according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / **Polymyxin B Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 778796-00023 Date of first issue: 23.06.2016 7.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name Mometasone / Posaconazole / Gentamicin / Polymyxin B

Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-: Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company **MSD**

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A H360D: May damage the unborn child.

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Hazard pictograms :



*

Signal word : Danger

Hazard statements : H360D May damage the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Gentamicin

Additional Labelling

EUH208 Contains 3-Mercaptopropane-1,2-diol. May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878 $\,$



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 778796-00023
 Date of first issue: 23.06.2016

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Gentamicin	1403-66-3 215-765-8	Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 1 - < 2.5
		M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	
Posaconazole	171228-49-2	Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Adrenal gland, Bone marrow, Kidney, Liv- er, Nervous system, Reproductive organs) Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 0.25 - < 1
		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410	>= 0.25 - < 0.3
		M-Factor (Chronic aquatic toxicity): 100	
3-Mercaptopropane-1,2-diol	96-27-5 202-495-0	Acute Tox. 4; H302 Acute Tox. 3; H311 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 0.1 - < 1

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.07.2024	
7.1		778796-00023	Date of first issue: 23.06.2016	
			Acute toxicity estimate Acute oral toxicity: 648 mg/kg Acute dermal toxicity: 673 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / **Polymyxin B Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 778796-00023 Date of first issue: 23.06.2016 7.1

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

5.3 Advice for firefighters

for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up Soak up with inert absorbent material.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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-

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.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

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

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with 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.

Do not eat, drink or smoke when using this product.

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

environment.

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 contami-

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 778796-00023
 Date of first issue: 23.06.2016

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal
	Further information: OTO			
Posaconazole	171228-49-	TWA	300 μg/m3 (OEB 2)	Internal
	2			
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 μg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
triacetin	Workers	Inhalation	Long-term systemic effects	35.275 mg/m3
	Workers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	8.7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2.5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.5 mg/kg bw/day
3-Mercaptopropane- 1,2-diol	Workers	Ingestion	Long-term systemic effects	0.49 mg/m3
	Workers	Skin contact	Long-term systemic effects	0.14 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.074 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.05 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.05 mg/kg bw/day

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment Value	
triacetin	Fresh water	1.88 mg/l
	Marine water	0.188 mg/l
	Intermittent use/release	1 mg/l
	Sewage treatment plant	1088 mg/l
	Fresh water sediment	4.73 mg/kg
	Marine sediment	0.47 mg/kg
	Soil	0.57 mg/kg
	Oral (Secondary Poisoning)	69.9 mg/kg food
3-Mercaptopropane-1,2-diol	Fresh water	0.006 mg/l
	Freshwater - intermittent	0.057 mg/l
	Marine water	0.001 mg/l

8.2 Exposure controls

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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation exposure Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Gentamicin:

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg

LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: No mortality observed at this dose.

Acute toxicity (other routes of:

administration)

LD50 (Rat): 67 - 96 mg/kg

Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg Application Route: Intramuscular

LDLo (Monkey): 30 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

3-Mercaptopropane-1,2-diol:

Acute oral toxicity : LD50 (Rat): 648 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 673 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Gentamicin:

Species : Rabbit

Result : Mild skin irritation

Posaconazole:

Species : Rabbit

Result : No skin irritation

Mometasone:

Species : Rabbit

Result : No skin irritation

3-Mercaptopropane-1,2-diol:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Gentamicin:

Species : Rabbit

Result : Mild eye irritation

Posaconazole:

Species : Rabbit

Result : Mild eye irritation

Mometasone:

Species : Rabbit

Result : No eye irritation

3-Mercaptopropane-1,2-diol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Gentamicin:

Remarks : No data available

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.

3-Mercaptopropane-1,2-diol:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Gentamicin:

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

Result: negative

Test Type: Chromosome aberration test in vitro

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / **Polymyxin B Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 778796-00023 Date of first issue: 23.06.2016 7.1

Result: equivocal

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

> cytogenetic assay) Species: Mouse

Application Route: Intravenous injection

Result: negative

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

3-Mercaptopropane-1,2-diol:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Gentamicin:

Carcinogenicity - Assess-

ment

No data available

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Application Route : Inhalation Exposure time : 19 Months

Dose : 0.160 mg/kg body weight

Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

Gentamicin:

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

Species: Rat

Fertility: NOAEL: 20 mg/kg body weight

Result: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Developmental Toxicity: NOAEL: 3.6 mg/kg body weight

Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intraperitoneal

Developmental Toxicity: LOAEL: 75 mg/kg body weight

Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Intraperitoneal

Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intraperitoneal

Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: foetal mortality, No malformations were observed.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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

Species: Rat

Application Route: Subcutaneous

Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight

Result: Effects on newborn

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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.

