

# Tildipirosin (18%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.1	28.09.2024	25246-00029	Date of first issue: 24.10.2014

### **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	he s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

1-908-423-6000

### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

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

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 H317: May cause an allergic skin reaction.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.

### 2.2 Label elements

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

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



# **Tildipirosin (18%) Formulation**

Version 5.1	Revision Date: 28.09.2024		S Number: 46-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
На	zard pictograms	:		!
Sig	gnal word	: V	Varning	• •
Ha	zard statements	ŀ	1317 1361f 1373 1410	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.
Pre	ecautionary statements	: F	Prevention	
		F	201 273 280	Obtain special instructions before use. Avoid release to the environment. Wear protective gloves/ protective clothing/ eye protection/ face protection.
		F	Response:	
		F	2308 + P31	3 IF exposed or concerned: Get medical advice/ attention.
		F	P333 + P31	3 If skin irritation or rash occurs: Get medical advice/ attention.
		F	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.

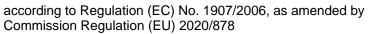
Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

## Components

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





# Tildipirosin (18%) Formulation

rsion	sion Revision Date: SDS Number: 28.09.2024 25246-00029		Date of last issue: 06.04.2024 Date of first issue: 24.10.2014				
			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 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 100				
Citric	acid monohydrate	5949-29-1	Eye Irrit. 2; H319 >= 1 - < 10 STOT SE 3; H335				

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 ad- vice 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.



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

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.1	28.09.2024	25246-00029	Date of first issue: 24.10.2014

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

Risks	<ul> <li>May cause an allergic skin reaction. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.</li> </ul>
	exposure.

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

Treatment :		Treat symptomatically and supportively.
-------------	--	---

### **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing	:	None known.

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

0.2 0	poolai nazai ao anonig nom		
	Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides
5.3 A	dvice for firefighters		
	Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
	Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

### **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 pro-
		tective equipment recommendations (see section 8).

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



# **Tildipirosin (18%) Formulation**

Version 5.1	Revision Date: 28.09.2024	SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014				
6.2 Enviro	nmental precautions						
Environmental precautions		Prevent furthe Prevent sprea barriers). Retain and dis Local authorit	<ul> <li>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.</li> </ul>				
6.3 Method	ds and material for co	ontainment and cle	aning up				
Methods for cleaning up		For large spill ment to keep be pumped, s Clean up rem bent. Local or natio posal of this n employed in t mine which re Sections 13 a	inert absorbent material. s, provide dyking or other appropriate contain- material from spreading. If dyked material can tore recovered material in appropriate container. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items he cleanup of releases. You will need to deter- gulations are applicable. nd 15 of this SDS provide information regarding or national requirements.				

### 6.4 Reference to other sections

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

### **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Technical measures	<ul> <li>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</li> </ul>
Local/Total ventilation Advice on safe handling	<ul> <li>Use only with adequate ventilation.</li> <li>Do not get on skin or clothing.</li> <li>Do not breathe mist or vapours.</li> <li>Do not swallow.</li> <li>Avoid contact with eyes.</li> </ul>
	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Take care to prevent spills, waste and minimize release to the environment.
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 stora	ge, including any incompatibilities

Requirements for storage	:	Keep in properly labelled containers. Store locked up. Store in
areas and containers		accordance with the particular national regulations.



# **Tildipirosin (18%) Formulation**

Version 5.1	Revision Date: 28.09.2024		DS Number: 5246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
Advice on common storage		:	: Do not store with the following product types: Strong oxidizing agents Gases	
-	<b>c end use(s)</b> ic 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/m3	IE OEL
		OELV - 8 hrs (TWA) (total (va- pour and parti- cles))	150 ppm 470 mg/m3	IE OEL
Tildipirosin 328898-40- 4		TWA	100 µg/m3 (OEB 2)	Internal
	Further inform	nation: DSEN		
		Wipe limit	100 µg/100 cm²	Internal

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

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3

### 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.)

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



# **Tildipirosin (18%) Formulation**

Vers 5.1	ion Revision Date: 28.09.2024	SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014	
F	Citric acid monohydrate	Fresh water Marine water	0.44 mg/ 0.044 mc	
		Sewage treat		
		Fresh water s	ediment 34.6 mg/ weight (d	• •
		Marine sedim	ent 3.46 mg/ weight (d	
		Soil	33.1 mg/ weight (d	

### 8.2 Exposure controls

#### **Engineering measures**

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipm	nent						
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 sub- stance 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 expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143					
Filter type	:	Particulates type (P)					

