

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

**Section 1: Identification**

**Product identifier** : Betamethasone Ointment Formulation

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

Recommended use : Pharmaceutical  
 Restrictions on use : Not applicable


**Manufacturer or supplier's details**

Company : Organon & Co.  
 Address : 30 Hudson Street, 33rd floor  
 Jersey City, New Jersey, U.S.A 07302  
 Telephone : +1-551-430-6000  
 Emergency telephone number : +1-215-631-6999  
 E-mail address : EHSSTEWARD@organon.com

**Section 2: Hazard identification****Classification of the substance or mixture**

Reproductive toxicity : Category 1B  
 Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)  
 Long-term (chronic) aquatic hazard : Category 1

**GHS Label elements, including precautionary statements**

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. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b>

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

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/ vapours/ spray.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

**Response:**

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

P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 90 -<= 100
Paraffin oil	8012-95-1	>= 1 -< 10
betamethasone	378-44-9	>= 0.025 -< 0.1

**Section 4: First-aid measures****Description of necessary 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.

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

If swallowed : Get medical attention if irritation develops and persists.  
 : If swallowed, DO NOT induce vomiting.  
 : Get medical attention.  
 : Rinse mouth thoroughly with water.

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

Risks : 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).

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

Treatment : Treat symptomatically and supportively.

---

**Section 5: Fire-fighting measures****Extinguishing media**

Suitable extinguishing media : Water spray  
 : Alcohol-resistant foam  
 : Carbon dioxide (CO<sub>2</sub>)  
 : Dry chemical

Unsuitable extinguishing media : None known.

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

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

Hazardous combustion products : Carbon oxides

**Special protective actions for fire-fighters**

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.

---

**Section 6: Accidental release measures****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).

**Environmental precautions**

Environmental precautions : Avoid release to the environment.

---

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

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.

**Methods and materials 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.

**Section 7: Handling and storage****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.  
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.

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

Conditions for safe storage : Keep in properly labelled 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:

## Betamethasone Ointment Formulation

Version 3.0      Revision Date: 06.04.2024      SDS Number: 1841075-00016      Date of last issue: 30.09.2023  
Date of first issue: 19.07.2017

Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Control parameters

#### Occupational Exposure Limits

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

**Appropriate engineering control 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.

#### Individual protection measures, such as personal protective equipment (PPE)

**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.

**Skin protection** : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

posable 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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

---

**Section 9: 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

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

Flammability (liquids) : Not applicable

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

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

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.
Particle characteristics		
Particle size	:	No data available

---

**Section 10: Stability and reactivity**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
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 Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

toxicity

Remarks: Based on data from similar materials

**Paraffin oil:**

Acute oral toxicity : LD50 (Rat): &gt; 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): &gt; 5,000 mg/kg

LD50 (Mouse): &gt; 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:****Petrolatum:**Species : Rabbit  
Method : OECD Test Guideline 404  
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



## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

**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:****Petrolatum:**

Test Type	: Buehler Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**betamethasone:**

Exposure routes	: Dermal
Species	: Guinea pig
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)
-----------------------	--

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

	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

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

**betamethasone:**

Effects on foetal development	: Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
-------------------------------	--

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

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.

**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 yr

**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

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

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.

**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****Toxicity****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 : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

## Betamethasone Ointment Formulation

Version 3.0      Revision Date: 06.04.2024      SDS Number: 1841075-00016      Date of last issue: 30.09.2023  
Date of first issue: 19.07.2017

aquatic invertebrates	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 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

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

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

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

**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

**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

**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste han-

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

ding site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information****International Regulations****UNRTDG**

UN number	:	UN 3077
UN proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Transport hazard class(es)	:	9
Packing group	:	III
Labels	:	9
Environmental hazards	:	yes

**IATA-DGR**

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

Transport hazard class(es)	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

**IMDG-Code**

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

Transport hazard class(es)	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

**Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

**Special precautions for user**

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

**Section 15: Regulatory information****Safety, health and environmental regulations specific for the product in question**

## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

**The components of this product are reported in the following inventories:**

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

---

**Section 16: Other information**

Revision Date : 06.04.2024

**Further information**

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

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
SG OEL	: Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA	: 8-hour, time-weighted average
SG OEL / PEL (long term)	: Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term)	: Permissible Exposure Level (PEL) Short Term

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-



## Betamethasone Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	06.04.2024	1841075-00016	Date of first issue: 19.07.2017

---

centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN