SECTION 1. IDENTIFICATION

Product name: Orbifloxacin Solid Formulation

Manufacturer or supplier’s details
- Company name of supplier: Merck & Co., Inc
- Address: 126 E. Lincoln Avenue, Rahway, New Jersey U.S.A. 07065
- Telephone: 908-740-4000
- Emergency telephone: 1-908-423-6000
- E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
- Recommended use: Veterinary product
- Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
- Combustible dust
- Reproductive toxicity: Category 2

GHS label elements
- Hazard pictograms: [Image]

Signal Word: Warning

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. H361d Suspected of damaging the unborn child.

Precautionary Statements:
- Prevention:
  - P201 Obtain special instructions before use.
  - P202 Do not handle until all safety precautions have been read and understood.
  - P280 Wear protective gloves, protective clothing, eye protection and face protection.
- Response:
  - P308 + P313 IF exposed or concerned: Get medical attention.
- Storage:
  - P405 Store locked up.
- Disposal:
Orbifloxacin Solid Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Suspected of damaging the unborn child.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

**inert or nuisance dust**
- 50 Million particles per cubic foot
  - Value type (Form of exposure): TWA (total dust)
  - Basis: OSHA Z-3
  - 15 mg/m³
  - Value type (Form of exposure): TWA (total dust)
  - Basis: OSHA Z-3
  - 5 mg/m³
  - Value type (Form of exposure): TWA (respirable fraction)
  - Basis: OSHA Z-3
  - 15 Million particles per cubic foot
  - Value type (Form of exposure): TWA (respirable fraction)
  - Basis: OSHA Z-3

**Dust, nuisance dust and particulates**
- 10 mg/m³
  - Value type (Form of exposure): PEL (Total dust)
  - Basis: CAL PEL
  - 5 mg/m³
  - Value type (Form of exposure): PEL (respirable dust fraction)
  - Basis: CAL PEL

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Orbifloxacin Solid Formulation

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory protection</td>
<td>General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.</td>
</tr>
<tr>
<td>Hand protection</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Work uniform or laboratory coat.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.</td>
</tr>
</tbody>
</table>

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | powder |
| Color | No data available |
| Odor | No data available |
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- May form explosive dust-air mixture during processing, handling or other means.
- Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

Incompatible materials:
- Oxidizing agents

Hazardous decomposition products:
- No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
- Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:

Orbifloxacin:
- Acute oral toxicity: LD50 (Rat): > 3,000 mg/kg
  Remarks: No mortality observed at this dose.
  LD50 (Mouse): > 2,000 mg/kg
  Remarks: No mortality observed at this dose.
  LD50 (Dog): > 600 mg/kg
  Symptoms: Vomiting
  Remarks: No mortality observed at this dose.

Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available
Acute toxicity (other routes of administration): LD50 (Rat): > 200 mg/kg
  Application Route: Intramuscular
  LD50 (Mouse): 500 mg/kg
  Application Route: Intramuscular
  LD50 (Rat): 233 mg/kg
**SAFETY DATA SHEET**

according to the OSHA Hazard Communication Standard

**Orbifloxacin Solid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>09/30/2023</td>
<td>801090-00018</td>
<td>04/04/2023</td>
<td>07/15/2016</td>
</tr>
</tbody>
</table>

Application Route: Intravenous

LD50 (Mouse): 250 mg/kg

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Application Route</th>
<th>LD50 (Mouse)</th>
<th>Method</th>
<th>Assessment</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>250 mg/kg</td>
<td>OECD Test Guideline 423</td>
<td>The substance or mixture has no acute oral toxicity</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral toxicity

Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Orbifloxacin:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draize Test</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draize Test</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Orbifloxacin:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draize Test</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Draize Test</td>
<td>No eye irritation</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

Orbifloxacin:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

Orbifloxacin:
Genotoxicity in vitro:
  Test Type: Bacterial reverse mutation assay (AMES)
  Result: equivocal
  Test Type: Mouse Lymphoma
  Result: positive
  Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: positive

Genotoxicity in vivo:
  Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Intraperitoneal injection
  Result: negative
  Test Type: unscheduled DNA synthesis assay
  Species: Rat
  Cell type: Liver cells
  Application Route: Oral
  Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Magnesium stearate:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Carcinogenicity
Not classified based on available information.

