

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Propylene glycol	1,2-Propanediol	57-55-6*	>= 30 - <= 60	TSC
Tildipirosin	No data available	328898-40-4*	>= 10 - <= 30	TSC
Citric acid monohydrate	1,2,3-Propanetricarboxylic acid	5949-29-1*	>= 5 - <= 10	TSC

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/13/2026
6.1	04/15/2026	25233-00031	Date of first issue: 10/24/2014

In case of eye contact	:	Thoroughly clean shoes before reuse. 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. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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

Tildipirosin (18%) Formulation

Version 6.1	Revision Date: 04/15/2026	SDS Number: 25233-00031	Date of last issue: 04/13/2026 Date of first issue: 10/24/2014
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cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust 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.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of)	Control parameters / Permissible	Basis
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SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

		exposure)	concentration	
Propylene glycol	57-55-6	TWA (Va- pour and aerosols)	50 ppm 155 mg/m ³	CA ON OEL
		TWA (aero- sol)	10 mg/m ³	CA ON OEL
Tildipirosin	328898-40-4	TWA	200 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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection
Material : Chemical-resistant gloves

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

Skin and body protection : Work uniform or laboratory coat.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

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	:	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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/13/2026
6.1	04/15/2026	25233-00031	Date of first issue: 10/24/2014

Acute toxicity (other routes of administration) : LD50 (Mouse): 6.25 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:

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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:

Propylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Tildipirosin:

Species : Rabbit
Result : No eye irritation

Citric acid monohydrate:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Propylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Tildipirosin:

Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Tildipirosin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo)

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

cytogenetic assay)
Species: Mouse
Application Route: Ingestion
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.

Components:

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Tildipirosin:

Remarks : No data available

Reproductive toxicity

May damage fertility or the unborn child.

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/13/2026
6.1	04/15/2026	25233-00031	Date of first issue: 10/24/2014

Tildipirosin:

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Developmental Toxicity: NOAEL: 80 mg/kg body weight
Result: Specific developmental abnormalities.

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Ingestion
Embryo-fetal toxicity.: NOAEL: 30 mg/kg body weight
Result: Reduced fetal weight.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, and/or on development, 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:

Tildipirosin:

Remarks : No data available

Citric acid monohydrate:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Causes damage to organs (Kidney, Liver, Adrenal gland, Central nervous system, thymus gland, Thyroid, spleen, Heart) through prolonged or repeated exposure if swallowed.

Components:

Tildipirosin:

Routes of exposure : Oral
Target Organs : Kidney, Liver, Adrenal gland, Central nervous system, thymus gland, Thyroid, spleen, Heart
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 y

Tildipirosin:

Species : Dog
NOAEL : 10 mg/kg
Application Route : Oral
Exposure time : 55 Weeks
Target Organs : Heart, Thyroid, spleen, thymus gland, Kidney, Liver, Central nervous system
Symptoms : Irregularities

Species : Rat
NOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Heart, Liver, Kidney, spleen, Thyroid, Adrenal gland
Symptoms : Irregularities

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.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d
Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

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): 0.027 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 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

Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

Persistence and degradability

Components:

Propylene glycol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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:

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

Citric acid monohydrate:

Partition coefficient: n-octanol/water : log Pow: -1.72

Mobility in soil

No data available

Other adverse effects

No data available

Endocrine disrupting properties

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version 6.1 Revision Date: 04/15/2026 SDS Number: 25233-00031 Date of last issue: 04/13/2026
Date of first issue: 10/24/2014

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
Remarks : This product can be subject to exemptions when packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids, or having a net mass of 5 kg or less for solids.

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes
Remarks : This product can be subject to exemptions when packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids, or having a net mass of 5 kg or less for solids.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/13/2026
6.1	04/15/2026	25233-00031	Date of first issue: 10/24/2014

(Tildipirosin)

Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Tildipirosin)

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

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

AICS : not determined

CA. DSL : not determined

CN IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)

AIC - 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 Standardization; 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 Organization for Standardization; KECl - 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concen-

SAFETY DATA SHEET

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Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/13/2026
6.1	04/15/2026	25233-00031	Date of first issue: 10/24/2014

tration; 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, Authorization 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/>

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Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8