirosin	328898-40-4	>= 10 -< 20
Citric acid monohydrate	5949-29-1	>= 5 -< 10

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

In case of eye contact

Most important symptoms and effects, both acute and

If swallowed

delayed



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of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. 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).

Treat symptomatically and supportively. Notes to physician

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

Carbon oxides

Hazardous combustion prod-

ucts

Specific extinguishing methods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances 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, protec- : tive equipment and emer-

gency 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.



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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.

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 parameters / Permissible concentration	Basis		
Tildipirosin	328898-40-4	TWA	100 μg/m3 (OEB 2)	Internal		
	Further information: DSEN					
		Wipe limit	100 μg/100 cm ²	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



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recommended guidelines, use respiratory protection.

Filter type
Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration 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).

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.

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



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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

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Autoignition 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 reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact



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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



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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



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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 dos-

es.

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 dos-

es.

Reproductive toxicity - As-

sessment

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.



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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
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



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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

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

M-Factor (Chronic aquatic

toxicity)

: 100

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



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> 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

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



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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 : 964

aircraft)

Packing instruction (passen:

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(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.

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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



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AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material Safety

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations

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

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



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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.

AR / Z8