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
              Shotton Lane
              NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2, Eye : H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : [Image of hazard pictogram]
   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.
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

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

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).

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 (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: 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.

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. 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**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm 79 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<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>TWA (respirable dust)</td>
<td>1.5 mg/m³ (Silica)</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>T</td>
<td>2 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>

Further information: Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4 mg/m³</td>
</tr>
</tbody>
</table>
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 NS 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

: **Odour Threshold** : No data available

: **pH** : No data available
Orbifloxacin Liquid Formulation

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

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 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
**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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**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

**Sodium hydroxide:**

Result: Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**

Not classified based on available information.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>
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.

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
  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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>200 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>200 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Lactic acid:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

### Reproductive toxicity

Suspected of damaging the unborn child.

**Components:**

**Orbifloxacin:**

**Effects on fertility**

<table>
<thead>
<tr>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>General Toxicity - Parent: NOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Early Embryonic Development: NOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No adverse effects</td>
</tr>
</tbody>
</table>

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>General Toxicity Maternal: NOAEL: 20 mg/kg body weight</td>
</tr>
<tr>
<td>Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight</td>
</tr>
<tr>
<td>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</td>
</tr>
</tbody>
</table>
# Or bifloxacin Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>23.03.2020</td>
<td>785875-00011</td>
<td>13.09.2019</td>
<td>28.06.2016</td>
</tr>
</tbody>
</table>

**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  
**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  
  - **Exposure time**: 30 Days

- **Species**: Cat  
  - **NOAEL**: 7.5 mg/kg  
  - **LOAEL**: 22.5 mg/kg  
  - **Application Route**: Oral  
  - **Exposure time**: 1 Month  
  - **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 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
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.
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
Orbifloxacin Liquid Formulation

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

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.
SAFETY DATA SHEET
corresponding to Regulation (EC) No. 1907/2006

Orbifloxacin Liquid Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 785875-00011
Date of last issue: 13.09.2019
Date of first issue: 28.06.2016

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.

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / FOR-2011-12-06-1358 / TWA

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; ICD - 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 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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
### Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
<th></th>
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<tbody>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
</tbody>
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NO / EN