

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

### SECTION 1. IDENTIFICATION

Product name : Mometasone / Clotrimazole / Gentamicin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : One Merck Drive  
Whitehouse Station - New Jersey - USA 08889

Telephone : 908-423-1000

Telefax : 908-735-1496

Emergency telephone : 908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product

---

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 1A

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

#### 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.

---

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 90 - <= 100
Polyethylene glycol	25322-68-3	>= 10 - < 20
Clotrimazole	23593-75-1	>= 1 - < 5
Gentamicin	1403-66-3	>= 0.1 - < 1
Mometasone	83919-23-7	>= 0.1 - < 1

### 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.

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/14/2015
2.0	07/26/2016	412827-00002	Date of first issue: 12/14/2015

---

- |   |   |   |
|---|---|---|
| Most important symptoms and effects, both acute and delayed | : | May damage the unborn child. Suspected of damaging fertility.<br>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 when the potential for exposure exists. |
| Notes to physician  | : | Treat symptomatically and supportively.   |
- 

### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                 | : | None known.   |
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                  | : | Carbon oxides   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations.   |
| Environmental precautions   | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0	Revision Date: 07/26/2016	SDS Number: 412827-00002	Date of last issue: 12/14/2015 Date of first issue: 12/14/2015
----------------	------------------------------	-----------------------------	---

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.

### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapors or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice.  
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  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Ingredients	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>	OSHA Z-1
		TWA (Inhalable fraction)	5 mg/m <sup>3</sup>	ACGIH
		TWA (Mist)	5 mg/m <sup>3</sup>	NIOSH REL

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

		ST (Mist)	10 mg/m <sup>3</sup>	NIOSH REL
Polyethylene glycol	25322-68-3	TWA (aero- sol)	10 mg/m <sup>3</sup>	US WEEL
Clotrimazole	23593-75-1	TWA	200 µg/m <sup>3</sup>	Merck
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup>	Merck
Mometasone	83919-23-7	TWA	1 µg/m <sup>3</sup>	Merck
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Merck

**Engineering measures** : Minimize workplace exposure concentrations.  
Use with local exhaust ventilation.

### Personal protective equipment

**Respiratory protection** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks**

: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

**Eye protection**

: Wear the following personal protective equipment:  
Safety glasses

**Skin and body protection**

: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**Hygiene measures**

: Ensure that eye flushing systems and safety showers are located close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	white to off-white
Odor	:	oily
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available

---

### SECTION 10. STABILITY AND REACTIVITY

---

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0	Revision Date: 07/26/2016	SDS Number: 412827-00002	Date of last issue: 12/14/2015 Date of first issue: 12/14/2015
----------------	------------------------------	-----------------------------	---

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

### SECTION 11. TOXICOLOGICAL INFORMATION

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

#### Ingredients:

##### 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

##### Polyethylene glycol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

### 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 : (Rat): 0.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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  
Symptoms: Breathing difficulties

### Skin corrosion/irritation

Not classified based on available information.



## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

### **Ingredients:**

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

Species: Rabbit  
Result: No skin irritation

#### **Polyethylene glycol:**

Species: Rabbit  
Result: No skin irritation  
Remarks: Based on data from similar materials

#### **Clotrimazole:**

Species: Rabbit  
Result: No skin irritation

#### **Gentamicin:**

Species: Rabbit  
Result: Mild skin irritant  
Remarks: slight irritation

#### **Mometasone:**

Species: Rabbit  
Result: No skin irritation

#### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Ingredients:**

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

Species: Rabbit  
Result: No eye irritation

#### **Polyethylene glycol:**

Species: Rabbit  
Result: No eye irritation  
Remarks: Based on data from similar materials

#### **Clotrimazole:**

Species: Rabbit  
Result: Mild eye irritation

#### **Gentamicin:**

Species: Rabbit  
Result: Mild eye irritant  
Remarks: slight irritation

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

**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.

**Ingredients:****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  
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.

