Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Enrocare 2.5, 5.0 & 10% Solution for Injection

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Enrocare 2.5% Solution for Injection
Enrocare 5% Solution for Injection
Enrocare 10% Solution for Injection

Product code(s): XVD714 (Enrocare 2.5%)
XVD716 (Enrocare 5%)
XVD718(Enrocare 10%)

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

Relevant identified uses: Veterinary medicinal product

Uses advised against: Not for human use. Refer to the product information leaflet

Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited

Address: 10 Great Northway
York Business Park
Nether Poppleton
York
YO26 6RB
United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Precautionary statements: People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product. This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water

Supplemental information: Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC) None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Substance name in the mixture	*CAS No*	*Quantity*
Enrofloxacin	[93106-60-3]	2.5 – 10 %
Potassium hydroxide	[1310-58-3]	Proprietary
Butyl alcohol	[71-36-3]	Proprietary
Water	[7732-18-5]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes: Irritating to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Skin: In case of skin contact, wash affected areas with soap and water. Seek medical attention if irritation develops

Ingestion: If vomiting occurs keep head lower than hips to help prevent aspiration. Seek medical attention if required

Inhalation: If inhaled remove to fresh air. If not breathing give artificial respiration

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Unsuitable extinguishing media: None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Not flammable or combustible

Hazardous combustion products: Decomposition products may include the following materials: Carbon oxides (CO_x), nitrogen oxides (NO_x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters: Fight fire in the early stages if safe to do so. Wear respiratory protection. In well ventilated areas wear full face mask with a combination filter. (Offers no protection from carbon monoxide). In enclosed premises: respirator with independent air supply. Contain firefighting water

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Refer to protective measures listed in sections 7 and 8

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any information is section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water of drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Large spills: Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

Small spills: Prevent spillage from spreading or entering soil, waterways and drains. Take up with absorbent material such as sawdust, peat or chemical binder. Fill material along with any contaminated soil etc., into sealable containers. Clean affected area with aqueous detergent and a small amount of water. Absorb this detergent/water with absorbent material. Place cleaning materials into the same container. Do not eat, drink or smoke during clean-up operation

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: If using other than according to label, wear suitable gloves and eye/face protection

Hygiene measures: No specific measures identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging

Storage temperature: Store below 25 ^{o}C. Protect from temperatures below 0 and above 50 degrees.

Further information on storage conditions: Protect from direct incidence of light. Keep away from heat and moisture

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit.
Data not known.

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Irritating to eyes. Wear suitable eye/face protection

Skin/body protection: Irritating to skin. Wear suitable gloves

Hand protection:	Rubber, latex gloves
Respiratory protection:	None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization
Environmental exposure controls:	Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Colour:	Clear, yellow-tinged to light yellow
Odour:	Slight characteristic smell
Odour threshold:	No data available
pH:	10.5 – 12.0
Density:	No data available
Melting point:	No data available
Boiling point:	> 100 ˚C
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	Miscible
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	slight viscous solution
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Enrofloxacin LD_{50} >5000 mg/kg (Rat, oral) Enrofloxacin LD_{50} >5000 mg/kg (Mouse, oral) Enrofloxacin LD_{50} >3547 mg/m^3 (Rat, inhalation) Potassium hydroxide LD_{50} 333 mg/kg (Rat, oral) Butyl alcohol LD_{50} 700 mg/kg (Rat, oral)
Chronic toxicity:	Chronic exposure (3 months to 2 years) of laboratory species to enrofloxacin has produced testicular degeneration and associated adverse effects on spermatogenesis. None of the other ingredients of the formulation have been shown to produce reproductive or teratogenic effects
Skin irritation/sensitization:	Irritant to the eye. Irritant to the skin. Non-sensitising to the skin Enrofloxacin LD_{50} >2000 mg/kg (Rabbit, dermal) Butyl alcohol LD_{50} 3402 mg/kg (Rabbit, dermal)
Reproductive toxicity:	No data available
Carcinogenicity:	Enrofloxacin has been shown in animal tests to have no carcinogenic potential. Other ingredients are not classified as carcinogens
Mutagenicity:	None of the ingredients of the formulation have been shown to produce mutagenic effects

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Fish	Enrofloxacin LC0 150 mg/L Golden orfe (Leuciscus idus) Enrofloxacin LC0 (96h) >10 mg/L Rainbow trout (Salmo gairdneri) Enrofloxacin LC0 (96h) >10 mg/L Lepomis macrochirus
Daphnia	Enrofloxacin EC0 (24h) >100 mg/L Water flea (Daphnia magna)
Bacteria	Enrofloxacin EC0 0.0037 mg/L Pseudomonas putida
	Studies on the influence of enrofloxacin on glucose stimulated respiration in the soil, and on microbial mineralisation of nitrogen in the soil, have shown no adverse effects after 14 days.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only
We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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