

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

### Section 1: Identification

Product name : Enrofloxacin / Diclofenac Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800  
CHEMCALL)

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: Hazard identification

#### GHS Classification

Skin corrosion/irritation : Category 1

Serious eye damage/eye irritation : Category 1

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

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

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate)

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3	Revision Date: 14.04.2025	SDS Number: 1239759-00020	Date of last issue: 28.09.2024 Date of first issue: 26.01.2017
----------------	------------------------------	------------------------------	---

### GHS label elements

Hazard pictograms



Signal word

: Danger

Hazard statements

- : H314 Causes severe skin burns and eye damage.
- : H317 May cause an allergic skin reaction.
- : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
- : H372 Causes damage to organs (cartilage, Testis) through prolonged or repeated exposure.
- : H373 May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.
- : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe mist or 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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- P284 Wear respiratory protection.

: **Response:**

- P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
- 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.
- P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P333 + P313 If skin irritation or rash occurs: Get medical ad-

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version  
7.3

Revision Date:  
14.04.2025

SDS Number:  
1239759-00020

Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

vice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P391 Collect spillage.

### 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)
Propylene glycol	57-55-6	>= 30 -< 50
Enrofloxacin	93106-60-6	>= 10 -< 20
Benzyl alcohol	100-51-6	>= 1 -< 10
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	>= 1 -< 2.5
Sodium metabisulphite	7681-57-4	>= 0.1 -< 1

## 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.

If not breathing, give artificial respiration.

If breathing is difficult, give oxygen.

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.

Get medical attention immediately.

Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

Most important symptoms and effects, both acute and delayed	Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Causes digestive tract burns. May cause an allergic skin reaction. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Causes severe burns.
Protection of first-aiders	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	Treat symptomatically and supportively.

---

### Section 5: Fire-fighting measures

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (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 Chlorine compounds Nitrogen oxides (NO <sub>x</sub> ) Sodium 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).
---	--

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

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.

---

### Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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.  
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

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3 Revision Date: 14.04.2025 SDS Number: 1239759-00020 Date of last issue: 28.09.2024 Date of first issue: 26.01.2017

Conditions for safe storage	: use of administrative controls. Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Self-reactive substances and mixtures Organic peroxides Oxidizing agents Explosives

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m3	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m3	NZ OEL
Enrofloxacin	93106-60-6	TWA	0.2 mg/m3 (OEB 2)	Internal
Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate	15307-79-6	TWA	100 µg/m3 (OEB 2)	Internal
		Further information: Skin		
Sodium metabisulphite	7681-57-4	WES-TWA	5 mg/m3	NZ OEL
		Further information: Skin sensitiser, Respiratory sensitiser		
		TWA	5 mg/m3	ACGIH

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
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,

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

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 : light yellow  
Odour : No data available  
Odour Threshold : No data available  
pH : 10.5 - 11.5  
(as aqueous solution)  
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 : 1.07 - 1.08 g/cm<sup>3</sup>  
Solubility(ies)  
Water solubility : soluble  
Partition coefficient: n-octanol/water : Not applicable  
Auto-ignition temperature : No data available

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

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  
Acids

Hazardous decomposition products : No hazardous decomposition products are known.

---

### 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

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### Components:

##### **Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**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

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Acute oral toxicity : LD50 (Rat): 55 - 240 mg/kg  
LD50 (Mouse): 170 - 389 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 97 - 161 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 92 - 147 mg/kg  
Application Route: Intravenous

**Sodium metabisulphite:**

Acute oral toxicity : LD50 (Rat): 1,540 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

Remarks: Based on data from similar materials

### **Skin corrosion/irritation**

Causes severe burns.

#### **Components:**

##### **Propylene glycol:**

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

##### **Enrofloxacin:**

Result : No skin irritation

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

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

##### **Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Result : irritating

##### **Sodium metabisulphite:**

Result : Skin irritation  
Remarks : Based on national or regional regulation.

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

Causes serious eye damage.

#### **Components:**

##### **Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

##### **Enrofloxacin:**

Result : Mild eye irritation

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

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

**Enrofloxacin / Diclofenac Liquid Formulation**

---

Version 7.3	Revision Date: 14.04.2025	SDS Number: 1239759-00020	Date of last issue: 28.09.2024 Date of first issue: 26.01.2017
----------------	------------------------------	------------------------------	---

---

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Result : Mild eye irritation

**Sodium metabisulphite:**

Species	:	Rabbit
Result	:	Irreversible effects on the eye
Method	:	OECD Test Guideline 405

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:****Propylene glycol:**

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

**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

**Sodium metabisulphite:**

Assessment	:	Probability or evidence of skin sensitisation in humans
Remarks	:	Based on national or regional regulation.
Assessment	:	May cause sensitisation by inhalation.
Remarks	:	Based on national or regional regulation.

