

## Betamethasone Ointment Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 1841072-00016      Date of last issue: 30.09.2023  
Date of first issue: 19.07.2017

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Betamethasone Ointment Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

H360D: May damage the unborn child.

Specific target organ toxicity - repeated exposure, Category 1

H372: Causes damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 1

H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.

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H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P201 Obtain special instructions before use.  
 P264 Wash skin thoroughly after handling.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

Hazardous components which must be listed on the label:

betamethasone

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 2,5 - < 10
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1.000	>= 0,025 - < 0,1

For explanation of abbreviations see section 16.

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**SECTION 4: First aid measures****4.1 Description of 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.
- 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).
- 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.

**4.2 Most important symptoms and effects, both acute and delayed**

- Risks : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

**4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically and supportively.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

- Specific hazards during fire- : Vapours may form explosive mixtures with air.
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fighting Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**6.2 Environmental precautions**

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. 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.

**6.4 Reference to other sections**

See sections: 7, 8, 11, 12 and 13.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

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

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.

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Do not breathe dust, fume, gas, mist, vapours or spray.  
Do not swallow.  
Avoid contact with 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  
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.

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.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

**7.3 Specific end use(s)**

Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
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

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

Substance name	End Use	Exposure routes	Potential health effects	Value
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m <sup>3</sup>

# SAFETY DATA SHEET



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	Workers	Inhalation	Short-term exposure	5 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	5 mg/m <sup>3</sup>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9,33 mg/kg food

## 8.2 Exposure controls

### 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.

### Personal protective equipment

- Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : ointment
- Colour : No data available
- Odour : No data available
- Odour 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 : > 93,3 °C

Evaporation rate : Not applicable

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

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 : 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  
Auto-ignition 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.

### 9.2 Other information

Flammability (liquids) : Not applicable

Particle size : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

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Hazardous reactions : Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

Information on likely routes of exposure : Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Paraffin oil:**

Acute oral toxicity	: LD50 (Rat): > 5.000 mg/kg
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:****Paraffin oil:**

Species	: Rabbit
Result	: No skin irritation

**betamethasone:**

Species	: Rabbit
Result	: Mild skin irritation



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**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Paraffin oil:**

Species	:	Rabbit
Result	:	No eye irritation

**betamethasone:**

Species	:	Rabbit
Result	:	No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****betamethasone:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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.

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**Reproductive toxicity**

May damage the unborn child.

**Components:****betamethasone:**

Effects on foetal development	:	Species: Rabbit
		Application Route: Intramuscular
		Developmental Toxicity: LOAEL: 0,05 mg/kg body weight Result: Fetotoxicity, Malformations were observed.
	:	Species: Rat
		Application Route: Subcutaneous
		Developmental Toxicity: LOAEL: 0,42 mg/kg body weight Result: Malformations were observed.
	:	Species: Mouse
		Application Route: Intramuscular
		Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Malformations were observed.
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:****betamethasone:**

Target Organs	:	Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****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

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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.

**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

**SECTION 12: Ecological information****12.1 Toxicity****Components:****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 Remarks: Based on data from similar materials
Toxicity to algae/aquatic	: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l

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plants  
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: 0,052 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
  
NOEC: 0,07 µg/l  
Exposure time: 219 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 229

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

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential****Components:****Paraffin oil:**

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

**betamethasone:**

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Partition coefficient: n-octanol/water : log Pow: 2,11

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

**SECTION 14: Transport information****14.1 UN number**

ADN : UN 3077  
 ADR : UN 3077  
 RID : UN 3077  
 IMDG : UN 3077  
 IATA : UN 3077

**14.2 UN proper shipping name**

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)

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**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone)

**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone)

**IATA** : Environmentally hazardous substance, solid, n.o.s.  
(betamethasone)

**14.3 Transport hazard class(es)**

	Class	Subsidiary risks
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 9	

**14.4 Packing group**

**ADN**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

**ADR**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

**RID**  
Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9

**IMDG**  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

**IATA (Cargo)**  
Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

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**IATA (Passenger)**

Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing group	:	III
Labels	:	Miscellaneous

**14.5 Environmental hazards****ADN**

Environmentally hazardous	:	yes
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**ADR**

Environmentally hazardous	:	yes
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**RID**

Environmentally hazardous	:	yes
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**IMDG**

Marine pollutant	:	yes
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**IATA (Passenger)**

Environmentally hazardous	:	yes
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**IATA (Cargo)**

Environmentally hazardous	:	yes
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**14.6 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.

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks	:	Not applicable for product as supplied.
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**SECTION 15: Regulatory information****15.1 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
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DSL	:	not determined
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IECSC	:	not determined
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**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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**SECTION 16: Other information**

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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**Full text of H-Statements**

H304 : May be fatal if swallowed and enters airways.  
H330 : Fatal if inhaled.  
H360D : May damage the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H410 : Very toxic to aquatic life with long lasting effects.  
H413 : May cause long lasting harmful effects to aquatic life.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Asp. Tox. : Aspiration hazard  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>



# SAFETY DATA SHEET



## Betamethasone Ointment Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
7.0	06.04.2024	1841072-00016	Date of first issue: 19.07.2017

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### Classification of the mixture:

Repr. 1B	H360D
STOT RE 1	H372
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

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