

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



ORGANON

## Betamethasone Ointment Formulation

Version 3.11      Revision Date: 09/30/2023      SDS Number: 1841074-00015      Date of last issue: 04/04/2023  
Date of first issue: 07/19/2017

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### SECTION 1. IDENTIFICATION

Product name : Betamethasone Ointment 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

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### SECTION 2. HAZARDS IDENTIFICATION

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

Reproductive toxicity : Category 1B  
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 : 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.  
P260 Do not breathe dust, fume, gas, mist, vapors or spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.

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### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name | CAS-No.   | Concentration (% w/w) |
|---------------|-----------|-----------------------|
| Petrolatum    | 8009-03-8 | $\geq 90 - \leq 100$  |
| Paraffin oil  | 8012-95-1 | $\geq 5 - < 10$       |
| 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.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : 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

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|  |   |   |
|--|---|---|
|  |   | Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical   |
| Unsuitable extinguishing media                 | : | None known.   |
| Specific hazards during fire fighting          | : | Vapors 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 fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

|   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.   |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<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. |

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### 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.  |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust, fume, gas, mist, vapors or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety |

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- practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
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.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components    | CAS-No.                   | Value type (Form of exposure)      | Control parameters / Permissible concentration | Basis     |
|---------------|---------------------------|------------------------------------|--|-----------|
| Petrolatum    | 8009-03-8                 | TWA (Inhalable particulate matter) | 5 mg/m <sup>3</sup>                            | ACGIH     |
|               |                           | TWA (Mist)                         | 5 mg/m <sup>3</sup>                            | OSHA Z-1  |
|               |                           | TWA (Mist)                         | 5 mg/m <sup>3</sup>                            | NIOSH REL |
|               |                           | ST (Mist)                          | 10 mg/m <sup>3</sup>                           | NIOSH REL |
| Paraffin oil  | 8012-95-1                 | TWA (Inhalable particulate matter) | 5 mg/m <sup>3</sup>                            | ACGIH     |
|               |                           | TWA (Mist)                         | 5 mg/m <sup>3</sup>                            | OSHA Z-1  |
|               |                           | TWA (Mist)                         | 5 mg/m <sup>3</sup>                            | NIOSH REL |
|               |                           | ST (Mist)                          | 10 mg/m <sup>3</sup>                           | NIOSH REL |
| Betamethasone | 378-44-9                  | TWA                                | 1 µg/m <sup>3</sup> (OEB 4)                    | Internal  |
|               | Further information: Skin |                                    |  |           |
|               |                           | Wipe limit                         | 10 µg/100 cm <sup>2</sup>                      | Internal  |

- Engineering measures : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Essentially no open handling permitted.  
Use closed processing systems or containment technologies.

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### 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.
- 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.
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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : ointment
- Color : No data available
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available

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Initial boiling point and boiling range : No data available

Flash point : > 199.9 °F / > 93.3 °C

Evaporation rate : Not applicable

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

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 : Not applicable

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 : Not applicable

Explosive properties : Not explosive

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

Particle size : No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Vapors may form explosive mixture with air.  
Can react with strong oxidizing agents.

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|                                  |   |  |
|----------------------------------|---|--|
| Conditions to avoid              | : | None known.                                    |
| Incompatible materials           | : | Oxidizing agents                               |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Petrolatum:**

|                       |   |  |
|-----------------------|---|--|
| Acute oral toxicity   | : | LD50 (Rat): > 5,000 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: Based on data from similar materials  |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity<br>Remarks: Based on data from similar materials |

##### **Paraffin oil:**

|                       |   |   |
|-----------------------|---|---|
| Acute oral toxicity   | : | LD50 (Rat): > 5,000 mg/kg   |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

##### **Betamethasone:**

|                           |   |  |
|---------------------------|---|--|
| Acute oral toxicity       | : | LD50 (Rat): > 5,000 mg/kg<br>LD50 (Mouse): > 4,500 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 0.4 mg/l<br>Exposure time: 4 h               |

#### **Skin corrosion/irritation**

Not classified based on available information.

