

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version  
5.2

Revision Date:  
14.04.2025

SDS Number:  
25246-00030

Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Tildipirosin (18%) Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 2	H361f: Suspected of damaging fertility.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

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	:	<b>Prevention:</b> P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  <b>Response:</b> P308 + P313 IF exposed or concerned: Get medical advice/ attention. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P391 Collect spillage.

### Hazardous components which must be listed on the label:

Tildipirosin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Tildipirosin	328898-40-4	Skin Sens. 1A; H317	>= 10 - < 20

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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Date of last issue: 28.09.2024  
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		Repr. 2; H361f STOT RE 2; H373 (Heart, Cardio- vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
Citric acid monohydrate	5949-29-1	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of 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.

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).

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.

# SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



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5.2

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SDS Number:  
25246-00030

Date of last issue: 28.09.2024  
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---

### 4.2 Most important symptoms and effects, both acute and delayed

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

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

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

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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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5.2

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SDS Number:  
25246-00030

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---

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe 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 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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

- : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2 Revision Date: 14.04.2025 SDS Number: 25246-00030 Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA) (total (vapour and particles))	150 ppm 470 mg/m <sup>3</sup>	IE OEL
Tildipirosin	328898-40-4	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2 Revision Date: 14.04.2025 SDS Number: 25246-00030 Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

---

Citric acid monohydrate	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)
	Soil	33.1 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### Engineering measures

Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations.

#### Personal protective equipment

Eye/face protection : Wear the following personal protective equipment:

Safety glasses

Equipment should conform to I.S. EN 166

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 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.

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).

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

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

# SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

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Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : 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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Evaporation rate	: No data available
Molecular weight	: No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2      Revision Date: 14.04.2025      SDS Number: 25246-00030      Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

---

### 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.

### Components:

#### Tildipirosin:

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Result : Sensitiser

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version  
5.2

Revision Date:  
14.04.2025

SDS Number:  
25246-00030

Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

### 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.

### **Reproductive toxicity**

Suspected of damaging fertility.

### Components:

#### **Tildipirosin:**

Effects on fertility

: Test Type: Two-generation reproduction toxicity study  
Species: Rat

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version  
5.2

Revision Date:  
14.04.2025

SDS Number:  
25246-00030

Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

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

### **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 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

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### 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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

#### Product:

Assessment : The substance/mixture does not contain components consid-

# SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

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25246-00030

Date of last issue: 28.09.2024  
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### Experience with human exposure

#### Components:

##### **Tildipirosin:**

General Information : No human information is available.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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

Toxicity to microorganisms : EC50 : 112.4 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version  
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14.04.2025

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Date of first issue: 24.10.2014

---

NOEC : 0.23 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

## 12.2 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

## 12.3 Bioaccumulative potential

### **Components:**

#### **Citric acid monohydrate:**

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

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

### **Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

# SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version  
5.2

Revision Date:  
14.04.2025

SDS Number:  
25246-00030

Date of last issue: 28.09.2024  
Date of first issue: 24.10.2014

---

### 12.6 Endocrine disrupting properties

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product

: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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.

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## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

### 14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 28.09.2024  
5.2 14.04.2025 25246-00030 Date of first issue: 24.10.2014

(Tildipirosin)

**IATA** : Environmentally hazardous substance, liquid, n.o.s.  
(Tildipirosin)

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

## 14.4 Packing group

ADN

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

ADR

Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)

RID

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

IMDG

**IMDG**  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

## IATA (Cargo)

IATA (cargo)  
Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
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### 14.5 Environmental hazards

**ADN**

Environmentally hazardous : yes

**ADR**

Environmentally hazardous : yes

**RID**

Environmentally hazardous : yes

**IMDG**

Marine pollutant : yes

**IATA (Passenger)**

Environmentally hazardous : yes

**IATA (Cargo)**

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: Conditions of restriction for the following entries should be considered:  
Number on list 3

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

: Not applicable

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



## **Tildipirosin (18%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 28.09.2024  
5.2 14.04.2025 25246-00030 Date of first issue: 24.10.2014

Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	:	Not applicable

Major environmental hazards involving dangerous substances		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

## Full text of H-Statements

H317 : May cause an allergic skin reaction.  
H319 : Causes serious eye irritation.  
H335 : May cause respiratory irritation.  
H361f : Suspected of damaging fertility.  
H373 : May cause damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard  
 Aquatic Chronic : Long-term (chronic) aquatic hazard  
 Eye Irrit. : Eye irritation

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

Repr.	: Reproductive toxicity
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
IE OEL	: Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	: Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Skin Sens. 1	H317
Repr. 2	H361f
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Tildipirosin (18%) Formulation

Version 5.2	Revision Date: 14.04.2025	SDS Number: 25246-00030	Date of last issue: 28.09.2024 Date of first issue: 24.10.2014
----------------	------------------------------	----------------------------	---

Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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IE / EN