

Material Safety Data Sheet

Marbocare 100 mg/ml Solution for Injection

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

1.1 Product identification

Product name(s): Marbocare 100 mg/ml Solution for Injection
 Product code(s): XVD505 (100 ml vial)

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: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust, fume, gas, mist, vapours or spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective equipment.

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

<i>Substance contained in the mixture</i>	<i>CAS No</i>	<i>% [weight]</i>
Marbofloxacin	115550-35-1	10.0%
Metacresol	108-39-4	0.2%
Monothioglycerol	96-27-5	0.1%
Disodium edetate	6381-92-6	0.01%
Gluconolactone	90-80-2	Proprietary
Water for injections	7732-18-5	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	In case of eye contact Rinse with water and maintain the eyelids open. In case of irritation consult with an ophthalmologist
Skin:	In case of skin contact Rinse with water
Ingestion:	Rinse mouth. Get medical attention if symptoms occur
Inhalation:	This route of exposure is unlikely. Get medical attention if symptoms occur

4.2 Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash (allergic skin rash); Difficulty in breathing. Quinolones may affect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhoea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur

4.3 Indication of any immediate medical attention and special treatment needed

May cause central nervous system effects. Monitor respiratory, cardiac and central nervous system. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. 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 fire-fighters:	Use standard firefighting procedures and consider the hazards of other involved materials. Use personal protective equipment
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:

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. Refer to protective measures listed in section 8

Advice for emergency responders:

If specialised clothing is required to deal with the spillage, take note of any information in 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 or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Large spills:

Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water

Small spills:

Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water

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:

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke.

Hygiene measures:

Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

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 °C

Further information on storage conditions:

Protect from direct incidence of light

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. At this time, the other constituents have no known exposure limits

<i>Substance contained in the mixture</i>	<i>Type</i>	<i>Value</i>
Marbofloxacin	TWA	0.2 mg/m ³

8.2 Exposure controls

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

Individual protection measures:

Hygiene measures: Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants

Eye/face protection: If contact is likely, safety glasses with side shields are recommended

Skin/body protection: Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas

Hand protection: Wear appropriate chemical resistant 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:	Yellow to orange
Odour:	None
Odour threshold:	No data available
pH:	3.3 – 4.3
Density:	~ 1.02
Melting point:	No data available
Boiling point:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	Soluble
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
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

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:	Marbofloxacin LD ₅₀ 1781 - 1822 mg/kg (Mouse, oral) Marbofloxacin LD ₅₀ 2720 - 3772 mg/kg (Rat, oral)
Chronic toxicity:	Marbofloxacin NOAEL 4 mg/kg/day (Rat, oral) – 13 weeks – Connective tissue Marbofloxacin NOAEL <11 mg/kg/day (Dog, oral) – 4 weeks – Connective tissue
Skin irritation/sensitization:	Marbofloxacin Eye irritation – Rabbit – Minimal Marbofloxacin Skin contact – Rabbit – Non-irritating
Reproductive toxicity:	Marbofloxacin NOAEL 700 mg/kg/day (Rat, oral) – Not teratogenic Marbofloxacin NOAEL 80 mg/kg/day (Rabbit, oral) – Not teratogenic Marbofloxacin NOAEL 10 mg/kg/day (Rat, oral) – Fetotoxicity
Carcinogenicity:	Not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA
Mutagenicity:	Marbofloxacin Positive bacterial mutagenicity (AMES) – Salmonella Marbofloxacin Negative <i>In vitro</i> chromosome aberration – Human lymphocytes Marbofloxacin Negative <i>In vivo</i> unscheduled DNA synthesis – Rat hepatocyte

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

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 as dangerous goods

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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