1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Clotrimazole / Gentamicin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: 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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: suspension
Colour: white to off-white
Odour: oily

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

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

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

**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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
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<table>
<thead>
<tr>
<th>Components</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt; 90 - &lt;= 100</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>1</td>
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<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>0.1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

| General advice | In the case of accident or if you feel unwell, seek medical advice immediately.
**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 when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>

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White mineral oil (petroleum) | 8042-47-5  | TWA (Inhalable particulate matter) | 5 mg/m³ | ACGIH | Wipe limit | 10 µg/100 cm² | Internal
--- | --- | --- | --- | --- | --- | --- | ---
clotrimazole | 23593-75-1  | TWA | 0.2 mg/m³ (OEB 2) | Internal | Skin | | |
Gentamicin | 1403-66-3  | TWA | 0.1 mg/m³ (OEB 2) | Internal | | | |
Mometasone | 83919-23-7  | TWA | 1 µg/m³ (OEB 4) | Internal | | | |

Further information: Skin

Engineering measures:
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
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<tr>
<td>Colour</td>
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<tr>
<td>Odour</td>
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<td>Odour Threshold</td>
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<tr>
<td>pH</td>
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<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
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<tr>
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<td>Flammability (liquids)</td>
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<tr>
<td></td>
<td>: No data available</td>
</tr>
</tbody>
</table>
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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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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

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

clotrimazole:
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Acute oral toxicity: LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Mouse): 923 mg/kg

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):
Application Route: Intravenous
LD50 (Rat): 67 - 96 mg/kg
LD50 (Rat): 371 - 384 mg/kg
Application Route: Intramuscular
LDLo (Monkey): 30 mg/kg
Application Route: Intravenous

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):
Application Route: Subcutaneous
Symptoms: Breathing difficulties
Skin corrosion/irritation
Not classified based on available information.

Components:

White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

cloztrimazole:
Species: Rabbit
Result: No skin irritation

Gentamicin:
Species: Rabbit
Result: Mild 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

cloztrimazole:
Species: Rabbit
Result: Mild eye irritation

Gentamicin:
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.
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

Gentamicin:
Remarks: No data available

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
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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: in vitro micronucleus test
Result: negative
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</tr>
</tbody>
</table>

### Genotoxicity in vivo

**Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- **Species:** Rat
- **Application Route:** Oral
- **Result:** negative

**Test Type:** Mammalian spermatogonial chromosome aberration test (in vivo)
- **Species:** Hamster
- **Result:** negative

### Germ cell mutagenicity - Assessment

Weight of evidence does not support classification as a germ cell mutagen.

### 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

### Mometasone:

### Genotoxicity in vitro

**Test Type:** Bacterial reverse mutation assay (AMES)
- **Result:** negative

**Test Type:** Chromosomal aberration
- **Test system:** Chinese hamster lung cells
- **Result:** negative

**Test Type:** Chromosomal aberration
- **Test system:** Chinese hamster ovary cells
- **Result:** positive

**Test Type:** Mouse Lymphoma
- **Result:** negative

### Genotoxicity in vivo

**Test Type:** Micronucleus test
- **Species:** Mouse
- **Application Route:** Oral
- **Result:** negative

**Test Type:** Chromosomal aberration
- **Species:** Rat
- **Cell type:** Bone marrow
- **Result:** negative
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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

clotrimazole:
Species: Rat
Application Route: Oral
Exposure time: 78 weeks
Result: negative

Gentamicin:
Carcinogenicity - Assessment: No data available

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
Species: Rat
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<tr>
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</tr>
</tbody>
</table>

**Application Route**: Skin contact  
**Result**: negative

**Effects on foetal development**:  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**clotrimazole**:

**Effects on fertility**:  
Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 50 mg/kg body weight  
Result: Effects on fertility

**Effects on foetal development**:  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

**Gentamicin**:

**Effects on fertility**:  
Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

**Effects on foetal development**:  
Test Type: Embryo-foetal development

---

**Reproductive toxicity - Assessment**:  
Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

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

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

Clotrimazole:  
Target Organs: Liver, Kidney, Adrenal gland  
Assessment: May cause damage to organs through prolonged or repeated exposure.