#### Components:

##### **Petrolatum:**

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Method  | : | OECD Test Guideline 404 |

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Result : No skin irritation  
Remarks : Based on data from similar materials

### Paraffin oil:

Species : Rabbit  
Result : No skin irritation

### Betamethasone:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Petrolatum:

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

#### Paraffin oil:

Species : Rabbit  
Result : No eye irritation

#### 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:

#### Petrolatum:

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

#### Betamethasone:

Routes of exposure : Dermal  
Species : Guinea pig



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Result : Weak sensitizer

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Petrolatum:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

#### **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:

#### **Petrolatum:**

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.

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**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:

#### **Petrolatum:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

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

#### **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**

Not classified based on available information.

### **STOT-repeated exposure**

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

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### 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:

##### **Petrolatum:**

Species : Rat  
NOAEL : 5,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

##### **Paraffin oil:**

Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

##### **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.

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### Components:

#### **Paraffin oil:**

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

#### **Experience with human exposure**

### Components:

#### **Betamethasone:**

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

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Components:

#### **Petrolatum:**

Toxicity to fish : LL50 (*Pimephales promelas* (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 10,000 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEL (*Pseudokirchneriella subcapitata* (green algae)): >= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 10 mg/l  
Exposure time: 21 d  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

#### **Paraffin oil:**

Toxicity to fish : LL50 (*Scophthalmus maximus* (turbot)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Acartia tonsa* (Calanoid copepod)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction

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Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### **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:**

##### **Petrolatum:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

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### Bioaccumulative potential

#### Components:

##### Paraffin oil:

Partition coefficient: n-octanol/water : log Pow: > 4  
Remarks: Calculation

##### 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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## 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.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(betamethasone)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Betamethasone)

Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

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### IMDG-Code

|                      |   |  |
|----------------------|---|--|
| UN number            | : | UN 3077  |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Betamethasone) |
| Class                | : | 9  |
| Packing group        | : | III  |
| Labels               | : | 9  |
| EmS Code             | : | F-A, S-F   |
| Marine pollutant     | : | yes  |

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

|                      |   |   |
|----------------------|---|---|
| UN/ID/NA number      | : | UN 3077   |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Betamethasone)  |
| Class                | : | 9   |
| Packing group        | : | III   |
| Labels               | : | CLASS 9   |
| ERG Code             | : | 171   |
| Marine pollutant     | : | yes(Betamethasone)  |
| Remarks              | : | Above applies only to containers over 119 gallons or 450 liters.<br>Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO. |

### 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.

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## 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.

|                             |   |   |
|-----------------------------|---|---|
| <b>SARA 311/312 Hazards</b> | : | Reproductive toxicity<br>Specific target organ toxicity (single or repeated exposure) |
|-----------------------------|---|---|

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## Betamethasone Ointment Formulation

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**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

Petrolatum 8009-03-8  
Paraffin oil 8012-95-1

#### California List of Hazardous Substances

Petrolatum 8009-03-8  
Paraffin oil 8012-95-1

#### California Permissible Exposure Limits for Chemical Contaminants

Petrolatum 8009-03-8  
Paraffin oil 8012-95-1

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

AICS : not determined

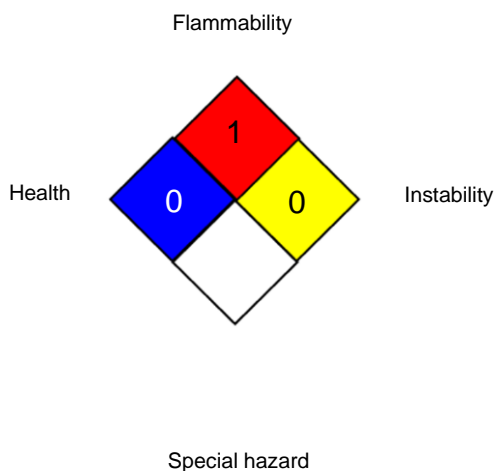
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 3 |
| FLAMMABILITY    |   | 1 |
| 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)



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ORGANON

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|         |                |               |                                 |
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|                 |   |   |
|-----------------|---|---|
| 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   |
| 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  |

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 : 09/30/2023

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

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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