

Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

SECTION 1. IDENTIFICATION

Product identifier : Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Eye irritation : Category 2B

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :

*

Signal Word : Warning

Hazard Statements : H320 Causes eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

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

Response:

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



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P391 Collect spillage.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Causes eye irritation.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency 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.



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

See Engineering measures under EXPOSURE Technical measures

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

Do not get on skin or clothing. Advice on safe handling

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.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.

Keep in properly labeled containers. Conditions for safe storage

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

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 (Inhalable particulate matter)	5 mg/m³	ACGIH	
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal	
Posaconazole	171228-49-2	TWA	300 μg/m3 (OEB 2)	Internal	
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal	
	Further information: Skin				
		Wipe limit	10 μg/100 cm ²	Internal	

All engineering controls should be implemented by facility **Engineering measures**

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

If adequate local exhaust ventilation is not available or Respiratory protection

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection

Combined particulates and organic vapor type

Material : Chemical-resistant gloves

Consider double gloving. Remarks

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.

Work uniform or laboratory coat. Skin and body protection

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Physical state : suspension

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

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 reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation exposure 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 inhala-

tion 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



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg Symptoms: Vomiting

Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of:

administration)

LD50 (Rat): > 200 mg/kg

Application Route: Intramuscular

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

LD50 (Rat): 233 mg/kg

Application Route: Intravenous

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

Posaconazole:

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

LD50 (Mouse): > 3.000 mg/kg

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

Mometasone:

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

LD50 (Mouse): > 2.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3,3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: No mortality observed at this dose.

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



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

Result : Mild skin irritation

Components:

White mineral oil (petroleum):

Species : Rabbit

Result : No skin irritation

Orbifloxacin:

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

Posaconazole:

Species : Rabbit

Result : No skin irritation

Mometasone:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes eye irritation.

Product:

Species : Rabbit

Result : Mild eye irritation

Components:

White mineral oil (petroleum):

Species : Rabbit

Result : No eye irritation

Orbifloxacin:

Species : Rabbit

Result : Mild eye irritation
Method : Draize Test

Posaconazole:

Species : Rabbit

Result : Mild eye irritation

Mometasone:

Species : Rabbit

Result : No eye irritation



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Product:

Test Type : Magnusson-Kligman-Test

Routes of exposure : Dermal

Result : Not a skin sensitizer.

Components:

White mineral oil (petroleum):

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

Orbifloxacin:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Posaconazole:

Test Type : Magnusson-Kligman-Test

Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Mometasone:

Test Type : Maximization Test

Routes of exposure : Dermal 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



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Test Type: Mammalian erythrocyte micronucleus test (in vivo Genotoxicity 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

Test Type: Micronucleus test Genotoxicity in vivo

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

Test Type: Micronucleus test Genotoxicity in vivo

Species: Mouse

Cell type: Bone marrow Application Route: Intravenous

Result: negative

Mometasone:

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

Result: negative



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

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: RatApplication Route: IngestionExposure time: 24 MonthsResult: 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



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Posaconazole:

Species : Rat
Application Route : oral (feed)
Exposure time : 2 Years
Result : positive

Remarks : The mechanism or mode of action is not relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : positive

Remarks : The mechanism or mode of action is not relevant in humans.

Mometasone:

Species : Rat
Application Route : Inhalation
Exposure time : 2 Years

Dose : 0.067 mg/kg body weight

Result : negative

Species : Mouse
Application Route : Inhalation
Exposure time : 19 Months

Dose : 0.160 mg/kg body weight

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

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



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

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 ma-

ternally 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 malfor-

mations.

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on development, based on

animal experiments.

Posaconazole:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male

General Toxicity Parent: NOAEL: 180 mg/kg body weight

Symptoms: No effects on mating performance.

Result: negative

Test Type: Fertility/early embryonic development

Species: Rat, female

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

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 - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

II

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 developmen-

tal toxicity

Test Type: Embryo-fetal development

Species: Rat

Application Route: Dermal

Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight

Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Dermal

Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Subcutaneous

Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight

Result: Effects on newborn.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

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

Reproductive toxicity - As-

sessment

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.



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

STOT-repeated exposure

Not classified based on available information.

