SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 3.9  Revision Date: 2021/08/27  SDS Number: 412818-00016  Date of last issue: 2020/10/10
Date of first issue: 2015/12/14

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Clotrimazole / Gentamicin Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

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.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>White mineral oil (petroleum)</td>
</tr>
<tr>
<td></td>
<td>clotrimazole</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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

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

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

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

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

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
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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 (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
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapours.
- Do not swallow.
- Avoid contact with eyes.
- 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.

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

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>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>NAB (Mist)</td>
<td>5 mg/m³ (Mist)</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD (Mist)</td>
<td>10 mg/m³ (Mist)</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³ (Inhalable particulate matter)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Hand protection Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a 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.

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

Odour: oily

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
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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 : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
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

Information on likely routes of exposure : Inhalation
                                            Skin contact
                                            Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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:
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) : LD50 (Rat): 67 - 96 mg/kg
Application Route: Intravenous
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LD$_{50}$ (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Mometasone:**

Acute oral toxicity: LD$_{50}$ (Rat): > 2,000 mg/kg  
LD$_{50}$ (Mouse): > 2,000 mg/kg

Acute inhalation toxicity: LC$_{50}$ (Rat): > 3.3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

LC$_{50}$ (Mouse): > 3.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of administration): LD$_{50}$ (Rat): 300 mg/kg  
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

**Clotrimazole:**

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

clotrimazole:
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 sensitisir.

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

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
- 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):**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**clotrimazole:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Fertility: LOAEL</td>
<td>50 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>Effects on fertility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL</td>
<td>100 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 200 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
</tbody>
</table>
Result: No effects on foetal development

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 180 mg/kg body weight
Result: No effects on 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.

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-foetal toxicity

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

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

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

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

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
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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.

- 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
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.

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:
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<td>412818-00016</td>
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<td>2015/12/14</td>
</tr>
</tbody>
</table>

#### Species

**Dog**

- **LOAEL**: 3 mg/kg
- **Application Route**: Intramuscular
- **Exposure time**: 12 Months
- **Target Organs**: Kidney
- **Symptoms**: Vomiting, Salivation

**Monkey**

- **LOAEL**: 50 mg/kg
- **Application Route**: Subcutaneous
- **Exposure time**: 3 Weeks
- **Target Organs**: Kidney, inner ear

**Monkey**

- **LOAEL**: 6 mg/kg
- **Application Route**: Intramuscular
- **Exposure time**: 3 Weeks
- **Target Organs**: Blood, Kidney, inner ear, Liver

**Rat**

- **NOAEL**: 5 mg/kg
- **LOAEL**: 10 mg/kg
- **Application Route**: Intramuscular
- **Exposure time**: 52 Weeks
- **Target Organs**: Kidney, Blood

**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
SAFETY DATA SHEET

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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
Target Organs: 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint Description</th>
<th>Endpoint</th>
<th>Method</th>
<th>NOEC/EC50/LC50/M-Factor</th>
<th>Exposure Time</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>OECD Test Guideline 202</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
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<td></td>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC</td>
<td>OECD Test Guideline 210</td>
<td>1,000 mg/l</td>
<td>28 d</td>
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<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC</td>
<td>OECD Test Guideline 211</td>
<td>1,000 mg/l</td>
<td>21 d</td>
<td></td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>Toxicity to fish</td>
<td>LC50</td>
<td>OECD Test Guideline 203</td>
<td>&gt; 0.29 mg/l</td>
<td>96 h</td>
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<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>OECD Test Guideline 202</td>
<td>0.02 mg/l</td>
<td>48 h</td>
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<td></td>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50</td>
<td>OECD Test Guideline 202</td>
<td>0.02 mg/l</td>
<td>48 h</td>
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<tr>
<td></td>
<td></td>
<td>NOEC</td>
<td>OECD Test Guideline 202</td>
<td>0.017 mg/l</td>
<td>72 h</td>
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<tr>
<td>Gentamicin</td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>OECD Test Guideline 202</td>
<td>86 mg/l</td>
<td>48 h</td>
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</tbody>
</table>
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

Mometasone:  
Toxicity to fish:  
LC50 (Menidia beryllina (Silverside)): 0.11 mg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l  
Exposure time: 7 d  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Daphnia magna (Water flea)): > 5 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

EC50 (Americamysis): > 5 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:  
EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

**Toxicity to fish (Chronic toxicity)**
- NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l
- Exposure time: 32 d
- Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 0.34 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211
- Remarks: No toxicity at the limit of solubility

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

**Toxicity to microorganisms**
- 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)
Bioaccumulative potential

Components:

Gentamicin:
Partition coefficient: n-octanol/water: log Pow: < -2

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)
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Version 3.9
Revision Date: 2021/08/27
SDS Number: 412818-00016
Date of last issue: 2020/10/10
Date of first issue: 2015/12/14

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (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.

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import: Not applicable
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Distribution and Supervision

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


Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ID OEL: Indonesia. Occupational Exposure Limits
- ACGIH / TWA: 8-hour, time-weighted average
- ID OEL / NAB: Long term exposure limit
- ID OEL / PSD: Short term exposure limit

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 Tem-
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