

Orbifloxacin / Posaconazole / Mometasone Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 3.1 2023/09/30 439116-00018 Date of first issue: 2016/01/06

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Orbifloxacin / Posaconazole / Mometasone Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

2. HAZARDS IDENTIFICATION

GHS Classification

Serious eye damage/eye irri-

tation

Category 2B

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements

Hazard pictograms

¥_2>

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/ at-

tention.

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)	
White mineral oil (petroleum)	8042-47-5	>= 60 -<= 100	
Orbifloxacin	113617-63-3	< 3	
Posaconazole	171228-49-2	>= 0.025 -< 0.25	
Mometasone	83919-23-7	>= 0.025 -< 0.25	

4. FIRST AID MEASURES

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

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

for at least 15 minutes.

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

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Causes eye irritation.



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Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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 pro-

tective 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 absor-

bent.

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-

mine which regulations are applicable.



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Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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 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 as-

sessment

Keep container tightly closed.

Take care to prevent spills, waste and minimize release to the

environment.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
White mineral oil (petroleum)	8042-47-5	NAB (Mist)	5 mg/m3	ID OEL	
		PSD (Mist)	10 mg/m3	ID OEL	
		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 inform	Further information: Skin			
		Wipe limit	10 μg/100 cm ²	Internal	

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to



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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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter 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, dis-

posable 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 work-

ing 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : white to off-white

Odour : odourless

Odour Threshold : No data available



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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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle size : Not applicable

10. STABILITY AND REACTIVITY



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Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

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

Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg



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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



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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



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Result : No 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.

Posaconazole:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact Species : Guinea pig Result : negative

Mometasone:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Result : negative

Remarks : The results of a test on guinea pigs showed this substance to

be a weak skin sensitiser.

Germ cell mutagenicity

Not classified based on available information.



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Components:

White mineral oil (petroleum):

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

Orbifloxacin:

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

Result: equivocal

Test Type: Mouse Lymphoma

Result: positive

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat

Cell type: Liver cells Application Route: Oral

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Posaconazole:

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

Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse



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Cell type: Bone marrow Application Route: Intravenous

Result: negative

Mometasone:

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

Result: negative

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

Result: negative

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

Result: positive

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow

Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat Cell type: Liver cells Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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



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Orbifloxacin:

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

NOAEL : 200 mg/kg body weight

Result : negative

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

NOAEL : 200 mg/kg body weight

Result : negative

Posaconazole:

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

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

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

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

Mometasone:

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

Dose : 0.067 mg/kg body weight

Result : negative

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

Dose : 0.160 mg/kg body weight

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

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

Species: Rat

Application Route: Skin contact

Result: negative



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Effects on foetal develop-

ment

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 develop-

ment

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 ma-

ternally 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 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



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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 develop-

ment

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 - As-

sessment

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 develop-

ment

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 developmen-

tal 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



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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 - 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.

STOT - repeated exposure

Not classified based on available information.

Components:

Posaconazole:

Exposure routes : Ingestion

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

organs, Nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

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.

Repeated dose toxicity

Components:

White mineral oil (petroleum):

Species : Rat LOAEL : 160

LOAEL : 160 mg/kg Application Route : Ingestion



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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 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



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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

Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal **Target Organs**

cord, lymphoid tissue

Species Monkey LÖAEL 15 mg/kg Application Route Oral 1 Months Exposure time

Bone marrow, Adrenal gland, Lymph nodes, Blood **Target Organs**

Species Doa 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



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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:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal

disturbance, liver function change, anaphylaxis, Rash

Remarks: May cause photosensitisation.

Posaconazole:

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

effects, Rash, pruritis, Diarrhoea, 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:



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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/

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l

Exposure time: 28 d

Toxicity to daphnia and other : aquatic 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

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- : 1



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icity)

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/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 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



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Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

: 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

Stability in water : Hydrolysis: 50 %(12 d)

Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Posaconazole:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)



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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

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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



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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 : 964

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.

(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.

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable



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Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to

compile the Safety Data

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit ID OEL / PSD : Short term exposure limit

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 con-



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centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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