SAFETY DATA SHEET

1. Identification

Product identifier: Dicural® Tablets

Other means of identification: None.

Recommended use: For the management of diseases in dogs associated with bacteria susceptible to difloxacin.

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer: Boehringer Ingelheim Vetmedica, Inc.
Address: 2621 North Belt Hwy
St. Joseph, MO 64506-2002

Transportation emergency: For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency (24HR): (866)638-2226
Non-Emergency calls: (800) 821-7467

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Hazard symbol: None.

Signal word: None.

Hazard statement: The mixture does not meet the criteria for classification.

Precautionary statement

Prevention: Observe good industrial hygiene practices.

Response: Wash hands after handling.

Storage: Store away from incompatible materials.

Disposal: Dispose of waste and residues in accordance with local authority requirements.

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

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>25-30</td>
</tr>
<tr>
<td>Difloxacin hydrochloride</td>
<td>91296-86-5</td>
<td>5-20</td>
</tr>
<tr>
<td>Magnesium distearate</td>
<td>557-04-0</td>
<td>5</td>
</tr>
<tr>
<td>Synthetic amorphous silica</td>
<td>112945-52-5</td>
<td>1-2</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Dusts may irritate the respiratory tract, skin and eyes. Ingestion of a large quantity may cause nausea and systemic effects.

Indication of immediate medical attention and special treatment needed
Not for human use. For use in animals only. Treat symptomatically. Persons developing anaphylactic (life threatening) reactions, such a as difficulty in breathing or unconsciousness, must receive immediate medical attention.

General information
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides, nitrogen oxides, magnesium oxides, silicon oxides, hydrogen chloride, hydrogen fluoride.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use water spray to cool unopened containers.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS. Stop the flow of material, if this is without risk. Collect dust using a vacuum cleaner equipped with HEPA filter.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Avoid the generation of dusts during clean-up. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid prolonged exposure. Practice good housekeeping.

Conditions for safe storage, including any incompatibilities
Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Store at temperatures not exceeding 40°C/104°F.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m3</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m3</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. OSHA Table Z-3 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic amorphous silica (CAS 112945-52-5)</td>
<td>TWA</td>
<td>0.8 mg/m3</td>
</tr>
</tbody>
</table>

Dicural® Tablets
925511     Version #: 01     Revision date: -     Issue date: 27-April-2015
US. OSHA Table Z-3 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium distearate (CAS 557-04-0)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Microcrystalline cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA 10 mg/m³ Magnesium distearate (CAS 557-04-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TWA 10 mg/m³ Microcrystalline cellulose (CAS 9004-34-6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA 5 mg/m³ Respirable Microcrystalline cellulose (CAS 9004-34-6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TWA 10 mg/m³ Resrable Total Synthetic amorphous silica (CAS 112945-52-5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, such as personal protective equipment

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection: Wear appropriate chemical resistant gloves.

Other: Wear suitable protective clothing.

Respiratory protection: If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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.

9. Physical and chemical properties

Appearance

Physical state: Solid.

Form: Tablet.

Color: Blue, White or Orange

Odor: Odorless.

pH: Not available.

Odor threshold: Not available.

Initial boiling point and boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid, gas): Will burn if involved in a fire.
Upper/lower flammability or explosive limits

- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.
- Explosive limit - lower (%): Not available.
- Explosive limit - upper (%): Not available.

Vapor pressure: Not available.
Vapor density: Not available.
Relative density: Not available.
Solubility(ies)
  - Solubility (water): Soluble
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.

10. Stability and reactivity

- Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.
- Chemical stability: Material is stable under normal conditions.
- Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
- Conditions to avoid: Contact with incompatible materials. High temperatures.
- Incompatible materials: Strong oxidizing agents.
- Hazardous decomposition products: No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

- Inhalation: Dust may irritate respiratory system. Prolonged inhalation may be harmful.
- Skin contact: Dust or powder may irritate the skin.
- Eye contact: Dust may irritate the eyes.
- Ingestion: Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics

Dusts may irritate the respiratory tract, skin and eyes. Ingestion of a large quantity may cause nausea and systemic effects.

Information on toxicological effects

Acute toxicity: Not expected to be acutely toxic.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difloxacin hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Rabbit Dermal Acute</td>
<td></td>
<td>&lt; 2000 mg/kg</td>
</tr>
<tr>
<td>Oral Rat Acute</td>
<td></td>
<td>1380 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation: Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

- Respiratory sensitization: Not a respiratory sensitizer.
- Skin sensitization: This product is not expected to cause skin sensitization.
Germ cell mutagenicity
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity
Synthetic amorphous silica (CAS 112945-52-5) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

Reproductive toxicity
This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -
single exposure
Not classified.

Specific target organ toxicity -
repeated exposure
Not classified.

Aspiration hazard
Not an aspiration hazard.

Chronic effects
Prolonged inhalation may be harmful. May cause photosensitization, evidenced by repeated occurrence of a dermatitic rash on exposure to sunlight.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

15. Regulatory information

US federal regulations
One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.
CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Microcrystalline cellulose (CAS 9004-34-6)
Synthetic amorphous silica (CAS 112945-52-5)

US. New Jersey Worker and Community Right-to-Know Act

Microcrystalline cellulose (CAS 9004-34-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Microcrystalline cellulose (CAS 9004-34-6)
Synthetic amorphous silica (CAS 112945-52-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 27-April-2015
Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

**HMIS® ratings**
- Health: 1
- Flammability: 1
- Physical hazard: 0

**NFPA ratings**
- Health: 1
- Flammability: 1
- Reactivity: 0

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