

# Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

Version 11.0      Revision Date: 03.12.2024      SDS Number: 772753-00022      Date of last issue: 06.07.2024  
Date of first issue: 23.06.2016

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## Section 1: Identification

Product name : Mometasone / Posaconazole / Gentamicin / Polymyxin B Formulation

### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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## Section 2: Hazard identification

### GHS Classification

Reproductive toxicity : Category 1

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, inner ear)

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360Df May damage the unborn child. Suspected of damaging

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fertility.

H373 May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.

P260 Do not breathe mist or vapours.

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.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Gentamicin	1403-66-3	>= 1 -< 2.5
Posaconazole	171228-49-2	>= 0.25 -< 1
Mometasone	83919-23-7	>= 0.25 -< 1
3-Mercaptopropane-1,2-diol	96-27-5	>= 0.1 -< 1

## Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.

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In case of eye contact	:	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.
If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May damage the unborn child. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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### Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Hazchem Code	:	3Z

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### Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
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- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**Section 7: Handling and storage**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe the 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 assessment  
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 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

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Conditions for safe storage : use of administrative controls.  
 : Keep in properly labelled containers.  
 : Store locked up.  
 : 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

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

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

**Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-

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Filter type	:	Recommended guidelines, use respiratory protection.
Hand protection	:	Combined particulates and organic vapour type
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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### Section 9: Physical and chemical properties

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

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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.

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

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**Section 10: Stability and reactivity**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-  
tions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition  
products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

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**Product:**

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



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**II****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

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**3-Mercaptopropane-1,2-diol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

**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

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

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**Components:****Gentamicin:**

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

Test Type: Chromosome aberration test in vitro  
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

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	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.

### 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 - Assessment	: No data available
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#### Posaconazole:

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

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

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### 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

May damage the unborn child. Suspected of damaging fertility.

### 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 development : 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 - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

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### Posaconazole:

- |                                    |   |
|------------------------------------|---|
| Effects on fertility               | : Test Type: Fertility/early embryonic development<br>Species: Rat, male<br>General Toxicity - Parent: NOAEL: 180 mg/kg body weight<br>Symptoms: No effects on mating performance<br>Result: negative<br><br>Test Type: Fertility/early embryonic development<br>Species: Rat, female<br>General Toxicity - Parent: NOAEL: 45 mg/kg body weight<br>Symptoms: No effects on mating performance<br>Result: negative |
| Effects on foetal development      | : Test Type: Embryo-foetal development<br>Species: Rat, female<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 29 mg/kg body weight<br>Result: Fetotoxicity, Malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit, female<br>Developmental Toxicity: LOAEL: 40 mg/kg body weight<br>Result: Fetotoxicity  |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on animal experiments.   |

### Mometasone:

- |                               |  |
|-------------------------------|--|
| Effects on fertility          | : Test Type: Fertility<br>Species: Rat<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0.015 mg/kg body weight<br>Symptoms: Reduced embryonic survival, Reduced foetal weight<br>Result: No effects on fertility, Effect on reproduction capacity  |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight<br>Result: Embryotoxic effects., Teratogenicity and developmental toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight<br>Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development |

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

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

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

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

### 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 development : 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 (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

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### 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 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



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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  
 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:

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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  
 NOAEL : 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

### 3-Mercaptopropane-1,2-diol:

Species : Rat  
 NOAEL : > 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

### Experience with human exposure

### Components:

#### Gentamicin:

|| Ingestion : Target Organs: Kidney

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||| Target Organs: inner ear  
 Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**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 respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion  
 ||| Skin contact : Symptoms: Dermatitis, Itching

**Further information**

**Components:**

**Mometasone:**

||| Remarks : Dermal absorption possible

## Section 12: Ecological information

**Ecotoxicity**

**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

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		Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 100	
M-Factor (Chronic aquatic toxicity)	: 1	
Toxicity to microorganisms	: EC50: 288.7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209	
<b>Posaconazole:</b>		
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 toxicity)	: 1	
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l Exposure time: 33 d Method: OECD Test Guideline 210	
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.244 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility	
M-Factor (Chronic aquatic toxicity)	: 1	
Toxicity to microorganisms	: EC50 (Natural microorganism): > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209	

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### Mometasone:

Toxicity to fish	: LC50 (Menidia beryllina (Silverside)): 0.11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility  LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l Exposure time: 7 d Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility  EC50 (Americamysis): > 5 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.34 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	: 100
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility  NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility

### 3-Mercaptopropane-1,2-diol:

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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

### Persistence and degradability

#### Components:

##### **Gentamicin:**

Biodegradability	: Result: rapidly degradable Biodegradation: 100 % Exposure time: 28 d Method: OECD Test Guideline 314
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##### **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 %
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Exposure time: 28 d  
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

**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-octanol/water : log Pow: -0.84  
Method: OECD Test Guideline 117

**Mobility in soil****Components:****Posaconazole:**

Distribution among environmental compartments : log Koc: 5.52

**Mometasone:**

Distribution among environmental compartments : log Koc: 4.02

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**Other adverse effects**

No data available

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

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**Section 14: Transport information****International Regulations****UNRTDG**

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

**IATA-DGR**

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Gentamicin, Mometasone)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

**IMDG-Code**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin, Mometasone)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****NZS 5433**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin, Mometasone)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 3Z  
Marine pollutant : no

**Special precautions for user**

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

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

not allocated

**Tolerable Exposure Limits (TEL)**

Not applicable

**Environmental Exposure Limits (EEL)**

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

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**Further information**

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

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

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