

**Betamethasone (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Betamethasone (0.05%) Cream Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
P264 Wash skin thoroughly after handling.

---

## Betamethasone (0.05%) Cream Formulation

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 20 -<= 30
Decamethylcyclopentasiloxane	541-02-6	7
Glyceryl monostearate	123-94-4	3
4-Chloro-3-methylphenol	59-50-7	0,1
Betamethasone	378-44-9	0,064

**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 : May damage the unborn child.  
Causes damage to organs through prolonged or repeated

# SAFETY DATA SHEET



## Betamethasone (0.05%) Cream Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

delayed exposure.  
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 : Vapors may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.  
Hazardous combustion products : Carbon oxides  
Silicon oxides  
Formaldehyde  
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.  
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 : 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 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.

---

# SAFETY DATA SHEET



## Betamethasone (0.05%) Cream Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
 Date of first issue: 17.05.2017

- 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 dust, fume, gas, mist, vapors or spray.  
 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.
- 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	CMP (Mist)	5 mg/m <sup>3</sup>	AR OEL
	Further information: Sampled by a method which does not include vapour, lung			
		CMP - CPT (Mist)	10 mg/m <sup>3</sup>	AR OEL
	Further information: lung			
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Glyceryl monostearate	123-94-4	CMP	10 mg/m <sup>3</sup>	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen, Irritation			
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			

## Betamethasone (0.05%) Cream Formulation

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
 Date of first issue: 17.05.2017

		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal
--	--	------------	---------------------------	----------

**Occupational exposure limits of decomposition products**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Formaldehyde	50-00-0	CMP-C	0,3 ppm	AR OEL
	Further information: A2 - Suspected human carcinogen, Sensitization, Cancer, Irritation			
		TWA	0,1 ppm	ACGIH
		STEL	0,3 ppm	ACGIH

**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**

**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, inorganic gas/vapor and organic vapor type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

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

**Skin and body protection** : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

# SAFETY DATA SHEET



## Betamethasone (0.05%) Cream Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

use of administrative controls.

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Color	:	white
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	:	> 93,3 °C
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	Not applicable
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	:	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
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

**Betamethasone (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

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

Particle size : Not applicable

---

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Vapors may form explosive mixture with air.  
Can react with strong oxidizing agents.  
Hazardous decomposition products will be formed at elevated temperatures.

Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents

**Hazardous decomposition products**

Thermal decomposition : Formaldehyde

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
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

**Decamethylcyclopentasiloxane:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 8,67 mg/l

---

**Betamethasone (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Glyceryl monostearate:**

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  
Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**

Acute oral toxicity : LD50 (Mouse): 600 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,871 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 5.000 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:****Petrolatum:**

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

**Decamethylcyclopentasiloxane:**

Species : Rabbit  
Result : No skin irritation

**Glyceryl monostearate:**

Species : Rabbit  
Result : No skin irritation



**Betamethasone (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

Remarks : Based on data from similar materials

**4-Chloro-3-methylphenol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Corrosive after 1 to 4 hours of exposure

**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

**Decamethylcyclopentasiloxane:**

Species : Rabbit  
Result : No eye irritation

**Glyceryl monostearate:**

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

**4-Chloro-3-methylphenol:**

Species : Rabbit  
Result : Irreversible effects on the eye  
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 (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

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

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

**Decamethylcyclopentasiloxane:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

**Glyceryl monostearate:**

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

**4-Chloro-3-methylphenol:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

**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

**Betamethasone (0.05%) Cream Formulation**

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

---

**Decamethylcyclopentasiloxane:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative
- 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: Rat  
Application Route: inhalation (vapor)  
Method: OECD Test Guideline 474  
Result: negative
- Test Type: Unscheduled DNA synthesis (UDS) test with  
mammalian liver cells in vivo  
Species: Rat  
Application Route: Inhalation  
Method: OECD Test Guideline 486  
Result: negative

**Glyceryl monostearate:**

- Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials
- Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**

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

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

Test Type: Chromosome aberration test in vitro  
Result: positive

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

**Reproductive toxicity**

May damage the unborn child.

