# SAFETY DATA SHEET

## Orbifloxacin / Posaconazole / Mometasone Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
|---|---|---|---|
| 7.0 | 03.12.2024 | 439123-00019 | Date of first issue: 06.01.2016 |

### 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 : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product
Restrictions on use : Not applicable

### Section 2: Hazard identification

**GHS Classification**

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 2

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H319 Causes serious eye irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| White mineral oil (petroleum) | 8042-47-5 | >= 50 -< 70 |
| Orbifloxacin | 113617-63-3 | >= 1 -< 10 |
| Mometasone | 83919-23-7 | >= 0.1 -< 0.25 |
| Posaconazole | 171228-49-2 | >= 0.1 -< 0.25 |

## Section 4: First-aid measures

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

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.

| | | |
|---|---|---|
| | | Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>May damage the unborn child. Suspected of damaging fertility. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Hazchem Code | : | 3Z |

## Section 6: Accidental release measures

| | | |
|---|---|---|
| Personal precautions, protective equipment and emer- | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal pro- |

| | | |
|---|---|---|
| gency procedures | | tective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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.<br>Do not breathe vapours or spray mist.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| White mineral oil (petroleum) | 8042-47-5 | WES-TWA (Mist) | 5 mg/m3 | NZ OEL |
| | | WES-STEL (Mist) | 10 mg/m3 | NZ OEL |
| | | TWA (Inhalable particulate matter) | 5 mg/m3 | ACGIH |
| Orbifloxacin | 113617-63-3 | TWA | 0.2 mg/m3 (OEB 2) | Internal |
| Posaconazole | 171228-49-2 | TWA | 300 µg/m3 (OEB 2) | Internal |
| Mometasone | 83919-23-7 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm² | Internal |

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.
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 poten-

tial 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 | | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Eye protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing. |

## Section 9: Physical and chemical properties

| | | |
|---|---|---|
| Appearance | : | suspension |
| Colour | : | white to off-white |
| Odour | : | odourless |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |

| | | |
|---|---|---|
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour 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 |
| Auto-ignition 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 characteristics | | |
| 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<br>Skin contact<br>Ingestion |

Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Remarks: No significant adverse effects were reported<br>No mortality observed at this dose. |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Orbifloxacin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 3,000 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>LD50 (Mouse): > 2,000 mg/kg<br>Remarks: No mortality observed at this dose.<br><br>LD50 (Dog): > 600 mg/kg<br>Symptoms: Vomiting<br>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<br>Application Route: Intramuscular<br><br>LD50 (Mouse): 500 mg/kg<br>Application Route: Intramuscular<br><br>LD50 (Rat): 233 mg/kg |

| | | |
|---|---|---|
| | | Application Route: Intravenous<br><br>LD50 (Mouse): 250 mg/kg<br>Application Route: Intravenous |

**Mometasone:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br><br>LD50 (Mouse): > 2,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 3.3 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose.<br><br>LC50 (Mouse): > 3.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 300 mg/kg<br>Application Route: Subcutaneous<br>Symptoms: Breathing difficulties |

**Posaconazole:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br><br>LD50 (Mouse): > 3,000 mg/kg |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg |

**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 |

**Mometasone:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**Posaconazole:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Product:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

**Components:**

**White mineral oil (petroleum):**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Orbifloxacin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |
| Method | : | Draize Test |

**Mometasone:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Posaconazole:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild 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. |

**Mometasone:**

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

**Posaconazole:**

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

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

**Orbifloxacin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: equivocal<br><br>Test Type: Mouse Lymphoma<br>Result: positive<br><br>Test Type: Chromosomal aberration<br>Test system: Human lymphocytes<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Intraperitoneal injection<br>Result: negative<br><br>Test Type: unscheduled DNA synthesis assay<br>Species: Rat<br>Cell type: Liver cells<br>Application Route: Oral<br>Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

**Mometasone:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Chinese hamster lung cells<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Test system: Chinese hamster ovary cells<br>Result: positive<br><br>Test Type: Mouse Lymphoma<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative<br><br>Test Type: Chromosomal aberration<br>Species: Rat |

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

**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 |

**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 |

**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. |

**Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

**Components:**

**White mineral oil (petroleum):**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Skin contact<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Orbifloxacin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>General Toxicity - Parent: NOAEL: 50 mg/kg body weight<br>Early Embryonic Development: NOAEL: 50 mg/kg body weight |

| | | |
|---|---|---|
| | | Result: No adverse effects |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight<br>Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>General Toxicity Maternal: NOAEL: 20 mg/kg body weight<br>Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight<br>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<br><br>Test Type: Development<br>Species: Dog<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 2.5 mg/kg body weight<br>Result: Effects on postnatal development, Skeletal malformations |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments. |