Gentamicin:  
Target Organs: Kidney, inner ear  
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.
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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

**Clotrimazole:**
Species : Rabbit  
LOAEL : 5 - 40 mg/kg  
Application Route : Skin contact  
Exposure time : 3 Weeks  
Target Organs : Skin  
Symptoms : Oedema, Fissuring, Necrosis, Redness  
Species : Rat  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 18 Months  
Target Organs : Liver, Kidney, Adrenal gland  
Species : Dog  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 6 - 12 Months  
Target Organs : Adrenal gland  
Symptoms : Salivation, Lachrymation, Vomiting

**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
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<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
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<tbody>
<tr>
<td>LOAEL</td>
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<tr>
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<td>3 Weeks</td>
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<tr>
<td>Target Organs</td>
<td>Blood, Kidney, inner ear, Liver</td>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
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<tr>
<td>Application Route</td>
<td>Intramuscular</td>
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<tr>
<td>Exposure time</td>
<td>52 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Blood</td>
</tr>
</tbody>
</table>

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 13 Weeks
Target Organs: Kidney

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

Experience with human exposure

Components:

Clotrimazole:
- Skin contact: Symptoms: Rash, Itching, Blistering, Oedema, Redness
- Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

Gentamicin:
- Ingestion: Target Organs: Kidney, inner ear
  - Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

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
  - 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 (Pseudokirchieriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
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</table>

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

**Clotrimazole:**
- Toxicity to fish:
  - LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l
    Exposure time: 96 h
    Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates:
  - EC50 (Daphnia magna (Water flea)): 0.02 mg/l
    Exposure time: 48 h
- Toxicity to algae/aquatic plants:
  - EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l
    Exposure time: 72 h
  - NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l
    Exposure time: 72 h

**M-Factor (Acute aquatic toxicity):**
- 10

**Toxicity to fish (Chronic toxicity):**
- NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 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)): 0.01 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

**M-Factor (Chronic aquatic toxicity):**
- 10

Toxicity to microorganisms:
- EC50: > 10,000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

**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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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<th>Substance/Property</th>
<th>Value</th>
<th>Method/Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>µg/l, Exposure time: 72 h</td>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l, Exposure time: 72 h</td>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l, Exposure time: 72 h</td>
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<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: 288.7 mg/l, Exposure time: 3 h, Test Type: Respiration inhibition, Method: OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Substance/Property</th>
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<th>Method/Remarks</th>
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</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Menidia beryllina (Silverside)): 0.11 mg/l, Exposure time: 96 h, Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l, Exposure time: 7 d, Remarks: No toxicity at the limit of solubility</td>
<td></td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 5 mg/l, Exposure time: 48 h, Method: OECD Test Guideline 202, Remarks: No toxicity at the limit of solubility</td>
<td></td>
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<tr>
<td></td>
<td>EC50 (Americamysis): &gt; 5 mg/l, Exposure time: 96 h, Method: US-EPA OPPTS 850.1035, Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 3.2 mg/l, Exposure time: 72 h, Method: OECD Test Guideline 201, Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l, Exposure time: 32 d, Method: OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other</td>
<td>NOEC (Daphnia magna (Water flea)): 0.34 mg/l</td>
<td></td>
</tr>
</tbody>
</table>

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aquatic invertebrates (Chronic toxicity) Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) Toxicity to microorganisms: 100

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:

White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

clotrimazole:
Stability in water: Hydrolysis: 50 % (242 d)

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

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:
Mometasone / Clotrimazole / Gentamicin Formulation

Partition coefficient: n-octanol/water

**Mometasone:**

Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305

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

**Mobility in soil**

Components:

**Mometasone:**

Distribution among environmental compartments: log Koc: 4.02

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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. (clotrimazole, Gentamicin)

Class: 9
Packing group: III
Labels: 9

**IATA-DGR**

UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, 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. (clotrimazole, 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. (clotrimazole, Gentamicin)

Class: 9
Packing group: III
Labels: 9

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

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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according to GB/T 16483 and GB/T 17519

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Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; 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 Chemicals 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; 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

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