

SAFETY DATA SHEETS

This SDS packet was issued with item:

078940791

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078940792 078940794 078940796 078940797 078940798 078946142

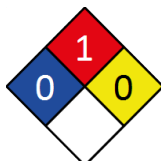


| SECTION 1: IDENTIFICATION | |
|---|---|
| 1.1 Product identifier | |
| Product name: | Marboquin™ (marbofloxacin) Tablets |
| Synonyms: | None |
| Proper Shipping name: | Not applicable |
| Other means of identification: | None |
| 1.2 Relevant identified uses of the substances or mixture and uses advised against | |
| Recommended uses: | Anti-bacterial |
| Uses advised against: | Not for human use. |
| 1.3 Details of the supplier of the substance or mixture | |
| Registered company name (US): | Dechra Veterinary Products, LLC |
| Address: | Dechra Veterinary Products, LLC 7015 College Blvd Suite 525 Overland Park KS 66211 USA |
| Telephone: | 866-933-2472 |
| Fax: | Not available |
| Website: | www.dechra-us.com |
| Email: | support@dechra.com |
| 1.4 Emergency Telephone Numbers | |
| Dechra (US): | 866-933-2472 |

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

NFPA 704 Diamond



2.2 Label Elements

Hazard Pictogram:



Signal Word: **WARNING**

Hazard statement(s):

H373 May cause damage to organs through prolonged or repeated exposure

Supplementary Statement(s):

Not applicable

Precautionary Statement(s) Prevention:

P270 Do not eat, drink or smoke when using this product

Precautionary Statement(s) Response:

P312 Call a poison center or doctor / physician if you feel unwell

Precautionary Statement(s) Storage:

P405 Store locked up

Precautionary Statement(s) Disposal:

P501 Dispose of contents/ container in accordance with local regulations

2.3 Other Hazard Information

Not applicable.

| SECTION 3: INFORMATION ON THE INGREDIENTS | | |
|---|---------------|--|
| 3.1 Substances | | |
| See section below for composition of mixtures | | |
| 3.2 Mixtures | | |
| 1.CAS No 2.EC Number 3.Index Number 4.REACH Number | % Weight | Name |
| 64044-51-5 | 50-100 | Lactose |
| 9004-34-6 | 10-30 | cellulose |
| 115550-35-1 | 10-30 | marbofloxacin |
| Other ingredients | Not indicated | Ingredients determined not to be hazardous |

| SECTION 4: FIRST AID MEASURES | |
|--|--|
| 4.1 Description of first aid measures | |
| Eye contact: | Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. |
| Skin contact: | Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. |
| Inhalation: | Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested. |
| Ingestion: | If swallowed, do not induce vomiting. Seek medical advice without delay and show the package leaflet or the label to the medical practitioner. Give water to rinse out mouth, then provide liquid slowly and as much as person can drink. |



| 4.2 Most important symptoms and effects, both acute and delayed | |
|---|---|
| Eye contact: | May cause eye irritation. |
| Skin contact: | May cause skin irritation. |
| Ingestion: | Fluoroquinolones may cause central nervous system disorders and connective tissue structures. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. Sensory/motor nerve injury (peripheral neuropathy) may occur. |
| See Section 11 for more detailed information | |
| 4.3 Indication of immediate medical attention and special treatment needed | |
| Treat symptomatically. Monitor respiratory, cardiac and central nervous system. | |

| SECTION 5: FIRE FIGHTING MEASURES | |
|---|---|
| 5.1 Extinguishing media | |
| Suitable: | Select extinguishing media suitable for surrounding area |
| Unsuitable: | There is no restriction on the type of extinguisher which may be used |
| 5.2 Special hazards arising from the substance or mixture | |
| Fire incompatibility: | None known |
| 5.3 Special protective actions for fire-fighters: | |
| Firefighting: | Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use. |
| Fire / explosion hazard: | Extremely high temperatures such as encountered in a fire may produce hazardous fumes. |

| SECTION 6: ACCIDENTAL RELEASE MEASURES | |
|---|--|
| 6.1 Personal precautions, protective equipment and emergency procedures | |
| For information on protective equipment, see section 8 | |
| 6.2 Environmental Precautions | |
| See section 12 | |



| | |
|--|--|
| 6.3 Methods and material for containment and cleaning up Spills are unlikely due to the nature of the product and how it is packaged | |
| Minor Spills: | Small spills should be cleaned up and placed in a closed container for disposal. |
| Major Spills: | Large spills should be diked and contained and then absorbed with no reactive materials and place in disposal drums. |

