

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version 3.5      Revision Date: 2023/09/30      SDS Number: 785427-00016      Date of last issue: 2023/04/04  
Date of first issue: 2016/06/28

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road  
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

**Appearance** : suspension

**Colour** : light brown

**Odour** : odourless

Suspected of damaging the unborn child. May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

#### 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version 3.5      Revision Date: 2023/09/30      SDS Number: 785427-00016      Date of last issue: 2023/04/04  
Date of first issue: 2016/06/28

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.

**Physical and chemical hazards**

Not classified based on available information.

**Health hazards**

Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.

**Environmental hazards**

Not classified based on available information.

**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)
Orbifloxacin	113617-63-3	>= 3 -< 10
Lactic acid	50-21-5	>= 1 -< 3
Sodium hydroxide	1310-73-2	>= 1 -< 2

### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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 (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.

---

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version 3.5      Revision Date: 2023/09/30      SDS Number: 785427-00016      Date of last issue: 2023/04/04  
Date of first issue: 2016/06/28

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

#### 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

#### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
------------	---------	------------	-----------------	-------

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version 3.5      Revision Date: 2023/09/30      SDS Number: 785427-00016      Date of last issue: 2023/04/04  
Date of first issue: 2016/06/28

		(Form of exposure)	ters / Permissible concentration	
Orbifloxacin	113617-63-3	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Sodium hydroxide	1310-73-2	MAC	2 mg/m <sup>3</sup>	CN OEL
		C	2 mg/m <sup>3</sup>	ACGIH

**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

**Eye/face 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.

**Hand protection** : Chemical-resistant gloves

**Material** : Chemical-resistant gloves

**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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

### 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

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
---------------------	---	--

Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
---------------------------	---	--

#### 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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  
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:

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



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

### 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
-----------------------	--

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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  
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:**

#### **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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version 3.5      Revision Date: 2023/09/30      SDS Number: 785427-00016      Date of last issue: 2023/04/04  
Date of first issue: 2016/06/28

---

LOAEL : 37.5 mg/kg  
Application Route : Oral  
Exposure time : 30 Days  
Symptoms : Gastrointestinal disturbance

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

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

### Components:

#### **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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

aquatic invertebrates                      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                      : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

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

---

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

### 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.

#### National Regulations

##### GB 6944/12268

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

#### Special precautions for user

Not applicable



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

### 15. REGULATORY INFORMATION

#### National regulatory information

##### Law on the Prevention and Control of Occupational Diseases

##### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

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

### 16. OTHER INFORMATION

Revision Date : 2023/09/30

#### 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)  
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / C : Ceiling limit  
CN OEL / MAC : Maximum allowable concentration

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
3.5	2023/09/30	785427-00016	Date of first issue: 2016/06/28

---

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

### Disclaimer

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.

CN / EN