according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 06.07.2024 9749474-00009 Date of first issue: 13.10.2021 5.0

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-: Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company **MSD**

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

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)

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 H372: Causes damage to organs through pro-

exposure, Category 1 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

H400: Very toxic to aquatic life.

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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 re-

peated 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 protec-

tion/ 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

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 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	>= 20 - < 25
		M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
Potassium hydroxide	1310-58-3 215-181-3 019-002-00-8	aquatic toxicity): 10 Met. Corr. 1; H290 Acute Tox. 4; H302 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH014, EUH071	>= 5 - < 10
Disodium EDTA, dihydrate	6381-92-6	Acute oral toxicity: 333 mg/kg Acute Tox. 4; H332	>= 1 - < 10

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

		STOT RE 2; H373 (Respiratory Tract)	
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 Acute toxicity estimate Acute oral toxicity: 1.620 mg/kg	>= 0,1 - < 1

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 ad-

vice immediately.

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.

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, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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.

Causes digestive tract burns.

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 (CO2)

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 prod- :

ucts

Carbon oxides Metal oxides

Nitrogen oxides (NOx)

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

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 pro-

tective equipment recommendations (see section 8).

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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

oarriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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 absor-

bent.

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 deter-

mine 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 as-

sessment

Keep container tightly closed.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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-

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	Control parameters	Basis
		of exposure)		
Enrofloxacin	93106-60-6	TWA	0.2 mg/m3 (OEB 2)	Internal
Potassium hydrox-	1310-58-3	Т	2 mg/m3	FOR-2011-
ide			_	12-06-1358

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

	` '	•	` '	
Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Potassium hydroxide	Workers	Inhalation	Long-term local effects	1 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	1 mg/m3

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

Disodium EDTA, di- hydrate	Workers	Inhalation	Long-term systemic effects	1,5 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	3 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1,5 mg/m3
	Workers	Inhalation	Acute local effects	3 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	0,6 mg/m3
	Consumers	Inhalation	Acute local effects	1,2 mg/m3
	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 ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5,4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

	T = 1	1
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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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

aerosols.

Hand protection

Filter type

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143

: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Aqueous solution

Colour : light yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 10,5 - 12,5

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : 0,950 - 1,150 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

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, han-

dling or other means.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion

Eye contact

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:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

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): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: OECD Test Guideline 403

Skin corrosion/irritation

Causes severe burns.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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

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 : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Enrofloxacin:

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: positive

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Mammalian bone marrow sister chromatid ex-

change

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

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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
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 develop-

ment

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

Reproductive toxicity - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

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 develop-

ment

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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

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

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

Enrofloxacin:

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous sys-

tem 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

EC50 (Daphnia magna (Water flea)): 79,9 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 3,1

mg/l

Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0,049 mg/l

Exposure time: 5 d

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 9,8 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

NOEC: 5 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

LOEC: 15 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

10

Disodium EDTA, dihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 140 mg/l

Exposure time: 48 h Method: DIN 38412

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

ma/

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (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

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

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 environ-

mental compartments

: Koc: 5,55

12.5 Results of PBT and vPvB assessment

Product:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

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)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 5.0 06.07.2024 9749474-00009 Date of first issue: 13.10.2021

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

IATA (Cargo)

Packing instruction (cargo : 855

aircraft)

Packing instruction (LQ) : Y840
Packing group : II

Labels : Corrosive

IATA (Passenger)

Packing instruction (passen: 851

ger aircraft)

Packing instruction (LQ) : Y840
Packing group : II

Labels : Corrosive

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 06.07.2024 9749474-00009 Date of first issue: 13.10.2021 5.0

ADR

Environmentally hazardous yes

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

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 not.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2 E1 **ENVIRONMENTAL** 100 t 200 t

HAZARDS

23 / 26

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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.

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

exposure.

H373 : 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.

EUH014 : Reacts violently with water. EUH071 : Corrosive to the respiratory tract.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Eve Dam. : Serious eye damage

Eye Irrit. : Eye irritation

Met. Corr. : Corrosive to metals

Repr. : Reproductive toxicity

Skin Corr. : Skin corrosion

STOT RE : Specific target organ toxicity - repeated exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / T : Ceiling

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 06.07.2024 9749474-00009 Date of first issue: 13.10.2021 5.0

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

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:

Classification procedure: Acute Tox. 4 Calculation method H302 Skin Corr. 1A H314 Calculation method Eye Dam. 1 H318 Calculation method Repr. 2 H361f Calculation method STOT RE 1 H372 Calculation method Aquatic Acute 1 H400 Calculation method Aquatic Chronic 1 H410 Calculation method

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Enrofloxacin Liquid (20%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 5.0
 06.07.2024
 9749474-00009
 Date of first issue: 13.10.2021

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.

NO / EN