| | |
|---|--|
| SECTION 7: HANDLING AND STORAGE | |
| 7.1 Precautions for safe handling | |
| Safe Handling: | Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations. |
| Other Information: | Store at room temperature (66-77°F). Keep out of the reach and sight of children. |
| 7.2 Conditions for safe storage, including any incompatibilities | |
| Suitable Container: | Store in original containers. Keep containers securely sealed. |
| Storage incompatibility: | No known incompatibilities. |
| 7.3 Specific end uses | |
| Not available | |

| | | | | |
|--|---------------|--------|--------------|--------|
| SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION | | | | |
| 8.1 Control parameters | | | | |
| OCCUPATIONAL EXPOSURE LIMITS (OEL) | | | | |
| INGREDIENT DATA | | | | |
| Not Available | | | | |
| EMERGENCY LIMITS (US): | | | | |
| Ingredient | Material Name | TEEL-1 | TEEL-2 | TEEL-3 |
| Not available | | | | |
| Ingredient | Original IDLH | | Revised IDLH | |
| Not available | | | | |



| 8.2 Exposure controls | |
|--|--|
| Appropriate engineering controls: | The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk. |
| Personal protection: | Non required |
| Eye and face protection: | Non required |
| Skin protection: | Non required |
| Hands/ feet protection: | No special equipment needed when handling small quantities. |
| Body protection: | Wear appropriate clothing. |
| Other protection: | No special equipment needed when handling small quantities. |
| Thermal hazards: | Not applicable |
| Respiratory protection: | Not applicable |
| 8.3 Environmental exposure controls | |
| See Section 12 | |

| SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES | |
|---|--|
| 9.1 Information on basic physical and chemical properties | |
| <p>Appearance: Scored tablets Container: Bottles of 25mg, 50mg, 100mg or 200mg Physical state: Tablet Odor: Not available Melting point / freezing point (degrees C): Not applicable Initial boiling point and boiling range: Not applicable Flash Point: Not applicable Evaporation rate Not applicable Flammability: Not available Upper/lower flammability or explosive limits: Not available Vapor pressure: Not applicable Specific Gravity: Not available Solubility in water and solvents (mg/l): Not available Auto ignition temperature (degrees C): Not available Decomposition temperature (degrees C): Not available Viscosity: (degrees C): Not available Explosive properties: Not available Oxidizing properties: Not available Partition Coefficient: Not available Taste: Not applicable Surface tension: Not available Volatile component: Not available Gas group: Not applicable pH: Not available VOC g/L: Not applicable</p> | |
| 9.2 Other information | |
| Not Available | |

| SECTION 10: STABILITY AND REACTIVITY | |
|---|--|
| 10.1 Reactivity: | See Section 7. |
| 10.2 Chemical stability: | Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur. |
| 10.3 Possibility of hazardous reactions: | The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur. |
| 10.4 Conditions to avoid: | Protect from light. |
| 10.5 Incompatible materials: | See section 7. |
| 10.6 Hazardous decomposition: | See Section 5. |

| SECTION 11: TOXICOLOGICAL INFORMATION | | |
|---------------------------------------|---|-------------------|
| Inhalation: | Due to the nature of the product, it is not expected to cause any irritation of the respiratory tract. However if it was in powder/ dust form, respiratory irritation can occur. | |
| Ingestion: | Accidental ingestion of the material may be harmful. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. Large doses of cellulose may be administered orally as non-nutritive bulk, with doses of up to 30 g/day tolerated as bulk laxative while extremely large oral doses may produce disturbances to the gut. Fluoroquinolones have been associated with kidney damage, effects after exposure to UV light, seizures, changes in blood sugar levels (especially in diabetics), and crystal formation in the urine. They can also cause disease in the joints. Polysaccharides are not easily absorbed from the digestive tract, but may produce a laxative effect. Larger doses may produce intestinal or stomach blockage. | |
| Skin contact: | May cause skin irritation | |
| Eye contact: | May cause eye irritation | |
| Chronic: | Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Inhalation studies using animals have shown that cellulose fibres can cause lung scarring, and humans exposed to cellulose at work are more likely to develop asthma and obstructive lung disease. Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms | |
| Marboquin™ Tablets: | Toxicity | Irritation |
| | Not available | Not available |
| Lactose | Toxicity | Irritation |
| | Oral (rat) LD50: >10000 mg/kg[2] | Not available |
| Cellulose | Toxicity | Irritation |
| | Dermal (rabbit) LD50: >2000mg/kg[2] Oral (rat) LD50: >5000 mg/kg[2] | Not available |
| marbofloxacin | Toxicity | Irritation |
| | Oral (mouse) LD50: >2000 mg/kg[2] | Not available |

