

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 4.9      Revision Date: 07/22/2022      SDS Number: 412812-00020      Date of last issue: 04/09/2022  
Date of first issue: 12/14/2015

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### SECTION 1. IDENTIFICATION

Product name : Mometasone / Clotrimazole / Gentamicin Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 1A  
Specific target organ toxicity : Category 2 (Liver, Kidney, Adrenal gland)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360Df May damage the unborn child. Suspected of damaging fertility.  
H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapors.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

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**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	Paraffinum liquidum	8042-47-5	> 90 - <= 100
clotrimazole	No data available	23593-75-1	1
Gentamicin	No data available	1403-66-3	0.5
Mometasone	No data available	83919-23-7	0.1

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**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May damage the unborn child. Suspected of damaging fertility.  
May cause damage to organs through prolonged or repeated exposure if swallowed.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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

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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
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 labeled 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist)	5 mg/m <sup>3</sup>	CA QC OEL
		STEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
clotrimazole	23593-75-1	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: OTO				
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

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**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 vapor 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : suspension

**Color** : white to off-white

**Odor** : oily

**Odor Threshold** : No data available

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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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition 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

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.

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tions  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****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

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**Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg  
LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous  
LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular  
LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Mometasone:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3.3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.  
LC50 (Mouse): > 3.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg  
Application Route: Subcutaneous  
Symptoms: Breathing difficulties

**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:**



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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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

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

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

**Gentamicin:**

Remarks : No data available

**Mometasone:**

Test Type : Maximization Test

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Routes of exposure	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Result	:	negative
Remarks	:	The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

### 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.
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#### **Gentamicin:**

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

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**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. Suspected of damaging fertility.

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

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

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

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Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 50 mg/kg body weight  
 Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 200 mg/kg body weight  
 Result: No effects on fetal development.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 180 mg/kg body weight  
 Result: No effects on fetal 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 fetal development : Test Type: Embryo-fetal development  
 Species: Rabbit  
 Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
 Result: No embryo-fetal toxicity.

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

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

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

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from

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essment 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 fetal weight.  
 Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Subcutaneous  
 Embryo-fetal toxicity.: LOAEL: 0.06 mg/kg body weight  
 Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Dermal  
 Embryo-fetal toxicity.: LOAEL: 0.3 mg/kg body weight  
 Result: Embryo-fetal toxicity.

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

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

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Embryo-fetal toxicity.: LOAEL: 0.7 mg/kg body weight  
 Result: Embryo-fetal 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.

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### STOT-repeated exposure

May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

#### 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:**

Routes of exposure : 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 : Edema, Fissuring, Necrosis, Redness

Species : Rat  
 LOAEL : 10 mg/kg  
 Application Route : Oral  
 Exposure time : 18 Months

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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

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

### 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



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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, Edema, Redness
Ingestion	:	Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

#### **Gentamicin:**

Ingestion	:	Target Organs: Kidney Target Organs: inner ear Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness
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#### **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
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### SECTION 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  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1,000 mg/l<br>Exposure time: 21 d   |

##### **clotrimazole:**

- |  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Brachydanio rerio (zebrafish)): > 0.29 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)): 0.02 mg/l<br>Exposure time: 48 h  |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 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)): 0.01 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211   |
| Toxicity to microorganisms   | : | EC50: > 10,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209  |

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### 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
- 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 : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2

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plants		mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.34 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility.
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility.
		NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility.

### Persistence and degradability

#### Components:

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

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

**Mometasone / Clotrimazole / Gentamicin For-  
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Stability in water : Hydrolysis: 50 %(12 d)  
Method: OECD Test Guideline 111

**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 environ-  
mental compartments : log Koc: 4.02

**Other adverse effects**

No data available

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**SECTION 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.

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

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

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(clotrimazole, Gentamicin)

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.

### Domestic regulation

### TDG

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

(clotrimazole, Gentamicin)

Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(clotrimazole, Gentamicin)

### Special precautions for user

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

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## SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA AB OEL / STEL	:	15-minute occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWA EV	:	Time-weighted average exposure value
CA QC OEL / STEV	:	Short-term exposure value

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

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



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Revision Date : 07/22/2022  
Date format : mm/dd/yyyy

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.

CA / Z8