SAFETY DATA SHEET
Orbifloxacin / Posaconazole / Mometasone Formulation

SECTION 1. IDENTIFICATION

Product name: Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATATESTAWARE@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation: Category 2B
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms: 

Signal Word: Danger
Hazard Statements: H320 Causes eye irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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.
P308 + P313 IF exposed or concerned: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</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>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 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. May damage the unborn child. Suspected of damaging fertility.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment.
SECTION 5. FIRE-FIGHTING 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.
SECTION 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 vapors 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 labeled 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 Self-reactive substances and mixtures Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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 (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST (Mist)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>300 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection:

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection:

Material: 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:

Material: 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:

Material: 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: suspension
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>odorless</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SECTION 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.

SECTION 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

Polyethylene glycol:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials
<table>
<thead>
<tr>
<th>Compound</th>
<th>Route of Administration</th>
<th>Toxicity (LD50)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orbifloxacin</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 3,000 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 2,000 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt; 600 mg/kg</td>
<td>Symptoms: Vomiting</td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>Remarks: No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Remarks: No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): &gt; 200 mg/kg</td>
<td>Application Route: Intramuscular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 500 mg/kg</td>
<td>Application Route: Intramuscular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 233 mg/kg</td>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 250 mg/kg</td>
<td>Application Route: Intravenous</td>
<td></td>
</tr>
<tr>
<td><strong>Posaconazole</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 3,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mometasone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 2,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 3.3 mg/l</td>
<td>Exposure time: 4 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td>Remarks: No mortality observed at this dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Mouse): &gt; 3.2 mg/l</td>
<td>Exposure time: 4 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 300 mg/kg</td>
<td>Application Route: Subcutaneous</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.10  Revision Date: 04/04/2023  SDS Number: 439125-00017  Date of last issue: 10/01/2022
Date of first issue: 01/06/2016

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

Polyethylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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
Polyethylene glycol:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

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 sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Product:
Test Type : Magnusson-Kligman-Test
Routes of exposure : Dermal
Result : Not a skin sensitizer.

Components:
White mineral oil (petroleum):
Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Polyethylene glycol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Orbifloxacin:
Test Type : Maximization Test
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

Polyethylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: equivocal
Remarks: Based on data from similar materials

Orbifloxacin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Mouse Lymphoma
Result: positive
Test Type: Chromosomal aberration
Test system: Human lymphocytes
Genotoxicity in vivo:

**Orbifloxacin**

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

**Posaconazole**

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

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo:

Species: Mouse
Cell type: Bone marrow
Application Route: Intravenous
Result: negative

**Mometasone**

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:

Species: Mouse
Application Route: Oral
Result: negative

Test Type: Micronucleus test
Species: Rat
**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>4.10</td>
<td>04/04/2023</td>
<td>439125-00017</td>
<td>10/01/2022</td>
<td>01/06/2016</td>
</tr>
</tbody>
</table>

- **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

**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  
  **Application Route:** Inhalation
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.10  Revision Date: 04/04/2023  SDS Number: 439125-00017  Date of last issue: 10/01/2022  Date of first issue: 01/06/2016

Exposure time: 2 Years
Dose: 0.067 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Inhalation
Exposure time: 19 Months
Dose: 0.160 mg/kg body weight
Result: negative

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage the unborn child. Suspected of damaging fertility.

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

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

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

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

Test Type: Embryo-fetal 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: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced fetal
Effects on fetal development:

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

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

- Test Type: Embryo-fetal development
  Species: Rabbit
  Application Route: Dermal
  Embryo-fetal toxicity: LOAEL: 0.15 mg/kg body weight
  Result: Effects on newborn.

