SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Orbifloxacin Liquid Formulation

Manufacturer or supplier's details

Company: MSD
Address: Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

GHS label elements

Signal Word: Warning
Hazard pictograms:

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

Response:
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>50-21-5</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 1 - &lt; 2</td>
</tr>
</tbody>
</table>

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.

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.
SAFETY DATA SHEET

Orbifloxacin Liquid Formulation

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 fire-fighters: 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 and personal protective equipment recommendations.

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.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSORAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Avoid inhalation of vapor or mist.
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 labeled 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

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>CMP-C</td>
<td>2 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information:
- Irritation

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Combined particulates and organic vapor 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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension
Color: light brown
Odor: odorless
Odor 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
Vapor pressure: No data available
Relative vapor 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
Autoignition 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 reac-
tions : 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

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

Acute toxicity
Not classified based on available information.

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

Components:
Orbifloxacin:
Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
  Remarks: No mortality observed at this dose.
  LD50 (Mouse): > 2,000 mg/kg
  Remarks: No mortality observed at this dose.
  LD50 (Dog): > 600 mg/kg
  Symptoms: Vomiting
  Remarks: No mortality observed at this dose.
Acute inhalation toxicity: Remarks: No data available

Acute dermal toxicity: Remarks: No data available

Acute toxicity (other routes of administration):
- LD50 (Rat): > 200 mg/kg
  Application Route: Intramuscular
- LD50 (Mouse): 500 mg/kg
  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
  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

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

**Lactic acid:**
Species: Rabbit  
Result: Skin irritation  
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  
Result: Mild eye irritation  
Method: Draize Test

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

**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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Product:
Test Type: Magnusson-Kligman-Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Components:
Orbifloxacin:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Lactic acid:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: 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.

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  
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.

Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal 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-fetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-fetal 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.

**Silicon dioxide:**
**Effects on fetal development**
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

**Lactic acid:**
**Effects on fetal development**
Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
Result: negative

**STOT-single exposure**
Not classified based on available information.

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

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

**Repeated dose toxicity**

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

Species: Dog
LOAEL: 75 mg/kg
Application Route: Oral
Exposure time: 10 Days
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
SAFETY DATA SHEET

Orbifloxacin Liquid Formulation

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
  - 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/m³
  - Application Route: inhalation (dust/mist/fume)
  - Exposure time: 13 Weeks

Lactic acid:
- Species: Rat
  - NOAEL: > 100 mg/kg
SAFETY DATA SHEET

Orbifloxacin Liquid Formulation

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 photosensitization.

SECTION 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 aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): > 10.000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (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 (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:

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

Bioaccumulative potential

Components:

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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
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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Sodium hydroxide

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / C : Ceiling limit
AR OEL / CMP : TLV (Threshold Limit Value)
AR OEL / CMP-C : Ceiling value
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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