

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

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

#### 1.1 Product identifier

Trade name : Tilmicosin 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  
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A  
Çubuk Yolu 2. Km  
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

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

#### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848 and subsequent amendments

Acute toxicity, Category 4	H302: Harmful if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 2	H361: Suspected of damaging fertility or the unborn child.
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 T.R. SEA No 28848 and subsequent amendments

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version 2.3      Revision Date: 30.09.2023      SDS Number: 10223661-00005      Date of last issue: 04.04.2023  
Date of first issue: 12.11.2021

- Hazard pictograms :
- Signal word : Warning
- Hazard statements :  
H302 Harmful if swallowed.  
H319 Causes serious eye irritation.  
H361 Suspected of damaging fertility or the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements :  
**Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P391 Collect spillage.

Hazardous components which must be listed on the label:

Tilmicosin

Phosphoric acid

### 2.3 Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Tilmicosin	137330-13-3	Acute Tox. 4; H302 Eye Irrit. 2; H319 Repr. 2; H361 STOT RE 2; H373 (Heart, Lungs)	>= 30 - < 50

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version 2.3      Revision Date: 30.09.2023      SDS Number: 10223661-00005      Date of last issue: 04.04.2023  
Date of first issue: 12.11.2021

		Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 10	
Phosphoric acid	7664-38-2 231-633-2 015-011-00-6	Met. Corr. 1; H290 Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 <hr/> specific concentration limit Skin Corr. 1B; H314 ≥ 25 % Skin Irrit. 2; H315 10 - < 25 % Eye Irrit. 2; H319 10 - < 25 % EUH071 ≥ 25 %	≥ 1 - < 3

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.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

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

Risks : Harmful if swallowed.  
Causes serious eye irritation.  
Suspected of damaging fertility or the unborn child.  
May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.

### 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

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  
Nitrogen oxides (NO<sub>x</sub>)  
Oxides of phosphorus

### 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.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

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 protective equipment recommendations (see section 8).

#### 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.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version 2.3      Revision Date: 30.09.2023      SDS Number: 10223661-00005      Date of last issue: 04.04.2023  
Date of first issue: 12.11.2021

- Local/Total ventilation : and bonding, or inert atmospheres.  
Advice on safe handling : Use only with adequate ventilation.  
Do not breathe mist or vapours.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
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. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 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.
- 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
Tilmicosin	137330-13-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Phosphoric acid	7664-38-2	TWA (8 Hour)	1 mg/m3	TR OEL
		STEL 15 min	2 mg/m3	TR OEL
		TWA	1 mg/m3	2000/39/EC
Further information: Indicative				

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version 2.3      Revision Date: 30.09.2023      SDS Number: 10223661-00005      Date of last issue: 04.04.2023  
Date of first issue: 12.11.2021

	STEL	2 mg/m3	2000/39/EC
Further information: Indicative			

### Derived No Effect Level (DNEL) :

Substance name	End Use	Exposure routes	Potential health effects	Value
Phosphoric acid	Workers	Inhalation	Long-term local effects	1 mg/m3
	Workers	Inhalation	Acute local effects	2 mg/m3
	Consumers	Inhalation	Long-term local effects	0,73 mg/m3
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3

### Predicted No Effect Concentration (PNEC) :

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.)

## 8.2 Exposure controls

### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### Personal protective equipment

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

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

### Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.  
Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

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 TS EN 14387

Filter type : Combined particulates, acidic and inorganic gas/vapour type (BE-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: dark yellow
Odour	: No data available
Odour Threshold	: No data available
pH	: 3,5 - 6,5
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)	: May form combustible dust concentrations in air during processing, handling or other means.
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
Density	: 1,00 - 1,200 g/cm <sup>3</sup>



# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

---

Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	: Not applicable
Molecular weight	: No data available
Particle size	: Not applicable

---

## 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	: May form combustible dust concentrations in air during processing, handling or other means. Can react with strong oxidizing agents.
---------------------	--

### 10.4 Conditions to avoid

Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
---------------------	---

### 10.5 Incompatible materials

Materials to avoid	: Oxidizing agents
--------------------	--------------------

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

##### Acute toxicity

Harmful if swallowed.

##### Product:

Acute oral toxicity : Acute toxicity estimate: 1.467 mg/kg  
Method: Calculation method

##### Components:

##### Tilmicosin:

Acute oral toxicity : LD50 (Rat): 800 - 850 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 97 mg/kg  
Application Route: Subcutaneous

LD50 (Rat): 185 mg/kg  
Application Route: Subcutaneous

##### Phosphoric acid:

Acute oral toxicity : LD50 (Rat): 2.000 mg/kg  
Method: OECD Test Guideline 423

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

##### Skin corrosion/irritation

Not classified based on available information.

##### Components:

##### Tilmicosin:

Species : Rabbit  
Result : No skin irritation

##### Phosphoric acid:

Result : Corrosive after 3 minutes to 1 hour of exposure  
Remarks : Based on national or regional regulation.