Components:

Orbifloxacin:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 200 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
NOAEL: 200 mg/kg body weight
Result: negative

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Orbifloxacin:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity Parent: NOAEL: 50 mg/kg body weight
Early Embryonic Development: NOAEL: 50 mg/kg body weight
Result: No adverse effects.
Effects on fetal development:

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 333 mg/kg body weight
Result: No teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain.

Test Type: Development
Species: Dog
Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Result: Effects on postnatal development., Skeletal malformations.

Reproductive toxicity - Assessment:
Some evidence of adverse effects on development, based on animal experiments.

Magnesium stearate:

Effects on fertility:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Orbifloxacin:**
- **Species:** Rat
- **NOAEL:** 20 mg/kg
- **LOAEL:** 80 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Testis, Liver, Kidney, spleen

- **Species:** Mouse
  - **NOAEL:** 80 mg/kg
  - **LOAEL:** 250 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 3 Months

- **Species:** Juvenile dog
  - **NOAEL:** 50 mg/kg
  - **LOAEL:** 250 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 14 Days
  - **Target Organs:** Heart, Bone
  - **Symptoms:** Gastrointestinal disturbance
  - **Remarks:** mortality observed

- **Species:** Juvenile dog
  - **NOAEL:** 2 mg/kg
  - **LOAEL:** 3 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 90 Days
  - **Target Organs:** Bone
  - **Remarks:** No significant adverse effects were reported

- **Species:** Dog
  - **NOAEL:** 37.5 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 30 Days

- **Species:** Cat
  - **NOAEL:** 7.5 mg/kg
  - **LOAEL:** 22.5 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 1 Months
  - **Symptoms:** Gastrointestinal disturbance

**Magnesium stearate:**
- **Species:** Rat
  - **NOAEL:** > 100 mg/kg
  - **Application Route:** Ingestion
  - **Exposure time:** 90 Days
  - **Remarks:** Based on data from similar materials
Orbifloxacin Solid Formulation

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Orbifloxacin:
Ingestion: Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash
Remarks: May cause photosensitization.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Magnesium stearate:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants:
EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms:
EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

13 / 17
Persistence and degradability

**Components:**

**Magnesium stearate:**
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:**

**Magnesium stearate:**
Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**Domestic regulation**

**49 CFR**
Not regulated as a dangerous good

**Special precautions for user**
Not applicable
SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards  :  Combustible dust
Reproductive toxicity

SARA 313  :  This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- D-Glucose, 4-O-β-D-galactopyranosyl-, monohydrate  64044-51-5
- Orbifloxacin  113617-63-3
- Polyvinyl pyrrolidone  9003-39-8
- Starch, carboxymethyl ether, sodium salt  9063-38-1

California List of Hazardous Substances
- Polyvinyl pyrrolidone  9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
- Magnesium stearate  557-04-0

The ingredients of this product are reported in the following inventories:
- AICS  :  not determined
- DSL  :  not determined
- IECSC  :  not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Orbifloxacin Solid Formulation

Version: 6.1  Revision Date: 09/30/2023  SDS Number: 801090-00018  Date of last issue: 04/04/2023
Date of first issue: 07/15/2016

NFPA 704:

Flammability  Instability  Health  Special hazard

0 1 0 0

HMIS® IV:

HEALTH  FLAMMABILITY  PHYSICAL HAZARD

* 0 3 0

Full text of other abbreviations:

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3 : USA, Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
CAL PEL / PEL : Permissible exposure limit
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-
stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative


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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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