

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Orbifloxacin / Posaconazole / Mometasone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.12	09/28/2024	439125-00019	Date of first issue: 01/06/2016

### SECTION 1. IDENTIFICATION

Product name : Orbifloxacin / Posaconazole / Mometasone Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Eye irritation : Category 2B

Reproductive toxicity : Category 1B

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H320 Causes eye irritation.  
H360Df May damage the unborn child. Suspected of damaging fertility.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

#### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308 + P313 IF exposed or concerned: Get medical attention.

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

### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	$\geq 50 - < 70$
Polyethylene glycol	25322-68-3	$\geq 30 - < 50$
Orbifloxacin	113617-63-3	$\geq 1 - < 5$
Posaconazole	171228-49-2	$\geq 0.1 - < 1$
Mometasone	83919-23-7	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

## 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.  
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.  
May damage the unborn child. Suspected of damaging fertility.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### SECTION 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 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

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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.

### 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.
- 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Mist)	5 mg/m <sup>3</sup>	NIOSH REL
		ST (Mist)	10 mg/m <sup>3</sup>	NIOSH REL
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL
Orbifloxacin	113617-63-3	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal

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Posaconazole	171228-49-2	TWA	300 µg/m3 (OEB 2)	Internal
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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.

**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

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engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	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
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available

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Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle size	:	Not applicable

### SECTION 10. STABILITY AND REACTIVITY

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

### SECTION 11. TOXICOLOGICAL INFORMATION

#### 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

### Polyethylene glycol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### 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



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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

### 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

##### Polyethylene glycol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

##### Orbifloxacin:

Species : Rabbit  
Method : Draize Test  
Result : No skin irritation

##### Posaconazole:

Species : Rabbit  
Result : No skin irritation

##### Mometasone:

Species : Rabbit  
Result : No skin irritation

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### 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

##### Polyethylene glycol:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

##### 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.

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### Components:

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

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

#### **Polyethylene glycol:**

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

#### **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
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

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Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### Polyethylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### Orbifloxacin:

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

Test Type: Mouse Lymphoma  
Result: positive

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: positive

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

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

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

### Posaconazole:

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

Test Type: Chromosomal aberration  
Result: negative

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

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

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

#### Orbifloxacin:

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

Species	: Mouse
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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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### White mineral oil (petroleum):

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

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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

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General Toxicity Parent: NOAEL: 45 mg/kg body weight  
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.



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Test Type: Embryo-fetal development  
Species: Rabbit  
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 :  $\geq 1$  mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 4 Weeks  
Method : OECD Test Guideline 412

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## Orbifloxacin / Posaconazole / Mometasone Formulation

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### Orbifloxacin:

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

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

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

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

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

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

### 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

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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

### 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

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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

### 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
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#### 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

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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

### Polyethylene glycol:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

### 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

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.

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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  
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.

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.

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### Persistence and degradability

#### Components:

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

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

##### **Polyethylene glycol:**

Biodegradability : Result: rapidly degradable  
Remarks: Based on data from similar materials

##### **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:

##### **Polyethylene glycol:**

Partition coefficient: n-octanol/water : log Pow: < 3

##### **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)

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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

##### **Other adverse effects**

No data available

## SECTION 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.

## 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



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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

#### 49 CFR

UN/ID/NA number : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Mometasone, Posaconazole)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Mometasone, Posaconazole)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity  
Serious eye damage or eye irritation

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**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

White mineral oil (petroleum)	8042-47-5
Polyethylene glycol	25322-68-3

#### California List of Hazardous Substances

White mineral oil (petroleum)	8042-47-5
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#### California Permissible Exposure Limits for Chemical Contaminants

White mineral oil (petroleum)	8042-47-5
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#### The ingredients of this product are reported in the following inventories:

AICS : not determined

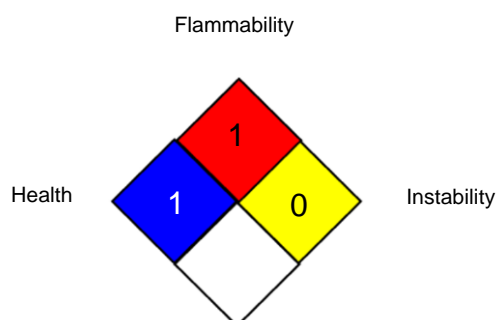
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	1
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

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ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	:	8-hour time weighted average
US WEEL / TWA	:	8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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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.

US / Z8