

**Orbifloxacin / Posaconazole / Mometasone  
Formulation**

Version 5.0      Revision Date: 2023/09/30      SDS Number: 439119-00018      Date of last issue: 2023/04/04  
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 : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

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:**

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

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

P391 Collect spillage.

### Disposal:

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

### 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 : Causes eye irritation.

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delayed  
 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.  
 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 deter-

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mine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/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.

### 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	Control parameters / Reference	Basis
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		exposure)	concentration / Permissible concentration	
White mineral oil (petroleum)	8042-47-5	TWA (Inhalable particulate 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** : 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**

**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

# SAFETY DATA SHEET



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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- : No data available  
per flammability limit

Lower explosion limit / : No data available  
Lower flammability limit

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n- : Not applicable  
octanol/water

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

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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

**Acute toxicity**

Not classified based on available information.

**Product:**

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

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: No significant adverse effects were reported

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

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

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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

### 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



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**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

**Posaconazole:**

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

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### Orbifloxacin:

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

### Mometasone:

Species	: Rabbit
Result	: No eye irritation

### Posaconazole:

Species	: Rabbit
Result	: Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Product:

Test Type	: Magnusson-Kligman-Test
Exposure routes	: Dermal
Result	: Not a skin sensitizer.

### Components:

#### White mineral oil (petroleum):

Test Type	: Buehler Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

### Orbifloxacin:

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

### Mometasone:

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

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|| 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)  
 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 - : Weight of evidence does not support classification as a germ

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Assessment 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  
 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

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### Carcinogenicity

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

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

#### Orbifloxacin:

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

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

#### Mometasone:

Species	: Rat
Application Route	: Inhalation
Exposure time	: 2 Years
Dose	: 0.067 mg/kg body weight
Result	: negative

Species	: Mouse
Application Route	: Inhalation
Exposure time	: 19 Months
Dose	: 0.160 mg/kg body weight
Result	: negative

#### Posaconazole:

Species	: Rat
Application Route	: oral (feed)
Exposure time	: 2 Years
Result	: positive
Remarks	: The mechanism or mode of action is not relevant in humans.

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
Result	: positive
Remarks	: The mechanism or mode of action is not relevant in humans.

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### 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 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

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

### Mometasone:

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

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

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

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

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

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

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

### Posaconazole:

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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.

#### 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



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|| exposure.

## Repeated dose toxicity

### Components:

#### White mineral oil (petroleum):

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

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

#### Orbifloxacin:

|| Species : Rat  
 || NOAEL : 20 mg/kg  
 || LOAEL : 80 mg/kg  
 || Application Route : Oral  
 || Exposure time : 3 Months  
 || Target Organs : Testis, Liver, Kidney, spleen

|| Species : Mouse  
 || NOAEL : 80 mg/kg  
 || LOAEL : 250 mg/kg  
 || Application Route : Oral  
 || Exposure time : 3 Months

|| Species : Juvenile dog  
 || NOAEL : 50 mg/kg  
 || LOAEL : 250 mg/kg  
 || Application Route : Oral  
 || Exposure time : 14 Days  
 || Target Organs : Heart, Bone  
 || Symptoms : Gastrointestinal disturbance  
 || Remarks : mortality observed

|| Species : Juvenile dog  
 || NOAEL : 2 mg/kg  
 || LOAEL : 3 mg/kg  
 || Application Route : Oral  
 || Exposure time : 90 Days  
 || Target Organs : Bone  
 || Remarks : No significant adverse effects were reported

|| Species : Dog

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NOAEL : 37.5 mg/kg  
 Application Route : Oral  
 Exposure time : 30 Days

Species : Cat  
 NOAEL : 7.5 mg/kg  
 LOAEL : 22.5 mg/kg  
 Application Route : Oral  
 Exposure time : 1 Months  
 Symptoms : Gastrointestinal disturbance

### Mometasone:

Species : Rat  
 NOAEL : 0.005 mg/kg  
 LOAEL : 0.3 mg/kg  
 Application Route : Oral  
 Exposure time : 30 d  
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog  
 LOAEL : 0.5 mg/kg  
 Application Route : Oral  
 Exposure time : 30 d  
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat  
 NOAEL : 0.00013 mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 90 d  
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species : Dog  
 NOAEL : 0.0005 mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 90 d  
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

### Posaconazole:

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

Species : Dog  
 LOAEL : 3 mg/kg  
 Application Route : Oral

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Exposure time : 392 Days  
 Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

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

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

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

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

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Mometasone:

Not applicable

### Experience with human exposure

### Components:

#### Orbifloxacin:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash  
 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

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|| 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

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**White mineral oil (petroleum):**

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

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

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

|| Toxicity to fish (Chronic 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

**Mometasone:**

|| Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l  
Exposure time: 7 d

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	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

### 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

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		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

### Persistence and degradability

#### Components:

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

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:**

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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

### Mobility in soil

#### Components:

##### **Mometasone:**

Distribution among environmental compartments	:	log Koc: 4.02
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##### **Posaconazole:**

Distribution among environmental compartments	:	log Koc: 5.52
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### 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 han-

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ding site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

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

### 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.



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ERG Code : 171

## 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

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

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

#### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Mineral oil	-

#### 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

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**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)

**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****Further information**

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

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

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

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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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