

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

SECTION 1: IDENTIFICATION

Product name : Enrofloxacin (10%) Formulation

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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**

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 1 (cartilage, Testis)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H361f Suspected of damaging fertility.
H372 Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Enrofloxacin	93106-60-6	>= 10 -< 30
Benzyl alcohol	100-51-6	>= 1 -< 10

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 : 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.

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

Most important symptoms and effects, both acute and delayed	: Rinse mouth thoroughly with water. May cause an allergic skin reaction. Suspected of damaging fertility. Causes 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.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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.
Hazchem Code	: •3Z

SECTION 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.

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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.

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 get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. 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.
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. 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 labelled 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

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

SECTION 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 ³ (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.

SECTION 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

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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
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 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 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.

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

|| Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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

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

Benzyl alcohol:

|| Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
|| Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

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

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

Serious eye damage/eye irritation

|| Not classified based on available information.

Components:**Enrofloxacin:**

|| Result : Mild eye irritation

Benzyl alcohol:

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

Respiratory or skin sensitisation**Skin sensitisation**

|| May cause an allergic skin reaction.

Respiratory sensitisation

|| Not classified based on available information.

Components:**Enrofloxacin:**

|| Test Type : Maximisation Test
|| Exposure routes : Dermal
|| Species : Guinea pig
|| Result : Not a skin sensitizer.

Benzyl alcohol:

|| Test Type : Human repeat insult patch test (HRIPT)
|| Exposure routes : Skin contact
|| Species : Humans
|| Result : positive

|| Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

Chronic toxicity**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

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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

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

Suspected of damaging fertility.

Components:**Enrofloxacin:**

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes 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.

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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 system effects, Sensitivity to light
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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Enrofloxacin:**

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l Exposure time: 96 h
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Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	28.09.2024	633935-00022	06.04.2024
			Date of first issue: 27.04.2016

	LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 196 mg/l Exposure time: 96 h
	LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (<i>Hyalella azteca</i> (Amphipod)): > 206 mg/l Exposure time: 96 h
	EC50 (<i>Daphnia magna</i> (Water flea)): 79.9 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 3.1 mg/l Exposure time: 72 h
	EC50 (<i>Microcystis aeruginosa</i> (blue-green algae)): 0.049 mg/l Exposure time: 5 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (<i>Daphnia magna</i> (Water flea)): 9.8 mg/l Exposure time: 21 d
	NOEC (<i>Daphnia magna</i> (Water flea)): 5 mg/l Exposure time: 21 d
	LOEC (<i>Daphnia magna</i> (Water flea)): 15 mg/l Exposure time: 21 d

Benzyl alcohol:

Toxicity to fish	: LC50 (<i>Pimephales promelas</i> (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (<i>Daphnia magna</i> (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (<i>Daphnia magna</i> (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

Persistence and degradability**Components:****Benzy 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
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Benzy alcohol:

Partition coefficient: n-octanol/water	:	log Pow: 1.05
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Mobility in soil**Components:****Enrofloxacin:**

Distribution among environmental compartments	:	Koc: 5.55
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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.
		()
Class	:	9
Packing group	:	III
Labels	:	9

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**ADG**

UN number	: UN 3082
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. ()
Class	: 9
Packing group	: III
Labels	: 9
Hazchem Code	: •3Z
Environmentally hazardous	: yes

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**

Therapeutic Goods (Poisons Standard) Instrument	: No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or
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Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

II threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date	: 28.09.2024
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/

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

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 Develop-

Enrofloxacin (10%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	28.09.2024	633935-00022	Date of first issue: 27.04.2016

ment; 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

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.

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