SAFETY DATA SHEET

Orbifloxacin Liquid Formulation

Version 4.0  Revision Date: 2020/03/23  SDS Number: 785433-00011  Date of last issue: 2019/09/13  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

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td></td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 1 - &lt; 2</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

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
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: Avoid inhalation of vapour or mist.
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 decontamination 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 / 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., drip-less 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.

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
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle characteristics
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:
Propylene glycol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute toxicity (other routes of administration)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orbifloxacin</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 3,000 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 2,000 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt; 600 mg/kg</td>
<td>Symptoms: Vomiting</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 200 mg/kg</td>
<td>Application Route: Intramuscular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide:</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>Method: OECD Test Guideline 401</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactic acid:</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Rat): &gt; 5 mg/l</td>
<td>Exposure time: 4 h</td>
<td>Test atmosphere: dust/mist</td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rabbit): &gt; 5,000 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
- **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

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

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

**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 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.

**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

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

Genotoxicity in vitro: 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

Silicon dioxide:
Species: Rat
Application Route: Ingestion
Exposure time: 103 weeks
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: Three-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 weight
Result: No adverse effects

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, Embryo-toxic 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

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.

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 |
| **Species** | Cat |
| **LOAEL** | 45 mg/kg |
| **Application Route** | Oral |
| **Exposure time** | 30 Days |
| **Target Organs** | Eye |
| **Symptoms** | Salivation, Gastrointestinal disturbance, Vomiting |

### 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 |

#### Remarks:
- mortality observed
- No significant adverse effects were reported

| Species | Dog |
| NOAEL | 37.5 mg/kg |
| Application Route | Oral |
| Exposure time | 30 Days |
### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Toxicty to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic</th>
<th>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l</th>
</tr>
</thead>
</table>
### Plants
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

### 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

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
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.

National Regulations
Refer to section 15 for specific national regulation.

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>Crystalline silica</td>
<td>165 2</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<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>Crystalline silica</td>
<td>165 2</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>319</td>
</tr>
</tbody>
</table>
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

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:

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

Date format: yyyy/mm/dd

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / C: Ceiling limit
- JP OEL JSOH / OEL-C: Occupational Exposure Limit - Ceiling

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