

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

---

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Betamethasone / Clotrimazole Ointment Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

---

### SECTION 2: Hazards identification



#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

Precautionary statements :

### Prevention:

- P201 Obtain special instructions before use.
- P264 Wash skin thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

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

Hazardous components which must be listed on the label:

betamethasone

### 2.3 Other hazards

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
clotrimazole	23593-75-1 245-764-8	Acute Tox. 4; H302 Acute Tox. 3; H311 Eye Irrit. 2; H319 Repr. 2; H361fd STOT RE 2; H373 (Liver, Kidney, Adrenal gland) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 1 - < 2,5
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)	>= 0,025 - < 0,1

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

		Aquatic Chronic 1; H410	
		M-Factor (Chronic aquatic toxicity): 1.000	

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides

#### 5.3 Advice for firefighters

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

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.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- |                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>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.<br>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. |

### 7.2 Conditions for safe storage, including any incompatibilities

- |                                               |   |                                                                                                                                           |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives<br>Gases                     |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	TWA (Vapour)	50 mg/m <sup>3</sup>	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m <sup>3</sup>	FOR-2011-12-06-1358
White mineral oil (petroleum)	8042-47-5	TWA (Vapour)	50 mg/m <sup>3</sup>	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m <sup>3</sup>	FOR-2011-12-06-1358
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

##### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9,33 mg/kg food

#### 8.2 Exposure controls

##### Engineering measures

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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.

##### Personal protective equipment

- 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to NS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance : Viscous semi-solid  
Colour : No data available  
Odour : No data available  
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available  
Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : Not classified as a flammability hazard

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available  
Partition coefficient: n-octanol/water : Not applicable  
Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available

Particle size : Not applicable

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : 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



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

---

### Components:

#### **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

#### **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:

#### **clotrimazole:**

Species : Rabbit  
Result : No skin irritation

#### **betamethasone:**

Species : Rabbit  
Result : Mild skin irritation

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

Not classified based on available information.

### Components:

#### **clotrimazole:**

Species : Rabbit  
Result : Mild eye irritation

#### **betamethasone:**

Species : Rabbit  
Result : No eye irritation

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

---

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### betamethasone:

Exposure routes                   : Dermal  
Species                               : Guinea pig  
Result                                 : Weak sensitizer

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### 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.

##### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

---

Genotoxicity in vivo : Result: positive  
: 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:

#### clotrimazole:

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

### Reproductive toxicity

May damage the unborn child.

### Components:

#### clotrimazole:

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

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

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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

---

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

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### **betamethasone:**

Effects on foetal 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 through prolonged or repeated exposure.

### **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, Adrenal gland  
Assessment : Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version 6.4      Revision Date: 10.10.2020      SDS Number: 610702-00013      Date of last issue: 23.03.2020  
Date of first issue: 08.04.2016

---

### Repeated dose toxicity

#### Components:

##### **clotrimazole:**

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

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

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

##### **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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### **clotrimazole:**

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

##### **betamethasone:**

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **clotrimazole:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 0,29 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,02 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l  
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 0,017 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50 : > 10.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,025 mg/l  
Exposure time: 32 d  
Species: Oncorhynchus mykiss (rainbow trout)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,01 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

M-Factor (Chronic aquatic toxicity) : 10

### 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

Toxicity to fish (Chronic toxicity) : NOEC: 0,052 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

NOEC: 0,07 µg/l  
Exposure time: 219 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

### 12.2 Persistence and degradability

#### Components:

##### clotrimazole:

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

### 12.3 Bioaccumulative potential

#### Components:

##### betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2,11

### 12.4 Mobility in soil

No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- |                        |   |                                                                                                                                                                                                                                                                       |
|------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : | Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. |
| 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

### 14.1 UN number

- |      |   |         |
|------|---|---------|
| ADN  | : | UN 3077 |
| ADR  | : | UN 3077 |
| RID  | : | UN 3077 |
| IMDG | : | UN 3077 |
| IATA | : | UN 3077 |

### 14.2 UN proper shipping name

- |      |   |                                                                                     |
|------|---|-------------------------------------------------------------------------------------|
| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(betamethasone, clotrimazole) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(betamethasone, clotrimazole) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(betamethasone, clotrimazole) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(betamethasone, clotrimazole) |
| IATA | : | Environmentally hazardous substance, solid, n.o.s.<br>(betamethasone, clotrimazole) |

### 14.3 Transport hazard class(es)

- |     |   |   |
|-----|---|---|
| ADN | : | 9 |
|-----|---|---|



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

---

**ADR** : 9  
**RID** : 9  
**IMDG** : 9  
**IATA** : 9

### 14.4 Packing group

#### ADN

Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

#### ADR

Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

#### RID

Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

#### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

#### IATA (Cargo)

Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

#### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
----	-----------------------	---------------------	---------------------

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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

#### Full text of H-Statements

H302 : Harmful if swallowed.  
H311 : Toxic in contact with skin.  
H319 : Causes serious eye irritation.  
H330 : Fatal if inhaled.  
H360D : May damage the unborn child.  
H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Irrit. : Eye irritation  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
6.4	10.10.2020	610702-00013	Date of first issue: 08.04.2016

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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

### Further information

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

### Classification of the mixture:

Repr. 1B	H360D
STOT RE 1	H372
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method

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.

NO / EN