- Test Type: Embryo-fetal development
  Species: Rat
  Application Route: Oral
  Embryo-fetal toxicity: LOAEL: 0.7 mg/kg body weight
  Result: Embryo-fetal 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:
Routes of exposure: Ingestion
### Target Organs
- Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system

### Assessment
- Causes damage to organs through prolonged or repeated exposure.

### Mometasone:
- **Routes of exposure**: 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):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>160 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

**Species** | Rat |
| LOAEL | >= 1 mg/l |
| Application Route | inhalation (dust/mist/fume) |
| Exposure time | 4 Weeks |

**Method**: OECD Test Guideline 412

**Orbifloxacin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>20 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>80 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>80 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>250 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Juvenile dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>250 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Days</td>
</tr>
</tbody>
</table>

**Target Organs**: Heart, Bone

**Symptoms**: Gastrointestinal disturbance

**Remarks**: mortality observed

**Species** | Juvenile dog |
| NOAEL | 2 mg/kg |
SAFETY DATA SHEET
Orbifloxacin / Posaconazole / Mometasone Formulation

Version: 4.10  Revision Date: 04/04/2023  SDS Number: 439125-00017  Date of last issue: 10/01/2022
Date of first issue: 01/06/2016

LOAEL: 3 mg/kg
Application Route: Oral
Exposure time: 90 Days
Target Organs: Bone
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 37.5 mg/kg
Application Route: Oral
Exposure time: 30 Days

Species: Cat
NOAEL: 7.5 mg/kg
LOAEL: 22.5 mg/kg
Application Route: Oral
Exposure time: 1 Months
Symptoms: Gastrointestinal disturbance

Posaconazole:
Species: Rat, female
LOAEL: 5 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species: Dog
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

**Mometasone**:

<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>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>
</tbody>
</table>

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

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

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

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

**Components:**

**Mometasone**:  
Not applicable

**Experience with human exposure**

**Components**:

**Orbifloxacin**:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash</td>
<td>May cause photosensitization</td>
</tr>
</tbody>
</table>

**Posaconazole**:

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritus, Diarrhea, hypertension, neutropenia, electrolyte imbalance</td>
<td></td>
</tr>
</tbody>
</table>
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

SECTION 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

Polyethylene glycol:
Toxicity to fish: LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

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

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.276 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 202</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 210</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 211</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Remarks | No toxicity at the limit of solubility. |

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Natural microorganism)</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 209</td>
<td></td>
<td>Respiration inhibition</td>
<td></td>
</tr>
</tbody>
</table>

**Mometasone:**

Toxicity to fish

<table>
<thead>
<tr>
<th>Method</th>
<th>LC50 (Menidia beryllina (Silverside))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 210</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 202</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Americamysis)</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>US-EPA OPPTS 850.1035</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notes</td>
<td>OECD Test Guideline 201</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

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

**Polyethylene glycol:**
Biodegradability: Result: rapidly degradable
Remarks: Based on data from similar materials

**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)
Bioaccumulative potential

**Components:**

**Polyethylene glycol:**
Partition coefficient: n-octanol/water: log Pow: < 3

**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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Mometasone, Posaconazole)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Mometasone, Posaconazole)
Remarks : Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.
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.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Reproductive toxicity
- Serious eye damage or eye irritation

SARA 313:
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- White mineral oil (petroleum) 8042-47-5
- Polyethylene glycol 25322-68-3

California List of Hazardous Substances
- White mineral oil (petroleum) 8042-47-5

California Permissible Exposure Limits for Chemical Contaminants
- White mineral oil (petroleum) 8042-47-5

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

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.10  Revision Date: 04/04/2023  SDS Number: 439125-00017  Date of last issue: 10/01/2022  Date of first issue: 01/06/2016

NFPA 704:

Flammability 1
Health 1
Instability 0
Special hazard

HMIS® IV:

HEALTH * 1
FLAMMABILITY 1
PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA: 8-hour time weighted average
US WEEL / TWA: 8-hr TWA

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.10 Revision Date: 04/04/2023 SDS Number: 439125-00017 Date of last issue: 10/01/2022 Date of first issue: 01/06/2016

Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date: 04/04/2023

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.

US / Z8