SAFETY DATA SHEET

Betamethasone Lotion Formulation

SECTION 1. IDENTIFICATION

Product name : Betamethasone Lotion Formulation

Manufacturer or supplier’s details
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

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 : ![Flammable], ![Eye Irritation], ![Danger]

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.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
</tr>
<tr>
<td>Propan-2-ol</td>
</tr>
<tr>
<td>Propylene glycol</td>
</tr>
<tr>
<td>Betamethasone</td>
</tr>
</tbody>
</table>

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. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
**SAFETY DATA SHEET**

**Betamethasone Lotion Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td>04/09/2021</td>
<td>1288511-00012</td>
<td>10/10/2020</td>
<td>02/16/2017</td>
</tr>
</tbody>
</table>

**SECTION 5. FIRE-FIGHTING MEASURES**

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Unsuitable extinguishing media</th>
<th>Specific hazards during fire fighting</th>
<th>Hazardous combustion products</th>
<th>Specific extinguishing methods</th>
<th>Special protective equipment for fire-fighters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water spray</td>
<td>High volume water jet</td>
<td>Do not use a solid water stream as it may scatter and spread fire.</td>
<td>Carbon oxides</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td>Alcohol-resistant foam</td>
<td></td>
<td>Flash back possible over considerable distance.</td>
<td></td>
<td>Use water spray to cool unopened containers.</td>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td>Carbon dioxide (CO2)</td>
<td></td>
<td>Vapors may form explosive mixtures with air.</td>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
<td></td>
</tr>
<tr>
<td>Dry chemical</td>
<td></td>
<td>Exposure to combustion products may be a hazard to health.</td>
<td></td>
<td>Evacuate area.</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove all sources of ignition.</td>
<td></td>
</tr>
<tr>
<td>Ventilate the area.</td>
<td></td>
</tr>
<tr>
<td>Use personal protective equipment.</td>
<td></td>
</tr>
<tr>
<td>Follow safe handling advice (see section 7) and personal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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.
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
- 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

**SECTION 8. EXPOSURE CONTROLS/PERSOAL PROTECTION**

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>400 ppm 980 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST</td>
<td>500 ppm 1,225 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>400 ppm 980 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Biological occupational exposure limits**

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

**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 use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: lotion

**Color**: colorless

**Odor**: No data available
Odor Threshold : No data available
pH : 4.5
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : 70.5 °F / 21.4 °C
   Method: closed cup
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : 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
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY
SAFETY DATA SHEET

Betamethasone Lotion Formulation

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

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

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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
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

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

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
Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Betamethasone:
Routes of exposure: 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

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

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

Components:

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
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 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

Components:

Propylene glycol:
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Betamethasone Lotion Formulation

Effects on fetal development:
- Application Route: Ingestion
  - Test Type: Embryo-fetal development
  - Species: Mouse
  - Result: negative

Betamethasone:
- Effects on fetal development:
  - Application Route: Intramuscular
    - Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
    - Result: Malformations were observed.
  - Application Route: Subcutaneous
    - Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
    - Result: Malformations were observed.
  - 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.

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

**Propylene glycol:**
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y

**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

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

Propylene glycol:
Toxicity to fish
LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates
EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants
ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms
NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

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) COD: 2.23 BOD/COD: 53 %

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

Bioaccumulative potential

Components:

Propan-2-ol:
Partition coefficient: n-octanol/water: log Pow: 0.05

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

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

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
SAFETY DATA SHEET
Betamethasone Lotion Formulation

Version: 5.5
Revision Date: 04/09/2021
SDS Number: 1288511-00012
Date of last issue: 10/10/2020
Date of first issue: 02/16/2017

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
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
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
This material does not contain any components with a CERCLA 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 %

US State Regulations
Pennsylvania Right To Know
Water 7732-18-5
Propylene glycol 57-55-6
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
SAFETY DATA SHEET

Betamethasone Lotion Formulation

Version 5.5    Revision Date: 04/09/2021    SDS Number: 1288511-00012
Date of last issue: 10/10/2020    Date of first issue: 02/16/2017

NFPA 704:

<table>
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<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
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<tr>
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<td>2</td>
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HMIS® IV:

<table>
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<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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</thead>
<tbody>
<tr>
<td>* 3</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

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
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
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 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
US WEEL / TWA : 8-hr TWA

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; IECS - 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; KECl - 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 Oth-
SAFETY DATA SHEET

Betamethasone Lotion Formulation

Version 5.5  Revision Date: 04/09/2021  SDS Number: 1288511-00012  Date of last issue: 10/10/2020  Date of first issue: 02/16/2017

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/09/2021

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.

US / Z8