

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Orbifloxacin Liquid Formulation

Version  
4.0

Revision Date:  
30.09.2023

SDS Number:  
785872-00016

Date of last issue: 04.04.2023  
Date of first issue: 28.06.2016

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

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:**

P203 Obtain, read and follow all safety instructions before use.

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P260 Do not breathe mist or vapours.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P318 IF exposed or concerned, get medical advice.

**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)
Orbifloxacin	113617-63-3	>= 3 - < 5
Silicon dioxide	7631-86-9	>= 1 - < 5
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.

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.

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

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Notes to physician : when the potential for exposure exists (see section 8).  
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 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 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

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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.
Conditions for safe storage	: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Orbifloxacin	113617-63-3	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Silicon dioxide	7631-86-9	TWA (Total dust)	10 mg/m <sup>3</sup> (Silica)	IN OEL
Sodium hydroxide	1310-73-2	CEIL	2 mg/m <sup>3</sup>	IN 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.
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### 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

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	aerosols.
Skin and body protection	: Work uniform or laboratory coat.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: suspension
Colour	: light brown
Odour	: odourless
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: No data available

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Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
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

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## 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.

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## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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### 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
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Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2,000 mg/kg

Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg

Symptoms: Vomiting

Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg  
Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg

Application Route: Intramuscular

LD50 (Rat): 233 mg/kg

Application Route: Intravenous

LD50 (Mouse): 250 mg/kg

Application Route: Intravenous

### Silicon dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

### 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

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### 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

#### Silicon dioxide:

Species : Rabbit  
Method : OECD Test Guideline 404  
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

#### 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  
Method : Draize Test  
Result : Mild eye irritation

#### Silicon dioxide:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

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### Lactic acid:

Species	:	Chicken eye
Remarks	:	Based on data from similar materials
Result	:	Irreversible effects on the eye

### Sodium hydroxide:

Result	:	Irreversible effects on the eye
Remarks	:	Based on skin corrosivity.

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Product:

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

### Components:

#### Orbifloxacin:

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

#### Lactic acid:

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

#### Sodium hydroxide:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

#### Germ cell mutagenicity

Not classified based on available information.

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### 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.

#### **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
	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

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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

#### 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:

#### 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
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Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight
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**Teratogenicity:**  
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

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

### **Silicon dioxide:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### **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

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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
Species	:	Dog
NOAEL	:	37.5 mg/kg

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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

### Silicon dioxide:

Species	:	Rat
NOAEL	:	1.3 mg/m <sup>3</sup>
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	13 Weeks

### 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.

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### 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	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

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aquatic invertebrates	Exposure time: 24 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 ( <i>Desmodesmus subspicatus</i> (green algae)): > 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
	NOEC ( <i>Desmodesmus subspicatus</i> (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 ( <i>Danio rerio</i> (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 ( <i>Daphnia magna</i> (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 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
	NOEC ( <i>Pseudokirchneriella subcapitata</i> (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
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### 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

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## 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.

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## 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 IMO instruments**

Not applicable for product as supplied.

#### **Special precautions for user**

Not applicable

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## 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

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### 16. OTHER INFORMATION

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#### 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/>

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / C : Ceiling limit  
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)  
IN OEL / CEIL : ceiling limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Orbifloxacin Liquid Formulation

Version  
4.0

Revision Date:  
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785872-00016

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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.

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