

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Lotion Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

<b>Appearance</b>	: lotion
<b>Colour</b>	: No data available
<b>Odour</b>	: No data available

Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

#### GHS Classification

Flammable liquids	: Category 2
Serious eye damage/eye irritation	: Category 2A
Reproductive toxicity	: Category 1B
Specific target organ toxicity - single exposure	: Category 3
Specific target organ toxicity - repeated exposure	: Category 1
Long-term (chronic) aquatic hazard	: Category 1

#### GHS label elements

# SAFETY DATA SHEET





according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

Hazard pictograms	:	   
Signal word	:	Danger
Hazard statements	:	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H360D May damage the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking. P233 Keep container tightly closed. P241 Use explosion-proof electrical/ ventilating/ lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. <b>Response:</b> P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P391 Collect spillage. <b>Storage:</b> P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. <b>Disposal:</b> P501 Dispose of contents/ container to an approved waste

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

|| disposal plant.

### Physical and chemical hazards

Highly flammable liquid and vapour.

### Health hazards

Causes serious eye irritation. May damage the unborn child. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure.

### Environmental hazards

Very toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification

|| Vapours may form explosive mixture with air.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	$\geq 30$ - $< 50$
betamethasone	378-44-9	$\geq 0.025$ - $< 0.1$

## 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 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- 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 : Causes serious eye irritation.  
May cause drowsiness or dizziness.  
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).

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
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.

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.  
Ventilate the area.  
Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and dis-

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

posal 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.

### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Do not get in 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  
Non-sparking tools should be used.  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

#### Storage

- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives
- Packaging material : Unsuitable material: None known.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	PC-TWA	350 mg/m <sup>3</sup>	CN OEL
		PC-STEL	700 mg/m <sup>3</sup>	CN OEL
		TWA	200 ppm	ACGIH
		STEL	400 ppm	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

#### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work-week	40 mg/l	ACGIH BEI

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Use explosion-proof electrical, ventilating and lighting equipment.

#### 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** : Organic vapour type

**Eye/face 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

---

contaminated clothing.

|| Hand protection  
|| Material : Chemical-resistant gloves

||| Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

||| 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.

---

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : lotion

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

||| Flash point : 21.4 °C

||| Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

---

Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

---

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

---

### 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Propan-2-ol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 25 mg/l



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

---

Exposure time: 6 h  
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 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:**

#### **Propan-2-ol:**

Species : Rabbit  
Result : No skin irritation

#### **betamethasone:**

Species : Rabbit  
Result : Mild skin irritation

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

Causes serious eye irritation.

### **Components:**

#### **Propan-2-ol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

#### **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.

### **Components:**

#### **Propan-2-ol:**

Test Type : Buehler Test

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

---

Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **betamethasone:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Propan-2-ol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
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: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

#### **betamethasone:**

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: positive

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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

---

### Components:

#### **Propan-2-ol:**

Species : Rat  
Application Route : inhalation (vapour)  
Exposure time : 104 weeks  
Method : OECD Test Guideline 451  
Result : negative

#### **Reproductive toxicity**

May damage the unborn child.

### Components:

#### **Propan-2-ol:**

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

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **betamethasone:**

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

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

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

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

#### **STOT - single exposure**

May cause drowsiness or dizziness.

### Components:

#### **Propan-2-ol:**

Assessment : May cause drowsiness or dizziness.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

---

### STOT - repeated exposure

Causes damage to organs 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:

##### Propan-2-ol:

Species	:	Rat
NOAEL	:	12.5 mg/l
Application Route	:	inhalation (vapour)
Exposure time	:	104 Weeks

##### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

### Experience with human exposure

#### Components:

##### **betamethasone:**

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

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Propan-2-ol:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l Exposure time: 96 h
------------------	---	--

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h
---	---	---

Toxicity to microorganisms	:	EC50 (Pseudomonas putida): > 1,050 mg/l Exposure time: 16 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)	:	1,000
----------------------------	---	-------

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

toxicity)

### Persistence and degradability

#### Components:

##### Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

### Bioaccumulative potential

#### Components:

##### Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

##### betamethasone:

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

### Mobility in soil

No data available

### Other adverse effects

No data available

## 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.  
Empty containers retain residue and can be dangerous.  
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.  
If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 1219  
Proper shipping name : ISOPROPANOL SOLUTION  
Class : 3  
Packing group : II  
Labels : 3

#### IATA-DGR

UN/ID No. : UN 1219  
Proper shipping name : Isopropanol solution

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version 3.0      Revision Date: 2020/09/30      SDS Number: 4371270-00004      Date of last issue: 2020/09/25  
Date of first issue: 2019/05/30

Class : 3  
Packing group : II  
Labels : Flammable Liquids  
Packing instruction (cargo aircraft) : 364  
Packing instruction (passenger aircraft) : 353

### IMDG-Code

UN number : UN 1219  
Proper shipping name : ISOPROPANOL SOLUTION (betamethasone)  
Class : 3  
Packing group : II  
Labels : 3  
EmS Code : F-E, S-D  
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

#### GB 6944/12268

UN number : UN 1219  
Proper shipping name : ISOPROPANOL SOLUTION  
Class : 3  
Packing group : II  
Labels : 3

### 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.

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : Listed

#### Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

No. / Code	Chemical name / Category	Threshold quantity
W5.3	Flammable liquids	1,000 t

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

### 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/>

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)  
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
CN OEL / PC-TWA : Permissible concentration - time weighted average  
CN OEL / PC-STEEL : Permissible concentration - short term exposure limit

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/09/25
3.0	2020/09/30	4371270-00004	Date of first issue: 2019/05/30

---

vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

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.

CN / EN