1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Orbifloxacin Solid Formulation

Supplier’s company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 2

GHS label elements
Hazard pictograms : ⚠️
Signal word : Warning
Hazard statements : H361d Suspected of damaging the unborn child.
Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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

Important symptoms and outlines of the emergency assumed:
- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
</tbody>
</table>

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:
- If in eyes, rinse well with water.
- 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.
- Contact with dust can cause mechanical irritation or drying of the skin.
- Dust contact with the eyes can lead to mechanical irritation.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical
Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling:
- Do not breathe dust.
- 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.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
- Oxidizing agents

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.

Storage:
- 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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment:

<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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures:
- Use feasible engineering controls to minimize exposure to compound.
- All engineering controls should be implemented by facility
design and operated in accordance with GMP principles to protect products, workers, and the environment.

**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: Particulates 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state**
- powder

**Colour**
- No data available

**Odour**
- No data available

**Odour Threshold**
- No data available

**Melting point/freezing point**
- No data available

**Boiling point, initial boiling point and boiling range**
- No data available

**Flammability (solid, gas)**
- May form explosive dust-air mixture during processing, handling or other means.

**Flammability (liquids)**
- No data available

**Lower explosion limit and upper explosion limit / flammability limit**
- No data available

**Upper explosion limit / Upper flammability limit**
- No data available

**Lower explosion limit / Lower flammability limit**
- No data available

**Flash point**
- Not applicable

**Decomposition temperature**
- No data available

**pH**
- No data available

**Evaporation rate**
- No data available

**Auto-ignition temperature**
- No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- May form explosive dust-air mixture during processing, handling or other means.
- Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks.
A void dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

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

Magnesium stearate:

- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity
  Remarks: Based on data from similar materials

- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Orbifloxacin:

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

Magnesium stearate:

- Species: Rabbit
- Result: No skin irritation
- Remarks: Based on data from similar materials
Serious eye damage/eye irritation
Not classified based on available information.

Components:

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

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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.

Magnesium stearate:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
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

Test Type: Bacterial reverse mutation assay (AMES)
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

Reproductive toxicity:
Suspected of damaging the unborn child.
Components:

**Orbifloxacin:**

**Effects on fertility:** Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 50 mg/kg body weight  
Early Embryonic Development: NOAEL: 50 mg/kg body weight  
Result: No adverse effects

**Effects on foetal development:** Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight  
Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

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

**Magnesium stearate:**

**Effects on fertility:** Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

**Effects on foetal development:** Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

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

**Magnesium stearate:**
- Species: Rat
SAFETY DATA SHEET

Orbifloxacin Solid Formulation

Version 3.0  Revision Date: 2020/10/01  SDS Number: 801084-00012  Date of last issue: 2020/03/23
Date of first issue: 2016/07/15

NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Magnesium stearate:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
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.

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.

National Regulations
Refer to section 15 for specific national regulation.
SAFETY DATA SHEET
Orbifloxacin Solid Formulation

Version 3.0  Revision Date: 2020/10/01  SDS Number: 801084-00012  Date of last issue: 2020/03/23  Date of first issue: 2016/07/15

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

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

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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.

JP / EN