1.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances



| |
|---|
| Skin corrosion/irritation: |
| Not expected to cause skin irritation. |
| Serious eye damage/irritation: |
| Not expected to cause any eye irritation |
| Respiratory or skin sensitization: |
| Not expected to be a respiratory sensitizer due to the nature of the product. |
| Individuals with a history of hypersensitivity to fluoroquinolones should avoid this product. In humans, there is a risk of use photosensitization with a few hours after excessive exposure to quinolones. If excessive accidental exposure occurs, avoid direct sunlight. |
| Germ cell mutagenicity: |
| Not available |
| Carcinogenicity: |
| Not expected to be carcinogenic. |
| Reproductive toxicity: |
| Not expected to have reproductive toxicity effects. |
| STOT – single exposure: |
| Not available |
| STOT–repeated exposure: |
| Marbofloxacin should usually be avoided in young animals because of potential cartilage abnormalities. In rare occasion, it can cause central nervous system (CNS) stimulation and should be used with caution in patients with seizure disorders. Under certain conditions it can cause discomfort such as cramps, treatable with diazepam. Other adverse effects are usually limited to gastrointestinal tract (GI) distress (vomiting, anorexia, soft stools, diarrhea) and decreased activity. If in dust form, Asthma-like symptoms may continue for months or even years after exposure to cellulose. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. |
| Aspiration hazard: |
| Not available |

| SECTION 12: ECOLOGICAL INFORMATION | | | | | |
|------------------------------------|---------------|--------------------|---------------|---------------|---------------|
| 12.1 Toxicity | | | | | |
| Ingredient | Endpoint | Test duration (hr) | Species | Value | Source |
| Marboquin™ Tablets | Not available | Not available | Not available | Not available | Not available |



| | | | | | |
|---------------|------------------|------------------|--|------------------------------|---------------|
| Lactose | LC50 EC50 | 96 96 | Fish Algae or other aquatic plants | 9160000mg/l 340000000mg/l | 3 3 |
| Marbofloxacin | Not available | Not available | Not available | Not available | Not available |

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|-------------------------|------------------|
| cellulose | LOW | LOW |
| lactose | LOW | LOW |

12.3 Bioaccumulative potential

| Ingredient | Bioaccumulative Potential |
|------------|---------------------------|
| cellulose | LOW (LogKOW = -5.1249) |
| lactose | LOW (LogKOW = -5.1249) |

12.4 Mobility in Soil

| Ingredient | Mobility |
|------------|----------------|
| cellulose | LOW (KOC = 10) |
| lactose | LOW (KOC = 10) |

12.5 Results of PBT and vPvB assessment

Not Available

12.6 Other adverse effects

Not Available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

| | |
|--|---|
| Product / packaging disposal: | <p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill.</p> |
|--|---|



| | |
|---------------------------------|---|
| | <p>Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p> |
| Waste Treatment Options: | Not Available |
| Sewage Disposal Options: | Not Available |

SECTION 14: TRANSPORT INFORMATION

Labels required:

| | |
|---|----|
| Marine pollutant: | NO |
| Land transport (US: DOT / TDG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Transport in bulk according to Annex II of MARPOL and the IBC code: Not applicable | |

SECTION 15: REGULATORY INFORMATION

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

LACTOSE IS FOUND IN THE FOLLOWING REGULATORY LISTS:

USA: TSCA

CELLULOSE IS FOUND IN THE FOLLOWING REGULATORY LISTS:

USA: OEL/ TLV/ WEELs/ TSCA/ RELs/ PELs

FEDERAL REGULATIONS:

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 Hazard Categories

| | |
|---------------------------------|----|
| Immediate (acute) health hazard | NO |
|---------------------------------|----|



| | |
|--|----|
| Delayed (chronic) health hazard | NO |
| Fire hazard | NO |
| Pressure hazard | NO |
| Reactivity hazard | NO |
| US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4) None reported | |

| | |
|---|---|
| STATE REGULATIONS: | |
| US. CALIFORNIA PROPOSITION 65 None reported | |
| National Inventory | Status |
| Australia - AICS | No (marbofloxacin) |
| Canada - DSL | No (marbofloxacin) |
| Canada - NDSL | No (lactose, marbofloxacin) |
| China - IECSC | No (marbofloxacin) |
| Europe - EINEC / ELINCS / NLP | No (marbofloxacin) |
| Japan - ENCS | No (Cellulose) |
| Korea - KECI | No (marbofloxacin) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (marbofloxacin) |
| USA - TSCA | No (marbofloxacin) |
| Taiwan – TCSI | Yes |
| Mexico – INSQ | No (marbofloxacin) |
| Vietnam – NCI | Yes |
| Russia – ARIPS | No (marbofloxacin) |
| Legend: | <i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i> |



SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by OSHA HazCom Standard (2012) requirements.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average

PC—STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit

IDLH: Immediately Dangerous to Life or Health Concentrations

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