

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2024/12/03  |
| 7.0     | 2025/04/14     | 1244490-00023 | Date of first issue: 2017/01/27 |

### 1. PRODUCT AND COMPANY 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 : MSD

Address : No. 485 Jing Tai Road  
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

|            |                      |
|------------|----------------------|
| Appearance | : suspension         |
| Colour     | : white to off-white |
| Odour      | : No data available  |

May damage the unborn child. Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

#### GHS Classification

Reproductive toxicity : Category 1A

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

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### GHS label elements

|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Hazard statements        | : | H360D May damage the unborn child.<br>H400 Very toxic to aquatic life.<br>H411 Toxic to aquatic life with long lasting effects.                                                                                                                                                                                                                                                                                                                                                           |
| Precautionary statements | : | <b>Prevention:</b><br>P203 Obtain, read and follow all safety instructions before use.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.<br><b>Response:</b><br>P318 IF exposed or concerned, get medical advice.<br>P391 Collect spillage.<br><b>Storage:</b><br>P405 Store locked up.<br><b>Disposal:</b><br>P501 Dispose of contents/ container to an approved waste disposal plant. |

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

May damage the unborn child.

### Environmental hazards

Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name                 | CAS-No.   | Concentration (% w/w)  |
|-------------------------------|-----------|------------------------|
| White mineral oil (petroleum) | 8042-47-5 | $\geq 90$ - $\leq 100$ |
| Polyethylene                  | 9002-88-4 | $\geq 1$ - $< 10$      |
| Gentamicin                    | 1403-66-3 | $\geq 0.3$ - $< 1$     |

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|              |             |                    |
|--------------|-------------|--------------------|
| Posaconazole | 171228-49-2 | $\geq 0.25$ -< 1   |
| Mometasone   | 83919-23-7  | $\geq 0.1$ -< 0.25 |

### 4. FIRST AID MEASURES

- |                                                             |                                                                                                                                                                                                                         |
|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact                                     | : In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>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 when the potential for exposure exists (see section 8).                                           |
| Notes to physician                                          | : Treat symptomatically and supportively.                                                                                                                                                                               |

### 5. FIREFIGHTING MEASURES

- |                                       |                                                                                                                                                           |
|---------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable extinguishing media          | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Use water spray to cool unopened containers. |

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Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and 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.  
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.

### 7. HANDLING AND STORAGE

#### 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 vapours or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety

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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.

Avoidance of contact : Oxidizing agents

**Storage**

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

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components                    | CAS-No.     | Value type<br>(Form of exposure)   | Control parameters / Permissible concentration | Basis    |
|-------------------------------|-------------|------------------------------------|------------------------------------------------|----------|
| White mineral oil (petroleum) | 8042-47-5   | TWA (Inhalable particulate matter) | 5 mg/m <sup>3</sup>                            | ACGIH    |
| Polyethylene                  | 9002-88-4   | PC-TWA (Total dust)                | 5 mg/m <sup>3</sup>                            | CN OEL   |
| 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

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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

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.

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : white to off-white

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|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| 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 <sup>3</sup>                                  |
| 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. |

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Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

### 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. |

### 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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Assessment: The substance or mixture has no acute inhalation toxicity |
| Acute dermal toxicity     | : LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity                                                 |

##### Polyethylene:

|                     |                                                                                                |
|---------------------|------------------------------------------------------------------------------------------------|
| Acute oral toxicity | : LD50 (Rat): > 3,000 mg/kg<br>Assessment: The substance or mixture has no acute oral toxicity |
|---------------------|------------------------------------------------------------------------------------------------|

##### Gentamicin:

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|                                                 |                                                                                                                                                                                                       |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity                             | : LD50 (Rat): 8,000 - 10,000 mg/kg<br>LD50 (Mouse): 10,000 mg/kg                                                                                                                                      |
| Acute inhalation toxicity                       | : LC50 (Rat): > 0.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose.                                                                          |
| Acute toxicity (other routes of administration) | : LD50 (Rat): 67 - 96 mg/kg<br>Application Route: Intravenous<br><br>LD50 (Rat): 371 - 384 mg/kg<br>Application Route: Intramuscular<br><br>LDLo (Monkey): 30 mg/kg<br>Application Route: Intravenous |

### Posaconazole:

|                       |                                                            |
|-----------------------|------------------------------------------------------------|
| Acute oral toxicity   | : LD50 (Rat): > 5,000 mg/kg<br>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<br>LD50 (Mouse): > 2,000 mg/kg                                                                                                                                                       |
| Acute inhalation toxicity                       | : LC50 (Rat): > 3.3 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose.<br><br>LC50 (Mouse): > 3.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : LD50 (Rat): 300 mg/kg<br>Application Route: Subcutaneous<br>Symptoms: Breathing difficulties                                                                                                                   |

### Skin corrosion/irritation

Not classified based on available information.

