Complying to Regulation (EC) 1907/2006

Material Safety Data Sheet
Marbocare Flavour Tablets 5mg/20mg/80mg

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

1.1 Product identification

Product name(s): Marbocare Flavour Tablets 5mg/20mg/80mg.

Product code(s): XVD 508 (5mg 100 tablets)
XVD 509 (20mg 100 tablets)
XVD 510 (80mg 72 tablets)

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: Not applicable

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*	*% [weight]*
Marbofloxacin	[115550-35-1]	5, 20 or 80 mg/tablet
Lactose, monohydrate	[5989-81-1]	Proprietary
Crospovidone	[9003-39-8]	Proprietary
Silica, colloidal hydrated	[7631-86-9]	Proprietary
Desiccated pork liver powder	n.a.	Proprietary
Dried yeast from Saccharomyces	n.a.	Proprietary
Povidone	[9003-39-8]	Proprietary
Magnesium stearate	[557-04-0]	Proprietary
Castor oil. hydrogenated	[8001-79-4]	Proprietary
Water, purified	[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 is symptoms occur

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure: No data available
Medical Conditions Aggravated by Exposure: None known
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 (CO_2, extinguishing powder, foam, or water)

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), fluorine-containing compounds

5.3 Advice for fire-fighters

Special protective equipment for firefighters: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire. 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:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. 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:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should be undertaken by trained personnel. Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway
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:	Keep away from heat. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Keep away from heat, sparks and flames.
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:	15 – 30 ˚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

Substance contained in the mixture	*Type*	*Value*
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: No specific measures identified

Eye/face protection: No specific measures identified

Skin/body protection: No specific measures identified

Hand protection: No specific measures identified

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	Film coated tablets
Colour:	Beige
Odour:	No data available
Odour threshold:	No data available
pH:	No data available
Density:	No data available
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:	No data available
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

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 *In vitro* chromosome aberration – Human lymphocytes Marbofloxacin Negative *In vi*vo 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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