1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier's details
Company : MSD
Address : No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China 200331
Telephone : +1-908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance : suspension
Colour : white to off-white
Odour : odourless
Causes eye irritation. Toxic to aquatic life with long lasting effects.

GHS Classification
Serious eye damage/eye irritation : Category 2B
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms :  🟡
Signal word : Warning
Hazard statements : H320 Causes eye irritation.
                   H411 Toxic to aquatic life with long lasting effects.
Precautionary statements : Prevention:
                          P264 Wash skin thoroughly after handling.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Orbifloxacin / Posaconazole / Mometasone
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P273 Avoid release to the environment.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes eye irritation.

Environmental hazards
Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Orbifloxacin</td>
<td>113617-63-3</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
## 5. FIREFIGHTING MEASURES

| Suitable extinguishing media | Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during firefighting</td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
</tbody>
</table>
| Specific extinguishing methods | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area. |
| Special protective equipment for firefighters | In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment. |

## 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
|---|---|
| Environmental precautions | Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate contain- |
ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSOAL 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.

Avoidance of contact : Oxidizing agents

Storage
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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (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)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit 10 µg/100 cm² Internal

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

Personal protective equipment

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

Filter type: Combined particulates and organic vapour type

Eye/face 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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.
Orbifloxacin / Posaconazole / Mometasone
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<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></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>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></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>
</tbody>
</table>
Particle size: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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: LD50 (Rat): > 3,000 mg/kg
Remarks: No mortality observed at this dose.
**Orbifloxacin / Posaconazole / Mometasone Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
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<th>Date of first issue:</th>
</tr>
</thead>
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<tr>
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<td>439113-00013</td>
<td>2021/01/04</td>
<td>2016/01/06</td>
</tr>
</tbody>
</table>

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)**

<table>
<thead>
<tr>
<th>LD50 (Rat):</th>
<th>Application Route:</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 200 mg/kg</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>500 mg/kg</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>233 mg/kg</td>
<td>Intravenous</td>
</tr>
<tr>
<td>250 mg/kg</td>
<td>Intravenous</td>
</tr>
</tbody>
</table>

**Posaconazole:**

**Acute oral toxicity**

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

**Acute dermal toxicity**

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

**Mometasone:**

**Acute oral toxicity**

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

**Acute inhalation toxicity**

<table>
<thead>
<tr>
<th>LC50 (Rat):</th>
<th>Exposure time:</th>
<th>Test atmosphere:</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 3.3 mg/l</td>
<td>4 h</td>
<td>dust/mist</td>
</tr>
<tr>
<td>&gt; 3.2 mg/l</td>
<td>4 h</td>
<td>dust/mist</td>
</tr>
</tbody>
</table>

**Acute toxicity (other routes of administration)**

<table>
<thead>
<tr>
<th>LD50 (Rat):</th>
<th>Application Route:</th>
<th>Symptoms:</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg/kg</td>
<td>Subcutaneous</td>
<td>Breathing difficulties</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

Not classified based on available information.
# Orbifloxacin / Posaconazole / Mometasone Formulation

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</tbody>
</table>

**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>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Draize Test</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>
</tbody>
</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>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye 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 eye irritation</td>
</tr>
</tbody>
</table>

**Orbifloxacin:**
<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
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</tbody>
</table>

**Posaconazole:**
<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>
Orbifloxacin / Posaconazole / Mometasone
Formulation

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.

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
SAFETY DATA SHEET
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Result: negative

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

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

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

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

Carcinogenicity
Not classified based on available information.

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

Orbifloxacin:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
NOAEL: 200 mg/kg body weight
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Orbifloxacin / Posaconazole / Mometasone Formulation

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</tr>
</tbody>
</table>

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 / Posaconazole / Mometasone
Formulation

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Orbifloxacin:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity - Parent: NOAEL: 50 mg/kg body weight
Early Embryonic Development: NOAEL: 50 mg/kg body weight
Result: No adverse effects

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

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain

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

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

Posaconazole:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity - Parent: NOAEL: 180 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity - Parent: NOAEL: 45 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat, female
Orbifloxacin / Posaconazole / Mometasone
Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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</thead>
<tbody>
<tr>
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<td>2021/08/27</td>
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<td>2021/01/04</td>
<td>2016/01/06</td>
</tr>
</tbody>
</table>

Application Route: Oral
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rabbit, female
Developmental Toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity

