SAFETY DATA SHEET

Orbifloxacin Liquid Formulation

Version: 5.1  Revision Date: 2021/08/27  SDS Number: 785433-00013  Date of last issue: 2020/10/01  Date of first issue: 2016/06/28

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Orbifloxacin Liquid Formulation

Supplier’s company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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 vapours. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Orbifloxacin</td>
</tr>
<tr>
<td></td>
<td>Lactic acid</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
</tr>
</tbody>
</table>

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.

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting:
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 firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Do not breathe mist or vapours.
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.

Avoidance of contact: Oxidizing agents
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.

Storage
Conditions for safe storage: Keep in properly labelled 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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>OEL-C</td>
<td>2 mg/m³</td>
<td>JP OEL JSOH</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 expo-
Filter type: Combined particulates and organic vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: suspension
Colour: light brown
Odour: odourless
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: No data available
Decomposition temperature: No data available
pH: No data available
Evaporation rate: No data available
Auto-ignition temperature: No data available
Viscosity
Viscosity, kinematic: No data available
Solubility(ies)
Water solubility: No data available
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity
Not classified based on available information.

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

**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
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

Lactic acid:
Species: Rabbit
Result: Skin irritation
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

Lactic acid:
Species: Chicken eye
Remarks: Based on data from similar materials
Result: Irreversible effects on the eye
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Sodium hydroxide:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Product:
Test Type: Magnusson-Kligman-Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Orbifloxacin:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

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

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: 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
Genotoxicity in vitro: 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)  
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.

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:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

**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

**Lactic acid:**
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 2 Years
- **Result:** negative

**Remarks:** Based on data from similar materials

**Reproductive toxicity**
Suspected of damaging the unborn child.

**Components:**

**Propylene glycol:**
- **Effects on fertility:** Test Type: Two-generation reproduction toxicity study
  - **Species:** Mouse
  - **Application Route:** Ingestion
  - **Result:** negative

- **Effects on foetal development:** Test Type: Embryo-foetal 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
Effects on foetal development:

- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Oral
- Embryo-foetal 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-foetal development
- Species: Rabbit
- Application Route: Oral
- General Toxicity Maternal: NOAEL: 20 mg/kg body weight
- Embryo-foetal 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:

- Test Type: Embryo-foetal development
- Species: Mouse
- 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

- **Species**: Dog
- **Application Route**: Oral
- **Exposure time**: 30 Days
- **Symptoms**: Gastrointestinal disturbance

### LOAEL

- **Species**: Cat
- **Application Route**: Oral
- **Exposure time**: 10 Days
- **Symptoms**: Salivation, Gastrointestinal disturbance, Vomiting

### LOAEL

- **Species**: Dog
- **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 yr

#### 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

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 photosensitisation.

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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>ErC50 (Skeletonema costatum (marine diatom))</td>
<td>19,300 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>NOEC (Ceriodaphnia dubia (water flea))</td>
<td>13,020 mg/l</td>
<td>7 d</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>NOEC (Pseudomonas putida)</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Lactic acid:**

Toxicity to fish:

<table>
<thead>
<tr>
<th>Substance</th>
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<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>LC50 (Danio rerio (zebra fish))</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
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<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Substance</th>
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<th>Value</th>
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<th>Method</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to microorganisms:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint</th>
<th>Value</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>EC50:</td>
<td>&gt; 10 - 100 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Persistence and degradability**

**Components:**

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Biodegradability</th>
<th>Result</th>
<th>Biodegradation</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Biodegradability</td>
<td>Readily biodegradable</td>
<td>98.3 %</td>
<td>28 d</td>
<td>OECD Test Guideline 301F</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Lactic acid:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Biodegradability</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactic acid</td>
<td>Biodegradability</td>
<td>Not readily biodegradable</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

IATA-DGR
- UN/ID No.: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- Packing instruction (cargo aircraft): Not applicable
- Packing instruction (passenger aircraft): Not applicable

IMDG-Code
- UN number: Not applicable
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>319</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>319</td>
</tr>
</tbody>
</table>
Orbifloxacin Liquid Formulation

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
**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>5.1</td>
<td>2021/08/27</td>
<td>785433-00013</td>
<td>2020/10/01</td>
<td>2016/06/28</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**


Date format: yyyy/mm/dd

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>ACGIH / C</td>
<td>Ceiling limit</td>
</tr>
<tr>
<td>JP OEL JSOH / OEL-C</td>
<td>Occupational Exposure Limit-Ceiling</td>
</tr>
</tbody>
</table>

All - 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 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; 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 - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN