

# SAFETY DATA SHEET



## Betamethasone Liquid Formulation



Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

---

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Liquid Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.  
Address : Rua Treze de Maio, 1161  
Campinas, São Paulo, Brazil B-2220  
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 in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B  
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)  
Short-term (acute) aquatic hazard : Category 3  
Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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.  
H402 Harmful to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**

---

# SAFETY DATA SHEET



## Betamethasone Liquid Formulation



Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

P201 Obtain special instructions before use.  
P264 Wash skin thoroughly after handling.  
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.

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

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Betamethasone	378-44-9	Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1	$\geq 0,3$ - $< 1$
Benzalkonium chloride	8001-54-5	Acute toxicity (Oral), Category 3 Acute toxicity (Inhalation), Category 2 Acute toxicity (Dermal), Category 3 Skin corrosion, Category 1 Serious eye damage, Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 2	$\geq 0,0025$ - $< 0,025$

### SECTION 4. FIRST AID MEASURES

## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

- |   |   |   |
|---|---|---|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.  |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : | May damage the unborn child.<br>Causes damage to organs through prolonged or repeated exposure.   |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).   |
| Notes to physician  | : | Treat symptomatically and supportively.   |
- 

**SECTION 5. FIRE-FIGHTING MEASURES**

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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                  | : | No hazardous combustion products are known  |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
- 

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions   | : | Discharge into the environment must be avoided.  |

## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

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.

**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 vapors or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
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 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

## Betamethasone Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

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
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** : Particulates 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

**Color** : colorless

**Odor** : No data available

# SAFETY DATA SHEET



## Betamethasone Liquid Formulation



Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

---

Odor Threshold : No data available

pH : 6,8 - 7,2

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

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 : Not applicable

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.

Particle size : Not applicable

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

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 exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
 Exposure time: 4 h  
 Test atmosphere: dust/mist  
 Method: Calculation method

**Components:****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

**Benzalkonium chloride:**

Acute oral toxicity : LD50 (Rat): 240 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 0,05 - 0,5 mg/l  
 Exposure time: 4 h  
 Test atmosphere: dust/mist  
 Method: OECD Test Guideline 403  
 Assessment: Corrosive to the respiratory tract.  
 Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat, female): 704 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Betamethasone:**

Species : Rabbit  
 Result : Mild skin irritation

## Betamethasone Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

---

**Benzalkonium chloride:**

Species : Human  
Result : Corrosive after 4 hours or less of exposure

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Betamethasone:**

Species : Rabbit  
Result : No eye irritation

**Benzalkonium chloride:**

Species : Rabbit  
Result : Irreversible effects on the eye

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

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Betamethasone:**

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

**Benzalkonium chloride:**

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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



## Betamethasone Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
 Date of first issue: 15.07.2016

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.

**Benzalkonium chloride:**

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

Test Type: In vitro mammalian cell gene mutation test  
 Method: OECD Test Guideline 476  
 Result: negative  
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative  
 Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Ingestion  
 Method: OECD Test Guideline 474  
 Result: negative  
 Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Benzalkonium chloride:**

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 2 Years  
 Method : OECD Test Guideline 453  
 Result : negative  
 Remarks : Based on data from similar materials

Species : Mouse  
 Application Route : Skin contact  
 Exposure time : 80 weeks  
 Result : negative

Species : Rabbit  
 Application Route : Skin contact  
 Exposure time : 90 weeks

## Betamethasone Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
Date of first issue: 15.07.2016

Result : negative

**Reproductive toxicity**

May damage the unborn child.

**Components:****Betamethasone:**

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.

**Benzalkonium chloride:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

**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

## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

|| exposure.

|| **Benzalkonium chloride:**

|| Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity**

Components:

|| **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

|| **Benzalkonium chloride:**

|| Species : Rat  
 || NOAEL : >= 100 mg/kg  
 || Application Route : Ingestion  
 || Exposure time : 12 Weeks

**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 Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
 Date of first issue: 15.07.2016

## SECTION 12. ECOLOGICAL INFORMATION

## Ecotoxicity

Components:**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 (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

**Benzalkonium chloride:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 0,28 mg/l  
 Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,0056 mg/l  
 Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Chlorella pyrenoidosa): 0,09 mg/l  
 Exposure time: 72 h
- M-Factor (Acute aquatic toxicity) : 100
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0,032 mg/l  
 Exposure time: 34 d

## Betamethasone Liquid Formulation

Version 5.0      Revision Date: 23.03.2020      SDS Number: 805305-00012      Date of last issue: 13.09.2019  
 Date of first issue: 15.07.2016

**Persistence and degradability****Components:****Benzalkonium chloride:**

Biodegradability : Result: Readily biodegradable.  
 Method: OECD Test Guideline 301D  
 Remarks: Based on data from similar materials

**Bioaccumulative potential****Components:****Betamethasone:**

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

**Benzalkonium chloride:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
 Bioconcentration factor (BCF): < 500  
 Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 1,692  
 Remarks: Calculation

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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

Waste from residues : Dispose of in accordance with local regulations.  
 Contaminated packaging : Empty containers should be taken to an approved waste 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

## Betamethasone Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

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.

**Domestic regulation****ANTT**

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

Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

**Special precautions for user**

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

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

# SAFETY DATA SHEET



## Betamethasone Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

### International Regulations

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

AICS : not determined

DSL : not determined

IECSC : 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

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET



## Betamethasone Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
5.0	23.03.2020	805305-00012	Date of first issue: 15.07.2016

---

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.

BR / Z8