

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

---

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

---

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name : Orbifloxacin Liquid Formulation

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A  
Çubuk Yolu 2. Km  
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

---

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification T.R. SEA No 28848

Reproductive toxicity, Category 2  
Specific target organ toxicity - repeated exposure, Category 2, Eye

H361d: Suspected of damaging the unborn child.  
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

### 2.2 Label elements

#### Labelling T.R. SEA No 28848

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.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3      Revision Date: 23.03.2020      SDS Number: 2569672-00006      Date of last issue: 13.09.2019  
Date of first issue: 27.02.2018

---

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
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.

Hazardous components which must be listed on the label:

Orbifloxacin

### 2.3 Other hazards

None known.

---

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Orbifloxacin	113617-63-3	Repr.2; H361d	>= 3 - < 10
Lactic acid	50-21-5 200-018-0	Skin Irrit.2; H315 Eye Dam.1; H318	>= 1 - < 3
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr.1; H290 Skin Corr.1A; H314 Eye Dam.1; H318	>= 1 - < 2

For explanation of abbreviations see section 16.

---

## SECTION 4: First aid measures

### 4.1 Description of 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.

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).

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

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.

### 4.2 Most important symptoms and effects, both acute and delayed

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

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically and supportively.
-----------	---

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
------------------------------	--

Unsuitable extinguishing media	: None known.
--------------------------------	---------------

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides

### 5.3 Advice for firefighters

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

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

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.
--------------------------------	---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
----------------------	--

### 6.2 Environmental precautions

Environmental precautions	: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
---------------------------	--

### 6.3 Methods and material for containment and cleaning up

Methods for 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.
-------------------------	---

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Avoid inhalation of vapour or mist. Do not swallow.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3      Revision Date: 23.03.2020      SDS Number: 2569672-00006      Date of last issue: 13.09.2019  
Date of first issue: 27.02.2018

---

	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.
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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s)	: No data available
-----------------	---------------------

---

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal

#### Derived No Effect Level (DNEL) :

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Silicon dioxide	Workers	Inhalation	Long-term systemic	4 mg/m3

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 2569672-00006 Date of last issue: 13.09.2019 Date of first issue: 27.02.2018

			effects	
Lactic acid	Workers	Inhalation	Long-term local effects	592 mg/m3
	Workers	Inhalation	Acute local effects	592 mg/m3
	Consumers	Inhalation	Acute local effects	296 mg/m3
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m3
	Workers	Inhalation	Long-term local effects	1 mg/m3

### Predicted No Effect Concentration (PNEC) :

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57,2 mg/kg
	Soil	50 mg/kg

## 8.2 Exposure controls

### 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

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.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 14387
Filter type	: Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	: suspension
Colour	: light brown
Odour	: odourless

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

---

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
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.

### 9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	No data available

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Orbifloxacin:**

Acute oral toxicity : LD50 (Rat): > 3.000 mg/kg  
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2.000 mg/kg  
Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg  
Symptoms: Vomiting  
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of ) : LD50 (Rat): > 200 mg/kg

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

---

administration) Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg  
Application Route: Intramuscular

LD50 (Rat): 233 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 250 mg/kg  
Application Route: Intravenous

### **Lactic acid:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

### **Sodium hydroxide:**

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

### **Skin corrosion/irritation**

Not classified based on available information.

### **Product:**

Species : Rabbit  
Result : No skin irritation

### **Components:**

#### **Orbifloxacin:**

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

#### **Lactic acid:**

Species : Rabbit  
Result : Skin irritation  
Remarks : Based on data from similar materials

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

### 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

#### Lactic acid:

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

### Sodium hydroxide:

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

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Product:

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

### Components:

#### Orbifloxacin:

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

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

### **Lactic acid:**

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

### **Sodium hydroxide:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Orbifloxacin:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: equivocal
		Test Type: Mouse Lymphoma Result: positive
		Test Type: Chromosomal aberration Test system: Human lymphocytes Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Intraperitoneal injection Result: negative
		Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Application Route: Oral Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

### **Lactic acid:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
		Test Type: In vitro mammalian cell gene mutation test

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

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
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

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  
LOAEL : 37,5 mg/kg  
Application Route : Oral  
Exposure time : 30 Days

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3      Revision Date: 23.03.2020      SDS Number: 2569672-00006      Date of last issue: 13.09.2019  
Date of first issue: 27.02.2018

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
Application Route	:	Oral

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
2.3	23.03.2020	2569672-00006	Date of first issue: 27.02.2018

---

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.

---

## SECTION 12: Ecological information

### 12.1 Toxicity

#### **Components:**

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

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

plants	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

### 12.2 Persistence and degradability

#### Components:

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

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

### 12.3 Bioaccumulative potential

#### Components:

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

Partition coefficient: n-octanol/water	: log Pow: -0,62
--	------------------

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal.

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)	: Conditions of restriction for the following entries should be considered: Number on list 3
Regulation on Persistent Organic Pollutants (Number 30595)	: Not applicable
Regulation on prevention of major industrial accidents. Reg number 30702	Not applicable

#### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

Version  
2.3

Revision Date:  
23.03.2020

SDS Number:  
2569672-00006

Date of last issue: 13.09.2019  
Date of first issue: 27.02.2018

---

### SECTION 16: Other information

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

#### Full text of H-Statements

H290 : May be corrosive to metals.  
H314 : Causes severe skin burns and eye damage.  
H315 : Causes skin irritation.  
H318 : Causes serious eye damage.  
H361d : Suspected of damaging the unborn child.

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

#### Full text of other abbreviations

Eye Dam. : Serious eye damage  
Met. Corr. : Corrosive to metals  
Repr. : Reproductive toxicity  
Skin Corr. : Skin corrosion  
Skin Irrit. : Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Orbifloxacin Liquid Formulation

---

Version 2.3	Revision Date: 23.03.2020	SDS Number: 2569672-00006	Date of last issue: 13.09.2019 Date of first issue: 27.02.2018
----------------	------------------------------	------------------------------	---

---

Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

### 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/>

### Classification of the mixture:

Repr. 2	H361d
STOT RE 2	H373

### Classification procedure:

Calculation method
Based on product data or assessment

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.

TR / EN