

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formulation



Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Clotrimazole Cream Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : +52 55 57284444  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)  
- repeated exposure  
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.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.  
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.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.

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# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion



Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

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

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 10 -< 20
White mineral oil (petroleum)	8042-47-5	>= 5 -< 10
clotrimazole	23593-75-1	>= 1 -< 5
Benzyl alcohol	100-51-6	>= 0.1 -< 1
Betamethasone	378-44-9	>= 0.01 -< 0.1

## 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.
- Most important symptoms and effects, both acute and delayed : May damage the unborn child. Suspected of damaging fertility.  
Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

### 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.

### 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

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula-tion



Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

certain local or national requirements.

### 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.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.
- 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
Petrolatum	8009-03-8	VLE-PPT (Mist)	5 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA (Inhalable)	5 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formulation

Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
 Date of first issue: 14.12.2015

		particulate matter)		
White mineral oil (petroleum)	8042-47-5	VLE-PPT (Mist)	5 mg/m <sup>3</sup>	NOM-010-STPS-2014
		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
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : cream

**Color** : white to off-white

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

---

Odor	:	No data available
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
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	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle size	:	Not applicable

# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

## SECTION 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.

## 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

### Components:

#### **Petrolatum:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity Remarks: Based on data from similar materials

#### **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

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion

Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

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

### Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

### Betamethasone:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Petrolatum:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

#### White mineral oil (petroleum):

Species : Rabbit  
Result : No skin irritation

### clotrimazole:

Species : Rabbit



**Betamethasone / Clotrimazole Cream Formula-  
tion**

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

---

||Result : No skin irritation

**Benzyl alcohol:**

||Species : Rabbit  
||Method : OECD Test Guideline 404  
||Result : No skin irritation

**Betamethasone:**

||Species : Rabbit  
||Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Petrolatum:**

||Species : Rabbit  
||Result : No eye irritation  
||Method : OECD Test Guideline 405  
||Remarks : Based on data from similar materials

**White mineral oil (petroleum):**

||Species : Rabbit  
||Result : No eye irritation

**clotrimazole:**

||Species : Rabbit  
||Result : Mild eye irritation

**Benzyl alcohol:**

||Species : Rabbit  
||Result : Irritation to eyes, reversing within 21 days  
||Method : OECD Test Guideline 405

**Betamethasone:**

||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.

# Betamethasone / Clotrimazole Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

---

**Components:****Petrolatum:**

Test Type	:	Buehler Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

**White mineral oil (petroleum):**

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

**Benzyl alcohol:**

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

**Betamethasone:**

Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	Weak sensitizer

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Petrolatum:**

Genotoxicity in vitro	:	Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on data from similar materials
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

**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)

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion



Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

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.

### Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### Betamethasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
  
Test Type: Chromosome aberration test in vitro  
Result: positive

# Betamethasone / Clotrimazole Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Components:

#### **Petrolatum:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

#### **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

#### **Benzyl alcohol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Method : OECD Test Guideline 451  
Result : negative

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### **Petrolatum:**

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

# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

### 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.

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

# Betamethasone / Clotrimazole Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

||| experiments.

### Benzyl alcohol:

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

||| Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### Betamethasone:

||| Effects on fetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
Result: Fetotoxicity., Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
Result: Malformations were observed.

Species: Mouse  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

||| Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or 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.

#### Betamethasone:

||| Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood,

# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

---

Assessment	:	Adrenal gland Causes damage to organs through prolonged or repeated exposure.
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### Repeated dose toxicity

#### Components:

##### **Petrolatum:**

Species	:	Rat
NOAEL	:	5,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 y

##### **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
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

##### **Benzyl alcohol:**

Species	:	Rat
NOAEL	:	1.072 mg/l
Application Route	:	inhalation (dust/mist/fume)

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion

Version 8.0      Revision Date: 06.04.2024      SDS Number: 412905-00021      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

---

Exposure time : 28 Days  
Method : OECD Test Guideline 412

### **Betamethasone:**

Species : Rabbit  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 10 - 30 d  
Target Organs : Pituitary gland, Immune system, muscle

Species : Rat  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Mouse  
LOAEL : 0.1 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Dog  
LOAEL : 0.05 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Target Organs : Blood, thymus gland, Adrenal gland

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### **Components:**

##### **clotrimazole:**

Skin contact : Symptoms: Rash, Itching, Blistering, Edema, Redness  
Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

##### **Betamethasone:**

Inhalation : Target Organs: Adrenal gland  
Skin contact : Symptoms: Redness, pruritis, Irritation

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### **Components:**

##### **Petrolatum:**

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction

---



# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

		Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

### White mineral oil (petroleum):

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOEC (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

### clotrimazole:

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

# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

	Exposure time: 72 h
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
Toxicity to microorganisms	: EC50: > 10,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Benzyl alcohol:

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	: NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

### Betamethasone:

Toxicity to daphnia and other aquatic invertebrates	: EC50 (Americamysis): > 50 mg/l Exposure time: 96 h
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
	: NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.

# Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
		NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l Exposure time: 219 d Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

## Persistence and degradability

### Components:

#### **Petrolatum:**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 31 % Exposure time: 28 d Method: OECD Test Guideline 301F Remarks: Based on data from similar materials
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#### **White mineral oil (petroleum):**

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 31 % Exposure time: 28 d
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#### **clotrimazole:**

Stability in water	:	Hydrolysis: 50 %(242 d)
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#### **Benzyl alcohol:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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## Bioaccumulative potential

### Components:

#### **Benzyl alcohol:**

Partition coefficient: n-octanol/water	:	log Pow: 1.05
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#### **Betamethasone:**

Partition coefficient: n-octanol/water	:	log Pow: 2.11
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#### **Mobility in soil**

No data available

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(clotrimazole, betamethasone)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(clotrimazole, Betamethasone)

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, Betamethasone)

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

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

### NOM-002-SCT

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

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

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

## SECTION 16. OTHER INFORMATION

Revision Date	:	06.04.2024
Date format	:	dd.mm.yyyy

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	:	Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value
PPT	:	

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

# SAFETY DATA SHEET



## Betamethasone / Clotrimazole Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
8.0	06.04.2024	412905-00021	Date of first issue: 14.12.2015

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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; TECl - 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, <http://echa.europa.eu/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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