

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Betamethasone Lotion Formulation

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

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

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

Telephone : 551-430-6000

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

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Flammable liquids, Category 2	H225: Highly flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 3	H336: May cause drowsiness or dizziness.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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

Hazardous components which must be listed on the label:

Propan-2-ol
betamethasone

2.3 Other hazards

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

Vapours may form explosive mixture with air.

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 30 - < 50
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410	>= 0,025 - < 0,1
		M-Factor (Chronic	

SAFETY DATA SHEET



Betamethasone Lotion Formulation



Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

		aquatic toxicity): 1.000	
--	--	-----------------------------	--

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with 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 : 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes serious eye irritation.
May cause drowsiness or dizziness.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Dry chemical

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

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 products : Carbon oxides

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.
Ventilate the area.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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.

6.3 Methods and material for containment and cleaning up

Methods for 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

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

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

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment. |
| 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 assessment
Non-sparking tools should be used.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition. |
|---|---|---|

SAFETY DATA SHEET



Betamethasone Lotion Formulation



Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propan-2-ol	67-63-0	STEL OEL-RL	500 ppm 1.225 mg/m ³	ZA OEL
		Further information: Absorption through the skin, Recommended Limit		
		TWA OEL-RL	400 ppm 960 mg/m ³	ZA OEL
		Further information: Absorption through the skin, Recommended Limit		
Propylene glycol	57-55-6	TWA OEL-RL (particulate)	10 mg/m ³	ZA OEL
		Further information: Recommended Limit		
		TWA OEL-RL (Vapour + particulates)	150 ppm 470 mg/m ³	ZA OEL
		Further information: Recommended Limit		
betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
		Further information: Skin		
		Wipe limit	10 µg/100 cm ²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m ³
	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic	26 mg/kg

SAFETY DATA SHEET



Betamethasone Lotion Formulation



Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
 Date of first issue: 16.02.2017

			effects	bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³

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

Substance name	Environmental Compartment	Value
Propan-2-ol	Fresh water	140,9 mg/l
	Marine water	140,9 mg/l
	Intermittent use/release	140,9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry weight (d.w.)
	Marine sediment	552 mg/kg dry weight (d.w.)
	Soil	28 mg/kg dry weight (d.w.)
Propylene glycol	Oral (Secondary Poisoning)	160 mg/kg food
	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57,2 mg/kg
	Soil	50 mg/kg

8.2 Exposure controls

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 equipment.

Personal protective equipment

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.

Hand protection

Material : Chemical-resistant gloves

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

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Skin and body protection	:	<p>mable, which may impact the selection of hand protection.</p> <p>Work uniform or laboratory coat.</p> <p>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</p> <p>Use appropriate degowning techniques to remove potentially contaminated clothing.</p>
Respiratory protection	:	<p>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</p>
Filter type	:	<p>Combined particulates and organic vapour type (A-P)</p>

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	lotion
Colour	:	colourless
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
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

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

Particle size : Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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

Information on likely routes of exposure : Inhalation
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

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

betamethasone:

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

LD50 (Mouse): > 4.500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0,4 mg/l
Exposure time: 4 h

Skin corrosion/irritation

Not classified based on available information.

Components:**Propan-2-ol:**

Species : Rabbit
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

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

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : negative

betamethasone:

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

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

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:**Propan-2-ol:**

Species : Rat

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

Application Route : inhalation (vapour)
Exposure time : 104 weeks
Method : OECD Test Guideline 451
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 development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

betamethasone:

Effects on foetal development : Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

May cause drowsiness or dizziness.

Components:**Propan-2-ol:**

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

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

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

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

SECTION 12: Ecological information**12.1 Toxicity****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:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): > 50 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: 0,052 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

NOEC: 0,07 µg/l
Exposure time: 219 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

12.2 Persistence and degradability**Components:****Propan-2-ol:**

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Biodegradability : Result: rapidly degradable

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

12.3 Bioaccumulative potential**Components:****Propan-2-ol:**

Partition coefficient: n-octanol/water : log Pow: 0,05

betamethasone:

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

12.4 Mobility in soil

No data available

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

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

12.6 Other adverse effects**Product:**

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

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

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

Contaminated packaging : Empty containers should be taken to an approved waste handling 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.

Betamethasone Lotion Formulation

Version 5.4 Revision Date: 09.04.2021 SDS Number: 1288512-00011 Date of last issue: 10.10.2020
Date of first issue: 16.02.2017

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

ADN : UN 1219
ADR : UN 1219
RID : UN 1219
IMDG : UN 1219
IATA : UN 1219

14.2 UN proper shipping name

ADN : ISOPROPANOL, SOLUTION
ADR : ISOPROPANOL, SOLUTION
RID : ISOPROPANOL, SOLUTION
IMDG : ISOPROPANOL, SOLUTION
(betamethasone)
IATA : Isopropanol, solution

14.3 Transport hazard class(es)

ADN : 3
ADR : 3
RID : 3
IMDG : 3
IATA : 3

14.4 Packing group

ADN
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

ADR
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

IMDG
Packing group : II
Labels : 3
EmS Code : F-E, S-D

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

IATA (Cargo)

Packing instruction (cargo aircraft)	:	364
Packing instruction (LQ)	:	Y341
Packing group	:	II
Labels	:	Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft)	:	353
Packing instruction (LQ)	:	Y341
Packing group	:	II
Labels	:	Flammable Liquids

14.5 Environmental hazards**ADN**

Environmentally hazardous	:	yes
---------------------------	---	-----

ADR

Environmentally hazardous	:	yes
---------------------------	---	-----

RID

Environmentally hazardous	:	yes
---------------------------	---	-----

IMDG

Marine pollutant	:	yes
------------------	---	-----

14.6 Special precautions for user

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

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

Remarks	:	Not applicable for product as supplied.
---------	---	---

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS	:	not determined
------	---	----------------

DSL	:	not determined
-----	---	----------------

IECSC	:	not determined
-------	---	----------------

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
-------------------	---	---

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
 H319 : Causes serious eye irritation.
 H330 : Fatal if inhaled.
 H336 : May cause drowsiness or dizziness.
 H360D : May damage the unborn child.
 H372 : Causes damage to organs through prolonged or repeated exposure.
 H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
 Aquatic Chronic : Long-term (chronic) aquatic hazard
 Eye Irrit. : Eye irritation
 Flam. Liq. : Flammable liquids
 Repr. : Reproductive toxicity
 STOT RE : Specific target organ toxicity - repeated exposure
 STOT SE : Specific target organ toxicity - single exposure
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
 ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations

Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
5.4	09.04.2021	1288512-00011	Date of first issue: 16.02.2017

Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bio-accumulative

Further information

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

Classification of the mixture:

Flam. Liq. 2	H225
Eye Irrit. 2	H319
Repr. 1B	H360D
STOT SE 3	H336
STOT RE 1	H372
Aquatic Chronic 1	H410

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

ZA / EN