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: \(\geq 1\) 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
### Orbifloxacin / Posaconazole / Mometasone Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testis, Liver, Kidney, spleen</td>
</tr>
</tbody>
</table>

| Species | Mouse                   |
| NOAEL   | 80 mg/kg                |
| LOAEL   | 250 mg/kg               |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Heart, Bone</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Gastrointestinal disturbance</td>
</tr>
<tr>
<td>Remarks</td>
<td>mortality observed</td>
</tr>
</tbody>
</table>

| Species | Juvenile dog            |
| NOAEL   | 50 mg/kg                |
| LOAEL   | 250 mg/kg               |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>14 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Heart, Bone</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Gastrointestinal disturbance</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

| Species | Dog                   |
| NOAEL   | 2 mg/kg               |
| LOAEL   | 3 mg/kg               |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone</td>
</tr>
</tbody>
</table>

| Species | Cat                   |
| NOAEL   | 7.5 mg/kg             |
| LOAEL   | 22.5 mg/kg            |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>1 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td></td>
</tr>
</tbody>
</table>

| Species | Rat, female           |
| LOAEL   | 5 mg/kg               |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>6 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary</td>
</tr>
</tbody>
</table>

| Species | Dog                   |
| LOAEL   | 3 mg/kg               |

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>392 Days</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue</td>
</tr>
</tbody>
</table>
### Or bifloxacin / Posaconazole / Mometasone Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th></th>
<th>LOAEL</th>
<th></th>
<th>Application Route</th>
<th></th>
<th>Exposure time</th>
<th></th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td></td>
<td>15 mg/kg</td>
<td></td>
<td>Oral</td>
<td></td>
<td>1 Months</td>
<td></td>
<td>Bone marrow, Adrenal gland, Lymph nodes, Blood</td>
</tr>
<tr>
<td>Dog</td>
<td></td>
<td>3 mg/kg</td>
<td></td>
<td>Oral</td>
<td></td>
<td>56 Weeks</td>
<td></td>
<td>Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue</td>
</tr>
<tr>
<td>Monkey</td>
<td></td>
<td>180 mg/kg</td>
<td></td>
<td>Oral</td>
<td></td>
<td>12 Months</td>
<td></td>
<td>Blood, Gastrointestinal tract, spleen</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td>8 mg/kg</td>
<td></td>
<td>Intravenous</td>
<td></td>
<td>1 Months</td>
<td></td>
<td>Cardio-vascular system, Lungs, Adrenal gland, Blood</td>
</tr>
<tr>
<td>Rat</td>
<td></td>
<td>0.005 mg/kg</td>
<td></td>
<td>Oral</td>
<td></td>
<td>30 d</td>
<td></td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td></td>
<td>30 d</td>
<td></td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td>0.00013 mg/l</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td></td>
<td>90 d</td>
<td></td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Species</td>
<td></td>
<td>0.0005 mg/l</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td></td>
<td>90 d</td>
<td></td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow,</td>
</tr>
</tbody>
</table>
Kidney, thymus gland, Liver

Aspiration toxicity
Not classified based on available information.

Components:
Mometasone:
Not applicable

Experience with human exposure

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

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

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

Further information

Components:
Mometasone:
Remarks: Dermal absorption possible

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Orbifloxacin / Posaconazole / Mometasone
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</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants:**
- NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**Toxicity to fish (Chronic toxicity):**
- NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
  - Exposure time: 28 d

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

**Posaconazole:**

**Toxicity to fish:**
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility

**Toxicity to daphnia and other aquatic invertebrates:**
- EC50 (Daphnia magna (Water flea)): 0.276 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants:**
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity):**
- 1

**Toxicity to fish (Chronic toxicity):**
- NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l
  - Exposure time: 33 d
  - Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**
- NOEC (Daphnia magna (Water flea)): 0.244 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
  - Remarks: No toxicity at the limit of solubility

**M-Factor (Chronic aquatic toxicity):**
- 1

**Toxicity to microorganisms:**
- EC50 (Natural microorganism): > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**Mometasone:**

**Toxicity to fish:**
- LC50 (Menidia beryllina (Silverside)): 0.11 mg/l
Orbifloxacin / Posaconazole / Mometasone
Formulation

Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

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

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

M-Factor (Chronic aquatic toxicity):
100

Toxicity to microorganisms:
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:
White mineral oil (petroleum):
**Biodegradability**

<table>
<thead>
<tr>
<th>Component</th>
<th>Result: Not readily biodegradable.</th>
<th>Biodegradation</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posaconazole</td>
<td></td>
<td><strong>31 %</strong></td>
<td><strong>28 d</strong></td>
</tr>
<tr>
<td>Mometasone</td>
<td></td>
<td><strong>50 %</strong></td>
<td><strong>28 d</strong></td>
</tr>
</tbody>
</table>

**Stability in water**

<table>
<thead>
<tr>
<th>Component</th>
<th>Degradation half life (DT50):</th>
<th>Method: OECD Test Guideline 111</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posaconazole</td>
<td>&gt; 30 d</td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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**
mental compartments

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Posaconazole)
Class : 9
Packing group : III
Labels : 9

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

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

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

National Regulations
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Orbifloxacin / Posaconazole / Mometasone
Formulation

Version 3.10 Revision Date: 2021/08/27 SDS Number: 439113-00013 Date of last issue: 2021/01/04
Date of first issue: 2016/01/06

GB 6944/12268
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Posaconazole)

Class : 9
Packing group : III
Labels : 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

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

Disclaimer
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.

CN / EN