SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 2.9  Revision Date: 10.10.2020  SDS Number: 439123-00011  Date of last issue: 23.03.2020

Section 1: Identification

Product name: Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 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: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

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>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 60 -&lt;= 100</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&lt; 0.3</td>
</tr>
</tbody>
</table>

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.
SAFETY DATA SHEET

Or bifloxacin / Posaconazole / Mometasone
Formulation

Version 2.9  
Revision Date: 10.10.2020
SDS Number: 439123-00011
Date of last issue: 23.03.2020
Date of first issue: 06.01.2016

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: None known.
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 firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Hazchem Code: 3Z

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.
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.

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 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.

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 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.
Section 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>WES-TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES- STEL (Mist)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

### Engineering measures

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

### Personal protective equipment

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Combined particulates and organic vapour type

**Hand protection**: 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, dis-
posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

### Section 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour 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>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version: 2.9
Revision Date: 10.10.2020
SDS Number: 439123-00011
Date of last issue: 23.03.2020
Date of first issue: 06.01.2016

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

Exposure routes: 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

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 3,000</td>
</tr>
<tr>
<td>Mouse</td>
<td>&gt; 2,000</td>
</tr>
<tr>
<td>Dog</td>
<td>&gt; 600</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>Application Route</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramuscular</td>
<td>&gt; 200</td>
</tr>
<tr>
<td>Intravenous</td>
<td>&gt; 233</td>
</tr>
<tr>
<td>Intravenous</td>
<td>&gt; 250</td>
</tr>
</tbody>
</table>

## Posaconazole:

### Acute oral toxicity

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 5,000</td>
</tr>
<tr>
<td>Mouse</td>
<td>&gt; 3,000</td>
</tr>
</tbody>
</table>

### Acute dermal toxicity

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 2,000</td>
</tr>
</tbody>
</table>

## Mometasone:

### Acute oral toxicity

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 2,000</td>
</tr>
<tr>
<td>Mouse</td>
<td>&gt; 2,000</td>
</tr>
</tbody>
</table>

### Acute inhalation toxicity

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>LC50 (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 h</td>
<td>&gt; 3.3</td>
</tr>
</tbody>
</table>

**Test atmosphere:** dust/mist

**Remarks:** No mortality observed at this dose.

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>LC50 (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 h</td>
<td>&gt; 3.2</td>
</tr>
</tbody>
</table>

**Test atmosphere:** dust/mist

### Acute toxicity (other routes of administration)

<table>
<thead>
<tr>
<th>Application Route</th>
<th>LD50 (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous</td>
<td>300</td>
</tr>
</tbody>
</table>

**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
Not classified based on available information.

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 sensitizer.

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

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.
Components:

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

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

Orbifloxacin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: equivocal

Test Type: Mouse Lymphoma
Result: positive

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: positive

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

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Application Route: Oral
Result: negative

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

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

Test Type: Chromosomal aberration
Result: negative

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

Orbifloxacin / Posaconazole / Mometasone
Formulation

Version  2.9  Revision Date:  10.10.2020  SDS Number:  439123-00011  Date of last issue:  23.03.2020
Date of first issue:  06.01.2016

Mometasone:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster lung cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: positive
- Test Type: Mouse Lymphoma
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative
- Test Type: Chromosomal aberration
  Species: Rat
  Cell type: Bone marrow
  Result: negative
- Test Type: unscheduled DNA synthesis assay
  Species: Rat
  Cell type: Liver cells
  Result: negative

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

Carcinogenicity:
Not classified based on available information.

Components:

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

Orbifloxacin:
- Species: Rat
- Application Route: Oral
- Exposure time: 2 Years
- NOAEL: 200 mg/kg body weight
- Result: negative
Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 200 mg/kg body weight
Result : negative

**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
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 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

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Test Type</th>
<th>Species</th>
<th>General Toxicity Maternal</th>
<th>Embryo-foetal toxicity</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>Embryo-foetal development</td>
<td>Rat, male</td>
<td>NOAEL: 20 mg/kg body weight</td>
<td>NOAEL: 60 mg/kg body weight</td>
<td></td>
<td></td>
<td>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>
</tr>
<tr>
<td>Oral</td>
<td>Development</td>
<td>Dog</td>
<td>Development Toxicity</td>
<td>LOAEL: 2.5 mg/kg body weight</td>
<td></td>
<td></td>
<td>Effects on postnatal development, Skeletal malformations</td>
</tr>
</tbody>
</table>

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
  - Frequency of Treatment: 6 - 15 days
  - Developmental Toxicity: LOAEL: 29 mg/kg body weight
  - Result: Fetotoxicity, Malformations were observed.
Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

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

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

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

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

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

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

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments, Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
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  
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  
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  
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:
Species: Rat
NOAEL: 0.005 mg/kg
LOAEL: 0.3 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

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.
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone
Formulation

Components:

Mometasone:
Not applicable

Experience with human exposure

Components:

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

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

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

Further information

Components:

Mometasone:
Remarks: Dermal absorption possible

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 tox-:
NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
SAFETY DATA SHEET

Orbifloxacin / Posaconazole / Mometasone Formulation

Version 2.9  Revision Date: 10.10.2020  SDS Number: 439123-00011  Date of last issue: 23.03.2020  Date of first issue: 06.01.2016

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)  Exposure time: 28 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

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

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

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:

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 :

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

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Posaconazole)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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.
Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substances not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
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.

NZ / EN