3-Mercaptopropane-1,2-diol:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

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

May cause damage to organs through prolonged or repeated exposure.

Components:

Gentamicin:

Target Organs : Kidney, inner ear

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Posaconazole:

Exposure routes : Ingestion

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

organs, Nervous system

Assessment : Causes damage to organs through prolonged or repeated

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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:

Gentamicin:

Species : Dog
LOAEL : 3 mg/kg
Application Route : Intramuscular
Exposure time : 12 Months
Target Organs : Kidney

Symptoms : Vomiting, Salivation

Species : Monkey
LOAEL : 50 mg/kg
Application Route : Subcutaneous
Exposure time : 3 Weeks

Target Organs : Kidney, inner ear

Species : Monkey
LOAEL : 6 mg/kg
Application Route : Intramuscular
Exposure time : 3 Weeks

Target Organs : Blood, Kidney, inner ear, Liver

Species : Rat

NOAEL : 5 mg/kg

LOAEL : 10 mg/kg

Application Route : Intramuscular

Exposure time : 52 Weeks

Target Organs : Kidney, Blood

Species : Rat

NOAEL : 12.5 mg/kg

LOAEL : 50 mg/kg

Application Route : Intramuscular

Exposure time : 13 Weeks

Target Organs : Kidney

Posaconazole:

Species : Rat, female LOAEL : 5 mg/kg Application Route : Oral

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Exposure time : 6 Months

Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species : Dog LOAEL : 3 mg/kg Application Route : Oral Exposure time : 392 Days

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

cord, lymphoid tissue

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

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

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 56 Weeks

Target Organs : Adrenal gland, Bone marrow, Kidney, Nervous system,

spleen, thymus gland, Testis, lymphoid tissue

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

Target Organs : Blood, Gastrointestinal tract, spleen

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

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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

3-Mercaptopropane-1,2-diol:

Species : Rat

LOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 55 Days

Method : OECD Test Guideline 422

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Components:

Mometasone:

Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

Gentamicin:

Ingestion : Target Organs: Kidney

Target Organs: inner ear

Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal

deafness

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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:

Remarks : Dermal absorption possible

SECTION 12: Ecological information

12.1 Toxicity

Components:

Gentamicin:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 86 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5

μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 100

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

icity)

Toxicity to microorganisms : EC50 : 288.7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

M-Factor (Chronic aquatic

toxicity)

: 1

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-

icity)

1

Toxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.206 mg/l Exposure time: 33 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.244 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

1

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 77.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

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 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

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.00014 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.34 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

100

3-Mercaptopropane-1,2-diol:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 10 - 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

10 - 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Raphidocelis subcapitata (freshwater green alga)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (activated sludge): > 1 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Gentamicin:

Biodegradability : Result: rapidly degradable

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Method: OECD Test Guideline 314

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

Method: OECD Test Guideline 111

3-Mercaptopropane-1,2-diol:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

Gentamicin:

Partition coefficient: n-

octanol/water

log Pow: < -2

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)

Bioconcentration factor (BCF): 107.1 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.68

3-Mercaptopropane-1,2-diol:

Partition coefficient: n- : log Pow: -0.84

octanol/water Method: OECD Test Guideline 117

12.4 Mobility in soil

Components:

Posaconazole:

Distribution among environ-

log Koc: 5.52

mental compartments

Mometasone:

Distribution among environ-

mental compartments

log Koc: 4.02

12.5 Results of PBT and vPvB assessment

Product:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Gentamicin, Mometasone)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

(Gentamicin, Mometasone)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Gentamicin, Mometasone)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Gentamicin, Mometasone)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Gentamicin, Mometasone)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

964

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

964

IATA (Passenger)

Packing instruction (passen:

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / **Polymyxin B Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 Date of first issue: 23.06.2016 28.09.2024 778796-00023 7.1

not.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1

E1 **ENVIRONMENTAL**

HAZARDS

100 t

Quantity 2 200 t

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

not determined AICS

DSL not determined

IECSC not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information 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 H-Statements

H302 Harmful if swallowed. H311 Toxic in contact with skin. Causes skin irritation. H315

May cause an allergic skin reaction. H317 Causes serious eye irritation. H319 H360D May damage the unborn child.

H360Df May damage the unborn child. Suspected of damaging fertili-

H361d Suspected of damaging the unborn child.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 7.1
 28.09.2024
 778796-00023
 Date of first issue: 23.06.2016

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H373 : May cause damage to organs through prolonged or repeated

exposure if inhaled.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 7.1 28.09.2024 778796-00023 Date of first issue: 23.06.2016

Sources of key data used to compile the Safety Data Sheet

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

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

Classification of the mixture: Classification procedure:

Repr. 1A	H360D	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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.

IE / EN