

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
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 : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

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

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Reproductive toxicity : Category 2

Specific target organ toxicity - : Category 2 (Eye)  
repeated exposure (Oral)

#### 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.

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

---

Version 10.1	Revision Date: 2025/04/14	SDS Number: 785433-00021	Date of last issue: 2024/09/28 Date of first issue: 2016/06/28
-----------------	------------------------------	-----------------------------	---

---

### **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

### **Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	>= 10 - < 20	2-234
Orbifloxacin	113617-63-3	>= 3 - < 10	-
Lactic acid	50-21-5	>= 1 - < 10	2-1369
Sodium hydroxide	1310-73-2	>= 1 - < 10	1-410

---

## 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 : Suspected of damaging the unborn child.  
May cause damage to organs through prolonged or repeated

**Orbifloxacin Liquid Formulation**

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

delayed Protection of first-aiders	exposure if swallowed. 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 (CO <sub>2</sub> ) 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 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 absor-

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

bent.

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

Components	CAS-No.	Value type (Form of	Control parameters / Concentra-	Basis
------------	---------	------------------------	---------------------------------	-------

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1	Revision Date: 2025/04/14	SDS Number: 785433-00021	Date of last issue: 2024/09/28 Date of first issue: 2016/06/28
-----------------	------------------------------	-----------------------------	---

		exposure)	tion standard / Permissible con- centration	
Orbifloxacin	113617-63-3	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Sodium hydroxide	1310-73-2	OEL-C	2 mg/m <sup>3</sup>	JP OEL JSOH
		C	2 mg/m <sup>3</sup>	ACGIH

**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 : Chemical-resistant gloves

Material : Chemical-resistant gloves

Remarks : Impermeable protective 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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Up- : No data available  
per flammability limit

Lower explosion limit / : No data available  
Lower flammability limit

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.

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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

**Orbifloxacin Liquid Formulation**Version  
10.1Revision Date:  
2025/04/14SDS Number:  
785433-00021Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

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  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

**Sodium hydroxide:**

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

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Species : Rabbit  
Result : No skin irritation

**Components:****Propylene glycol:**

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

**Orbifloxacin:**

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

**Lactic acid:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Corrosive after 1 to 4 hours of exposure

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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

#### **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.

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

### 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

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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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 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

**Orbifloxacin Liquid Formulation**

Version 10.1	Revision Date: 2025/04/14	SDS Number: 785433-00021	Date of last issue: 2024/09/28 Date of first issue: 2016/06/28
-----------------	------------------------------	-----------------------------	---

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

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  
LOAEL : 75 mg/kg  
Application Route : Oral  
Exposure time : 10 Days

**Orbifloxacin Liquid Formulation**

Version 10.1 Revision Date: 2025/04/14 SDS Number: 785433-00021 Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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 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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1 Revision Date: 2025/04/14 SDS Number: 785433-00021 Date of last issue: 2024/09/28 Date of first issue: 2016/06/28

---

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:**

#### **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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1      Revision Date: 2025/04/14      SDS Number: 785433-00021      Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

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

### **Lactic acid:**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

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

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

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

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

### **Persistence and degradability**

#### **Components:**

##### **Propylene glycol:**

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

##### **Lactic acid:**

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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

### Bioaccumulative potential

#### Components:

##### **Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

##### **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.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## 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  
Environmentally hazardous : no

##### **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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1 Revision Date: 2025/04/14 SDS Number: 785433-00021 Date of last issue: 2024/09/28 Date of first issue: 2016/06/28

---

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.

### National Regulations

Refer to section 15 for specific national regulation.

### Special precautions for user

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

Chemical name	Number
Propane-1,2-diol	106

#### 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

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1 Revision Date: 2025/04/14 SDS Number: 785433-00021 Date of last issue: 2024/09/28 Date of first issue: 2016/06/28

Chemical name	Concentration (%)	Remarks
Propylene glycol	>=10 - <20	From April 1st, 2025
Lactic acid	>=1 - <10	From April 1st, 2025
Sodium hydroxide	>=1 - <10	-

### Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Propylene glycol	From April 1st, 2025
Lactic acid	From April 1st, 2025
Sodium hydroxide	-

### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Chemical name
Lactic acid (DL-, L-, D-)
Sodium hydroxide

### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

### 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

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version 10.1 Revision Date: 2025/04/14 SDS Number: 785433-00021 Date of last issue: 2024/09/28 Date of first issue: 2016/06/28

---

### 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

---

## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / C : Ceiling limit  
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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 con-

# SAFETY DATA SHEET



## Orbifloxacin Liquid Formulation

Version  
10.1

Revision Date:  
2025/04/14

SDS Number:  
785433-00021

Date of last issue: 2024/09/28  
Date of first issue: 2016/06/28

---

centration; 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; KECL - 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