

## Betamethasone (0.05%) Ointment Formulation



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

**SECTION 1: IDENTIFICATION** 

Product name : Betamethasone (0.05%) Ointment Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd 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

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

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 pro-

longed 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/ vapours/ spray.

P264 Wash skin thoroughly after handling.



## **Betamethasone (0.05%) Ointment Formulation**



Revision Date: Date of last issue: 30.09.2023 Version SDS Number: 06.04.2024 1681990-00014 Date of first issue: 18.05.2017 4.5

> P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

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

attention.

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	>= 60 -<= 100
Propylene glycol	57-55-6	>= 10 -< 30
Propylene glycol monostearate	1323-39-3	< 10
betamethasone	378-44-9	>= 0.01 -< 0.3

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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. 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

In case of eye contact

May damage the unborn child.

and effects, both acute and

Causes damage to organs through prolonged or repeated

delayed

exposure.



## Betamethasone (0.05%) Ointment Formulation



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 06.04.2024 1681990-00014 4.5 Date of first issue: 18.05.2017

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. FIREFIGHTING MEASURES**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Special protective equipment

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Hazchem Code 2Z

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Avoid release to the environment. **Environmental precautions** 

> 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 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

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 as-

sessment

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 : 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:

Strong oxidizing agents

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m3	AU OEL
		TWA (Inhal-	5 mg/m3	ACGIH
		able particu-		
		late matter)		
Propylene glycol	57-55-6	TWA (partic-	10 mg/m3	AU OEL
		ulate)		
		TWA (Total	150 ppm	AU OEL
		(vapour and	474 mg/m3	
		particles))		
Propylene glycol monostearate	1323-39-3	TWA	10 mg/m3	AU OEL
		TWA (Inhal-	10 mg/m3	ACGIH



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

		able particu- late matter)				
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH		
betamethasone	378-44-9	TWA	1 μg/m3 (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.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

Appearance : ointment

Colour : white to off-white

Odour : No data available



## **Betamethasone (0.05%) Ointment Formulation**

♣ ORGANON

Version 4.5

Revision Date: 06.04.2024

SDS Number: 1681990-00014

Date of last issue: 30.09.2023 Date of first issue: 18.05.2017

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

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 : Not applicable



## Betamethasone (0.05%) Ointment Formulation



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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**

Exposure routes : 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

toxicity

Remarks: Based on data from similar materials

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Propylene glycol monostearate:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

betamethasone:



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

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:**

#### Petrolatum:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

## Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

### Propylene glycol monostearate:

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

## Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

#### betamethasone:

Species : Rabbit



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

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

### Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

#### betamethasone:

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

#### **Chronic toxicity**

#### 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 (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

betamethasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral 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

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative



## **Betamethasone (0.05%) Ointment Formulation**

♣ ORGANON

Version 4.5

Revision Date: 06.04.2024

SDS Number: 1681990-00014

Date of last issue: 30.09.2023 Date of first issue: 18.05.2017

### 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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

betamethasone:

Effects on foetal develop-

ment

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 - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.



## **Betamethasone (0.05%) Ointment Formulation**



Version 4.5

Revision Date: 06.04.2024

SDS Number: 1681990-00014

Date of last issue: 30.09.2023 Date of first issue: 18.05.2017

## 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

### Propylene glycol:

Species : Rat, male NOAEL : >= 1,700 mg/kg

Application Route : Ingestion Exposure time : 2 yr

#### 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



## Betamethasone (0.05%) Ointment Formulation



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 06.04.2024 1681990-00014 4.5 Date of first issue: 18.05.2017

LOAEL 0.05 mg/kg **Application Route** Oral Exposure time 28 d

**Target Organs** Blood, thymus gland, Adrenal gland

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

betamethasone:

Inhalation Target Organs: Adrenal gland

Skin contact Symptoms: Redness, pruritis, Irritation

#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

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

ic toxicity)

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 (Chron-

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Propylene glycol:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

aguatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

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

Exposure time: 18 h

betamethasone:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Americamysis): > 50 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 34

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

**Bioaccumulative potential** 

Components:

Propylene glycol:

Partition coefficient: n-

octanol/water

log Pow: -1.07

Method: Regulation (EC) No. 440/2008, Annex, A.8

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-

dling 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

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)



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen-

ger aircraft)

: 956

Environmentally hazardous : yes

**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.

## **National Regulations**

**ADG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(betamethasone)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z
Environmentally hazardous : yes

## 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/legislation specific for the substance or mix-

Therapeutic Goods (Poisons:

Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements :

There is no applicable prohibition, authorisation and restricted use requirements, including for carcino-



## **Betamethasone (0.05%) Ointment Formulation**



Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

gens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

#### **Further information**

Revision Date : 06.04.2024

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

AU OEL : Australia. Workplace Exposure Standards for Airborne Con-

taminants.

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

AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response: ELx - Loading rate associated with x% response: EmS - Emergency Schedule: ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association: IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk, IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-



## **Betamethasone (0.05%) Ointment Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 4.5 06.04.2024 1681990-00014 Date of first issue: 18.05.2017

es; (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.

AU / EN