

# SAFETY DATA SHEET



## Betamethasone (0.05%) Liquid Formulation



Version 2.0      Revision Date: 10.10.2020      SDS Number: 4659289-00004      Date of last issue: 23.03.2020  
Date of first issue: 11.07.2019

---

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Liquid Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

---

### 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)

Long-term (chronic) aquatic hazard : Category 1

#### 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 prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

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 mist or vapors.  
P264 Wash skin thoroughly after handling.

---

## Betamethasone (0.05%) Liquid Formulation

Version 2.0      Revision Date: 10.10.2020      SDS Number: 4659289-00004      Date of last issue: 23.03.2020  
Date of first issue: 11.07.2019

P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

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

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	>= 50 -< 70
Ethanol#	64-17-5	>= 0,1 -< 1
Betamethasone	378-44-9	>= 0,025 -< 0,1

# Voluntarily-disclosed non-hazardous substance

**SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.  
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 and effects, both acute and delayed : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

---

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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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.

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

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective 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 : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can 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.

## Betamethasone (0.05%) Liquid Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 23.03.2020  
2.0                    10.10.2020                4659289-00004            Date of first issue: 11.07.2019

**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.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled 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  
Organic peroxides  
Explosives  
Gases

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	CMP (Mist)	10 mg/m <sup>3</sup>	AR OEL
	Further information: Irritation			
Ethanol	64-17-5	CMP	1.000 ppm	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen, Irritation			
		STEL	1.000 ppm	ACGIH
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

- 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

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

---

exist, handle over lined trays or benchtops.

**Personal protective equipment**

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapor type
Hand protection		
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, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor 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	:	No data available
Evaporation rate	:	No data available

# SAFETY DATA SHEET



## Betamethasone (0.05%) Liquid Formulation



Version 2.0      Revision Date: 10.10.2020      SDS Number: 4659289-00004      Date of last issue: 23.03.2020  
Date of first issue: 11.07.2019

---

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor 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 : No data available

Autoignition 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.

Molecular weight : No data available

Particle size : Not applicable

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

---

exposure

Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Glycerine:**

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

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

**Ethanol:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapor

**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:****Glycerine:**

Species : Rabbit

Result : No skin irritation

**Ethanol:**

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

**Betamethasone:**

Species : Rabbit

Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

---

**Components:****Glycerine:**

Species	:	Rabbit
Result	:	No eye irritation

**Ethanol:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days
Method	:	OECD Test Guideline 405

**Betamethasone:**

Species	:	Rabbit
Result	:	No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Ethanol:**

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

**Betamethasone:**

Routes of exposure	:	Dermal
Species	:	Guinea pig
Result	:	Weak sensitizer

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Glycerine:**

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
-----------------------	---	---

	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
--	---	--

	:	Test Type: Chromosome aberration test in vitro Result: negative
--	---	--

	:	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
--	---	---



## Betamethasone (0.05%) Liquid Formulation

Version 2.0      Revision Date: 10.10.2020      SDS Number: 4659289-00004      Date of last issue: 23.03.2020  
Date of first issue: 11.07.2019

Result: negative

**Ethanol:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Ingestion  
Result: equivocal

**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:****Glycerine:**

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

**Reproductive toxicity**

May damage the unborn child.

**Components:****Glycerine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

		Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
<b>Ethanol:</b>		
Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
<b>Betamethasone:</b>		
Effects on fetal development	:	Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 0,05 mg/kg body weight Result: Fetotoxicity., Malformations were observed.
		Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 0,42 mg/kg body weight Result: Malformations were observed.
		Species: Mouse Application Route: Intramuscular Developmental Toxicity: LOAEL: 1 mg/kg body weight Result: Malformations were observed.
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Causes damage to organs (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:****Glycerine:**

Species	:	Rat
---------	---	-----

## Betamethasone (0.05%) Liquid Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 23.03.2020  
2.0                10.10.2020                4659289-00004            Date of first issue: 11.07.2019

---

NOAEL                : 0,167 mg/l  
LOAEL                : 0,622 mg/l  
Application Route    : inhalation (dust/mist/fume)  
Exposure time        : 13 Weeks

Species              : Rat  
NOAEL                : 8.000 - 10.000 mg/kg  
Application Route    : Ingestion  
Exposure time        : 2 y

Species              : Rabbit  
NOAEL                : 5.040 mg/kg  
Application Route    : Skin contact  
Exposure time        : 45 Weeks

**Ethanol:**  
Species              : Rat  
NOAEL                : 1.280 mg/kg  
LOAEL                : 3.156 mg/kg  
Application Route    : Ingestion  
Exposure time        : 90 Days

**Betamethasone:**  
Species              : Rabbit  
LOAEL                : 0.05 %  
Application Route    : Skin contact  
Exposure time        : 10 - 30 d  
Target Organs        : Pituitary gland, Immune system, muscle

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.

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

**Experience with human exposure****Components:****Betamethasone:**

Inhalation	:	Target Organs: Adrenal gland
Skin contact	:	Symptoms: Redness, pruritis, Irritation

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Glycerine:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l Exposure time: 96 h
------------------	---	--

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1.955 mg/l Exposure time: 48 h
---	---	--

Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 10.000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8
----------------------------	---	--

**Ethanol:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l Exposure time: 96 h
------------------	---	--

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l Exposure time: 48 h
---	---	---

Toxicity to algae/aquatic plants	:	ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
----------------------------------	---	---

	:	EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l Exposure time: 72 h
--	---	---

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 9,6 mg/l Exposure time: 9 d
--	---	---

Toxicity to microorganisms	:	EC50 (Pseudomonas putida): 6.500 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.
----------------------------------	---	---

## Betamethasone (0.05%) Liquid Formulation

Version 2.0      Revision Date: 10.10.2020      SDS Number: 4659289-00004      Date of last issue: 23.03.2020  
Date of first issue: 11.07.2019

	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 (Pimephales promelas (fathead minnow)): 0,052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
	NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l Exposure time: 219 d Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 1.000

**Persistence and degradability****Components:****Glycerine:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 92 % Exposure time: 30 d Method: OECD Test Guideline 301D
------------------	---

**Ethanol:**

Biodegradability	: Result: Readily biodegradable. Biodegradation: 84 % Exposure time: 20 d
------------------	---

**Bioaccumulative potential****Components:****Glycerine:**

Partition coefficient: n-octanol/water	: log Pow: -1,75
--	------------------

**Ethanol:**

Partition coefficient: n-octanol/water	: log Pow: -0,35
--	------------------

**Betamethasone:**

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

**Mobility in soil**

No data available

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

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

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)

Class	:	9
Packing group	:	III
Labels	:	9

**IATA-DGR**

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)

Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

**IMDG-Code**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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.

**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

## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Ethanol

#### International Regulations

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

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

### SECTION 16. OTHER INFORMATION

#### Further information

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

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

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 AR OEL : Argentina. Occupational Exposure Limits  
 ACGIH / STEL : Short-term exposure limit  
 AR OEL / CMP : TLV (Threshold Limit Value)

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

# SAFETY DATA SHEET



## Betamethasone (0.05%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
2.0	10.10.2020	4659289-00004	Date of first issue: 11.07.2019

---

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

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.

AR / Z8