

SAFETY DATA SHEET

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



Enrofloxacin (2.5%) Formulation

Version
4.1

Revision Date:
14.04.2025

SDS Number:
9372666-00009

Date of last issue: 28.09.2024
Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Enrofloxacin (2.5%) Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

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

Telephone : +1-908-740-4000

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

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

| | |
|--|--|
| Skin sensitisation, Category 1 | H317: May cause an allergic skin reaction. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |
| Long-term (chronic) aquatic hazard, Category 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

: H317 May cause an allergic skin reaction.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:

P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Enrofloxacin
Benzyl alcohol

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.

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) | >= 2.5 - < 3 |

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| | | | |
|----------------|---------------------------------------|--|-------------|
| | | Aquatic Acute 1; H400 Aquatic Chronic 1; H410 | |
| Benzyl alcohol | 100-51-6 202-859-9 603-057-00-5 | Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 | >= 1 - < 10 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
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.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.
May cause damage to organs through prolonged or repeated exposure.

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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 products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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6.3 Methods and material for containment and cleaning up

Methods for 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.

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

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. 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

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Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--------------|------------|-------------------------------|--------------------|----------|
| Enrofloxacin | 93106-60-6 | TWA | 0.2 mg/m3 (OEB 2) | Internal |

Derived No Effect Level (DNEL)

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|-----------|-----------------|----------------------------|-----------------|
| Benzyl alcohol | Workers | Inhalation | Long-term systemic effects | 22 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 110 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 8 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 40 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 5.4 mg/m3 |
| | Consumers | Inhalation | Acute systemic effects | 27 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 20 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 20 mg/kg bw/day |

Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------------|
| 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 |

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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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to BS EN 14387 |
| Filter type | : Combined particulates and organic vapour type (A-P) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|---------------------|
| Appearance | : liquid |
| Colour | : No data available |
| Odour | : No data available |
| Odour Threshold | : No data available |
| pH | : No data available |
| Melting point/freezing point | : No data available |
| Initial boiling point and boiling range | : No data available |
| Flash point | : No data available |
| 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 |

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Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

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

Components:

Enrofloxacin:

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg
LD50 (Rat): > 5,000 mg/kg
LD50 (Mouse): > 5,000 mg/kg

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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Enrofloxacin:

Result : No skin irritation

Benzyl alcohol:

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

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Enrofloxacin:

Result : Mild eye irritation

Benzyl alcohol:

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

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Enrofloxacin:

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

Benzyl alcohol:

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

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

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-

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change
Species: Hamster
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Result: negative

Benzyl alcohol:

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

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

Carcinogenicity

Not classified based on available information.

Components:

Enrofloxacin:

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

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

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Enrofloxacin:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 15 mg/kg body weight

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Result: Effects on fertility, alteration in sperm morphology

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 210 mg/kg body weight
Result: Reduced foetal weight, No teratogenic effects
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No fetotoxicity, No teratogenic effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Benzyl alcohol:

Effects on fertility

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

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.

Repeated dose toxicity

Components:

Enrofloxacin:

Species : Rat
NOAEL : 36 mg/kg
LOAEL : 150 mg/kg
Application Route : Oral

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| | | |
|-------------------|---|--|
| Exposure time | : | 13 Weeks |
| Target Organs | : | Testis |
| Species | : | Dog |
| NOAEL | : | 3 mg/kg |
| LOAEL | : | 9.6 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 13 Weeks |
| Target Organs | : | cartilage |
| Species | : | Cat |
| NOAEL | : | 25 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 Days |
| Remarks | : | No significant adverse effects were reported |

Benzyl alcohol:

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat |
| NOAEL | : | 1.072 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 28 Days |
| Method | : | OECD Test Guideline 412 |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Enrofloxacin:

| | | |
|-----------|---|--|
| Ingestion | : | Symptoms: Gastrointestinal disturbance, central nervous system effects, Sensitivity to light |
|-----------|---|--|

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 |

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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 toxicity) : 10

Toxicity to daphnia and other aquatic invertebrates (Chronic 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
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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12.2 Persistence and degradability

Components:

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

Benzyl alcohol:

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

12.4 Mobility in soil

Components:

Enrofloxacin:

Distribution among environmental compartments : Koc: 5.55

12.5 Results of PBT and vPvB assessment

Product:

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

12.6 Other adverse effects

Product:

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

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

SECTION 14: Transport information

14.1 UN number

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.
(
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(
IATA : Environmentally hazardous substance, liquid, n.o.s.
(

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

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ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
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) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
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

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : 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.

SAFETY DATA SHEET

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



Enrofloxacin (2.5%) Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 4.1 | Revision Date: 14.04.2025 | SDS Number: 9372666-00009 | Date of last issue: 28.09.2024 Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

| | | | |
|---|---|---------------------|---------------------|
| UK REACH List of restrictions (Annex 17) | : Conditions of restriction for the following entries should be considered: Number on list 3 | | |
| | Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. | | |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | : Not applicable | | |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : Not applicable | | |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : Not applicable | | |
| UK REACH List of substances subject to authorisation (Annex XIV) | : Not applicable | | |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation | : Not applicable | | |
| Control of Major Accident Hazards Regulations 2015 (COMAH) | | | |
| E1 | ENVIRONMENTAL HAZARDS | Quantity 1 100 t | Quantity 2 200 t |

Other regulations:

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

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

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

| | |
|-------|------------------|
| AICS | : not determined |
| DSL | : not determined |
| IECSC | : not determined |

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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

| | |
|-------|---|
| H302 | : Harmful if swallowed. |
| H317 | : May cause an allergic skin reaction. |
| H319 | : Causes serious eye irritation. |
| 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 Irrit. | : Eye irritation |
| Repr. | : Reproductive toxicity |
| Skin Sens. | : Skin sensitisation |
| STOT RE | : Specific target organ toxicity - repeated exposure |

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; KECL - 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 sub-

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stance; 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:

| | |
|-------------------|------|
| Skin Sens. 1 | H317 |
| STOT RE 2 | H373 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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