

# SAFETY DATA SHEET



## Betamethasone (0.05%) Lotion Formulation



Version 3.0      Revision Date: 30.09.2020      SDS Number: 4371237-00004      Date of last issue: 25.09.2020  
Date of first issue: 30.05.2019

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Lotion Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

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### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

|| Very highly flammable liquids

##### 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 (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 : H225 Highly flammable liquid and vapour.

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|                          |  |
|--------------------------|--|
| Precautionary statements | <p>H319 Causes serious eye irritation.<br/>H336 May cause drowsiness or dizziness.<br/>H360D May damage the unborn child.<br/>H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.<br/>H410 Very toxic to aquatic life with long lasting effects.</p> <p><b>Prevention:</b></p> <p>P203 Obtain, read and follow all safety instructions before use.<br/>P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br/>P260 Do not breathe mist or vapours.<br/>P264 Wash skin thoroughly after handling.<br/>P270 Do not eat, drink or smoke when using this product.<br/>P271 Use only outdoors or in a well-ventilated area.<br/>P273 Avoid release to the environment.<br/>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p><b>Response:</b></p> <p>P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water.<br/>P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.<br/>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/>P318 IF exposed or concerned, get medical advice.<br/>P337 + P317 If eye irritation persists: Get medical help.<br/>P391 Collect spillage.</p> <p><b>Storage:</b></p> <p>P405 Store locked up.</p> <p><b>Disposal:</b></p> <p>P501 Dispose of contents/ container to an approved waste disposal plant.</p> |
|--------------------------|--|

**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  | >= 30 - < 50          |
| betamethasone | 378-44-9 | >= 0.025 - < 0.1      |

**4. FIRST AID MEASURES**

## Betamethasone (0.05%) Lotion Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

|   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>May cause drowsiness or dizziness.<br>May damage the unborn child.<br>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.  |

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**5. FIREFIGHTING MEASURES**

|   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Flash back possible over considerable distance.<br>Vapours may form explosive mixtures with air.<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

## Betamethasone (0.05%) Lotion Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

**6. ACCIDENTAL RELEASE MEASURES**

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | <p>Remove all sources of ignition.<br/>Ventilate the area.<br/>Use personal protective equipment.<br/>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p>  |
| Environmental precautions   | : | <p>Avoid release to the environment.<br/>Prevent further leakage or spillage if safe to do so.<br/>Prevent spreading over a wide area (e.g. by containment or oil barriers).<br/>Retain and dispose of contaminated wash water.<br/>Local authorities should be advised if significant spillages cannot be contained.</p>   |
| Methods and materials for containment and cleaning up               | : | <p>Non-sparking tools should be used.<br/>Soak up with inert absorbent material.<br/>Suppress (knock down) gases/vapours/mists with a water spray jet.<br/>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.<br/>Clean up remaining materials from spill with suitable absorbent.<br/>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.<br/>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</p> |

**7. HANDLING AND STORAGE**

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | <p>If sufficient ventilation is unavailable, use with local exhaust ventilation.<br/>Use explosion-proof electrical, ventilating and lighting equipment.</p>   |
| Advice on safe handling | : | <p>Do not get on skin or clothing.<br/>Do not breathe the mist or vapours.<br/>Do not swallow.<br/>Do not get in eyes.<br/>Wash skin thoroughly after handling.<br/>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br/>Non-sparking tools should be used.<br/>Keep container tightly closed.<br/>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br/>Take precautionary measures against static discharges.<br/>Do not eat, drink or smoke when using this product.</p> |

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Version 3.0      Revision Date: 30.09.2020      SDS Number: 4371237-00004      Date of last issue: 25.09.2020  
 Date of first issue: 30.05.2019

|                             |   |
|-----------------------------|---|
| Conditions for safe storage | : Take care to prevent spills, waste and minimize release to the environment.<br>Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.<br>Keep away from heat and sources of ignition. |
| Materials to avoid          | : Do not store with the following product types:<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Oxidizing agents<br>Flammable gases<br>Pyrophoric liquids<br>Pyrophoric solids<br>Self-heating substances and mixtures<br>Poisonous gases<br>Explosives   |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components                | CAS-No.  | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|---------------------------|----------|----------------------------------|--|----------|
| Propan-2-ol               | 67-63-0  | 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<br>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.

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|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

**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  |
| 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.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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 |

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---

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

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

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### 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.

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### 11. TOXICOLOGICAL INFORMATION

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Version 3.0      Revision Date: 30.09.2020      SDS Number: 4371237-00004      Date of last issue: 25.09.2020  
Date of first issue: 30.05.2019

---

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: 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



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|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

**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            |
| 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  |

## Betamethasone (0.05%) Lotion Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

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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 (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.

# Betamethasone (0.05%) Lotion Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

**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.

**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

## Betamethasone (0.05%) Lotion Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

---

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

|   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l<br>Exposure time: 24 h        |
| Toxicity to microorganisms                          | : | EC50 (Pseudomonas putida): > 1,050 mg/l<br>Exposure time: 16 h                 |

**betamethasone:**

|   |   |   |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): > 50 mg/l<br>Exposure time: 96 h   |
| Toxicity to algae/aquatic plants                    | : | EC50 ( Pseudokirchneriella subcapitata (green algae)): > 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
|   |   | NOEC ( Pseudokirchneriella subcapitata (green algae)): 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility   |
| Toxicity to fish (Chronic toxicity)                 | : | NOEC: 0.052 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210   |
|   |   | NOEC: 0.07 µg/l<br>Exposure time: 219 d<br>Species: Oryzias latipes (Japanese medaka)<br>Method: OECD Test Guideline 229  |

# SAFETY DATA SHEET



## Betamethasone (0.05%) Lotion Formulation



Version 3.0      Revision Date: 30.09.2020      SDS Number: 4371237-00004      Date of last issue: 25.09.2020  
Date of first issue: 30.05.2019

---

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

### 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

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## 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.

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## 14. TRANSPORT INFORMATION

### International Regulations

UNRTDG

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|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

|                      |   |                      |
|----------------------|---|----------------------|
| 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 |
| 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<br>(betamethasone) |
| Class                | : | 3                                       |
| Packing group        | : | II                                      |
| Labels               | : | 3                                       |
| EmS Code             | : | F-E, S-D                                |
| Marine pollutant     | : | yes                                     |

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

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

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

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

|   |   |   |
|---|---|---|
| Sources of key data used to compile the Safety Data | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- |
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## Betamethasone (0.05%) Lotion Formulation

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|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 25.09.2020  |
| 3.0     | 30.09.2020     | 4371237-00004 | Date of first issue: 30.05.2019 |

Sheet cy, <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 : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : 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; 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.

# SAFETY DATA SHEET



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