according to the Globally Harmonized System



Tildipirosin (4%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 2.9 30.09.2023 1078779-00014 Date of first issue: 18.11.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tildipirosin (4%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

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 Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Skin sensitisation : Category 1

Reproductive toxicity : 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.

according to the Globally Harmonized System



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H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P261 Avoid breathing 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 protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P318 IF exposed or concerned, get medical advice.

P333 + P317 If skin irritation or rash occurs: Get medical help. 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Tildipirosin	328898-40-4	>= 3 - < 5
Citric acid monohydrate	5949-29-1	>= 1 - < 5

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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.

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Flush eyes with water as a precaution. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction. Suspected of damaging fertility.

Most important symptoms and effects, both acute and

delayed

First Aid responders should pay attention to self-protection, Protection of first-aiders and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING 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 prod-

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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

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 absor-

bent.

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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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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 as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Tildipirosin	328898-40-4	TWA	100 μg/m3 (OEB	Internal	
			2)		
	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

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

according to the Globally Harmonized System



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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.

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.

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

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Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.0499 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition 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

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

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Tildipirosin:

according to the Globally Harmonized System



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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 sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

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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

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.

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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 develop-

ment

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 dos-

es.

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 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 foetal develop-

ment

Test Type: Embryo-foetal 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

Not classified based on available information.

Components:

Tildipirosin:

Target Organs : Heart, Cardio-vascular system, Nervous system, eye - retina,

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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

Aspiration toxicity

Not classified based on available information.

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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

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

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

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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M-Factor (Chronic aquatic

toxicity)

100

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

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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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 : 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 IMO instruments

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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

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DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

Sources of key data used to

compile the Safety Data

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

Date format : dd.mm.yyyy

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

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

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

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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.

IN / EN