

SAFETY DATA SHEET



Gentamicin / Posaconazole / Mometasone Suspension Formulation

Version 5.0

Revision Date: 03.12.2024

SDS Number: 1244484-00021

Date of last issue: 06.04.2024
Date of first issue: 27.01.2017

SECTION 1: IDENTIFICATION

Product name : Gentamicin / Posaconazole / Mometasone Suspension Formulation
Product code : Mometamax Single
Other means of identification : Mometamax Ultra Ear Drops Suspension for Dogs (91464)

Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)
Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia
Telephone : 1 800 033 461
Emergency telephone number : Poisons Information Centre: Phone 13 11 26
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1A

GHS label elements

Hazard pictograms : 
Signal word : Danger
Hazard statements : H360D May damage the unborn child.
Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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Response:

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

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) |
|-------------------------------|-------------|-----------------------|
| White mineral oil (petroleum) | 8042-47-5 | >= 60 -<= 100 |
| Gentamicin | 1403-66-3 | >= 0.3 -< 1 |
| Posaconazole | 171228-49-2 | < 1 |
| Mometasone | 83919-23-7 | < 0.3 |

SECTION 4. FIRST AID MEASURES

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

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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

Hazardous combustion 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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

| | |
|-----------------------------|--|
| Technical measures | : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment. |
| 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 use of administrative controls. |
| Conditions for safe storage | : 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 parame- ters / Permissible concentration | Basis |
|------------|---------|-------------------------------------|--|-------|
| | | | | |

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| | | | | |
|-------------------------------|---------------------------|------------------------------------|-------------------------------|----------|
| White mineral oil (petroleum) | 8042-47-5 | TWA (Mist) | 5 mg/m ³ | AU OEL |
| | | TWA (Inhalable particulate matter) | 5 mg/m ³ | ACGIH |
| Gentamicin | 1403-66-3 | TWA | 0.1 mg/m ³ (OEB 2) | Internal |
| | Further information: OTO | | | |
| Posaconazole | 171228-49-2 | TWA | 300 µg/m ³ (OEB 2) | Internal |
| Mometasone | 83919-23-7 | TWA | 1 µg/m ³ (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm ² | 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 recommended guidelines, use respiratory protection. |
| Filter type | : Combined particulates and organic vapour type |
| Hand protection | |
| Material | : Chemical-resistant gloves |
| Remarks | : Consider double gloving. |
| Eye protection | : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a |

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Skin and body protection : potential for direct contact to the face with dusts, mists, or aerosols.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------------|
| Appearance | : | suspension |
| Colour | : | white to off-white |
| 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 |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 0.874 g/cm ³ |
| Solubility(ies) | | |
| Water solubility | : | No data available |

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| | | |
|--|---|--|
| 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 |

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

| | | |
|-----------------|---|--|
| Exposure routes | : | Inhalation Skin contact Ingestion Eye contact |
|-----------------|---|--|

Acute toxicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity |

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Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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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Not classified based on available information.

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

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Gentamicin:

| | | |
|---------|---|----------------------|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

Posaconazole:

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Mometasone:

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

Serious eye damage/eye irritation

Not classified based on available information.

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

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Gentamicin:

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

Posaconazole:

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

Mometasone:

| | | |
|---------|---|-------------------|
| Species | : | Rabbit |
| Result | : | No eye irritation |

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

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Not classified based on available information.

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

| | | |
|-----------------|---|--------------|
| Test Type | : | Buehler Test |
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

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. |

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

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

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: In vitro mammalian cell gene mutation test Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials |

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| | |
|-----------------------|--|
| 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 Species: Rat Cell type: Bone marrow |

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Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat

Cell type: Liver cells

Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative**Gentamicin:**

Carcinogenicity - Assessment : 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 : negativeSpecies : Mouse
Application Route : Inhalation
Exposure time : 19 Months
Dose : 0.160 mg/kg body weight

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Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

White mineral oil (petroleum):

| | |
|-------------------------------|--|
| Effects on fertility | : <p>Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative</p> |
| Effects on foetal development | : <p>Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative</p> |

Gentamicin:

| | |
|------------------------------------|---|
| Effects on fertility | : <p>Test Type: Two-generation reproduction toxicity study Species: Rat Fertility: NOAEL: 20 mg/kg body weight Result: No significant adverse effects were reported</p> |
| Effects on foetal development | : <p>Test Type: Embryo-foetal development Species: Rabbit Developmental Toxicity: NOAEL: 3.6 mg/kg body weight Result: No embryo-foetal toxicity</p> |
| | : <p>Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 75 mg/kg body weight Result: Embryo-foetal toxicity</p> |
| | : <p>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.</p> |
| | : <p>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.</p> |
| Reproductive toxicity - Assessment | : <p>Positive evidence of adverse effects on development from human epidemiological studies.</p> |

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Effects on fertility

: Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity - Parent: NOAEL: 180 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity - Parent: NOAEL: 45 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Effects on foetal development

: 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 - Assessment

: Some evidence of adverse effects on development, based on animal experiments.

Mometasone:

Effects on fertility

: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced foetal weight
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development

: 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 developmental 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

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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.

STOT - single exposure

Not classified based on available information.

Components:**Mometasone:**

Remarks : Based on available data, the classification criteria are not met.

STOT - repeated exposure

Not classified based on available information.

Components:**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

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Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****White mineral oil (petroleum):**

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| LOAEL | : | 160 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat |
| LOAEL | : | >= 1 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 4 Weeks |
| Method | : | OECD Test Guideline 412 |

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 |

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| | | |
|----------------------|---|---|
| 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: | | |
| 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 |

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| | | |
|-------------------|---|---|
| Species | : | Dog |
| LOAEL | : | 0.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |
| Target Organs | : | Lymph nodes, Liver, Adrenal gland, Skin, thymus gland |
| Species | : | Rat |
| NOAEL | : | 0.00013 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 90 d |
| Target Organs | : | Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland |
| Species | : | Dog |
| NOAEL | : | 0.0005 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 90 d |
| Target Organs | : | Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver |

Aspiration toxicity

Not classified based on available information.

Components:**Mometasone:**

|| Not applicable

Experience with human exposure**Components:****Gentamicin:**

| | | |
|-----------|---|---|
| Ingestion | : | Target Organs: Kidney 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 |

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||| Remarks : Dermal absorption possible

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****White mineral oil (petroleum):**

| | | |
|--|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d |

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 |

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Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
Exposure time: 72 h
Method: OECD Test Guideline 201Toxicity to microorganisms : EC50: 288.7 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209**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 solubilityToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.276 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210Toxicity 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 solubilityToxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209**Mometasone:**

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

Persistence and degradability**Components:****White mineral oil (petroleum):**

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

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
Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

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

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Partition coefficient: n-octanol/water : log Pow: 4.68

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

Distribution among environmental compartments : log Koc: 5.52

Mometasone:

Distribution among environmental compartments : log Koc: 4.02

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Gentamicin)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Mometasone, Gentamicin)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

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Environmentally hazardous : yes

IMDG-Code

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

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

Not applicable for product as supplied.

National Regulations

ADG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Gentamicin)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z
Environmentally hazardous : yes

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

Therapeutic Goods (Poisons Standard) Instrument : Schedule 4

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined

DSL : not determined

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IECSC : not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Revision Date : 03.12.2024
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/>

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal 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 - Trans-

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portion of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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