1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Orbifloxacin Liquid Formulation

Manufacturer or supplier's details
Company: MSD
Address: 50 Tuas West Drive
          Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
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>Orbifloxacin</td>
</tr>
<tr>
<td>Chemical name</td>
<td>113617-63-3</td>
</tr>
<tr>
<td>CAS-No.</td>
<td></td>
</tr>
<tr>
<td>Concentration (%) w/w</td>
<td>&gt;= 3 -&lt; 10</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

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

Exposure to combustion products may be a hazard to health.

Carbon oxides
Metal oxides

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.

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

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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.
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 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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>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>PEL (short term)</td>
<td>2 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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 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.
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: suspension
- Colour: light brown
- Odour: odourless
- Odour 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
- Vapour pressure: No data available
- Relative vapour 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
- Auto-ignition 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

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:
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:**

**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:

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

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:

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:
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:
Orbifloxacin:
Species: Rat
### 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>3.1</td>
<td>27.08.2021</td>
<td>785438-00012</td>
<td>01.10.2020</td>
<td>28.06.2016</td>
</tr>
</tbody>
</table>

#### 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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>2 Years</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

---

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**Orbifloxacin:**

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

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

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

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

Lactic acid:
Effects on foetal development: 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: 37.5 mg/kg
Application Route: Oral
Exposure time: 30 Days
Symptoms: Gastrointestinal disturbance

Species: Dog
NOAEL: 75 mg/kg
LOAEL: 10 Days
Symptoms: Salivation, Gastrointestinal disturbance, Vomiting

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

Components:

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

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

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

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

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

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

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:**

**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:**

**Lactic acid:**

Biodegradability: Result: Not readily biodegradable.
Remarks: Based on data from similar materials
Bioaccumulative potential

Components:

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

Mobility in soil
No data available

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
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
EmS Code: Not applicable
Marine pollutant: Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

The components of this product are reported in the following inventories:

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

16. OTHER INFORMATION

Further information

Date format: dd.mm-yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / C: Ceiling limit
SG OEL / PEL (short term): Permissible Exposure Level (PEL) Short Term

AIIC - 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.

SG / EN