1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 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

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 + 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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 60 -&lt; 100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&lt; 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 0.025 -&lt; 0.25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.025 -&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**
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
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.
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 2.11  Revision Date: 2021/08/27  SDS Number: 439116-00013  Date of last issue: 2021/01/04  Date of first issue: 2016/01/06

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>NAB (Mist)</td>
<td>5 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD (Mist)</td>
<td>10 mg/m³</td>
<td>ID 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>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>300 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
- Wipe limit 10 µg/100 cm² Internal

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: Combined particulates and organic vapour type
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
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper : 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
Result: Mild eye irritation
Method: Draize Test

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 sensitiser.

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
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 sensitiser.

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

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
## Germ cell mutagenicity - Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>24 Months</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Orbifloxacin:

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

#### Posaconazole:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
</tbody>
</table>

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

#### Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Dose</td>
<td>0.067 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Species | Mouse |
Application Route | Oral |
Exposure time | 2 Years |
Result            | positive |
Remarks: The mechanism or mode of action is not relevant in humans.
Exposure time : 19 Months  
Dose : 0.160 mg/kg body weight  
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  
Embryotoxicity: 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.

**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

**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.

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:

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.

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.
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
  - **Application Route:** Oral
  - **Exposure time:** 30 Days

- **Species:** Cat
<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAFETY DATA SHEET</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Orbifloxacin / Posaconazole / Mometasone</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
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</table>

**Version** 2.11  
**Revision Date:** 2021/08/27  
**SDS Number:** 439116-00013  
**Date of last issue:** 2021/01/04  
**Date of first issue:** 2016/01/06

<table>
<thead>
<tr>
<th><strong>NOAEL</strong></th>
<th>7.5 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOAEL</strong></td>
<td>22.5 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>1 Months</td>
</tr>
<tr>
<td><strong>Symptoms</strong></td>
<td>Gastrointestinal disturbance</td>
</tr>
</tbody>
</table>

**Posaconazole:**

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

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

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

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

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

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

**Mometasone:**

<table>
<thead>
<tr>
<th><strong>Species</strong></th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOAEL</strong></td>
<td>0.005 mg/kg</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>0.3 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>30 d</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone
Formulation

Species: Dog
LOAEL: 0.5 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

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:
### 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

**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

### 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 aquatic invertebrates

- **EC50 (Daphnia magna (Water flea)):** > 5 mg/l
- **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

### 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
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

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
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 2.11  Revision Date: 2021/08/27  SDS Number: 439116-00013  Date of last issue: 2021/01/04  Date of first issue: 2016/01/06

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.

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 2.11  Revision Date: 2021/08/27  SDS Number: 439116-00013  Date of last issue: 2021/01/04

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ID OEL / NAB: Long term exposure limit
ID OEL / PSD: Short term exposure limit

All other abbreviations are defined in the text of the Safety Data Sheet.

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.

ID / EN