

Orbifloxacin Liquid Formulation

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Section 1: Identification

Product name : Orbifloxacin Liquid Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification

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 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.

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: |
| 6.0 | 30.09.2023 | 785437-00017 | 04.04.2023 |
| | | | Date of first issue: 28.06.2016 |

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

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

Section 4: First-aid measures

| | |
|---|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

| | | |
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| 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. |

Section 5: Fire-fighting measures

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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. |

Section 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. |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Section 7: Handling and storage

- 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.
- 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.
- 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------|-------------|-----------------------------------|--|----------|
| Propylene glycol | 57-55-6 | WES-TWA (particulate) | 10 mg/m ³ | NZ OEL |
| | | WES-TWA (Vapour and particulates) | 150 ppm 474 mg/m ³ | NZ OEL |
| Orbifloxacin | 113617-63-3 | TWA | 0.2 mg/m ³ (OEB 2) | Internal |
| Sodium hydroxide | 1310-73-2 | WES-Ceiling | 2 mg/m ³ | NZ OEL |
| | | C | 2 mg/m ³ | ACGIH |

- Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

| | | |
|--------------------------|---|--|
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Combined particulates and organic vapour type |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Eye protection | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat. |

Section 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 |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

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|--|---|--|
| 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 |

Section 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. |

Section 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Orbifloxacin:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2,000 mg/kg
Remarks: No mortality observed at this dose.

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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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

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

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

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

| | |
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| 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 oral toxicity | : Acute toxicity estimate: 500 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation. |
| Acute inhalation toxicity | : Assessment: Corrosive to the respiratory tract. |
| Acute dermal toxicity | : Acute toxicity estimate: 1,100 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation. |

Skin corrosion/irritation

Not classified based on available information.

Product:

| | |
|---------|----------------------|
| Species | : Rabbit |
| Result | : No skin irritation |

Components:**Propylene glycol:**

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

Orbifloxacin:

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

Lactic acid:

| | |
|---------|--|
| Species | : Rabbit |
| Method | : OECD Test Guideline 404 |
| Result | : Corrosive after 1 to 4 hours of exposure |
| Remarks | : Based on data from similar materials |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : Mild eye irritation

Components:**Propylene glycol:**

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

Orbifloxacin:

Species : Rabbit
Result : Mild eye irritation
Method : Draize Test

Lactic acid:

Species : Chicken eye
Remarks : Based on data from similar materials

Result : Irreversible effects on the eye

Sodium hydroxide:

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

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

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

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Components:**Propylene glycol:**

| | |
|-----------------|---------------------|
| Test Type | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Result | : negative |

Orbifloxacin:

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

Lactic acid:

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

Sodium hydroxide:

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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Propylene glycol:**

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
| | Result: negative |
| | Test Type: Chromosome aberration test in vitro |
| | Method: OECD Test Guideline 473 |
| Genotoxicity in vivo | Result: negative |
| | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
| | Species: Mouse |
| | Application Route: Intraperitoneal injection |
| | Result: negative |

Orbifloxacin:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
|-----------------------|--|

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

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|-------------------------------------|--|
| | 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 |
| | Method: OECD Test Guideline 476 |
| | Result: negative |
| | Remarks: Based on data from similar materials |
| | Test Type: Chromosome aberration test in vitro |
| | Method: OECD Test Guideline 473 |
| | Result: negative |
| | Remarks: Based on data from similar materials |

Carcinogenicity

Not classified based on available information.

Components:**Propylene glycol:**

| | |
|-------------------|-------------|
| Species | : Rat |
| Application Route | : Ingestion |
| Exposure time | : 2 Years |
| Result | : negative |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

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:**Propylene glycol:**

| | |
|-------------------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative |

Orbifloxacin:

| | |
|-------------------------------|--|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight Early Embryonic Development: NOAEL: 50 mg/kg body weight Result: No adverse effects |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight Result: No teratogenic effects, Embryotoxic effects and ad- |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

verse 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.

Lactic acid:

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Product:

Target Organs : Eye
 Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Product:**

Species : Dog
 NOAEL : 22.5 mg/kg
 LOAEL : 37.5 mg/kg
 Application Route : Oral
 Exposure time : 30 Days
 Symptoms : Gastrointestinal disturbance

Species : Dog

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

| | | |
|-------------------|---|---|
| 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:**Propylene glycol:**

| | | |
|-------------------|---|----------------|
| Species | : | Rat, male |
| NOAEL | : | >= 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 2 yr |

Orbifloxacin:

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|-------------------|---|-------------------------------|
| 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 |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

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|-------------------|--------------|
| 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. |
|-----------|--|

Section 12: Ecological information**Ecotoxicity****Components:****Propylene glycol:**

| | |
|---|--|
| Toxicity to fish | : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic | : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l |

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

| | |
|--|---|
| plants | Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d |
| Toxicity to microorganisms | : NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h |

Lactic acid:

| | |
|---|--|
| Toxicity to fish | : LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| | NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : EC50: > 10 - 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials |

Persistence and degradability**Components:****Propylene glycol:**

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

Lactic acid:

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

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

Bioaccumulative potential**Components:****Propylene glycol:**

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

Lactic acid:

| | | |
|--|---|----------------|
| Partition coefficient: n-octanol/water | : | log Pow: -0.62 |
|--|---|----------------|

Mobility in soil

No data available

Other adverse effects

No data available

Section 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. |

Section 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

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

| | |
|----------------------|------------------|
| 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**NZS 5433**

| | |
|----------------------|------------------|
| UN number | : Not applicable |
| Proper shipping name | : Not applicable |
| Class | : Not applicable |
| Subsidiary risk | : Not applicable |
| Packing group | : Not applicable |
| Labels | : Not applicable |
| Hazchem Code | : Not applicable |

Special precautions for user

Not applicable

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

| | |
|-------|------------------|
| AICS | : not determined |
| DSL | : not determined |
| IECSC | : not determined |

Section 16: Other information

| | |
|---------------|--------------|
| Revision Date | : 30.09.2023 |
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Further information

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: |
| 6.0 | 30.09.2023 | 785437-00017 | 04.04.2023 |
| | | | Date of first issue: 28.06.2016 |

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)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / C : Ceiling limit
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-Ceiling : Workplace Exposure Standard - Ceiling

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory 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

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

Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 6.0 | 30.09.2023 | 785437-00017 | Date of first issue: 28.06.2016 |

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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