**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

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

**Decamethylcyclopentasiloxane:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: inhalation (vapor)  
Method: OPPTS 870.3800  
Result: negative

Effects on fetal development : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: inhalation (vapor)  
Method: OPPTS 870.3800

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

Result: negative

**Glyceryl monostearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 422  
 Result: negative  
 Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**

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

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test  
 Species: Rat  
 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.



## Betamethasone (0.05%) Cream Formulation

Version 3.4      Revision Date: 10.10.2020      SDS Number: 1685861-00008      Date of last issue: 23.03.2020  
Date of first issue: 17.05.2017

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:****Betamethasone:**

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

**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  
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

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

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

**Decamethylcyclopentasiloxane:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 16 µg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 2,9 µg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 12 µg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

EC10 (Pseudokirchneriella subcapitata (green algae)): > 12 µg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 14 µg/l  
Exposure time: 90 d  
Method: OECD Test Guideline 210  
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 15 µg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms : EC50: > 2.000 mg/l  
Exposure time: 3 h  
Method: 88/302/EC

**Glyceryl monostearate:**

Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 32 mg/l  
Exposure time: 47 h  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: No toxicity at the limit of solubility.  
Based on data from similar materials



## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOELR (Oryzias latipes (Japanese medaka)): > 1 mg/l  
 Exposure time: 14 d  
 Method: OECD Test Guideline 204  
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 0,22 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211  
 Remarks: No toxicity at the limit of solubility.  
 Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1 mg/l  
 Exposure time: 18 h  
 Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l  
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,5 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Chlorella pyrenoidosa): 15 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

EC10 (Chlorella pyrenoidosa): 2,3 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 0,15 mg/l  
 Exposure time: 28 d  
 Method: OECD Test Guideline 204

Toxicity to daphnia and other aquatic invertebrates (Chronic) : NOEC (Daphnia magna (Water flea)): 0,32 mg/l  
 Exposure time: 21 d

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

ic toxicity) Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 22,86 mg/l  
Exposure time: 60 h

**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 (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

M-Factor (Chronic aquatic toxicity) : 1.000

**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

**Decamethylcyclopentasiloxane:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 0,14 %  
Exposure time: 28 d  
Method: OECD Test Guideline 310

**Glyceryl monostearate:**

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 78 %  
Exposure time: 15 d  
Method: OECD Test Guideline 301

**Bioaccumulative potential****Components:****Decamethylcyclopentasiloxane:**

Bioaccumulation : Species: Pimephales promelas (fathead minnow)  
Bioconcentration factor (BCF): 7.060 - 13.300  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 8,023

**Glyceryl monostearate:**

Partition coefficient: n-octanol/water : log Pow: 6,1

**4-Chloro-3-methylphenol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 5,5 - 13

Partition coefficient: n-octanol/water : log Pow: 0,477

**Betamethasone:**

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

**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.  
If not otherwise specified: Dispose of as unused product.

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

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

**UNRTDG**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)  
 Class : 9  
 Packing group : III  
 Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077  
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Betamethasone)  
 Class : 9  
 Packing group : III  
 Labels : Miscellaneous  
 Packing instruction (cargo aircraft) : 956  
 Packing instruction (passenger aircraft) : 956  
 Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3077  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (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.

**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**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

## Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

**International Regulations**

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

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

**SECTION 16. OTHER INFORMATION****Further information**

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/>

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AR OEL / CMP	:	TLV (Threshold Limit Value)
AR OEL / CMP - CPT	:	STEL (Short Term Limit Value)
AR OEL / CMP-C	:	Ceiling value

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - 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; TSCA - Toxic Substances Control Act (United States); UN - United Na-

# SAFETY DATA SHEET



## Betamethasone (0.05%) Cream Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	1685861-00008	Date of first issue: 17.05.2017

---

tions; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AR / Z8