**Ingredients:****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

**Polyethylene glycol:**

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

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

		Remarks: Based on data from similar materials
<b>Clotrimazole:</b>		
	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.
<b>Gentamicin:</b>		
	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
<b>Mometasone:</b>		
	Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		: Test Type: Chromosomal aberration Species: Chinese hamster lung cells Result: negative
		: Test Type: Chromosomal aberration Species: Chinese hamster ovary cells Result: positive

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

Genotoxicity in vivo	: Test Type: Mouse Lymphoma Result: negative
	: 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.

### Ingredients:

#### White mineral oil (petroleum):

Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
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

### IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

**OSHA**      No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**      No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

|| May damage the unborn child. Suspected of damaging fertility.

### **Ingredients:**

#### **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

#### **Polyethylene glycol:**

|| Effects on fertility      :    Test Type: Reproduction/Developmental toxicity screening test  
Species: Rabbit  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

|| Effects on fetal development      :    Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

#### **Clotrimazole:**

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

|| 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.

Test Type: Embryo-fetal development

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

	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
	Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 180 mg/kg body weight
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 human epidemiological studies.

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

### Mometasone:

Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Subcutaneous Fertility: NOAEL: 0.015 mg/kg body weight Result: No effects on fertility.
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  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.

### Ingredients:

#### Mometasone:

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

### STOT-repeated exposure

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

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

### **Ingredients:**

#### **Clotrimazole:**

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

#### **Gentamicin:**

Target Organs: Kidney  
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**

#### **Ingredients:**

##### **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

##### **Polyethylene glycol:**

Species: Rat  
NOAEL: 1,100 mg/kg  
Application Route: Ingestion  
Exposure time: 13 Weeks  
Remarks: Based on data from similar materials

#### **Clotrimazole:**

Species: Rabbit  
LOAEL: 5 - 40 mg/kg  
Application Route: Skin contact  
Exposure time: 3 Weeks  
Target Organs: Skin  
Symptoms: Edema, Fissuring, Necrosis

Species: Rat  
LOAEL: 10 mg/kg  
Application Route: Oral  
Exposure time: 18 Months  
Target Organs: Liver, Kidney, Adrenal gland



**Mometasone / Clotrimazole / Gentamicin For-  
mulation**

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

---

Species: Dog  
LOAEL: 25 mg/kg  
Application Route: Oral  
Exposure time: 6 - 12 Months  
Target Organs: Adrenal gland  
Symptoms: Salivation, Lachrymation

**Gentamicin:**

Species: Dog  
LOAEL: 3 mg/kg  
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

Species: Monkey  
LOAEL: 6 mg/kg  
Exposure time: 3 Weeks  
Target Organs: Blood

Species: Rat  
NOAEL: 5 mg/kg  
LOAEL: 10 mg/kg  
Exposure time: 52 Weeks  
Target Organs: Kidney, Blood

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

**Mometasone:**

Species: Rat  
LOAEL: 0.3 mg/kg  
Application Route: Oral  
Target Organs: lymph node, Liver, Adrenal gland, Skin, thymus

Species: Dog  
LOAEL: 0.5 mg/kg  
Application Route: Oral  
Exposure time: 30 d  
Target Organs: lymph node, Liver, Adrenal gland, Skin, thymus

Species: Rat  
NOAEL: 0.00013 mg/l

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

Application Route: inhalation (dust/mist/fume)  
 Exposure time: 90 d  
 Target Organs: Adrenal gland, Lungs, lymph node, spleen, Bone marrow, Kidney, Liver, thymus

Species: Dog  
 NOAEL: 0.0005 mg/l  
 Application Route: inhalation (dust/mist/fume)  
 Exposure time: 90 d  
 Target Organs: Adrenal gland, Lungs, lymph node, spleen, Bone marrow, Kidney, thymus, Liver

### Aspiration toxicity

Not classified based on available information.

### Ingredients:

#### Mometasone:

No aspiration toxicity classification

### Experience with human exposure

#### Ingredients:

#### Clotrimazole:

Skin contact : Symptoms: Rash, Itching, Blistering, Edema, Dermatitis

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

#### Gentamicin:

Ingestion : Target Organs: Kidney  
 Symptoms: Dizziness, Vertigo, hearing loss

#### 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

### Ingredients:

#### Mometasone:

Remarks: Chronic Health Hazard  
 Dermal absorption possible

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Ingredients:

White mineral oil (petroleum):

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

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

### Polyethylene glycol:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
------------------	---	--

### 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	:	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

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

Toxicity to bacteria : 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 : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

EC50 (Microcystis aeruginosa (blue-green algae)): 4.7 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

NOEC (Microcystis aeruginosa (blue-green algae)): 1.6 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

Toxicity to bacteria : 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

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
 Date of first issue: 12/14/2015

		Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility.
Toxicity to algae	:	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)	:	100
Toxicity to bacteria	:	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

#### Ingredients:

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

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

#### **Polyethylene glycol:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 68 % Exposure time: 28 d Remarks: Based on data from similar materials
------------------	---	--

#### **Clotrimazole:**

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

## Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0	Revision Date: 07/26/2016	SDS Number: 412827-00002	Date of last issue: 12/14/2015 Date of first issue: 12/14/2015
----------------	------------------------------	-----------------------------	---

### II

#### Gentamicin:

Biodegradability	:	Result: Not readily biodegradable. 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

##### Ingredients:

#### Polyethylene glycol:

Biaccumulation	:	Species: Fish Bioconcentration factor (BCF): 3.2 Remarks: Based on data from similar materials
----------------	---	--

#### Gentamicin:

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

#### Mometasone:

Biaccumulation	:	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

No data available

#### Other adverse effects

No data available

### 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.
------------------------	---	--

## Mometasone / Clotrimazole / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/14/2015
2.0	07/26/2016	412827-00002	Date of first issue: 12/14/2015

If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Clotrimazole, Mometasone)
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, Mometasone)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964

##### IMDG-Code

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

##### 49 CFR

UN/ID/NA number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Clotrimazole, Mometasone)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes (Clotrimazole, Mometasone)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; how-

## Mometasone / Clotrimazole / Gentamicin Formulation

Version 2.0	Revision Date: 07/26/2016	SDS Number: 412827-00002	Date of last issue: 12/14/2015 Date of first issue: 12/14/2015
----------------	------------------------------	-----------------------------	---

ever it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### SECTION 15. REGULATORY INFORMATION

#### EPCRA - Emergency Planning and Community Right-to-Know

##### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

##### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

**SARA 311/312 Hazards** : Chronic Health Hazard

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

White mineral oil (petroleum)	8042-47-5
Polyethylene glycol	25322-68-3

**California Prop. 65** WARNING: This product contains a chemical known in the State of California to cause birth defects or other reproductive harm.

Gentamicin	1403-66-3
------------	-----------

##### California List of Hazardous Substances

<b>  </b>	White mineral oil (petroleum)	8042-47-5
-----------	-------------------------------	-----------

##### California Permissible Exposure Limits for Chemical Contaminants

<b>  </b>	White mineral oil (petroleum)	8042-47-5
-----------	-------------------------------	-----------

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

AICS	not determined
DSL	not determined
IECSC	not determined



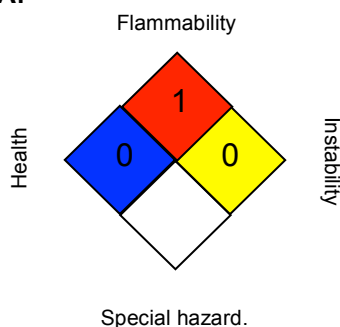
# Mometasone / Clotrimazole / Gentamicin For- mulation

Version 2.0      Revision Date: 07/26/2016      SDS Number: 412827-00002      Date of last issue: 12/14/2015  
Date of first issue: 12/14/2015

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA:



#### HMIS III:

HEALTH	<b>0*</b>
FLAMMABILITY	<b>1</b>
PHYSICAL HAZARD	<b>0</b>

0 = not significant, 1 = Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	: 8-hour, time-weighted average
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA	: 8-hour time weighted average
US WEEL / TWA	: 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Ob-

## Mometasone / Clotrimazole / Gentamicin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/14/2015
2.0	07/26/2016	412827-00002	Date of first issue: 12/14/2015

---

served (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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, <http://echa.europa.eu/>

Revision Date : 07/26/2016

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8