SECTION 1. IDENTIFICATION

Product name: Orbifloxacin Liquid Formulation
Other means of identification: No data available

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 Hazardous Products Regulations
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>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td></td>
<td>Orbifloxacin</td>
<td>No data available</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide</td>
<td>Silica</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td></td>
<td>Lactic acid</td>
<td>Propanoic acid, 2-hydroxy-</td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
<td>Caustic soda</td>
<td>1310-73-2</td>
<td>&gt;= 1 - &lt; 2 *</td>
</tr>
</tbody>
</table>

| * Actual concentration or concentration range 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

Unsuitable extinguishing media: None known.

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
**SAFETY DATA SHEET**
according to the Hazardous Products Regulations

**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>5.0</td>
<td>09/30/2023</td>
<td>785424-00018</td>
<td>04/04/2023</td>
<td>06/28/2016</td>
</tr>
</tbody>
</table>

**Local/Total ventilation**: Use only with adequate ventilation.

**Advice on safe handling**: Do not breathe mist or vapors.
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.
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 (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWAEV (respirable dust)</td>
<td>6 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>(c)</td>
<td>2 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td>ACGIH</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**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Combined particulates and organic vapor type

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: 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
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Orbifloxacin Liquid Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
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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 : Can react with strong oxidizing agents.
Conditions to avoid : None known.
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: > 2,000 mg/kg
### Method: Calculation method

**Acute inhalation toxicity**: Acute toxicity estimate: > 5 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist

**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
Orbifloxacin Liquid Formulation

<table>
<thead>
<tr>
<th>components</th>
<th>species</th>
<th>method</th>
<th>result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>Rabbit</td>
<td>Draize Test</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>
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 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
Orbifloxacin Liquid Formulation

Application Route: Intraperitoneal injection
Result: negative

**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.

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

| Result | negative |

**Orbifloxacin:**

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

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>200 mg/kg body weight</th>
</tr>
</thead>
</table>

| Result | negative |

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>200 mg/kg body weight</th>
</tr>
</thead>
</table>

| Result | negative |

**Silicon dioxide:**

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

| Result | negative |

**Lactic acid:**

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

| Result | negative |

| Remarks | Based on data from similar materials |

**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></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>
**Orbifloxacin Liquid Formulation**

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

**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

**Silicon dioxide:**

**Effects on fetal development**
- **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.

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

**Lactic acid:**

**Effects on fetal development**
- **Test Type:** Embryo-fetal development
- **Species:** Mouse
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Orbifloxacin Liquid Formulation

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

Species : Cat
LOAEL : 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 Month
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
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Orbifloxacin Liquid Formulation

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
SAFETY DATA SHEET according to the Hazardous Products Regulations

Orbifloxacin Liquid Formulation

Version 5.0  Revision Date: 09/30/2023  SDS Number: 785424-00018  Date of last issue: 04/04/2023  Date of first issue: 06/28/2016

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

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
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Orbifloxacin Liquid Formulation

Version 5.0  Revision Date: 09/30/2023  SDS Number: 785424-00018  Date of last issue: 04/04/2023
Date of first issue: 06/28/2016

Bioaccumulative potential

Components:

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

Lactic acid:
Partition coefficient: n-octanol/water: log Pow: -0.62

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
Orbifloxacin Liquid Formulation

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / C : Ceiling limit
CA AB OEL / (c) : ceiling occupational exposure limit
CA BC OEL / C : ceiling limit
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value
CA QC OEL / C : Ceiling

AICL - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transporta-
# Orbifloxacin Liquid Formulation

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**Sources of key data used to compile the Material Safety Data Sheet:**

**Revision Date:** 09/30/2023  
**Date format:** mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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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