**Mometasone:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0.015 mg/kg body weight<br>Symptoms: Reduced embryonic survival, Reduced foetal weight<br>Result: No effects on fertility, Effect on reproduction capacity |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight<br>Result: Embryotoxic effects., Teratogenicity and developmental toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight |

| | | |
|---|---|---|
| | | Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight<br>Result: Embryo-foetal toxicity, Malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight<br>Result: Effects on newborn<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight<br>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. |

**Posaconazole:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat, male<br>General Toxicity - Parent: NOAEL: 180 mg/kg body weight<br>Symptoms: No effects on mating performance<br>Result: negative<br><br>Test Type: Fertility/early embryonic development<br>Species: Rat, female<br>General Toxicity - Parent: NOAEL: 45 mg/kg body weight<br>Symptoms: No effects on mating performance<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat, female<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 29 mg/kg body weight<br>Result: Fetotoxicity, Malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit, female<br>Developmental Toxicity: LOAEL: 40 mg/kg body weight<br>Result: Fetotoxicity |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, 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:**

**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. |

**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. |

**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 |

**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 |

**Posaconazole:**

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

| | | |
|---|---|---|
| Species | : | Dog |
| LOAEL | : | 3 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 392 Days |
| Target Organs | : | Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 15 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 Months |
| Target Organs | : | Bone marrow, Adrenal gland, Lymph nodes, Blood |

| | | |
|---|---|---|
| Species | : | Dog |
| LOAEL | : | 3 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 56 Weeks |
| Target Organs | : | Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 180 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 12 Months |
| Target Organs | : | Blood, Gastrointestinal tract, spleen |

| | | |
|---|---|---|
| Species | : | Monkey |

| | | |
|---|---|---|
| LOAEL | : | 8 mg/kg |
| Application Route | : | Intravenous |
| Exposure time | : | 1 Months |
| Target Organs | : | Cardio-vascular system, Lungs, Adrenal gland, Blood |

**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<br>Remarks: May cause photosensitisation. |

**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 |

**Posaconazole:**

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

**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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l<br>Exposure time: 28 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1,000 mg/l<br>Exposure time: 21 d |

**Mometasone:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Menidia beryllina (Silverside)): 0.11 mg/l<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility<br><br>LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l<br>Exposure time: 7 d<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility<br><br>EC50 (Americamysis): > 5 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.34 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility |

| | | |
|---|---|---|
| M-Factor (Chronic aquatic toxicity) | : | 100 |
| Toxicity to microorganisms | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC: 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility |

**Posaconazole:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0.276 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l<br>Exposure time: 72 h<br>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<br>Exposure time: 33 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.244 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility |
| M-Factor (Chronic aquatic toxicity) | : | 1 |
| Toxicity to microorganisms | : | EC50 (Natural microorganism): > 1,000 mg/l<br>Exposure time: 3 h |

Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**

**White mineral oil (petroleum):**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 31 %<br>Exposure time: 28 d |

**Mometasone:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
| Stability in water | : | Hydrolysis: 50 %(12 d)<br>Method: OECD Test Guideline 111 |

**Posaconazole:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 28 h<br>Method: OECD Test Guideline 314 |
| Stability in water | : | Degradation half life (DT50): > 30 d<br>Method: OECD Test Guideline 111 |

**Bioaccumulative potential**

**Components:**

**Mometasone:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 107.1<br>Method: OECD Test Guideline 305 |
| Partition coefficient: n-octanol/water | : | log Pow: 4.68 |

**Posaconazole:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 20<br>Method: OECD Test Guideline 305 |
| Partition coefficient: n-octanol/water | : | log Pow: 4.15 |

**Mobility in soil**

**Components:**

**Mometasone:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 4.02 |

**Posaconazole:**

| | | |
|---|---|---|
| Distribution among environmental compartments | : | log Koc: 5.52 |

**Other adverse effects**

No data available

## Section 13: Disposal considerations

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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.<br>(Mometasone, Posaconazole) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s.<br>(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 |
| Marine pollutant | : | no |

**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**

**HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

**HSW Controls**

Certified handler certificate not required.
Tracking hazardous substance 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

| | | |
|---|---|---|
| Revision Date | : | 03.12.2024 |

**Further information**

| | | |
|---|---|---|
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

| | | |
|---|---|---|
| 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 |

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 Substanc-

es; (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

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