

# SAFETY DATA SHEET



## Betamethasone (0.05%) Cream Formulation



Version 3.10      Revision Date: 30.09.2023      SDS Number: 1682146-00014      Date of last issue: 04.04.2023  
Date of first issue: 17.05.2017

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) 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 - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

#### 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.

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.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

**Storage:**

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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	$\geq 20$ - $\leq 30$
Decamethylcyclopentasiloxane	541-02-6	7
Glyceryl monostearate	123-94-4	3
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 delayed : May damage the unborn child.  
Causes damage to organs through prolonged or repeated 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

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- 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.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe 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.
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- Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : Do not breathe decomposition products.  
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.
- Conditions for safe storage : 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.  
Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.
- Materials to avoid : Store in accordance with the particular national regulations.  
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 particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Glyceryl monostearate	123-94-4	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		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			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

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### Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Formaldehyde	50-00-0	VLE-P	0.3 ppm	NOM-010-STPS-2014
		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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : cream

**Color** : white

**Odor** : No data available

**Odor Threshold** : No data available

**pH** : No data available

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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

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

Particle size : Not applicable

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Vapors may form explosive mixture with air.



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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

**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  
Remarks : Based on data from similar materials

**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



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### **Decamethylcyclpentasiloxane:**

Species	:	Rabbit
Result	:	No eye irritation

### **Glyceryl monostearate:**

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

### **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.

### **Components:**

#### **Petrolatum:**

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

#### **Decamethylcyclpentasiloxane:**

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

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

### **Germ cell mutagenicity**

Not classified based on available information.

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**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

**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

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Result: negative  
Remarks: Based on data from similar materials

### **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

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:**

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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  
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

**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.

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**STOT-repeated exposure**

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

**Components:****Betamethasone:**

Target Organs	:	Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Petrolatum:**

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

**Decamethylcyclopentasiloxane:**

Species	:	Rat
NOAEL	:	1,000 mg/kg
LOAEL	:	> 1,000 mg/kg
Application Route	:	Ingestion
Method	:	OECD Test Guideline 408

**Glyceryl monostearate:**

Species	:	Rat
NOAEL	:	>= 12,500 mg/kg
Application Route	:	Ingestion
Exposure time	:	84 Days
Remarks	:	Based on data from similar materials

**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

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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

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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 Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
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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
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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
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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
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**Decamethylcyclopentasiloxane:**

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

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Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

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

**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

**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

**Decamethylcyclpentasiloxane:**



# SAFETY DATA SHEET



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Version 3.10      Revision Date: 30.09.2023      SDS Number: 1682146-00014      Date of last issue: 04.04.2023  
Date of first issue: 17.05.2017

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Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 0.14 %  
Exposure time: 28 d  
Method: OECD Test Guideline 310

### **Glyceryl monostearate:**

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

### **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

#### **Betamethasone:**

Partition coefficient: n-octanol/water : log Pow: 2.11

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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## 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.

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## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

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

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Packing group : III  
Labels : 9  
Environmentally hazardous : yes

### 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 : 956  
aircraft)  
Packing instruction (passen- : 956  
ger aircraft)  
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.

### Domestic regulation

#### NOM-002-SCT

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

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## SECTION 15. REGULATORY INFORMATION

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

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

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### 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	:	30.09.2023
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
ACGIH / STEL	:	Short-term exposure limit
NOM-010-STPS-2014 / VLE-	:	Time weighted average limit value
PPT	:	
NOM-010-STPS-2014 / VLE-	:	Ceiling value
P	:	

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recom-

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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/>

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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