

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

---

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

#### 1.1 Product identifier

Trade name : Enrofloxacin Liquid (20%) Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Acute toxicity, Category 4	H302: Harmful if swallowed.
Skin corrosion, Sub-category 1A	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Reproductive toxicity, Category 2	H361f: Suspected of damaging fertility.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version 8.0	Revision Date: 14.04.2025	SDS Number: 9749481-00011	Date of last issue: 28.09.2024 Date of first issue: 13.10.2021
----------------	------------------------------	------------------------------	---

Long-term (chronic) aquatic hazard, Category 1

H410: Very toxic to aquatic life with long lasting effects.

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms :

Signal word : Danger

Hazard statements :  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H361f Suspected of damaging fertility.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements : EUH071 Corrosive to the respiratory tract.

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:**  
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P391 Collect spillage.

Hazardous components which must be listed on the label:

Enrofloxacin

Potassium hydroxide

EUH208 Contains Benzyl alcohol. May produce an allergic reaction.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

May form explosive dust-air mixture during processing, handling or other means.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version 8.0      Revision Date: 14.04.2025      SDS Number: 9749481-00011      Date of last issue: 28.09.2024  
Date of first issue: 13.10.2021

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Enrofloxacin	93106-60-6	Acute Tox. 4; H302 Repr. 2; H361f STOT RE 1; H372 (cartilage, Testis) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 20 - < 25
Potassium hydroxide	1310-58-3 215-181-3 019-002-00-8	Met. Corr. 1; H290 Acute Tox. 4; H302 Skin Corr. 1A; H314 Eye Dam. 1; H318  specific concentra- tion limit Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0.5 - < 2 % Eye Irrit. 2; H319 0.5 - < 2 % EUH071 >= 2 %	>= 5 - < 10
Disodium EDTA, dihydrate	6381-92-6 205-358-3	Acute Tox. 4; H332 STOT RE 2; H373 (Respiratory Tract)	>= 1 - < 10
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 0.1 - < 1

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

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.<br>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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention immediately.  |
| In case of skin contact    | : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention immediately.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately.   |
| If swallowed               | : If swallowed, DO NOT induce vomiting.<br>If vomiting occurs have person lean forward.<br>Call a physician or poison control centre immediately.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.      |

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

- |       |  |
|-------|--|
| Risks | : Causes digestive tract burns.<br><br>May produce an allergic reaction. |
|-------|--|

	Harmful if swallowed. Causes serious eye damage. Suspected of damaging fertility. Causes damage to organs through prolonged or repeated exposure. Causes severe burns. Corrosive to the respiratory tract.
--	---

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

### 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  
Metal oxides  
Nitrogen oxides (NO<sub>x</sub>)

### 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.  
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.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

---

### 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 and bonding, or inert atmospheres.
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in 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 Keep container tightly closed. 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 contami-

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version 8.0      Revision Date: 14.04.2025      SDS Number: 9749481-00011      Date of last issue: 28.09.2024  
Date of first issue: 13.10.2021

nated 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. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
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
Enrofloxacin	93106-60-6	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Potassium hydroxide	1310-58-3	STEL	2 mg/m <sup>3</sup>	GB EH40

#### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Potassium hydroxide	Workers	Inhalation	Long-term local effects	1 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	1 mg/m <sup>3</sup>
Disodium EDTA, dihydrate	Workers	Inhalation	Long-term systemic effects	1.5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	3 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	1.5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	3 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	0.6 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute local effects	1.2 mg/m <sup>3</sup>

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version 8.0      Revision Date: 14.04.2025      SDS Number: 9749481-00011      Date of last issue: 28.09.2024  
Date of first issue: 13.10.2021

	Consumers	Ingestion	Long-term systemic effects	25 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Disodium EDTA, dihydrate	Fresh water	2.5 mg/l
	Marine water	0.25 mg/l
	Sewage treatment plant	50 mg/l
	Soil	1.1 mg/kg dry weight (d.w.)
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg

## 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.

Laboratory operations do not require special containment.

### 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



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

Hand protection	aerosols.
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: light yellow
Odour	: No data available
Odour Threshold	: No data available
pH	: 10.5 - 12.5
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 explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
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	: 0.950 - 1.150 g/cm <sup>3</sup>
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

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

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 explosive dust-air mixture 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 Acids
--------------------	---	---------------------------

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

### Acute toxicity

Harmful if swallowed.

### Product:

Acute oral toxicity : Acute toxicity estimate: 1,818 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
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

#### Potassium hydroxide:

Acute oral toxicity : LD50 (Rat): 333 mg/kg

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

#### Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 1 mg/l  
Exposure time: 6 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 412

#### 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

Causes severe burns.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

---

### Components:

#### **Enrofloxacin:**

|| Result : No skin irritation

#### **Potassium hydroxide:**

|| Species : Rabbit  
|| Result : Corrosive after 3 minutes or less of exposure

#### **Benzyl alcohol:**

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

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

Causes serious eye damage.

### Components:

#### **Enrofloxacin:**

|| Result : Mild eye irritation

#### **Potassium hydroxide:**

|| Species : Rabbit  
|| Result : Irreversible effects on the eye

#### **Disodium EDTA, dihydrate:**

|| Species : Rabbit  
|| Result : No 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 REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

Result : Not a skin sensitizer.

### Potassium hydroxide:

Test Type : Intracutaneous test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

### Disodium EDTA, dihydrate:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

### 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

### 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

### Potassium hydroxide:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

||

### Disodium EDTA, dihydrate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
		Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Method: OECD Test Guideline 474 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

#### Disodium EDTA, dihydrate:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

Result	: negative
Remarks	: Based on data from similar materials

### 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:

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.

#### Disodium EDTA, dihydrate:

Effects on fertility	: Test Type: Four-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

### Benzyl alcohol:

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

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

Corrosive to the respiratory tract.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### Components:

#### Enrofloxacin:

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

#### Disodium EDTA, dihydrate:

Exposure routes : inhalation (dust/mist/fume)  
Target Organs : Respiratory Tract  
Assessment : May cause 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



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

Exposure time	: 30 Days
Remarks	: No significant adverse effects were reported

### Disodium EDTA, dihydrate:

Species	: Rat
NOAEL	: 500 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

Species	: Rat
LOAEL	: 0.03 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 4 Weeks
Method	: OECD Test Guideline 412

### 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
-----------	--

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

		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
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: <i>Daphnia magna</i> (Water flea)
		NOEC: 5 mg/l Exposure time: 21 d Species: <i>Daphnia magna</i> (Water flea)
		LOEC: 15 mg/l Exposure time: 21 d Species: <i>Daphnia magna</i> (Water flea)
M-Factor (Chronic aquatic toxicity)	:	10

### Disodium EDTA, dihydrate:

Toxicity to fish	:	LC50 ( <i>Lepomis macrochirus</i> (Bluegill sunfish)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 ( <i>Daphnia magna</i> (Water flea)): 140 mg/l Exposure time: 48 h Method: DIN 38412
Toxicity to algae/aquatic plants	:	ErC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		EC10 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC10 (activated sludge): > 500 mg/l Exposure time: 30 min Method: OECD Test Guideline 209

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 25 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l  
Exposure time: 96 h

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

## 12.2 Persistence and degradability

### Components:

#### Disodium EDTA, dihydrate:

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 2 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D

#### Benzyl alcohol:

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

## 12.3 Bioaccumulative potential

### Components:

#### Enrofloxacin:

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

### Disodium EDTA, dihydrate:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): < 500  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: -4.3

### Benzyl alcohol:

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

## 12.4 Mobility in soil

### Components:

#### Enrofloxacin:

Distribution among environmental compartments : Koc: 5.55

## 12.5 Results of PBT and vPvB assessment

### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 12.6 Other adverse effects

### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.

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

## SECTION 14: Transport information

### 14.1 UN number

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

ADN	:	UN 1814
ADR	:	UN 1814
RID	:	UN 1814
IMDG	:	UN 1814
IATA	:	UN 1814

### 14.2 UN proper shipping name

ADN	:	POTASSIUM HYDROXIDE SOLUTION
ADR	:	POTASSIUM HYDROXIDE SOLUTION
RID	:	POTASSIUM HYDROXIDE SOLUTION
IMDG	:	POTASSIUM HYDROXIDE SOLUTION (Enrofloxacin)
IATA	:	Potassium hydroxide solution

### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	8
ADR	:	8
RID	:	8
IMDG	:	8
IATA	:	8

### 14.4 Packing group

ADN	
Packing group	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8

ADR	
Packing group	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8
Tunnel restriction code	: (E)

RID	
Packing group	: II
Classification Code	: C5
Hazard Identification Number	: 80
Labels	: 8

IMDG	
Packing group	: II
Labels	: 8
EmS Code	: F-A, S-B

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

### IATA (Cargo)

Packing instruction (cargo aircraft)	:	855
Packing instruction (LQ)	:	Y840
Packing group	:	II
Labels	:	Corrosive

### IATA (Passenger)

Packing instruction (passenger aircraft)	:	851
Packing instruction (LQ)	:	Y840
Packing group	:	II
Labels	:	Corrosive

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

## 14.6 Special precautions for user

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

## 14.7 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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	not.		
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable		
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable		
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable		
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable		
Control of Major Accident Hazards Regulations 2015 (COMAH)	:			
E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t	

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### 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.
-------------------	---	--

### Full text of H-Statements

H290	:	May be corrosive to metals.
H302	:	Harmful if swallowed.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H361f	:	Suspected of damaging fertility.
H372	:	Causes damage to organs through prolonged or repeated

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

H373 : exposure.  
: May cause damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### 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  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated exposure  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Enrofloxacin Liquid (20%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
8.0	14.04.2025	9749481-00011	Date of first issue: 13.10.2021

### 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
Skin Corr. 1A	H314
Eye Dam. 1	H318
Repr. 2	H361f
STOT RE 1	H372
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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

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.

GB / EN