

## **Tilmicosin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.04.2024

 4.0
 06.07.2024
 9456720-00013
 Date of first issue: 08.09.2021

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Tilmicosin Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Acute toxicity (Oral) : Category 4

Serious eye damage/eye

irritation

Category 2A

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure (Oral)

Category 2 (Heart, Lungs)

**GHS** label elements

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 (Heart, Lungs) through

prolonged or repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/



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face protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P337 + P313 If eye irritation persists: Get medical advice/ atten-

tion.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

#### Other hazards

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Tilmicosin	137330-13-3	>= 30 -< 50
Phosphoric acid	7664-38-2	>= 1 -< 3

#### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

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.



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Most important symptoms and effects, both acute and

delayed

: 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 if swallowed.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx) Oxides of phosphorus

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

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.

Special protective equipment

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES** 

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.



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> Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Use only with adequate ventilation. Advice on safe handling

Do not breathe mist or vapors.

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

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.

Conditions for safe storage Keep in properly labeled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

Gases

# SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Tilmicosin	137330-13-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Phosphoric acid	7664-38-2	VLE-PPT	1 mg/m³	NOM-010- STPS-2014
		VLE-CT	3 mg/m³	NOM-010- STPS-2014



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	TWA	1 mg/m³	ACGIH
	STEL	3 mg/m³	ACGIH

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection. Combined particulates, acidic and inorganic gas/vapor type

Filter type
Hand protection

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : dark yellow

Odor : No data available

Odor 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) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available



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Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure No data available

Relative vapor density No data available

Relative density No data available

1.00 - 1.200 g/cm<sup>3</sup> Density

Solubility(ies)

No data available Water solubility

Partition coefficient: n-

octanol/water

No data available

Autoignition 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.

Molecular weight No data available

Particle characteristics

Particle size Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

# **SECTION 11. TOXICOLOGICAL INFORMATION**

# Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact



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**Acute toxicity** 

Harmful if swallowed.

**Product:** 

: Acute toxicity estimate: 1,467 mg/kg Acute oral toxicity

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 : LD50 (Mouse): 97 mg/kg

administration)

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.

**Components:** 

Tilmicosin:

Species Rabbit

Result Mild eye irritation

Phosphoric acid:

Species Rabbit

Result Irreversible effects on the eye



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#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

## **Respiratory sensitization**

Not classified based on available information.

#### Components:

#### Tilmicosin:

Test Type : Intracutaneous test

Routes of exposure : 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:

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



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#### 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 fetal 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 fetal weight.,

Skeletal and visceral variations.

Reproductive toxicity - As-

sessment

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 fetal development : 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

#### STOT-single exposure

Not classified based on available information.

#### STOT-repeated exposure

May cause damage to organs (Heart, Lungs) through prolonged or repeated exposure if swallowed.



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#### **Components:**

#### Tilmicosin:

Routes of exposure : 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

#### **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



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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**

## **Ecotoxicity**

#### 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

Phosphoric acid:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

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



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Persistence and degradability

No data available

**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

Mobility in soil
No data available

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

**International Regulations** 

**UNRTDG** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tilmicosin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Tilmicosin)

964

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 964



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ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

**UN** number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

(Tilmicosin)

Class 9 Packing group Ш Labels 9 F-A, S-F **EmS Code** Marine pollutant yes

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

Not applicable for product as supplied.

**Domestic regulation** 

NOM-002-SCT

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Tilmicosin)

9 Class Packing group Ш Labels 9

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

: Not applicable

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

**AICS** not determined

**DSL** not determined

**IECSC** not determined

### **SECTION 16. OTHER INFORMATION**

**Revision Date** 06.07.2024 Date format dd.mm.yyyy



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#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

NOM-010-STPS-2014 / VLE- : Short term exposure limit value

CT

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety
Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.



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MX / Z8