SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
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 + P317 If eye irritation persists: Get medical help.
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>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 0.25</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
Protection of first-aiders : Causes eye irritation.
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).
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
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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m3</td>
<td>IN OEL</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>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>0.2 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>300 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Essentially no open handling permitted.
- Use closed processing systems or containment technologies.
- If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
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
Hand protection : Combined particulates and organic vapour type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : white to off-white

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available
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:**
- **Acute oral toxicity**: LD50 (Rat): > 2,000 mg/kg
  Remarks: No significant adverse effects were reported
  No mortality observed at this dose.
- **Acute dermal toxicity**: LD50 (Rat): > 2,000 mg/kg
  Remarks: No significant adverse effects were reported

**Components:**
- **White mineral oil (petroleum):**
  - **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - **Acute inhalation toxicity**: LC50 (Rat): > 5 mg/l
    Exposure time: 4 h
    Test atmosphere: dust/mist
    Assessment: The substance or mixture has no acute inhalation toxicity
  - **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
    Assessment: The substance or mixture has no acute dermal toxicity

- **Orbifloxacin:**
  - **Acute oral toxicity**: LD50 (Rat): > 3,000 mg/kg
    Remarks: No mortality observed at this dose.
    LD50 (Mouse): > 2,000 mg/kg
    Remarks: No mortality observed at this dose.
    LD50 (Dog): > 600 mg/kg
    Symptoms: Vomiting
    Remarks: No mortality observed at this dose.
  - **Acute inhalation toxicity**: Remarks: No data available
  - **Acute dermal toxicity**: Remarks: No data available
  - **Acute toxicity (other routes of administration)**: LD50 (Rat): > 200 mg/kg
    Application Route: Intramuscular
    LD50 (Mouse): 500 mg/kg
    Application Route: Intramuscular
    LD50 (Rat): 233 mg/kg
    Application Route: Intravenous
    LD50 (Mouse): 250 mg/kg
Application Route: Intravenous

**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

**Orbifloxacin:**
Species: Rabbit
Method: Draize Test
Result: No skin irritation

**Posaconazole:**
Species: Rabbit
Result: No skin irritation
Mometasone:
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
Method: Draize Test
Result: Mild eye irritation

Posaconazole:
Species: Rabbit
Result: Mild eye irritation

Mometasone:
Species: Rabbit
Result: No 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
Result: Not a skin sensitizer.

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.

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

**Mometasone:**
- Test Type: Maximisation Test
- Exposure routes: Dermal
- Species: Guinea pig
- Result: negative
- Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

**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.

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

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.

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

Remarks: The mechanism or mode of action is not relevant in humans.

Posaconazole:
Species: Rat
Application Route: oral (feed)
Exposure time: 2 Years
Result: positive
Remarks: The mechanism or mode of action is not relevant in humans.

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: positive
Remarks: The mechanism or mode of action is not relevant in humans.

Mometasone:
Species: Rat
### Reproductive toxicity

Not classified based on available information.

### Components:

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Skin contact</td>
<td>0.067 mg/kg body weight</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Skin contact</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Effect</th>
<th>Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on foetal development</td>
<td>Test Type: Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>0.160 mg/kg body weight</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td></td>
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</tr>
</tbody>
</table>

**Orbifloxacin:**

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

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

| 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 |         |               |                  |                      |
**Orbifloxacin / Posaconazole / Mometasone Formulation**

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.

**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

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.

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: 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.

**Mometasone:**

Effects on fertility:  
Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 0.06 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 development-
### Reproductive toxicity - Assessment

<table>
<thead>
<tr>
<th>Component</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
</tbody>
</table>

### STOT - single exposure

Not classified based on available information.

**Components:**

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

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

Species: Rat
- LOAEL: >= 1 mg/l
- Application Route: inhalation (dust/mist/fume)
- Exposure time: 4 Weeks
- Method: OECD Test Guideline 412

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
<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>30 Days</td>
</tr>
</tbody>
</table>

**Species:** Cat  
**NOAEL:** 7.5 mg/kg  
**LOAEL:** 22.5 mg/kg

**Application Route:** Oral  
**Exposure time:** 1 Months  
**Symptoms:** Gastrointestinal disturbance

### Posaconazole:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>392 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow, Adrenal gland, Lymph nodes, Blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>56 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>180 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Gastrointestinal tract, spleen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>8 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Cardio-vascular system, Lungs, Adrenal gland, Blood</td>
</tr>
</tbody>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.005 mg/kg</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone 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>2.11</td>
<td>27.08.2021</td>
<td>441603-00013</td>
<td>04.01.2021</td>
<td>06.01.2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

Species: Dog

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

Species: Rat

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00013 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>
</tbody>
</table>

Species: Dog

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<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>

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.

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

**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
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: 1,000 mg/l
  - Exposure time: 28 d
  - Species: Oncorhynchus mykiss (rainbow trout)

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

**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
### Orbifloxacin / Posaconazole / Mometasone Formulation

<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50 (Natural microorganism): &gt; 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC: 0.206 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 33 d</td>
<td>Species: Pimephales promelas (fathead minnow)</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 210</td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>1</th>
</tr>
</thead>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Menidia beryllina (Silverside)): 0.11 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 7 d</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EC50 (Americamysis): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: US-EPA OPPTS 850.1035</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 3.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
</tbody>
</table>
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

Toxicity to fish (Chronic toxicity): NOEC: 0.00014 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.34 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 100

Persistence and degradability

Components:

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

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

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
Bioaccumulative potential

Components:

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

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

Mobility in soil

Components:

Posaconazole:
Distribution among environmental compartments: log Koc: 5.52

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

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)

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 IMO instruments
Not applicable for product as supplied.

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

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

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: dd.mm.yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- IN OEL: India. Permissible levels of certain chemical substances in work environment.
- ACGIH / TWA: 8-hour, time-weighted average
- IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
- IN OEL / STEL: Short-term exposure Limit STEL (15 min)

Abbreviations:
- AICI: Australian Inventory of Industrial Chemicals; ANTT: National Agency for Transport by Land of Brazil; ASTM: American Society for the Testing of Materials; bw: Body weight; CMR: Carcinogen, Mutagen or Reproductive Toxicant; DIN: Standard of the German Institute for Standardisation; DSL: Domestic Substances List (Canada); ECx: Concentration associated with x% response; ELx: Loading rate associated with x% response; EmS: Emergency Schedule; ENCS: Existing and New Chemical Substances (Japan); ErCx: Concentration associated with x% growth rate response; ERG: Emergency Response Guide; GHS: Globally Harmonized System; GLP: Good Laboratory Practice; IARC: International Agency for Research on Cancer; IATA: International Air Transport Association; IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50: Half maximal inhibitory concentration; ICAO: International Civil Aviation Organization; IECSC: Inventory of Existing Chemical Substances in China; IMDG: International Maritime Dangerous Goods; IMO: International Maritime Organization; ISHL: Industrial Safety and Health Law (Japan); ISO: International Organisation for Standardization; KECI: Korea Existing Chemicals Inventory; LC50: Lethal Concentration to 50% of a test population; LD50: Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL: International Convention for the Prevention of Pollution from Ships; n.o.s.: Not Otherwise Specified; Nch: Chilean Norm; NO(A)EC: No Observed (Adverse) Effect Concentration; NO(A)EL: No Observed (Adverse) Effect Level; NOELR: No Observable Effect Loading Rate; NOM: Official Mexican Norm; NTP: National Toxicology Program; NZIoC: New Zealand Inventory of Chemicals; OECD: Organization for Economic Co-operation and Development; OPPTS: Office of Chemical Safety and Pollution Prevention; PBT: Persistent, Bioaccumulative and Toxic substance; PICCS: Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR: (Quantitative) Structure Activity Relationship; REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT: Self-Accelerating Decomposition Temperature; SDS: Safety Data Sheet; TCSI: Taiwan Chemical Substance Inventory; TDG: Transportation of Dangerous Goods; TECI: Thailand Existing Chemicals Inventory; TSCA: Toxic Substances Control Act (United States); UN: United Nations; UNRTDG: United Nations Recommendations on the Transport of Dangerous Goods; vPvB: Very Persistent and Very Bioaccumulative; WHMIS: Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only
to the specific material identified at the top of this SDS and may not be valid when the SDS mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

IN / EN