

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0      Revision Date: 03.12.2024      SDS Number: 439109-00020      Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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### SECTION 1. IDENTIFICATION

Product identifier : Orbifloxacin / Posaconazole / Mometasone Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Eye irritation : Category 2B

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H320 Causes eye irritation.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**

P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.

**Response:**

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

easy to do. Continue rinsing.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P391 Collect spillage.

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name                 | CAS-No.     | Classification  | Concentration (% w/w) |
|-------------------------------|-------------|---|-----------------------|
| White mineral oil (petroleum) | 8042-47-5   |   | >= 50 - < 70          |
| Orbifloxacin                  | 113617-63-3 | Acute Tox. (Oral), 5<br>Repr., 2  | >= 1 - < 3            |
| Posaconazole                  | 171228-49-2 | Eye Irrit., 2B<br>Repr., 2<br>STOT RE,<br>(Oral)(Adrenal gland,<br>Bone marrow, Kidney,<br>Liver, Nervous system,<br>Reproductive organs) , 1<br>Aquatic Acute, 1<br>Aquatic Chronic, 1 | >= 0,1 - < 0,25       |
| Mometasone                    | 83919-23-7  | Repr., 1B<br>STOT RE, (Inhalation)(Immune system,<br>Liver, Kidney, Skin) , 2<br>Aquatic Chronic, 1   | >= 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.  
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.

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

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|   |   |
|---|---|
| If swallowed  | If easy to do, remove contact lens, if worn.<br>Get medical attention.  |
| Most important symptoms and effects, both acute and delayed | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Protection of first-aiders                                  | : Causes eye irritation.  |
| Notes to physician  | : 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). |
|   | : Treat symptomatically and supportively.   |

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**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 fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

Methods and materials for containment and cleaning up : Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe vapors or spray mist. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

# Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 28.09.2024  
6.0 03.12.2024 439109-00020 Date of first issue: 06.01.2016

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

| Components                    | CAS-No.                   | Value type<br>(Form of<br>exposure)         | Control parame-<br>ters / Permissible<br>concentration | Basis    |
|-------------------------------|---------------------------|---|--|----------|
| White mineral oil (petroleum) | 8042-47-5                 | TWA<br>(Inhalable<br>particulate<br>matter) | 5 mg/m <sup>3</sup>                                    | ACGIH    |
| Orbifloxacin                  | 113617-63-3               | TWA   | 0.2 mg/m <sup>3</sup> (OEB<br>2)                       | Internal |
| Posaconazole                  | 171228-49-2               | TWA   | 300 µg/m <sup>3</sup> (OEB<br>2)                       | Internal |
| Mometasone                    | 83919-23-7                | TWA   | 1 µg/m <sup>3</sup> (OEB 4)                            | Internal |
|                               | Further information: Skin |   |  |          |
|                               |                           | Wipe limit                                  | 10 µg/100 cm <sup>2</sup>                              | 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 potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops. |
|----------------------|--|
|----------------------|--|

## Personal protective equipment

|                        |  |
|------------------------|--|
| Respiratory protection | : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type            | : Combined particulates and organic vapor type   |
| Hand protection        |  |
| Material               | : Chemical-resistant gloves  |
| Remarks                | : Consider double gloving.   |
| Eye protection         | : Wear safety glasses with side shields or goggles.  |

**Orbifloxacin / Posaconazole / Mometasone Formulation**

Version 6.0

Revision Date: 03.12.2024

SDS Number: 439109-00020

Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

|                          |  |
|--------------------------|--|
|                          | <p>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</p> <p>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</p>   |
| Skin and body protection | <p>: Work uniform or laboratory coat.</p> <p>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p> |

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

|  |                      |
|--|----------------------|
| Physical state                                   | : suspension         |
| Color  | : white to off-white |
| Odor   | : odorless           |
| Odor Threshold                                   | : No data available  |
| pH   | : No data available  |
| Melting point/freezing point                     | : No data available  |
| Initial boiling point and boiling range          | : No data available  |
| Flash point                                      | : No data available  |
| Evaporation rate                                 | : No data available  |
| Flammability (solid, gas)                        | : Not applicable     |
| Flammability (liquids)                           | : No data available  |
| Upper explosion limit / Upper flammability limit | : No data available  |
| Lower explosion limit / Lower flammability limit | : No data available  |
| Vapor pressure                                   | : No data available  |
| Relative vapor density                           | : No data available  |
| Relative density                                 | : No data available  |
| Density  | : No data available  |
| Solubility(ies)                                  |                      |
| Water solubility                                 | : No data available  |

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0      Revision Date: 03.12.2024      SDS Number: 439109-00020      Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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|  |   |  |
|--|---|--|
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Autoignition temperature               | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              |   |  |
| Viscosity, kinematic                   | : | No data available  |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics               |   |  |
| Particle size                          | : | Not applicable   |

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## 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. |

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## SECTION 11. TOXICOLOGICAL INFORMATION

|  |   |              |
|--|---|--------------|
| Information on likely routes of exposure | : | Inhalation   |
|  |   | Skin contact |
|  |   | Ingestion    |
|  |   | Eye contact  |

### Acute toxicity

Not classified based on available information.

