SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.1  
Revision Date: 10.10.2020  
SDS Number: 439109-00011  
Date of last issue: 23.03.2020  
Date of first issue: 06.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil  
CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Eye irritation: Category 2B
Long-term (chronic) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

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.
Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>Acute toxicity (Oral), Reproductive toxicity, Repeated exposure (Oral)</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>Reproductive toxicity, Category 2</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>Reproductive toxicity, Category 2</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Reproductive toxicity, Category 1B Specific target organ toxicity - repeated</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>exposure (Inhalation) (Immune system, Liver, Kidney, Skin), Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, 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.

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 fire fighting : 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.

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.

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
- 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>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: 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 vapor 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: suspension
- **Color**: white to off-white
- **Odor**: odorless
- **Odor 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 flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
Viscosity
Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

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
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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Orbifloxacin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Posaconazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
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</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Causes eye irritation.

**Product:**

<table>
<thead>
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<th>Species</th>
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</tr>
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<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Components:**

**White mineral oil (petroleum):**

<table>
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<tr>
<th>Species</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
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</tbody>
</table>

**Orbifloxacin:**

<table>
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<tr>
<th>Species</th>
<th>Result</th>
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<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Posaconazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td></td>
</tr>
</tbody>
</table>
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

**Orbifloxacin:**
Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

**Posaconazole:**
Test Type : Magnusson-Kligman-Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

**Mometasone:**
Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Result : negative
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.
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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: 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
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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
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NOAEL: 200 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years

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.

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

Species: Mouse
Application Route: Inhalation
Exposure time: 19 Months
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 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
Species: Rabbit
Application Route: Oral
Embryo-fetal toxicity: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain.

Test Type: Development
Species: Dog
Application Route: Oral
Developmental Toxicity: LOAEL: 2,5 mg/kg body weight
Result: Effects on postnatal development., Skeletal malformations.

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

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
Frequency of Treatment: 6 - 15 days
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rabbit, female
Frequency of Treatment: 7 - 19 days
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 weight.
Result: No effects on fertility., Effect on reproduction capacity.

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: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
Result: Effects on newborn.

Test Type: Embryo-fetal development
Species: Rabbit
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):
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
NOAEL: 7.5 mg/kg
LOAEL: 22.5 mg/kg
Application Route: Oral
Exposure time: 1 Month
Symptoms: Gastrointestinal disturbance

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

Species: Dog
NOAEL: 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
<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mg/kg</td>
<td>Oral</td>
<td>1 Months</td>
<td>Bone marrow, Adrenal gland, Lymph nodes, Blood</td>
</tr>
<tr>
<td>Species</td>
<td>Dog</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>3 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>56 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Monkey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>180 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Gastrointestinal tract, spleen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Monkey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td>8 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>1 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Cardio-vascular system, Lungs, Adrenal gland, Blood</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Mometasone:**

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.00013 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</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>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>0.0005 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</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 photosensitization.

Posaconazole:
Ingestion: Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhea, 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

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
<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 28 d</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)): 1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
</tbody>
</table>

## Posaconazole:

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Method</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 0.95 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

**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)): 0.276 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 0.509 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 201

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**

| Method                   | 1                                                      |

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 33 d</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Daphnia magna (Water flea)): 0.244 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
</tbody>
</table>

**Method**: OECD Test Guideline 211

**Remarks**: No toxicity at the limit of solubility.

**M-Factor (Chronic aquatic toxicity)**

| Method                   | 1                                                      |

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Natural microorganism): &gt; 1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
</tbody>
</table>

**Test Type**: Respiration inhibition

**Method**: OECD Test Guideline 209

## Mometasone:

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Method</th>
<th>LC50 (Menidia beryllina (Silverside)): 0.11 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

**Remarks**: No toxicity at the limit of solubility.

<table>
<thead>
<tr>
<th>Method</th>
<th>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l</th>
</tr>
</thead>
</table>
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:**

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

**Mometasone**:


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
SECTION 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.

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

ANTT
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 4.1
Revision Date: 10.10.2020
SDS Number: 439109-00011
Date of last issue: 23.03.2020
Date of first issue: 06.01.2016

(Mometasone, Posaconazole)

Class: 9
Packing group: III
Labels: 9
Hazard Identification Number: 90

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

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

International Regulations
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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average
AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with
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.

BR / Z8