### **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

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



Vers 5.1	VersionRevision Date:5.128.09.2024		SDS Number: 25246-00029		Date of last issue: 06.04.2024 Date of first issue: 24.10.2014	
	O day in T					
	Odour Threshold		:	No data available		
	Melting point/freezing point		:	No data available		
	Initial boiling point and boiling range		:	No data available		
	Flamma	ability (solid, gas)	:	Not applicable		
	Flamma	ability (liquids)	:	No data available	•	
		explosion limit / Upper bility limit	:	No data available		
		explosion limit / Lower bility limit	:	No data available		
	Flash p	oint	:	No data available		
	Auto-igi	nition temperature	:	No data available		
	Decom	position temperature	:	No data available	•	
	pН		:	No data available		
	Viscosit Visc	y osity, dynamic	:	No data available		
	Visc	osity, kinematic	:	No data available	•	
	Solubilit Wate	ty(ies) er solubility	:	soluble		
	Partitior octanol/	n coefficient: n- /water	:	No data available		
	Vapour	pressure	:	No data available		
	Relative	e density	:	No data available		
	Relative	e vapour density	:	No data available		
		characteristics cle size	:	No data available		
	<b>)ther in</b> Explosi <sup>,</sup>	formation ves	:	Not explosive		

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



Version 5.1	Revision Date: 28.09.2024	SDS Nui 25246-0		Date of last issue: 06.04.2024 Date of first issue: 24.10.2014				
Oxidizing properties		: The	: The substance or mixture is not classified as oxidizing.					
Evap	oration rate	: No c	data availab	le				
Mole	cular weight	: No d	data availab	le				
SECTION	N 10: Stability and	eactivity						
10.1 Read	-	bozord						
	lassified as a reactivity	1182810.						
	<b>nical stability</b> e under normal condit	ons.						
	sibility of hazardous							
	rdous reactions		react with s	strong oxidizing agents.				
10.4 Cond	ditions to avoid							
Cond	litions to avoid	: Non	: None known.					
10.5 Inco	mpatible materials							
Mate	rials to avoid	: Oxic	Oxidizing agents					
10.6 Haza	rdous decompositio	n products						
	azardous decompositi	-	are known.					
SECTION	N 11: Toxicological	informatio	on					
				gulation (EC) No 1272/2008				
Inforr expo	nation on likely routes sure	Skin Inges	contact					
Acut	e toxicity							
Not c	lassified based on ava	ilable inform	ation.					
Com	ponents:							

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

Species

Result

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



# **Tildipirosin (18%) Formulation**

ersion 1	Revision Date: 28.09.2024		Number: 6-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014	
Citric	acid monohydrate:				
	Acute oral toxicity Acute dermal toxicity		050 (Mouse): 5	5,400 mg/kg	
Acute				000 mg/kg Test Guideline 402 e substance or mixture has no acute dermal	
-	corrosion/irritation lassified based on ava	ilable info	ormation.		
Com	ponents:				
Tildip	pirosin:				
Spec Resu			abbit o skin irritation		
Citric	acid monohydrate:				
Speci Resu			abbit o skin irritation		
	<b>us eye damage/eye</b> i lassified based on ava		ormation.		
Com	ponents:				
Tildip	pirosin:				
Spec Resu			abbit b eye irritation		
Citric	acid monohydrate:				
Spec Resu			abbit itation to eyes	reversing within 21 days	
Resp	iratory or skin sensi	tisation			
<b>Skin sensitisation</b> May cause an allergic skin reaction. <b>Respiratory sensitisation</b> Not classified based on available information.					
Test	sure routes		aximisation Te ermal	st	

: Guinea pig

Sensitiser

:

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



ersion	Revision Date: 28.09.2024	SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014					
Germ	n cell mutagenicity							
Not c	lassified based on ava	ilable information.						
<u>Com</u>	ponents:							
-	pirosin:							
Geno	toxicity in vitro		Bacterial reverse mutation assay (AMES) ctivation: with and without metabolic activation ative					
		Test system	Chromosomal aberration n: Human lymphocytes ctivation: with and without metabolic activation ative					
		Test system	In vitro mammalian cell gene mutation test n: mouse lymphoma cells ctivation: with and without metabolic activation ative					
Geno	toxicity in vivo	Species: M	Route: Oral					
Citric	Citric acid monohydrate:							
Geno	toxicity in vitro	: Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative					
		Test Type: Result: pos	in vitro micronucleus test itive					
		Test Type: Result: neg	Bacterial reverse mutation assay (AMES) ative					
Geno	toxicity in vivo	cytogenetic Species: Ra						
		Result: neg	Route: Ingestion ative					
	i <b>nogenicity</b> lassified based on ava	ilable information.						
Repr	oductive toxicity ected of damaging fer							
	ponents:							
	birosin:							
-	ts on fertility	: Test Type: Species: Ra	Two-generation reproduction toxicity study at					

