SAFETY DATA SHEET
Orbifloxacin Liquid Formulation

SECTION 1. IDENTIFICATION

Product name: Orbifloxacin Liquid 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)
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Eye)

GHS label elements
Hazard pictograms: 

Signal Word: Warning
Hazard Statements: H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
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:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 1 - &lt; 2</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 : Flush eyes with water as a precaution. 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. May cause damage to organs through prolonged or repeated exposure if swallowed.

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

Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
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.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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:
Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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:
See Engineering measures under EXPOSURE CONTROLS/PERSO...
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

<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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<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>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³ / %SiO2 (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>

**Engineering measures:**
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

**Personal protective equipment**

**Respiratory protection:** 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.

Hand protection
Material : Chemical-resistant gloves

Eye protection : 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.

Skin and body protection
Hygiene measures : Work uniform or laboratory coat.

Hygiene measures : 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : light brown

Odor : odorless

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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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
## SAFETY DATA SHEET

### Orbifloxacin Liquid 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>4.9</td>
<td>04/04/2023</td>
<td>785439-00017</td>
<td>10/01/2022</td>
<td>06/28/2016</td>
</tr>
</tbody>
</table>

### Components:

**Propylene glycol:**
- **Acute oral toxicity**: LD50 (Rat): 22,000 mg/kg
- **Acute inhalation toxicity**: LC50 (Rat): > 44.9 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity

**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
  - Application Route: Intravenous
  - LD50 (Mouse): 250 mg/kg
  - Application Route: Intravenous

**Silicon dioxide:**
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
- **Acute inhalation toxicity**: LC50 (Rat): > 2.08 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhal-
Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Lactic acid:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials
Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity.
Remarks: Based on data from similar materials

Sodium hydroxide:
Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation
Not classified based on available information.

Product:
Species: Rabbit
Result: No skin irritation

Components:
Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Orbifloxacin:
Species: Rabbit
Method: Draize Test
Result: No skin irritation

Silicon dioxide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Lactic acid:
Species: Rabbit
Method: OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
Remarks : Based on data from similar materials

**Sodium hydroxide:**
Result : Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**
Not classified based on available information.

**Product:**
Species : Rabbit
Result : Mild eye irritation

**Components:**
**Propylene glycol:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**Orbifloxacin:**
Species : Rabbit
Result : Mild eye irritation
Method : Draize Test

**Silicon dioxide:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**Lactic acid:**
Species : Chicken eye
Remarks : Based on data from similar materials
Result : Irreversible effects on the eye

**Sodium hydroxide:**
Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

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

**Product:**
Test Type : Magnusson-Kligman-Test
Routes of exposure : Dermal  
Species : Guinea pig  
Result : Not a skin sensitizer.

Components:

Propylene glycol:
Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

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

Lactic acid:
Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

Sodium hydroxide:
Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

Orbifloxacin:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
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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.

Silicon dioxide:
Genotoxicity in vitro:

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo:

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Lactic acid:
Genotoxicity in vitro:

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity:
Not classified based on available information.
## Components:

### Propylene glycol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Orbifloxacin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>200 mg/kg body weight</td>
<td>negative</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>200 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Silicon dioxide:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>103 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Lactic acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Remarks:

Based on data from similar materials

#### 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:

#### Propylene glycol:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Application Route: Ingestion</td>
</tr>
</tbody>
</table>
-effects on fetal development:

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

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

Silicon dioxide:

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

Lactic acid:

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Mouse
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Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Product:
Target Organs: Eye
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Product:
Species: Dog
NOAEL: 22.5 mg/kg
LOAEL: 37.5 mg/kg
Application Route: Oral
Exposure time: 30 Days
Symptoms: Gastrointestinal disturbance

Species: Dog
NOAEL: 75 mg/kg
Application Route: Oral
Exposure time: 10 Days
Symptoms: Salivation, Gastrointestinal disturbance, Vomiting

Species: Cat
NOAEL: 45 mg/kg
Application Route: Oral
Exposure time: 30 Days
Target Organs: Eye
Symptoms: Salivation, Lachrymation, Gastrointestinal disturbance, Liver disorders

Components:

Propylene glycol:
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y

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

Silicon dioxide:
Species: Rat
NOAEL: 1.3 mg/m³
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks

Lactic acid:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Species: Rat
LOAEL: 886 mg/kg
Application Route: Skin contact
Exposure time: 13 Weeks
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:

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d
Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Silicon dioxide:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
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Lactic acid:
Toxicity to fish:
- LC50 (Danio rerio (zebra fish)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

  NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

Toxicity to microorganisms:
- EC50: > 10 - 100 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - Remarks: Based on data from similar materials

Persistence and degradability

Components:

Propylene glycol:
Biodegradability:
- Result: Readily biodegradable.
  - Biodegradation: 98.3 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F

Lactic acid:
Biodegradability:
- Result: Not readily biodegradable.
  - Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-octanol/water:
- log Pow: -1.07

Lactic acid:
Partition coefficient: n-octanol/water

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>1000</td>
<td>100000</td>
</tr>
</tbody>
</table>

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
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
</tr>
<tr>
<td>Malt Extract</td>
<td>8002-48-0</td>
</tr>
<tr>
<td>2-Propenoic acid, 2-methyl-, polymer with methyl 2-methyl-2-propenoate</td>
<td>25086-15-1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
</tr>
</tbody>
</table>

California List of Hazardous Substances

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Sodium hydroxide</td>
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</tbody>
</table>

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
</tr>
</tbody>
</table>

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

Orbifloxacin Liquid Formulation

Version 4.9  Revision Date: 04/04/2023  SDS Number: 785439-00017  Date of last issue: 10/01/2022  Date of first issue: 06/28/2016

NFPA 704:

- Health: 0
- Flammability: 1
- Instability: 0
- Special hazard: 0

HMIS® IV:

- HEALTH: 2
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- OSHA Z-3: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
- US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
- ACGIH / C: Ceiling limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- NIOSH REL / C: Ceiling value not be exceeded at any time.
- OSHA Z-1 / TWA: 8-hour time weighted average
- OSHA Z-3 / TWA: 8-hour time weighted average
- US WEEL / TWA: 8-hr TWA

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; BC - 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; IISHL - 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 Oth-

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# SAFETY DATA SHEET

## Orbifloxacin Liquid 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>
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<td>04/04/2023</td>
<td>785439-00017</td>
<td>10/01/2022</td>
<td>06/28/2016</td>
</tr>
</tbody>
</table>


Revision Date: 04/04/2023

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.

US / Z8