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## **Enrofloxacin Liquid Formulation**

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 SDS Number:
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 6.0
 06.07.2024
 10225234-00008
 Date of first issue: 12.11.2021

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

1.1 Product identifier

Trade name : Enrofloxacin Liquid 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 : Not applicable

on use

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)

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation. Reproductive toxicity, Category 2 H361f: Suspected of damaging fertility.

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

aorv 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

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#### 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 : Warning

Hazard statements : H315 Causes skin irritation.

H319 Causes serious eye irritation. H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Enrofloxacin

#### 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.

#### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No. | Classification  | Concentration<br>(% w/w) |
|---------------|--------------------------------|---|--------------------------|
| Enrofloxacin  | 93106-60-6                     | Acute Tox. 4; H302<br>Repr. 2; H361f<br>STOT RE 1; H372 | >= 3 - < 10              |

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| Potassium hydroxide                          | 1310-58-3<br>215-181-3<br>019-002-00-8 | (cartilage, Testis) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  ——————————————————————————————————— | >= 1 - < 2   |
|--|--|--|--------------|
| Benzyl alcohol                               | 100-51-6<br>202-859-9<br>603-057-00-5  | Acute Tox. 4; H302<br>Acute Tox. 4; H332<br>Eye Irrit. 2; H319   | >= 0.1 - < 1 |
| Substances with a workplace exposure limit : |  |  |              |
| Propylene glycol                             | 57-55-6                                |  | >= 20 - < 30 |
|  | 200-338-0                              |  |              |

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).

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If inhaled : If inhaled, remove to fresh air.

Get medical attention.

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.
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.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes skin irritation.

Causes serious eye irritation. Suspected of damaging fertility.

May cause damage to organs through prolonged or repeated

exposure.

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

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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).

#### 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).

#### 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.

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#### **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 : Use only with adequate ventilation. Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. 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

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. 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

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## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

## **Occupational Exposure Limits**

| Components               | CAS-No.    | Value type (Form of exposure)              | Control parameters   | Basis    |
|--------------------------|------------|--|----------------------|----------|
| Propylene glycol         | 57-55-6    | TWA (Total va-<br>pour and parti-<br>cles) | 150 ppm<br>474 mg/m3 | GB EH40  |
|                          |            | TWA (particles)                            | 10 mg/m3             | GB EH40  |
| Enrofloxacin             | 93106-60-6 | TWA  | 0.2 mg/m3 (OEB 2)    | Internal |
| Potassium hydrox-<br>ide | 1310-58-3  | STEL                                       | 2 mg/m3              | GB EH40  |

## **Derived No Effect Level (DNEL):**

| Substance name      | End Use   | Exposure routes | Potential health effects     | Value              |
|---------------------|-----------|-----------------|------------------------------|--------------------|
| Potassium hydroxide | Workers   | Inhalation      | Long-term local ef-<br>fects | 1 mg/m3            |
|                     | Consumers | Inhalation      | Long-term local effects      | 1 mg/m3            |
| Propylene glycol    | Workers   | Inhalation      | Long-term local effects      | 10 mg/m3           |
|                     | Workers   | Inhalation      | Long-term systemic effects   | 168 mg/m3          |
|                     | Consumers | Inhalation      | Long-term local effects      | 10 mg/m3           |
|                     | Consumers | Inhalation      | Long-term systemic effects   | 50 mg/m3           |
| 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<br>bw/day  |
|                     | Workers   | Skin contact    | Acute systemic effects       | 40 mg/kg<br>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<br>bw/day  |
|                     | Consumers | Skin contact    | Acute systemic effects       | 20 mg/kg<br>bw/day |
|                     | Consumers | Ingestion       | Long-term systemic effects   | 4 mg/kg<br>bw/day  |
|                     | Consumers | Ingestion       | Acute systemic effects       | 20 mg/kg<br>bw/day |

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#### **Predicted No Effect Concentration (PNEC):**

| Substance name   | Environmental Compartment | Value                           |
|------------------|---------------------------|---------------------------------|
| Propylene glycol | Fresh water               | 260 mg/l                        |
|                  | Freshwater - intermittent | 183 mg/l                        |
|                  | Marine water              | 26 mg/l                         |
|                  | Sewage treatment plant    | 20000 mg/l                      |
|                  | Fresh water sediment      | 572 mg/kg dry<br>weight (d.w.)  |
|                  | Marine sediment           | 57.2 mg/kg dry<br>weight (d.w.) |
|                  | Soil                      | 50 mg/kg dry<br>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

aerosols.

