SAFETY DATA SHEET
Orbifloxacin / Posaconazole / Mometasone Formulation

Version: 3.3     Revision Date: 2021/08/27     SDS Number: 439119-00013
Date of last issue: 2021/01/04     Date of first issue: 2016/01/06

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Orbifloxacin / Posaconazole / Mometasone 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
Serious eye damage/eye irritation: Category 2B
Long-term (chronic) aquatic hazard: Category 2

GHS label elements

Hazard pictograms: □

Signal word: Warning
Hazard statements: H320 Causes eye irritation.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements: Prevention:
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P391 Collect spillage.

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

Other hazards which do not result in classification
None known.

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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 60 - &lt; 70</td>
<td>9-1700</td>
</tr>
<tr>
<td></td>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

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 : Causes eye 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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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.
                           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.

7. HANDLING AND STORAGE

Handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation

: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling

: Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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.
Keep tightly closed.
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/PERSONAL 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 / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information: Group 1: carcinogenic to humans</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>0.2 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>300 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Mometasone

<table>
<thead>
<tr>
<th>Material</th>
<th>Chemical-resistant gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Wear safety glasses with side shields or goggles.</td>
</tr>
<tr>
<td></td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td></td>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Work uniform or laboratory coat.</td>
</tr>
<tr>
<td></td>
<td>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</td>
</tr>
<tr>
<td></td>
<td>Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state</th>
<th>suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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.

### 11. TOXICOLOGICAL INFORMATION

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

**Acute toxicity:**
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity (Rat)</td>
<td>&gt; 2,000 mg/kg</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No mortality observed at this dose.</td>
</tr>
<tr>
<td>Acute dermal toxicity (Rat)</td>
<td>&gt; 2,000 mg/kg</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity (Rat)</td>
<td>&gt; 5,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity (Rat)</td>
<td>&gt; 5 mg/l</td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Acute dermal toxicity (Rabbit)</td>
<td>&gt; 2,000 mg/kg</td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

**Orbifloxacin:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity (Rat)</td>
<td>&gt; 3,000 mg/kg</td>
<td>No mortality observed at this dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 (Mouse): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 (Dog): &gt; 600 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symptoms: Vomiting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Route</th>
<th>Value</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>
Acute toxicity (other routes of administration):

**Orbifloxacin**:
- 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

**Posaconazole**:
- Acute oral toxicity:
  - LD50 (Rat): > 5,000 mg/kg
  - LD50 (Mouse): > 3,000 mg/kg
- Acute dermal toxicity:
  - LD50 (Rat): > 2,000 mg/kg

**Mometasone**:
- Acute oral toxicity:
  - LD50 (Rat): > 2,000 mg/kg
  - LD50 (Mouse): > 2,000 mg/kg
- Acute inhalation toxicity:
  - LC50 (Rat): > 3.3 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
    - Remarks: No mortality observed at this dose.
  - LC50 (Mouse): > 3.2 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
- Acute toxicity (other routes of administration):
  - LD50 (Rat): 300 mg/kg
    - Application Route: Subcutaneous
    - Symptoms: Breathing difficulties

**Skin corrosion/irritation**
Not classified based on available information.

**Product**
- **Species**: Rabbit
- **Result**: Mild skin irritation

**Components**

**White mineral oil (petroleum)**:
- **Species**: Rabbit
- **Result**: No skin irritation
Species: Rabbit
Method: Draize Test
Result: No skin irritation

Mometasone:
Species: Rabbit
Result: No skin irritation

Posaconazole:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes eye irritation.

Product:
Species: Rabbit
Result: Mild eye irritation

Components:
White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation

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

Mometasone:
Species: Rabbit
Result: No eye irritation

Posaconazole:
Species: Rabbit
Result: Mild eye irritation

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
Components:

White mineral oil (petroleum):
Test Type: Buehler 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.

Mometasone:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative
Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

Posaconazole:
Test Type: Magnusson-Kligman-Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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.

Mometasone:

Genotoxicity in vitro:

: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo:

: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Result: negative
Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Posaconazole:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Intravenous
Result: negative

Carcinogenicity
Not classified based on available information.

Components:
White mineral oil (petroleum):
Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

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

Mometasone:
Species : Rat
Application Route : Inhalation
Exposure time : 2 Years
Dose : 0.067 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Inhalation
Exposure time : 19 Months
<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbifloxacin</td>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td></td>
<td>No adverse effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Test Type: Embryo-foetal development Species: Rat Application Route: Oral 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</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>Oral</td>
<td></td>
<td></td>
<td>Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral</td>
</tr>
</tbody>
</table>

| Posaconazole                  | One-generation reproduction toxicity study     | Rat       | Skin contact      | 2 Years       | negative | The mechanism or mode of action is not relevant in humans.                                                                                          |
|                               |                                               |           |                   |               |         | Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative                                                                 |

| White mineral oil (petroleum) |                                               |           |                   |               |         | Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative                                                                 |

**Reproductive toxicity**
Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**
Effects on fertility:
- Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Skin contact
  - Result: negative

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rat
  - 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 adverse effects on the offspring were detected only at high maternally toxic doses

- Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Oral
General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development. Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain

Test Type: Development
Species: Dog
Application Route: Oral
Developmental Toxicity: LOAEL: 2.5 mg/kg body weight
Result: Effects on postnatal development, Skeletal malformations

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

Mometasone:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced foetal weight
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
Result: Effects on newborn

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment:
Clear evidence of adverse effects on development, based on animal experiments. Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Posaconazole:
Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity - Parent: NOAEL: 180 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity - Parent: NOAEL: 45 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat, female
Application Route: Oral
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rabbit, female
Developmental Toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity

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

STOT - single exposure
Not classified based on available information.

