

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tildipirosin (18%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

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

Emergency Overview

Appearance	: liquid
Colour	: No data available
Odour	: No data available

May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification

Skin sensitisation	: Category 1
Reproductive toxicity	: Category 2
Specific target organ toxicity - repeated exposure	: Category 2
Short-term (acute) aquatic hazard	: Category 1
Long-term (chronic) aquatic hazard	: Category 1

GHS label elements


SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	2025/04/14	25239-00028	2024/09/28
			Date of first issue: 2014/10/24

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 through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe 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 protection/ face protection/ hearing protection. Response: P318 IF exposed or concerned, get medical advice. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. 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.

Physical and chemical hazards

Not classified based on available information.

Health hazards

May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

Substance / Mixture : Mixture

Components

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

4. FIRST AID MEASURES

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

5. FIREFIGHTING 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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide 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 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.

7. HANDLING AND STORAGE

Handling

- 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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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

Engineering measures : 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 : Particulates type

Eye/face 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).

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

Hygiene measures : 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.

: 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.

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
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Solubility(ies) Water solubility	: soluble

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

Partition coefficient: n-octanol/water	:	No data available
Auto-ignition 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 characteristics		
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 reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes	:	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
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

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 foetal development	: 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 doses. 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 doses.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Citric acid monohydrate:

Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative
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STOT - single exposure

Not classified based on available information.

Components:

Citric acid monohydrate:

Assessment	: May cause respiratory irritation.
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

STOT - repeated exposure

May cause damage to organs 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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

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.

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 toxicity)	: 10
M-Factor (Chronic aquatic toxicity)	: 100

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	2025/04/14	25239-00028	2024/09/28
			Date of first issue: 2014/10/24

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.
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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Tildipirosin)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

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.

National Regulations

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

GB 6944/12268

UN number	: UN 3082
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
Class	: 9
Packing group	: III
Labels	: 9
Marine pollutant	: no

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

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	: This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.
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Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	: Not listed
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Hazardous Chemicals for Priority Management under SAWS	: Not listed
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Catalogue of Specially Controlled Hazardous Chemicals	: Not listed
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List of Explosive Precursors	: Not listed
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Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals	: Not listed
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Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export	: Not listed
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Regulation on the Administration of Precursor Chemicals

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export	: Not listed
List of Controlled Ozone Depleting Substances	: Not listed

Environmental Protection Law

List of Priority Controlled Chemicals	: Not listed
List of Key Controlled New Pollutants	: Not listed

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

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

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

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 con-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
7.0	2025/04/14	25239-00028	Date of first issue: 2014/10/24

centration; 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

Disclaimer

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.

CN / EN