**Enrofloxacin / Diclofenac Liquid Formulation**Version  
7.3Revision Date:  
14.04.2025SDS Number:  
1239759-00020Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Propylene glycol:**

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

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

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

**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

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

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

**Enrofloxacin / Diclofenac Liquid Formulation**

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

Test Type: Mouse Lymphoma  
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: CHO  
Result: negative

**Sodium metabisulphite:**

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Subcutaneous  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Propylene glycol:**

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

**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

**Enrofloxacin / Diclofenac Liquid Formulation**

---

Version 7.3	Revision Date: 14.04.2025	SDS Number: 1239759-00020	Date of last issue: 28.09.2024 Date of first issue: 26.01.2017
----------------	------------------------------	------------------------------	---

---

Method : OECD Test Guideline 451  
Result : negative

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

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

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

**Sodium metabisulphite:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 24 Months  
Result : negative  
Remarks : Based on data from similar materials

**Reproductive toxicity**

Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:****Propylene glycol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

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

**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.

## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

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

### **Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male and female  
Application Route: Oral  
Fertility: NOAEL: 4 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

### **Sodium metabisulphite:**

Effects on fertility : Test Type: Three-generation study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024  
7.3 14.04.2025 1239759-00020 Date of first issue: 26.01.2017

Species: Rabbit  
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.  
May cause damage to organs (Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate) through prolonged or repeated exposure.

## **Components:**

## Enrofloxacin:

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

**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate  
Assessment : Causes damage to organs through prolonged or repeated exposure.

## Repeated dose toxicity

## **Components:**

## Propylene glycol:

Species : Rat, male  
NOAEL :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

## 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

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

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

### **Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Species : Rat  
LOAEL : 0.25 mg/kg  
Application Route : Oral  
Exposure time : 98 w  
Target Organs : Gastrointestinal tract, Blood, lymphatic system, Liver, Prostate

Species : Dog  
LOAEL : 1 mg/kg  
Application Route : Oral  
Exposure time : 12 w  
Target Organs : Blood

Species : Baboon  
NOAEL : 0.5 mg/kg  
LOAEL : 5 mg/kg  
Application Route : Oral  
Exposure time : 52 w  
Target Organs : Gastrointestinal tract, Blood  
Symptoms : constipation, Diarrhoea

### **Sodium metabisulphite:**

Species : Rat  
NOAEL : 110 mg/kg  
LOAEL : 220 mg/kg  
Application Route : Ingestion  
Exposure time : 104 Weeks

### **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

**Enrofloxacin / Diclofenac Liquid Formulation**Version  
7.3Revision Date:  
14.04.2025SDS Number:  
1239759-00020Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017**Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Ingestion : Symptoms: Abdominal pain, Diarrhoea, constipation, heart-burn, Ulceration, Dizziness, Headache, Breathing difficulties, Rash

**Section 12: Ecological information****Ecotoxicity****Components:****Propylene glycol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

**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

## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

M-Factor (Acute aquatic toxicity) : 10

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9.8 mg/l  
Exposure time: 21 d

NOEC (Daphnia magna (Water flea)): 5 mg/l  
Exposure time: 21 d

LOEC (Daphnia magna (Water flea)): 15 mg/l  
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 10

### 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 (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 166.6 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 80.1 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 71.9 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 49.2 mg/l

**Enrofloxacin / Diclofenac Liquid Formulation**Version  
7.3Revision Date:  
14.04.2025SDS Number:  
1239759-00020Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.32 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Sodium metabisulphite:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 89 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l  
Exposure time: 72 h  
EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l  
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): >= 316 mg/l  
Exposure time: 34 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): >= 10 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10 (Pseudomonas putida): 30.8 mg/l  
Exposure time: 17 h

**Persistence and degradability****Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Benzyl alcohol:**

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

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3 Revision Date: 14.04.2025 SDS Number: 1239759-00020 Date of last issue: 28.09.2024 Date of first issue: 26.01.2017

---

### Bioaccumulative potential

#### Components:

##### **Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

##### **Enrofloxacin:**

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

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

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

##### **Sodium [2-[(2,6-dichlorophenyl)amino]phenyl]acetate:**

Partition coefficient: n-octanol/water : log Pow: 4.51

### **Mobility in soil**

#### Components:

##### **Enrofloxacin:**

Distribution among environmental compartments : Koc: 5.55

### **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.  
(Enrofloxacin)  
Class : 9  
Packing group : III  
Labels : 9

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

Environmentally hazardous : yes

### IATA-DGR

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Enrofloxacin)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo  
aircraft) : 964

Packing instruction (passen-  
ger aircraft) : 964

Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Enrofloxacin)

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

#### NZS 5433

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(Enrofloxacin)

Class : 9

Packing group : III

Labels : 9

Hazchem Code : 3Z

Marine pollutant : no

### Special precautions for user

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

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

Version 7.3      Revision Date: 14.04.2025      SDS Number: 1239759-00020      Date of last issue: 28.09.2024  
Date of first issue: 26.01.2017

---

### Section 15: Regulatory information

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

**HSNO Approval Number**

not allocated

**Tolerable Exposure Limits (TEL)**

Not applicable

**Environmental Exposure Limits (EEL)**

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

### Section 16: Other information

Revision Date : 14.04.2025

**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**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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

# SAFETY DATA SHEET



## Enrofloxacin / Diclofenac Liquid Formulation

---

Version 7.3	Revision Date: 14.04.2025	SDS Number: 1239759-00020	Date of last issue: 28.09.2024 Date of first issue: 26.01.2017
----------------	------------------------------	------------------------------	---

---

Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

NZ / EN