Components:
Mometasone:
Remarks:
Based on available data, the classification criteria are not met.

STOT - repeated exposure
Not classified based on available information.

Components:
Mometasone:
Exposure routes: inhalation (dust/mist/fume)
Target Organs: Immune system, Liver, Kidney, Skin
Assessment: May cause damage to organs through prolonged or repeated
exposure.

**Posaconazole:**
- **Exposure routes**: Ingestion
- **Target Organs**: Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

**Components:**

**White mineral oil (petroleum):**
- **Species**: Rat
- **LOAEL**: 160 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

**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
## Orbifloxacin / Posaconazole / Mometasone Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>37.5 mg/kg</td>
<td>22.5 mg/kg</td>
<td>Oral</td>
<td>30 Days</td>
<td>Bone</td>
</tr>
<tr>
<td>Cat</td>
<td>7.5 mg/kg</td>
<td>22.5 mg/kg</td>
<td>Oral</td>
<td>1 Month</td>
<td>No significant adverse effects were reported</td>
</tr>
<tr>
<td>Rat</td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Rat</td>
<td>0.00013 mg/l</td>
<td>0.0005 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.0005 mg/l</td>
<td>0.0005 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver</td>
</tr>
</tbody>
</table>

### Mometasone:

**Species**: Rat, female

**NOAEL**: 5 mg/kg

**Application Route**: Oral

**Exposure time**: 6 Months

**Target Organs**: Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

**Species**: Dog

**NOAEL**: 37.5 mg/kg

**Application Route**: Oral

**Exposure time**: 90 Days

**Target Organs**: Bone

**Remarks**: No significant adverse effects were reported

**Species**: Cat

**NOAEL**: 7.5 mg/kg

**Application Route**: Oral

**Exposure time**: 30 Days

**Target Organs**: Bone

**Species**: Rat

**NOAEL**: 0.005 mg/kg

**Application Route**: Oral

**Exposure time**: 30 d

**Target Organs**: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

**Species**: Dog

**NOAEL**: 0.005 mg/kg

**Application Route**: Oral

**Exposure time**: 30 d

**Target Organs**: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

**Species**: Rat

**NOAEL**: 0.00013 mg/l

**Application Route**: inhalation (dust/mist/fume)

**Exposure time**: 90 d

**Target Organs**: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

**Species**: Dog

**NOAEL**: 0.0005 mg/l

**Application Route**: inhalation (dust/mist/fume)

**Exposure time**: 90 d

**Target Organs**: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver
**LOAEL** : 3 mg/kg  
**Application Route** : Oral  
**Exposure time** : 392 Days  
**Target Organs** : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

**Species** : Monkey  
**LOAEL** : 15 mg/kg  
**Application Route** : Oral  
**Exposure time** : 1 Months  
**Target Organs** : Bone marrow, Adrenal gland, Lymph nodes, Blood

**Species** : Dog  
**LOAEL** : 3 mg/kg  
**Application Route** : Oral  
**Exposure time** : 56 Weeks  
**Target Organs** : Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue

**Species** : Monkey  
**LOAEL** : 180 mg/kg  
**Application Route** : Oral  
**Exposure time** : 12 Months  
**Target Organs** : Blood, Gastrointestinal tract, spleen

**Species** : Monkey  
**LOAEL** : 8 mg/kg  
**Application Route** : Intravenous  
**Exposure time** : 1 Months  
**Target Organs** : Cardio-vascular system, Lungs, Adrenal gland, Blood

**Aspiration toxicity**  
Not classified based on available information.

**Components:**

**Mometasone:**  
Not applicable

**Experience with human exposure**

**Components:**

**Orbifloxacin:**  
**Ingestion** : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash  
Remarks: May cause photosensitisation.

**Mometasone:**  
**Inhalation** : Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion
Skin contact: Symptoms: Dermatitis, Itching

Posaconazole:
Ingestion: Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance

Further information
Components:
Mometasone:
Remarks: Dermal absorption possible

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 21 d

Mometasone:
Toxicity to fish: LC50 (Menidia beryllina (Silverside)): 0.11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): > 5 mg/l
aquatic invertebrates

Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity)

: NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

: NOEC (Daphnia magna (Water flea)): 0.34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity)

: 100

Toxicity to microorganisms

: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Posaconazole:

Toxicity to fish

: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 0.276 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1
Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 0.244 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 1
Toxicity to microorganisms:
EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Mometasone:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water: Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

Posaconazole:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 h
Method: OECD Test Guideline 314

Stability in water: Degradation half life (DT50): > 30 d
Method: OECD Test Guideline 111
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone
Formulation

Bioaccumulative potential

Components:

Mometasone:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water: log Pow: 4.68

Posaconazole:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 20
Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water: log Pow: 4.15

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Posaconazole:
Distribution among environmental compartments: log Koc: 5.52

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Posaconazole)
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version: 3.3
Revision Date: 2021/08/27
SDS Number: 439119-00013
Date of last issue: 2021/01/04
Date of first issue: 2016/01/06

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Mometasone, Posaconazole)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Posaconazole)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Related Regulations

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

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>Mineral oil</td>
<td>168</td>
<td>&gt;=60 - &lt;70</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>Mineral oil</td>
<td>168</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
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone
Formulation

Version 3.3  Revision Date: 2021/08/27  SDS Number: 439119-00013  Date of last issue: 2021/01/04

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation: Noxious liquid substance (Category Z)
Pack transportation: 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
Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

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 Chemi-
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.