

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
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 number : 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)

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.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Response:

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

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

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 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.
- 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. FIREFIGHTING MEASURES

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

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

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 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.

Betamethasone (0.05%) Liquid Formulation

Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

- 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 ³ | AU OEL |
| | Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica | | | |
| Propylene glycol | 57-55-6 | TWA (particulate) | 10 mg/m ³ | AU OEL |
| | | TWA (Total (vapour and particles)) | 150 ppm 474 mg/m ³ | AU OEL |
| Ethanol | 64-17-5 | TWA | 1,000 ppm 1,880 mg/m ³ | AU OEL |
| | | STEL | 1,000 ppm | ACGIH |
| betamethasone | 378-44-9 | TWA | 1 µg/m ³ (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm ² | Internal |

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

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 |
| 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 |

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

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 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

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Betamethasone (0.05%) Liquid Formulation

Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

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): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rabbit): > 159 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

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

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

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 |

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:**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 |

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

| | |
|---------|------------|
| Species | : Mouse |
| Result | : negative |

betamethasone:

| | |
|-----------------|-------------------|
| 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:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative |

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:

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

| | | |
|-------------------------------------|---|--|
| 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 |

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: Three-generation reproduction toxicity study |
|----------------------|---|---|

Betamethasone (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

| | | | |
|--|------------------------------------|---|--|
| | | | 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. |
| | | | 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. |

Betamethasone (0.05%) Liquid Formulation

Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
 Date of first issue: 11.07.2019

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
 NOAEL : 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

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

Species : Dog
LOAEL : 0.05 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Blood, thymus gland, Adrenal gland

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

betamethasone:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Betamethasone (0.05%) Liquid Formulation

Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

| | | |
|--|---|--|
| | | 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 |
| | | 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 |
|------------------|---|---|

Betamethasone (0.05%) Liquid Formulation

Version 2.0 Revision Date: 10.10.2020 SDS Number: 4659288-00003 Date of last issue: 30.07.2019
Date of first issue: 11.07.2019

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 %
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

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

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 (0.05%) Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

(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 : 964
aircraft)
Packing instruction (passen- : 964
ger aircraft)
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

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**

Prohibition/Licensing Requirements : There is no applicable prohibition,

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

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 |

SECTION 16. OTHER INFORMATION

Further information

| | | |
|---|---|---|
| Revision Date | : | 10.10.2020 |
| 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/ |

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

| | | |
|-------------|---|------------|
| 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 |

AllC - 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

SAFETY DATA SHEET



Betamethasone (0.05%) Liquid Formulation



| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.07.2019 |
| 2.0 | 10.10.2020 | 4659288-00003 | Date of first issue: 11.07.2019 |

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.

AU / EN