

# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Tildipirosin (18%) 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.



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/

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 dis-

posal 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	>= 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

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.

May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

Suspected of damaging fertility.

delayed

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.



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

#### **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 prod-

ucts

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

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 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.

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.



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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.

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	Internal	
			<b>( ( )</b>		
	Further information: DSEN				
		Wipe limit	100 μg/100 cm <sup>2</sup>	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

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



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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).

#### **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

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature

: No data available



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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

#### **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



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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.



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

**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.



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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.

### 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



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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.



# **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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)

Packing instruction (passen-

acking in

: 964

964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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



# Tildipirosin (18%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.9 30.09.2023 25252-00025 Date of first issue: 24.10.2014

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