

## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Enrofloxacin (2.5%) Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.



##### GHS Classification

Specific target organ toxicity - repeated exposure : Category 2 (cartilage, Testis)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

##### GHS label elements

Hazard pictograms :  

Signal word : Warning

Hazard statements : H373 May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

Precautionary statements : **Prevention:**  
P260 Do not breathe mist or vapours.  
P273 Avoid release to the environment.

**Response:**  
P319 Get medical help if you feel unwell.  
P391 Collect spillage.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Enrofloxacin	93106-60-6	>= 2.5 - < 3
Benzyl alcohol	100-51-6	>= 1 - < 5

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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### 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
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# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

- Local/Total ventilation : Use only with adequate ventilation.  
Advice on safe handling : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with 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.
- Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Enrofloxacin	93106-60-6	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal

- 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.
- Filter type : Combined particulates and organic vapour 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.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

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.

Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

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

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### Enrofloxacin:

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg  
LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 5,000 mg/kg

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### **Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Components:**

##### **Enrofloxacin:**

Result : No skin irritation

##### **Benzyl alcohol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Components:**

##### **Enrofloxacin:**

Result : Mild eye irritation

##### **Benzyl alcohol:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irritation to eyes, reversing within 21 days

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

##### **Enrofloxacin:**

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

Result : Not a skin sensitizer.

### **Benzyl alcohol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Enrofloxacin:**

Genotoxicity in vitro : Test Type: Chromosomal aberration  
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Mammalian bone marrow sister chromatid exchange  
Species: Hamster  
Result: negative

Test Type: Chromosomal aberration  
Species: Rat  
Result: negative

#### **Benzyl alcohol:**

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Enrofloxacin:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

### **Benzyl alcohol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Method : OECD Test Guideline 451  
Result : negative

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Enrofloxacin:**

Effects on fertility : Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 15 mg/kg body weight  
Result: Effects on fertility, alteration in sperm morphology

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 210 mg/kg body weight  
Result: Reduced foetal weight, No teratogenic effects  
Remarks: Maternal toxicity observed.

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: No fetotoxicity, No teratogenic effects

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

#### **Benzyl alcohol:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.

### Components:

#### Enrofloxacin:

Target Organs : cartilage, Testis  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Enrofloxacin:

Species : Rat  
NOAEL : 36 mg/kg  
LOAEL : 150 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks  
Target Organs : Testis

Species : Dog  
NOAEL : 3 mg/kg  
LOAEL : 9.6 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks  
Target Organs : cartilage

Species : Cat  
NOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Remarks : No significant adverse effects were reported

#### Benzyl alcohol:

Species : Rat  
NOAEL : 1.072 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### Enrofloxacin:

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous sys-

## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

tem effects, Sensitivity to light

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Enrofloxacin:**

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l  
Exposure time: 96 h
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l  
Exposure time: 96 h
- LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Hyalella azteca (Amphipod)): > 206 mg/l  
Exposure time: 96 h
- EC50 (Daphnia magna (Water flea)): 79.9 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 ( Pseudokirchneriella subcapitata (green algae)): 3.1 mg/l  
Exposure time: 72 h
- EC50 ( Microcystis aeruginosa (blue-green algae)): 0.049 mg/l  
Exposure time: 5 d
- M-Factor (Acute aquatic toxicity) : 10
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.8 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)
- NOEC: 5 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)
- LOEC: 15 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)
- M-Factor (Chronic aquatic toxicity) : 10
- Benzyl alcohol:**
- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

---

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 ( Pseudokirchneriella subcapitata (green algae)): 770 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC ( Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Persistence and degradability

#### Components:

##### **Benzyl alcohol:**

- Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

### Bioaccumulative potential

#### Components:

##### **Enrofloxacin:**

- Partition coefficient: n-octanol/water : log Pow: 0.5

##### **Benzyl alcohol:**

- Partition coefficient: n-octanol/water : log Pow: 1.05

### Mobility in soil

#### Components:

##### **Enrofloxacin:**

- Distribution among environmental compartments : Koc: 5.55

### Other adverse effects

No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version 5.9      Revision Date: 30.09.2023      SDS Number: 641554-00019      Date of last issue: 04.04.2023  
Date of first issue: 27.04.2016

### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
( )  
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.  
( )  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
( )  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.9	30.09.2023	641554-00019	Date of first issue: 27.04.2016

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 15. REGULATORY INFORMATION

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

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

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

### 16. OTHER INFORMATION

Revision Date : 30.09.2023

#### 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/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory 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,

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Enrofloxacin (2.5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.9	30.09.2023	641554-00019	Date of first issue: 27.04.2016

---

tion, 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

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.

IN / EN