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### 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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### Respiratory sensitisation

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

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

#### Polyethylene:

|                 |                                          |
|-----------------|------------------------------------------|
| Test Type       | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact                           |
| 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. |

### 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<br>Result: negative                                                                        |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection |

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Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### Polyethylene:

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

### 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

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|                                     |                                                                                                          |
|-------------------------------------|----------------------------------------------------------------------------------------------------------|
|                                     | Result: negative                                                                                         |
| Genotoxicity in vivo                | : Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative          |
|                                     | Test Type: Chromosomal aberration<br>Species: Rat<br>Cell type: Bone marrow<br>Result: negative          |
|                                     | Test Type: unscheduled DNA synthesis assay<br>Species: Rat<br>Cell type: Liver cells<br>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. |

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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.

### Components:

#### White mineral oil (petroleum):

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

### Gentamicin:

|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Fertility: NOAEL: 20 mg/kg body weight<br>Result: No significant adverse effects were reported                                                                                                                                                                                                                                                                             |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rabbit<br>Developmental Toxicity: NOAEL: 3.6 mg/kg body weight<br>Result: No embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 75 mg/kg body weight<br>Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Intraperitoneal |

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

|         |                |               |                                 |
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|                                    |                                                                                                                                                                                                                |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    | Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: foetal mortality, No malformations were observed.                                                                                               |
|                                    | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>Result: foetal mortality, No malformations were observed. |
| Reproductive toxicity - Assessment | : Positive evidence of adverse effects on development from human epidemiological studies.                                                                                                                      |

### 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 |
|                      | 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. |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on foetal development      | :<br>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<br>Species: Rabbit<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight<br>Result: Embryo-foetal toxicity, Malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight<br>Result: Effects on newborn<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight<br>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.

# SAFETY DATA SHEET

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## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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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:

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

|                   |                               |
|-------------------|-------------------------------|
| Species           | : Rat                         |
| LOAEL             | : 160 mg/kg                   |
| Application Route | : Ingestion                   |
| Exposure time     | : 90 Days                     |
| Species           | : Rat                         |
| LOAEL             | : $\geq 1$ 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         |

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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

# SAFETY DATA SHEET

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## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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### Experience with human exposure

#### Components:

##### **Gentamicin:**

|           |                                                                                                                             |
|-----------|-----------------------------------------------------------------------------------------------------------------------------|
| Ingestion | : Target Organs: Kidney<br>Target Organs: inner ear<br>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 |
|---------|------------------------------|

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

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

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

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d

### Polyethylene:

Toxicity to fish : LC50 : > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50: > 100 mg/l  
Exposure time: 72 h

### 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 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

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II

### Posaconazole:

|                                                                        |                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility                                                                                           |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 0.276 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                                                                                                                        |
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l<br>Exposure time: 72 h<br>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<br>Exposure time: 33 d<br>Method: OECD Test Guideline 210                                                                                                                                              |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 0.244 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility                                                                                                     |
| M-Factor (Chronic aquatic toxicity)                                    | : 1                                                                                                                                                                                                                                                              |
| Toxicity to microorganisms                                             | : EC50 (Natural microorganism): > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                                                                                                                       |

### Mometasone:

|                  |                                                                                                                                                                                                                                                                        |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (Menidia beryllina (Siverside)): 0.11 mg/l<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility<br><br>LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l<br>Exposure time: 7 d<br>Remarks: No toxicity at the limit of solubility |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

### Persistence and degradability

#### Components:

#### White mineral oil (petroleum):

|                  |                                                                                     |
|------------------|-------------------------------------------------------------------------------------|
| Biodegradability | : Result: Not readily biodegradable.<br>Biodegradation: 31 %<br>Exposure time: 28 d |
|------------------|-------------------------------------------------------------------------------------|

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### Polyethylene:

Biodegradability : Result: Not readily biodegradable.

### 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

## 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.

## 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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Packing instruction (passenger aircraft) : 964  
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

#### GB 6944/12268

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

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

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Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

### Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

### Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 16. OTHER INFORMATION

Revision Date : 2025/04/14

### Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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compile the Safety Data  
Sheet

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 : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average  
CN OEL / PC-TWA : Permissible concentration - 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 - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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### Disclaimer

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.

CN / EN