##### Serious eye damage/eye irritation

Causes serious eye irritation.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

---

### Components:

#### **Tilmicosin:**

Species	:	Rabbit
Result	:	Mild eye irritation

#### **Phosphoric acid:**

Species	:	Rabbit
Result	:	Irreversible effects on the eye

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Tilmicosin:**

Test Type	:	Intracutaneous test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Tilmicosin:**

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

Test Type: Mouse Lymphoma  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Test system: Chinese hamster ovary cells  
Result: negative

Genotoxicity in vivo	:	Test Type: sister chromatid exchange assay Species: Hamster Result: negative
----------------------	---	--

Test Type: Chromosomal aberration  
Species: Rat  
Result: negative

#### **Phosphoric acid:**

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version 2.3	Revision Date: 30.09.2023	SDS Number: 10223661-00005	Date of last issue: 04.04.2023 Date of first issue: 12.11.2021
----------------	------------------------------	-------------------------------	---

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

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

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging fertility or the unborn child.

### Components:

#### Tilmicosin:

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: Maternal toxicity observed.

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 8 mg/kg body weight  
Result: Maternal toxicity observed., Reduced foetal weight, Skeletal and visceral variations

Reproductive toxicity - Assessment : May damage the unborn child.

#### Phosphoric acid:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Components:

##### Tilmicosin:

Exposure routes	: Oral
Target Organs	: Heart, Lungs
Assessment	: May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### Tilmicosin:

Species	: Rat
NOAEL	: 50 mg/kg
LOAEL	: 250 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Kidney, Liver, Heart, spleen, Gastrointestinal tract, Adrenal gland
Symptoms	: weight loss, reduced food consumption

Species	: Dog
NOAEL	: 4 mg/kg
LOAEL	: 12 mg/kg
Application Route	: Oral
Exposure time	: 12 Months
Target Organs	: Heart
Symptoms	: weight loss, Increased heart rate

Species	: Dog
LOAEL	: 47 mg/m3
Application Route	: Inhalation
Exposure time	: 16 d
Target Organs	: Lungs

##### Phosphoric acid:

Species	: Rat
NOAEL	: 250 mg/kg
Application Route	: Ingestion
Exposure time	: 40 - 52 Days
Method	: OECD Test Guideline 422

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Tilmicosin:

Inhalation	:	Target Organs: Gastrointestinal tract Symptoms: Nausea, Vomiting
Skin contact	:	Target Organs: Skin Symptoms: tingling
Eye contact	:	Target Organs: Eye Symptoms: burning or stinging of the eye, Swelling of tissue
Ingestion	:	Target Organs: Central nervous system Symptoms: anxiety, Headache, Light-headedness, Thirst

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Tilmicosin:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 851 mg/l Exposure time: 96 h Method: OECD Test Guideline 203  LC50 (Lepomis macrochirus (Bluegill sunfish)): 716 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 57,3 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Selenastrum capricornutum (green algae)): 0,354 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  EC10 (Anabaena flos-aquae (cyanobacterium)): 0,008 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
M-Factor (Chronic aquatic toxicity)	:	10
Phosphoric acid:		
Toxicity to fish	:	LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

	Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC50 : > 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

#### **Tilmicosin:**

Bioaccumulation	: Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 450 Method: OECD Test Guideline 305
-----------------	--

Partition coefficient: n-octanol/water	: log Pow: 3,8
--	----------------

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 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.
---------	---

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

Contaminated packaging : Do not dispose of waste into sewer.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN 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. (Tilmicosin)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tilmicosin)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tilmicosin)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tilmicosin)
IATA	: Environmentally hazardous substance, liquid, n.o.s. (Tilmicosin)

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

#### 14.4 Packing group

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



# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

### 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

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

### 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

## 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.

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

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.

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable  
Regulation on prevention of major industrial accidents. Reg number 30702

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

#### Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on health and safety measures regarding working with chemicals (Number: 28733, 2013). Occupational Exposure Limit Values (Annex 1)

#### 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.  
The SDS has been prepared by: Name: Gökhan Ardıç; Con-

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

tact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

### Full text of H-Statements

H290	: May be corrosive to metals.
H302	: Harmful if swallowed.
H314	: Causes severe skin burns and eye damage.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H361	: Suspected of damaging fertility or the unborn child.
H373	: May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

### Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Met. Corr.	: Corrosive to metals
Repr.	: Reproductive toxicity
Skin Corr.	: Skin corrosion
STOT RE	: Specific target organ toxicity - repeated exposure
2000/39/EC	: Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
TR OEL	: Türkiye. Chemical Agents at Work - Annex I: Indicative occupational exposure limit values
2000/39/EC / TWA	: Limit Value - eight hours
2000/39/EC / STEL	: Short term exposure limit
TR OEL / TWA (8 Hour)	: Measured or calculated in relation to a reference period of eight-hour time-weighted average
TR OEL / STEL 15 min	: A limit value above which exposure should not occur and is related to a 15-minute period, unless otherwise specified

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 car-

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Tilmicosin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.3	30.09.2023	10223661-00005	Date of first issue: 12.11.2021

rying 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; 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

### 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:

Acute Tox. 4	H302
Eye Irrit. 2	H319
Repr. 2	H361
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

#### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
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.

TR / EN