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



Version 5.1	'n	Revision Date: 28.09.2024		9S Number: 246-00029	Date of last issue: 06.04.2024 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 develop- ment		:	Species: Rabbit, f Embryo-foetal tox Symptoms: Reduc Result: No teratog	icity: NOAEL: 30 mg/kg body weight ced body weight		
			Species: Rat, fer Embryo-foetal to Symptoms: Redu Result: No terato		icity: NOAEL: 30 mg/kg body weight ced body weight		
			:	f adverse effects on sexual function and animal experiments.			
Ci	itric a	cid monohydrate:					
	ffects nent	on foetal develop-	:	Test Type: Embry Species: Rat Application Route Result: negative	o-foetal development : Ingestion		
	STOT - single exposure Not classified based on available		able	information.			
<u>C</u>	ompo	nents:					
	i <b>tric a</b> ssessi	<b>cid monohydrate:</b> ment	:	May cause respira	atory irritation.		
	<b>STOT - repeated exposure</b> May cause damage to organs th		s thre	ough prolonged or	repeated exposure.		
<u>C</u>	ompo	nents:					
	ildipir						
Та	arget	Organs	:		cular system, Nervous system, eye - retina, land, spleen, Pancreas		
As	SSESS	ment	:		ge to organs through prolonged or repeated		

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



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

Version Revision Date: 5.1 28.09.2024		SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
Rep	eated dose toxicity		
<u>Cor</u>	nponents:		
	ipirosin:	5.	
NÖ LOA App Exp Tar	cies AEL AEL lication Route osure time get Organs nptoms	: Rat : 20 mg/kg : 60 mg/kg : Oral : 90 d : spleen, thymu : Salivation	us gland
LOA App Exp Targ	cies AEL lication Route osure time get Organs nptoms	: Dog : 20 mg/kg : Oral : 28 d : Heart, Centra : Tremors	ıl nervous system, Blood
NÖ App Exp Tar	cies AEL lication Route osure time get Organs nptoms	: Dog : 6 mg/kg : Oral : 90 d : Heart, Cardio : Irritability	-vascular system
NO LOA App Exp	cies AEL AEL lication Route osure time get Organs	: Dog : 10 mg/kg : 50 mg/kg : Oral : 55 Weeks : Nervous syst gland, Pancre	em, eye - retina, Heart, Thyroid, spleen, thymus eas
Spe NO/ LO/ App	<b>ic acid monohydrate:</b> cies AEL AEL lication Route osure time	: Rat : 4,000 mg/kg : 8,000 mg/kg : Ingestion : 10 Days	

### Aspiration toxicity

Not classified based on available information.

:

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

### Product:

Assessment

The substance/mixture does not contain components considered to have endocrine disrupting properties according to



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

Version 5.1	Revision Date: 28.09.2024		OS Number: 246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
				7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
Expe	rience with human exp	osi	ıre	
Com	ponents:			
-	<b>birosin:</b> eral Information	:	No human inform	ation is available.
SECTION	N 12: Ecological infor	ma	tion	
2.1 Toxi	city			
<u>Com</u>	ponents:			
Tildi	pirosin:			
Toxic	ity to fish	:	Exposure time: 9	s promelas (fathead minnow)): > 138 mg/l 6 h est Guideline 203
	ity to daphnia and other	:		nagna (Water flea)): 32 mg/l
aqua	tic invertebrates		Exposure time: 4 Method: OECD T	8 h est Guideline 202
Toxic plants	rity to algae/aquatic s	:	mg/l Exposure time: 7	chneriella subcapitata (green algae)): 0.12 2 h est Guideline 201
			mg/l Exposure time: 7	rchneriella subcapitata (green algae)): 0.04 2 h est Guideline 201
			EC50 (Anabaena	flos-aquae (cyanobacterium)): 0.027 mg/l

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.00011 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 10 icity) Toxicity to microorganisms : EC50 : 112.4 mg/l

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

Exposure time: 72 h

Method: OECD Test Guideline 201

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



Version 5.1	on Revision Date: 28.09.2024		OS Number: 246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014	
			NOEC : 0.23 mg/ Exposure time: 3 Test Type: Respi Method: OECD T	h	
M-Fac toxicit	ctor (Chronic aquatic y)	:	100		
Citric	acid monohydrate:				
Toxici	ty to fish	:	LC50 (Pimephale Exposure time: 9	es promelas (fathead minnow)): > 100 mg/l 6 h	
	ty to daphnia and other ic invertebrates	:	EC50 (Daphnia r Exposure time: 2	nagna (Water flea)): 1,535 mg/l 4 h	
12.2 Persi	stence and degradabil	ity			
<u>Comp</u>	oonents:				
Tildip	irosin:				
-	gradability	:	Biodegradation: Exposure time: 2	14.7 %	
Citric	acid monohydrate:				
	gradability	:	Result: Readily b Biodegradation: Exposure time: 2 Method: OECD T	97 %	
12.3 Bioad	cumulative potential				
Comp	oonents:				
Partiti	acid monohydrate: on coefficient: n- ol/water	:	log Pow: -1.72		
1 <b>2.4 Mobi</b> l No da	l <b>ity in soil</b> ta available				
12.5 Resu	Its of PBT and vPvB as	sse	ssment		
Produ	<u>uct:</u>				
	sment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels or	



