

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone (0.05%) Ointment Formulation

#### Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

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

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

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

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION



#### GHS classification of chemical product

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/ vapours/ spray.  
P264 Wash skin thoroughly after handling.

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
 Date of first issue: 2017/05/18

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.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Petrolatum	8009-03-8	>= 80 - < 90	
Propylene glycol	57-55-6	>= 10 - < 20	2-234
Propylene glycol monostearate	1323-39-3	>= 1 - < 10	2-772, 2-2523
betamethasone	378-44-9	>= 0.025 - < 0.1	

**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 : May damage the unborn child.

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
3.0	2020/03/23	1681978-00007	Date of first issue: 2017/05/18

---

and effects, both acute and delayed  
Protection of first-aiders : Causes damage to organs through prolonged or repeated exposure.  
: 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.

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### 5. FIREFIGHTING 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 : Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.  
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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### 7. HANDLING AND STORAGE

#### Handling

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

- 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 swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Storage**
- Conditions for safe storage : Keep in properly labelled 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
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	OEL-M (Mist)	3 mg/m <sup>3</sup>	JP OEL JSOH
	Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans			
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Propylene glycol monostearate	1323-39-3	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Res-	3 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

		pirable particulate matter)		
betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : 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** : Particulates 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state** : ointment

**Colour** : white to off-white

**Odour** : No data available

**Odour Threshold** : No data available

**Melting point/freezing point** : No data available

**Boiling point, initial boiling point and boiling range** : No data available

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

---

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

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : > 93.3 °C

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : Not applicable

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reac- : Vapours may form explosive mixture with air.

## Betamethasone (0.05%) Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
3.0	2020/03/23	1681978-00007	Date of first issue: 2017/05/18

tions	Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**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

**Propylene glycol:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	: LC50 (Rabbit): > 159 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

**Propylene glycol monostearate:**

Acute oral toxicity	: LD50 (Mouse): > 5,000 mg/kg
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**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

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

---

**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

**Propylene glycol:**

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

**Propylene glycol monostearate:**

Result : No skin irritation

**betamethasone:**

Species : Rabbit  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

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

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

**Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**betamethasone:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.



## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
 Date of first issue: 2017/05/18

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

Test Type : Buehler Test  
 Exposure routes : Skin contact  
 Species : Guinea pig  
 Result : negative  
 Remarks : Based on data from similar materials

**Propylene glycol:**

Test Type : Maximisation Test  
 Exposure routes : Skin contact  
 Species : Guinea pig  
 Result : negative

**betamethasone:**

Exposure routes : 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

**Propylene glycol:**

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

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

**betamethasone:**

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

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
 Date of first issue: 2017/05/18

		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

**Propylene glycol:**

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

**Propylene glycol:**

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study
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## Betamethasone (0.05%) Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
3.0	2020/03/23	1681978-00007	Date of first issue: 2017/05/18

			Species: Mouse Application Route: Ingestion Result: negative
	Effects on foetal development	:	Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative
	<b>betamethasone:</b>		
	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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

**Components:**

<b>betamethasone:</b>			
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:**

<b>Petrolatum:</b>			
Species	:		Rat
NOAEL	:		5,000 mg/kg
Application Route	:		Ingestion
Exposure time	:		2 yr

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

---

### Propylene glycol:

Species : Rat, male  
NOAEL : 1,700 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

### betamethasone:

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

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

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

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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

### betamethasone:

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

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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

### Petrolatum:

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

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
 Date of first issue: 2017/05/18

		Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
<b>Propylene glycol:</b>		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h
<b>betamethasone:</b>		
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 tox-	:	NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

icity)      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

**Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Bioaccumulative potential****Components:****Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07

**betamethasone:**

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

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version      Revision Date:      SDS Number:      Date of last issue: 2019/09/13  
3.0          2020/03/23          1681978-00007      Date of first issue: 2017/05/18

---

### 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.

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### 14. TRANSPORT INFORMATION

#### International Regulations

##### 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  
Subsidiary risk                 : ENVIRONM.  
Packing group                  : III  
Labels                          : 9 (ENVIRONM.)  
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.

#### National Regulations

Refer to section 15 for specific national regulation.

#### 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

## Betamethasone (0.05%) Ointment Formulation

Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Designated Flammable Substances, Flammable solid, (3000 kilogram)

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Number	Concentration (%)
Mineral oil	168	>=80 - <90

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Number
Mineral oil	168

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable



# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version 3.0      Revision Date: 2020/03/23      SDS Number: 1681978-00007      Date of last issue: 2019/09/13  
Date of first issue: 2017/05/18

---

### **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

### **Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

### **Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

### **Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

### **Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Y)

Pack transportation : Classified as marine pollutant

### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### **Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## 16. OTHER INFORMATION

### **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/>

# SAFETY DATA SHEET



## Betamethasone (0.05%) Ointment Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2019/09/13
3.0	2020/03/23	1681978-00007	Date of first issue: 2017/05/18

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

AICS - Australian Inventory of Chemical Substances; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN