

# SAFETY DATA SHEET



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version  
8.1

Revision Date:  
2025/04/14

SDS Number:  
439119-00022

Date of last issue: 2024/12/03  
Date of first issue: 2016/01/06

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Orbifloxacin / Posaconazole / Mometasone Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Serious eye damage/eye irritation : Category 2B

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Warning

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

Precautionary statements :

#### Prevention:

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

#### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water

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for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P391 Collect spillage.

### Disposal:

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

### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
White mineral oil (petroleum)	8042-47-5	>= 60 - < 70	9-1700
Orbifloxacin	113617-63-3	>= 1 - < 3	-
Mometasone	83919-23-7	>= 0.1 - < 0.25	
Posaconazole	171228-49-2	>= 0.1 - < 0.25	

## 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.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes eye irritation.

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- 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.
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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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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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**7. HANDLING AND STORAGE****Handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapours or spray mist.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- 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.

**Storage**

- Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Inhal- able particu- late matter)	5 mg/m <sup>3</sup>	ACGIH
Orbifloxacin	113617-63-3	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Posaconazole	171228-49-2	TWA	300 µg/m <sup>3</sup> (OEB 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 vapour type

Hand protection

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: suspension
Colour	: white to off-white
Odour	: odourless
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Up- per flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: No data available
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: No data available

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Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: No data available
Density and / or relative density	
Relative density	: No data available
Density	: No data available
Relative vapour density	: 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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## 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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## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	: Inhalation Skin contact Ingestion Eye contact
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### Acute toxicity

Not classified based on available information.

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**Product:**

- Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: No significant adverse effects were reported  
No mortality observed at this dose.
- Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: No significant adverse effects were reported

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

- Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Orbifloxacin:**

- Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg  
Remarks: No mortality observed at this dose.
- LD50 (Mouse): > 2,000 mg/kg  
Remarks: No mortality observed at this dose.
- LD50 (Dog): > 600 mg/kg  
Symptoms: Vomiting  
Remarks: No mortality observed at this dose.
- Acute inhalation toxicity : Remarks: No data available
- Acute dermal toxicity : Remarks: No data available
- Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg  
Application Route: Intramuscular
- LD50 (Mouse): 500 mg/kg  
Application Route: Intramuscular
- LD50 (Rat): 233 mg/kg  
Application Route: Intravenous
- LD50 (Mouse): 250 mg/kg  
Application Route: Intravenous

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### **Mometasone:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3.3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

LC50 (Mouse): > 3.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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

### **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

### **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

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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:**

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.

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### 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

#### **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)
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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.

**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

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Species: Rat  
Cell type: Liver cells  
Result: negative

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

**Posaconazole:**

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

Test Type: Chromosomal aberration  
Result: negative

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

**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

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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**

Not classified based on available information.

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

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

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

**Orbifloxacin:**

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

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat

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

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

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

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

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

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

Test Type: Embryo-foetal development  
Species: Rabbit

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

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

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

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

**Posaconazole:**

Effects on fertility

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

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

Effects on foetal development

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

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

Reproductive toxicity - Assessment

: Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

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### 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

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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>Mometasone:</b>		
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)

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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

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**Aspiration toxicity**

Not classified based on available information.

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

Not applicable

**Experience with human exposure****Components:****Orbifloxacin:**

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

**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

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**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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l

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aquatic invertebrates	Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic 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
<b>Mometasone:</b>	
Toxicity to fish	: LC50 (Menidia beryllina (Silverside)): 0.11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility
	LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l Exposure time: 7 d Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
	EC50 (Americamysis): > 5 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.34 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic)	: 100

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toxicity)

- 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

**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

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Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

**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

**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

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

**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

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### Mobility in soil

#### Components:

##### **Mometasone:**

Distribution among environmental compartments : log Koc: 4.02

##### **Posaconazole:**

Distribution among environmental compartments : log Koc: 5.52

#### **Hazardous to the ozone layer**

Not applicable

#### **Other adverse effects**

No data available

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## 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

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

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.

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## 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

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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

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

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## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

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Not applicable

**Substances Subject to be Notified Names**

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Mineral oil	>=60 - <70	-

**Substances Subject to be Indicated Names**

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Mineral oil	-

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

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### Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)  
Pack transportation : Classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)  
Not applicable  
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)  
Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

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

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## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

### 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/>  
Date format : yyyy/mm/dd

### Full text of other abbreviations

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

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

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- 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.

JP / EN