# **Tildipirosin (18%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.1	28.09.2024	25246-00029	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

### **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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

14.1 UN number or ID number						
ADN	: UN 3082					
ADR	: UN 3082					
RID	: UN 3082					
IMDG	: UN 3082					
ΙΑΤΑ	: 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.					

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



# Tildipirosin (18%) Formulation

Versio 5.1	on	Revision Date: 28.09.2024	SDS Number: 25246-00029		Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
				(Tildipirosin)	
I.	ΑΤΑ		:	Environmentally h (Tildipirosin)	azardous substance, liquid, n.o.s.
14.3 T	Fransp	oort hazard class(es)			
				Class	Subsidiary risks
Α	ADN		:	9	
Α	ADR		:	9	
R	RID		:	9	
I	MDG		:	9	
14	ΑΤΑ		:	9	
14.4 P	Packir	ng group			
P C H L	Classifi Hazard Labels	g group ication Code I Identification Number	:	III M6 90 9	
P C H L	Classifi Hazard Labels	g group ication Code I Identification Number restriction code	:	III M6 90 9 (-)	
P C H	Classifi	g group ication Code I Identification Number	:	III M6 90 9	
P L	<b>MDG</b> Packing abels EmS C	g group ode	:	III 9 F-A, S-F	
Р		Cargo) g instruction (cargo )	:	964	
P P	Packin	g instruction (LQ) g group	: : :	Y964 III Miscellaneous	
Р		Passenger) g instruction (passen- craft)	:	964	
P P	Packin	g instruction (LQ) g group	:	Y964 III Miscellaneous	

### 14.5 Environmental hazards

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



# Tildipirosin (18%) Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
ADN			
	onmentally hazardous	: yes	
<b>ADR</b> Envir	onmentally hazardous	: yes	
<b>RID</b> Envir	onmentally hazardous	: yes	
<b>IMDO</b> Marir	<b>3</b> ne pollutant	: yes	
	( <b>Passenger)</b> conmentally hazardous	: yes	
	( <b>Cargo)</b> conmentally 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.

### **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 fol- lowing 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.
REACH - Candidate List of Substances of Very High		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 condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not. Not applicable
Concern for Authorisation (Article 59).	·	
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable



# **Tildipirosin (18%) Formulation**

Version 5.1	Revision Date: 28.09.2024	SDS Number: 25246-00029		ast issue: 06.04.2 first issue: 24.10.2		
Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable tants (recast)						
Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals						
REAG	CH - List of substances ex XIV)	ion :	Not applicable			
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the cor major-accident hazards involving dangerous substances.						
Е1		ENVIRONME		Quantity 1 100 t	Quantity 2 200 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:

HAZARDS

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**

Full text of H-Statements

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

H317 H319 H335 H361f H373	May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. Suspected of damaging fertility. May cause damage to organs through prolonged or repo	eated
H400 H410 Full text of other abbreviation	exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.	
Aquatic Acute Aquatic Chronic Eye Irrit. Repr. Skin Sens.	Short-term (acute) aquatic hazard Long-term (chronic) aquatic hazard Eye irritation Reproductive toxicity Skin sensitisation	



## Tildipirosin (18%) Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Nu 25246-0		Date of last issue: 06.04.2024 Date of first issue: 24.10.2014
ST	OT RE OT SE OEL	: Spe : Irela	cific target or nd. List of C onal Exposur	gan toxicity - repeated exposure gan toxicity - single exposure nemical Agents and Carcinogens with Occu- e Limit Values - Code of Practice, Schedule 1
IE	OEL / OELV - 8 hrs (TWA)		—	oosure 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 :	Internal technical data, data from raw material SDSs, OECD
compile the Safety Data	eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

Classification of the mixture:		Classification procedure:
Skin Sens. 1	H317	Calculation method
Repr. 2	H361f	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method

Commission Regulation (EU) 2020/878

# Tildipirosin (18%) Formulation

Version 5.1	Revision Date: 28.09.2024	SDS Number: 25246-00029	Date of last issue: 06.04.2024 Date of first issue: 24.10.2014	
Aqua	tic Chronic 1	H410	Calculation method	

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.

IE / EN