

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version 4.1      Revision Date: 04/06/2024      SDS Number: 4371267-00012      Date of last issue: 09/30/2023  
Date of first issue: 05/30/2019

### SECTION 1. IDENTIFICATION

Product name : Betamethasone (0.05%) Lotion Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 1-551-430-6000  
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

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids : Category 2  
Eye irritation : Category 2A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity - single exposure : Category 3  
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 : H225 Highly flammable liquid and vapor.  
H319 Causes serious eye irritation.  
H336 May cause drowsiness or dizziness.  
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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version 4.1      Revision Date: 04/06/2024      SDS Number: 4371267-00012      Date of last issue: 09/30/2023  
Date of first issue: 05/30/2019

P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical, ventilating and lighting equipment.  
P242 Use only non-sparking tools.  
P243 Take precautionary measures against static discharge.  
P260 Do not breathe mist or vapors.  
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.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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 attention.  
P337 + P313 If eye irritation persists: Get medical attention.

### Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.  
P405 Store locked up.

### Disposal:

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

### Other hazards

Vapors may form explosive mixture with air.

## SECTION 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	$\geq 0.01 - < 0.1$

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

		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).
Notes to physician	:	Treat symptomatically and supportively.

---

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	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. Vapors 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

- 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/vapors/mists with a water spray jet.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

---

### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- 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 vapors.  
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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version 4.1      Revision Date: 04/06/2024      SDS Number: 4371267-00012      Date of last issue: 09/30/2023  
Date of first issue: 05/30/2019

- Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
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:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Flammable solids  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Substances and mixtures which in contact with water emit flammable gases  
Explosives  
Gases  
Very acutely toxic substances and mixtures

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		ST	500 ppm 1,225 mg/m <sup>3</sup>	NIOSH REL
		TWA	400 ppm 980 mg/m <sup>3</sup>	NIOSH REL
		TWA	400 ppm 980 mg/m <sup>3</sup>	OSHA Z-1
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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.

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

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

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	lotion
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	70.5 °F / 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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
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	:	No data available

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Highly flammable liquid and vapor.  
Vapors 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.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

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  
Exposure time: 6 h  
Test atmosphere: vapor

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



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

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 sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Propan-2-ol:

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

##### Betamethasone:

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

### 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.

#### Components:

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

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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### Betamethasone:

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

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

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

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

### STOT-single exposure

May cause drowsiness or dizziness.

### Components:

#### Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

### STOT-repeated exposure

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version 4.1      Revision Date: 04/06/2024      SDS Number: 4371267-00012      Date of last issue: 09/30/2023  
Date of first issue: 05/30/2019

---

### 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 (vapor)  
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.

### **Experience with human exposure**

#### Components:

##### **Betamethasone:**

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

### SECTION 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

#### Persistence and degradability

##### Components:

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

- Biodegradability : Result: rapidly degradable
- BOD/COD : BOD: 1,19 (BOD5)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

COD: 2,23  
BOD/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

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations. Do not dispose of waste into sewer.

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.

---

## SECTION 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

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

#### **IATA-DGR**

UN/ID No. : UN 1219  
Proper shipping name : Isopropanol solution  
Class : 3  
Packing group : II  
Labels : Flammable Liquids  
Packing instruction (cargo) : 364

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

aircraft)

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.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 1219  
Proper shipping name : Isopropanol SOLUTION  
Class : 3  
Packing group : II  
Labels : FLAMMABLE LIQUID  
ERG Code : 129  
Marine pollutant : yes(Betamethasone)

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Flammable (gases, aerosols, liquids, or solids)  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

**SARA 313** : The following components are subject to reporting levels established by SARA Title III, Section 313:

Propan-2-ol	67-63-0	>= 30 - < 50 %
-------------	---------	----------------

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version 4.1      Revision Date: 04/06/2024      SDS Number: 4371267-00012      Date of last issue: 09/30/2023  
Date of first issue: 05/30/2019

### US State Regulations

#### Pennsylvania Right To Know

Water      7732-18-5  
Propan-2-ol      67-63-0

#### California List of Hazardous Substances

Propan-2-ol      67-63-0

#### California Permissible Exposure Limits for Chemical Contaminants

Propan-2-ol      67-63-0

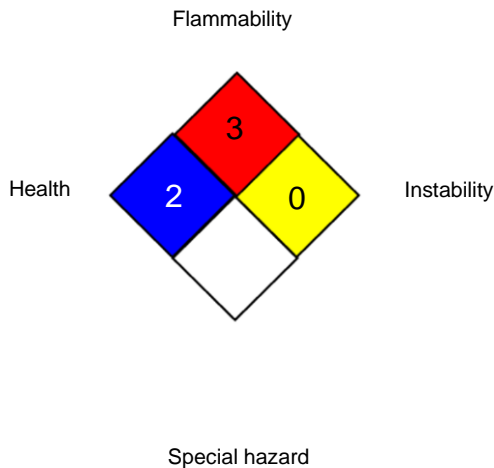
The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

workday during a 40-hour workweek  
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded  
at any time during a workday  
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 04/06/2024

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Betamethasone (0.05%) Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.1	04/06/2024	4371267-00012	Date of first issue: 05/30/2019

---

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.

US / Z8