Hand protection

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 BS EN 143

Filter type : Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Appearance : Aqueous solution
Colour : Clear white to yellow.
Odour : No data available

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Odour Threshold : No data available

pH : 10.5 - 12.5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Flash point : Not applicable

Evaporation rate : No data available

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

dling or other means.

Upper explosion limit / Upper

flammability limit

No data available

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility
Partition coefficient: n-

octanol/water

No data available

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : Not applicable

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### **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.

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 : Inhalation

exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

**Components:** 

**Enrofloxacin:** 

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg

LD50 (Rat): > 5,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

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

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Potassium hydroxide:

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

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

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

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

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

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Causes skin irritation.

**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

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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**Components:** 

**Enrofloxacin:** 

Result : Mild eye irritation

Potassium hydroxide:

Species : Rabbit

Result : Irreversible effects on the eye

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

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

Benzyl alcohol:

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

Method : OECD Test Guideline 406

Result : negative

Propylene glycol:

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

#### Germ cell mutagenicity

Not classified based on available information.

**Components:** 

**Enrofloxacin:** 

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Mammalian bone marrow sister chromatid 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

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

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

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cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### **Enrofloxacin:**

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

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

## Benzyl alcohol:

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

Method : OECD Test Guideline 451

Result : negative

### Propylene glycol:

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

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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 - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

**Application Route: Ingestion** 

Result: negative

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### **Components:**

**Enrofloxacin:** 

Target Organs : cartilage, Testis

Assessment : Causes damage to organs through prolonged or repeated

exposure.

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#### Repeated dose toxicity

#### **Components:**

#### **Enrofloxacin:**

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

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

Species : Cat

NOAEL : 25 mg/kg

Application Route : Oral

Exposure time : 30 Days

Remarks : No significant adverse effects were reported

### Benzyl alcohol:

Species : Rat NOAEL : 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

#### Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

## **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

#### **Components:**

#### **Enrofloxacin:**

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous sys-

tem effects, Sensitivity to light

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#### **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)

LOEC: 15 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

: 10

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

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



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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

Exposure time: 72 h

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

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

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

Exposure time: 18 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

NOEC: 13,020 mg/l Exposure time: 7 d

ic toxicity) Species: Ceriodaphnia dubia (water flea)

#### 12.2 Persistence and degradability

#### **Components:**

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

Propylene glycol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

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### 12.3 Bioaccumulative potential

**Components:** 

**Enrofloxacin:** 

Partition coefficient: n-

octanol/water

log Pow: 0.5

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1.05

Propylene glycol:

Partition coefficient: n-

octanol/water

log Pow: -1.07

Method: Regulation (EC) No. 440/2008, Annex, A.8

12.4 Mobility in soil

**Components:** 

**Enrofloxacin:** 

Distribution among environ-

mental 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 poten-

tial

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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



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### **SECTION 14: Transport information**

#### 14.1 UN number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Enrofloxacin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Enrofloxacin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Enrofloxacin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Enrofloxacin)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Enrofloxacin)

#### 14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

### 14.4 Packing group

#### **ADN**

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90

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Labels : 9 Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo :

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

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

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



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UK REACH List of restrictions (Annex 17) : Conditions of restriction for the fol-

lowing 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.

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

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

plete the ozone layer

UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

E1 ENVIRONMENTAL

HAZARDS

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

(AH)

Quantity 1 Quantity 2 100 t 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.

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



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#### **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.

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

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
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

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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 Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture:

#### Classification procedure: Skin Irrit. 2 Calculation method H315 Eye Irrit. 2 H319 Calculation method Repr. 2 H361f Calculation method STOT RE 2 H373 Calculation method Aquatic Acute 1 H400 Calculation method Calculation method Aquatic Chronic 1 H410

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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