Components:

Posaconazole:

Routes of exposure : Ingestion

Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive

organs, Nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Mometasone:

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Immune system, Liver, Kidney, Skin

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

White mineral oil (petroleum):

Species : Rat

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

 Species
 : Rat

 LOAEL
 : >= 1 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

Orbifloxacin:

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



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Exposure time : 14 Days
Target Organs : Heart, Bone

Symptoms : Gastrointestinal disturbance

Remarks : mortality observed

Species: Juvenile dogNOAEL: 2 mg/kgLOAEL: 3 mg/kgApplication Route: OralExposure time: 90 DaysTarget Organs: Bone

Remarks : No significant adverse effects were reported

Species: DogNOAEL: 37,5 mg/kgApplication Route: OralExposure 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

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



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

LOAEL : 180 mg/kg Application Route : Oral Exposure time : 12 Months

Target Organs : Blood, Gastrointestinal tract, spleen

Species : Monkey
LOAEL : 8 mg/kg
Application Route : Intravenous
Exposure time : 1 Months

Target Organs : Cardio-vascular system, Lungs, Adrenal gland, Blood

Mometasone:

Species : Rat

NOAEL : 0,005 mg/kg
LOAEL : 0,3 mg/kg
Application Route : Oral
Exposure time : 30 d

Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog
LOAEL : 0,5 mg/kg
Application Route : Oral
Exposure time : 30 d

Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat

NOAEL : 0,00013 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 90 d

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

Kidney, Liver, thymus gland

Species : Dog NOAEL : 0,0005 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 90 d

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:



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Symptoms: central nervous system effects, Gastrointestinal Ingestion

disturbance, liver function change, anaphylaxis, Rash

Remarks: May cause photosensitization.

Posaconazole:

Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver Ingestion

effects, Rash, pruritis, Diarrhea, hypertension, neutropenia,

electrolyte imbalance

Mometasone:

Inhalation Symptoms: allergic rhinitis, Headache, pharyngitis, upper res-

> piratory 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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

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 tox-

NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l

Exposure time: 28 d

Toxicity to daphnia and other: aguatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1.000 mg/l

Exposure time: 21 d

Posaconazole:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,95 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility.



Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

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 tox-

city)

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,244 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic

toxicity)

: 1

Toxicity to microorganisms

: EC50 (Natural microorganism): > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Mometasone:

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0,11 mg/l

Exposure time: 96 h

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/aguatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

plants mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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 to microorganisms

toxicity)

: 100

: EC50: > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility.

NOEC: 1.000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility.

Persistence and degradability

Components:

White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d

Posaconazole:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 28 h

Method: OECD Test Guideline 314

Stability in water : Degradation half life (DT50): > 30 d

Method: OECD Test Guideline 111

Mometasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 %

Exposure time: 28 d

Method: OECD Test Guideline 314



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

Stability in water Hydrolysis: 50 %(12 d)

Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Posaconazole:

Species: Lepomis macrochirus (Bluegill sunfish) Bioaccumulation

> Bioconcentration factor (BCF): 20 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

: log Pow: 4,15

Mometasone:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

> Bioconcentration factor (BCF): 107,1 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4,68

Mobility in soil

Components:

Posaconazole:

Distribution among environ-

mental compartments

: log Koc: 5,52

Mometasone:

Distribution among environ-

mental compartments

log Koc: 4,02

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Do not dispose of waste into sewer. Waste from residues

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN 3082 **UN** number



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

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)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(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

ANTT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Mometasone, Posaconazole)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

Special precautions for user

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



Orbifloxacin / Posaconazole / Mometasone **Formulation**

Revision Date: SDS Number: Date of last issue: 30.09.2023 Version 5.0 28.09.2024 439109-00019 Date of first issue: 06.01.2016

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans -: Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal Not applicable

Police

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

AICS not determined

DSL not determined

IECSC not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 dd.mm.yyyy Date format

Further information

Sources of key data used to compile the Material Safety

Data Sheet

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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 Con-



Orbifloxacin / Posaconazole / Mometasone Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.0
 28.09.2024
 439109-00019
 Date of first issue: 06.01.2016

centration 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.

BR / Z8