#### Product:

|                       |   |   |
|-----------------------|---|---|
| Acute oral toxicity   | : | LD50 (Rat): > 2.000 mg/kg                             |
|                       |   | Remarks: No significant adverse effects were reported |
|                       |   | No mortality observed at this dose.                   |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg                             |
|                       |   | Remarks: No significant adverse effects were reported |

#### Components:

##### **White mineral oil (petroleum):**

|                           |   |  |
|---------------------------|---|--|
| Acute oral toxicity       | : | LD50 (Rat): > 5.000 mg/kg                  |
| Acute inhalation toxicity | : | LC50 (Rat): > 5 mg/l<br>Exposure time: 4 h |

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Orbifloxacin:**

Acute oral toxicity : LD50 (Rat): > 3.000 mg/kg  
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2.000 mg/kg  
Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg  
Symptoms: Vomiting  
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg  
Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg  
Application Route: Intramuscular

LD50 (Rat): 233 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 250 mg/kg  
Application Route: Intravenous

**Posaconazole:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
LD50 (Mouse): > 3.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

**Mometasone:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
LD50 (Mouse): > 2.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3,3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

LC50 (Mouse): > 3,2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg  
Application Route: Subcutaneous  
Symptoms: Breathing difficulties

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

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**

Causes eye irritation.

**Product:**

Species : Rabbit  
Result : Mild eye irritation

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

Species : Rabbit  
Result : No eye irritation

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016**Orbifloxacin:**

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

**Posaconazole:**

Species : Rabbit  
Result : Mild eye irritation

**Mometasone:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Product:**

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

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

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

**Orbifloxacin:**

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

**Posaconazole:**

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

**Mometasone:**

Test Type : Maximization Test  
Routes of exposure : Dermal

**Orbifloxacin / Posaconazole / Mometasone Formulation**

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|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

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Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Result : negative  
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

**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

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

Test Type: Chromosomal aberration  
Result: negative

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

**Mometasone:**

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

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

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

Test Type: Mouse Lymphoma  
Result: negative

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

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

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

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

**Carcinogenicity**

Not classified based on available information.

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

Species : Rat  
Application Route : Ingestion  
Exposure time : 24 Months  
Result : negative

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016**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                                      |

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Orbifloxacin:**

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

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

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

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

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

**Posaconazole:**

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

Test Type: Fertility/early embryonic development  
Species: Rat, female  
General Toxicity Parent: NOAEL: 45 mg/kg body weight

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

Symptoms: No effects on mating performance.  
Result: negative

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

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

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

**Mometasone:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 0,015 mg/kg body weight  
Symptoms: Reduced embryonic survival, Reduced fetal weight.  
Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Subcutaneous  
Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight  
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Dermal  
Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight  
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Dermal  
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight  
Result: Embryo-fetal toxicity., Malformations were observed.

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

Test Type: Embryo-fetal development  
Species: Rabbit

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

Application Route: Oral  
Embryo-fetal toxicity.: LOAEL: 0,7 mg/kg body weight  
Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

**STOT-single exposure**

Not classified based on available information.

**Components:****Mometasone:**

Remarks : Based on available data, the classification criteria are not met.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Posaconazole:**

Routes of exposure : Ingestion  
Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Mometasone:**

Routes of exposure : inhalation (dust/mist/fume)  
Target Organs : Immune system, Liver, Kidney, Skin  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****White mineral oil (petroleum):**

Species : Rat  
LOAEL : 160 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

Species : Rat  
LOAEL : >= 1 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 4 Weeks  
Method : OECD Test Guideline 412

**Orbifloxacin:**

## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0      Revision Date: 03.12.2024

SDS Number:  
439109-00020

Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

|                      |   |   |
|----------------------|---|---|
| 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                              |
| <b>Posaconazole:</b> |   |   |
| 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  |

## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0      Revision Date: 03.12.2024

SDS Number:  
439109-00020

Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

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Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, 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 photosensitization.

**Posaconazole:**

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

**Mometasone:**

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

Skin contact : Symptoms: Dermatitis, Itching

**Further information****Components:****Mometasone:**

Remarks : Dermal absorption possible

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**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

**Orbifloxacin / Posaconazole / Mometasone Formulation**

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

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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

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,041 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  
Exposure time: 96 h

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version  
6.0

Revision Date:  
03.12.2024

SDS Number:  
439109-00020

Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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 : Result: Not readily biodegradable.  
Biodegradation: 31 %

**Orbifloxacin / Posaconazole / Mometasone Formulation**Version  
6.0Revision Date:  
03.12.2024SDS Number:  
439109-00020Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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:**

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

**Bioaccumulative potential****Components:****Posaconazole:**

- Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 20  
Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water : log Pow: 4,15

**Mometasone:**

- Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 107,1  
Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water : log Pow: 4,68

**Mobility in soil****Components:****Posaconazole:**

- Distribution among environmental compartments : log Koc: 5,52

**Mometasone:**

- Distribution among environmental compartments : log Koc: 4,02

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0 Revision Date: 03.12.2024 SDS Number: 439109-00020 Date of last issue: 28.09.2024 Date of first issue: 06.01.2016

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

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

#### IATA-DGR

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

#### IMDG-Code

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

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version 6.0      Revision Date: 03.12.2024      SDS Number: 439109-00020      Date of last issue: 28.09.2024  
Date of first issue: 06.01.2016

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### ANTT

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Mometasone, Posaconazole)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

### Special precautions for user

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

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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable  
Brazil. List of chemicals controlled by the Federal Police : Not applicable

### The ingredients of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 03.12.2024  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material 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.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ACGIH / TWA : 8-hour, time-weighted average

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

|                |                              |                             |   |
|----------------|------------------------------|-----------------------------|---|
| Version<br>6.0 | Revision Date:<br>03.12.2024 | SDS Number:<br>439109-00020 | Date of last issue: 28.09.2024<br>Date of first issue: 06.01.2016 |
|----------------|------------------------------|-----------------------------|---|

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

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.

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