

# **Betamethasone Lotion Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

**Section 1: Identification** 

Product name : Betamethasone Lotion Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification

**GHS Classification** 

Flammable liquids : Category 2

Serious eye damage/eye irri-

tation

Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

single exposure

Category 3

Specific target organ toxicity - :

repeated exposure

Category 1 (Pituitary gland, Immune system, muscle, thymus

gland, Blood, Adrenal gland)

**GHS** label elements

Hazard pictograms :







Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H360D May damage the unborn child.

H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-

longed or repeated exposure.



# **Betamethasone Lotion Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

Precautionary statements

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P281 Use personal protective equipment as required.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.

P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P337 + P313 If eye irritation persists: Get medical advice/ attention.

#### Storage:

P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up.

#### Disposal:

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

## Other hazards which do not result in classification

Vapours may form explosive mixture with air.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 60
Propylene glycol	57-55-6	>= 30 -< 60
betamethasone	378-44-9	>= 0.01 -< 0.3



# **Betamethasone Lotion Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 10.10.2020 09.04.2021 1288509-00012 Date of first issue: 16.02.2017 4.7

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 contact, immediately flush skin with plenty of water. In case of skin contact

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Causes serious eye irritation.

May cause drowsiness or dizziness. May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Protection of first-aiders First Aid responders should pay attention to self-protection.

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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.



# **Betamethasone Lotion Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

Evacuate area.

Special protective equipment :

for firefighters

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

Use personal protective equipment.

Hazchem Code : 2YE

#### Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Remove all sources of ignition.

Ventilate the area.

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

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

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Non-sparking tools should be used.

Materials to avoid



# **Betamethasone Lotion Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.7	09.04.2021	1288509-00012	Date of first issue: 16.02.2017

Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

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.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition. Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases

**Explosives** 

# Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Propan-2-ol	67-63-0	WES-TWA	400 ppm 983 mg/m3	NZ OEL	
		WES-STEL	500 ppm 1,230 mg/m3	NZ OEL	
		TWA	200 ppm	ACGIH	
		STEL	400 ppm	ACGIH	
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m3	NZ OEL	
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m3	NZ OEL	
betamethasone	378-44-9	TWA	1 μg/m3 (OEB 4)	Internal	
	Further information: Skin				



# **Betamethasone Lotion Formulation**

- ⇔ ORGANON

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

Wipe limit 10 μg/100 cm<sup>2</sup> Internal

## **Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentra-tion	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

**Engineering measures** : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist,

handle over lined trays or benchtops.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

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. Combined particulates and organic vapour type

Filter type

Material

Hand protection

: Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

## Section 9: Physical and chemical properties

Appearance : lotion

Colour : colourless



# **Betamethasone Lotion Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

Odour : No data available

Odour Threshold : No data available

pH : 4.5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 21.4 °C

Method: closed cup

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle size : Not applicable



# **Betamethasone Lotion Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 10.10.2020 09.04.2021 1288509-00012 Date of first issue: 16.02.2017 4.7

## Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Highly flammable liquid and vapour.

Possibility of hazardous reac-

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

Conditions to avoid Heat, flames and sparks. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

## **Section 11: Toxicological information**

Inhalation Exposure routes

> Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Propan-2-ol:

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

Acute inhalation toxicity LC50 (Rat): > 25 mg/l

> Exposure time: 6 h Test atmosphere: vapour

Acute dermal toxicity LD50 (Rabbit): > 5,000 mg/kg

Propylene glycol:

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

Acute inhalation toxicity LC50 (Rabbit): > 159 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

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



# **Betamethasone Lotion Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

#### Skin corrosion/irritation

Not classified based on available information.

## **Components:**

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

betamethasone:

Species : Rabbit

Result : Mild skin irritation

## Serious eye damage/eye irritation

Causes serious eye irritation.

#### **Components:**

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

betamethasone:

Species : Rabbit

Result : No eye irritation

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

# **Components:**

## Propan-2-ol:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative



# **Betamethasone Lotion Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

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:** 

Propan-2-ol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Propylene glycol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

betamethasone:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive



# **Betamethasone Lotion Formulation**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

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:** 

Propan-2-ol:

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

Propylene glycol:

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

Reproductive toxicity

May damage the unborn child.

**Components:** 

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Propylene glycol:

Effects on fertility : Test Type: Three-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 Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

betamethasone:

Effects on foetal develop-

ment

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 0.05 mg/kg body weight

 $Result: Fe to toxicity, \, Malformations \,\, were \,\, observed.$ 

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.

## STOT - single exposure

May cause drowsiness or dizziness.

#### **Components:**

# Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

# STOT - repeated exposure

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

#### **Components:**

#### betamethasone:

Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood,

Adrenal gland

Assessment : Causes damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

## **Components:**

#### Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time : 104 Weeks

Propylene glycol:

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



# **Betamethasone Lotion Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

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

Target Organs : Blood, thymus gland, Adrenal gland

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

betamethasone:

Inhalation : Target Organs: Adrenal gland

Skin contact : Symptoms: Redness, pruritis, Irritation

**Section 12: Ecological information** 

**Ecotoxicity** 

Components:

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h



# **Betamethasone Lotion Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 4.7
 09.04.2021
 1288509-00012
 Date of first issue: 16.02.2017

Propylene glycol:

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (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:

Propan-2-ol:

Biodegradability : Result: rapidly degradable



# **Betamethasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

**Bioaccumulative potential** 

**Components:** 

Propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0.05

Propylene glycol:

Partition coefficient: n-

octanol/water

log Pow: -1.07

betamethasone:

Partition coefficient: n-

octanol/water

log Pow: 2.11

**Mobility in soil**No data available

Other adverse effects

No data available

Section 13: Disposal considerations

**Disposal methods** 

Waste from residues

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information** 

**International Regulations** 

**UNRTDG** 

UN number : UN 1219

Proper shipping name : ISOPROPANOL SOLUTION

Class : 3
Packing group : II
Labels : 3

**IATA-DGR** 

UN/ID No. : UN 1219



# **Betamethasone Lotion Formulation**



Version **Revision Date:** SDS Number: Date of last issue: 10.10.2020 09.04.2021 1288509-00012 Date of first issue: 16.02.2017 4.7

Proper shipping name Isopropanol solution

Class 3 Packing group Ш

Flammable Liquids Labels

Packing instruction (cargo 364

aircraft)

Packing instruction (passen-353

ger aircraft)

**IMDG-Code** 

UN number UN 1219

ISOPROPANOL SOLUTION Proper shipping name

(betamethasone)

Class 3 Packing group Ш Labels 3 **EmS Code** F-E, S-D Marine pollutant yes

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

Not applicable for product as supplied.

## **National Regulations**

#### **NZS 5433**

**UN** number UN 1219

Proper shipping name ISOPROPANOL SOLUTION

Class 3 Packing group Ш Labels 3 Hazchem Code 2YE

## 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 mixture

# **HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

## **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

**AICS** not determined

# Public

# **Betamethasone Lotion Formulation**



Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

DSL : not determined

IECSC : not determined

#### **Section 16: Other information**

#### **Further information**

Sheet

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-

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

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 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; 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



# **Betamethasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 10.10.2020 4.7 09.04.2021 1288509-00012 Date of first issue: 16.02.2017

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.

NZ / EN