

**Betamethasone (0.05%) Liquid Formulation**

Version 3.5      Revision Date: 06.04.2024      SDS Number: 4659288-00010      Date of last issue: 30.09.2023  
Date of first issue: 11.07.2019

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**SECTION 1: IDENTIFICATION**

Product name : Betamethasone (0.05%) Liquid Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

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

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.

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

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

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

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

None known.

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

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	>= 60 -<= 100
Propylene glycol	57-55-6	>= 30 -< 60
Ethanol#	64-17-5	< 10
betamethasone	378-44-9	>= 0.01 -< 0.3

# Voluntarily-disclosed 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	:	May damage the unborn child. Causes damage to organs through prolonged or repeated

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delayed 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.

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**SECTION 5. FIREFIGHTING 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
 Use personal protective equipment.

Hazchem Code : •3Z

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**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 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 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 deter-

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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.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	AU OEL
Propylene glycol	57-55-6	TWA (particulate)	10 mg/m <sup>3</sup>	AU OEL
		TWA (Total vapour and	150 ppm 474 mg/m <sup>3</sup>	AU OEL

# SAFETY DATA SHEET



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		particles))		
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m <sup>3</sup>	AU OEL
		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 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 vapour 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : liquid

**Colour** : No data available

**Odour** : No data available

**Odour Threshold** : No data available

**pH** : No data available

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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
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
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	:	No data available
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.
Molecular weight	:	No data available
Particle characteristics Particle size	:	Not applicable

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### SECTION 10. STABILITY AND REACTIVITY

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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.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

Exposure routes : Inhalation  
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

**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**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: vapour

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Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l

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Exposure time: 4 h

**Skin corrosion/irritation**

Not classified based on available information.

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

Species : Rabbit  
Result : No skin irritation

**Propylene glycol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
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.

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

Species : Rabbit  
Result : No eye irritation

**Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

**Ethanol:**

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

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Species : Rabbit  
Result : No eye irritation



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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Propylene glycol:**

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

**Ethanol:**

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : negative

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

**Chronic toxicity****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)  
Result: negative

**Propylene glycol:**

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

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

**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

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

### Propylene glycol:

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  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

#### Propylene glycol:

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

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

#### Ethanol:

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

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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  
 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 yr

Species : Rabbit  
 NOAEL : 5,040 mg/kg  
 Application Route : Skin contact  
 Exposure time : 45 Weeks

#### Propylene glycol:

Species : Rat, male

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NOAEL :  $\geq 1,700$  mg/kg  
 Application Route : Ingestion  
 Exposure time : 2 yr

### 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.

### Experience with human exposure

### Components:

#### betamethasone:

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

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### 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

##### **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 (Chronic 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

##### **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

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Toxicity to microorganisms : EC50 (*Pseudomonas putida*): 6,500 mg/l  
Exposure time: 16 h

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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 (*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

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

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

**Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %

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Exposure time: 20 d

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

Partition coefficient: n-octanol/water : log Pow: -1.75

**Propylene glycol:**Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8**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

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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**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
Environmentally hazardous	:	yes

**IATA-DGR**



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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.

### National Regulations

#### ADG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,  
N.O.S.  
(betamethasone)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : •3Z  
Environmentally hazardous : yes

### Special precautions for user

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

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## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

# SAFETY DATA SHEET



## Betamethasone (0.05%) Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.5	06.04.2024	4659288-00010	Date of first issue: 11.07.2019

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Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

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### SECTION 16: ANY OTHER RELEVANT INFORMATION

#### Further information

Revision Date : 06.04.2024  
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/>  
Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.  
ACGIH / STEL : Short-term exposure limit  
AU OEL / TWA : Exposure standard - time weighted average

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

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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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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