

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

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

Trade name : Betamethasone (0.05%) Cream Formulation

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

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

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

Telephone : 551-430-6000

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

1.4 Emergency telephone number

215-631-6999

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

Reproductive toxicity, Category 1B

H360D: May damage the unborn child.

Specific target organ toxicity - repeated exposure, Category 1

H372: Causes damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 1

H410: Very toxic to aquatic life with long lasting effects.

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

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.
 H372 Causes damage to organs through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.

Betamethasone (0.05%) Cream Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
 Date of first issue: 17.05.2017

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.

Hazardous components which must be listed on the label:
 betamethasone

Additional Labelling

EUH208 Contains 4-Chloro-3-methylphenol.
 May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
4-Chloro-3-methylphenol	59-50-7 200-431-6 604-014-00-3	Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1C; H314 Eye Dam. 1; H318 Skin Sens. 1B; H317 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	0,1
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland)	0,064

Betamethasone (0.05%) Cream Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

		Aquatic Chronic 1; H410	
		M-Factor (Chronic aquatic toxicity): 1.000	
PBT and vPvB substance :			
Decamethylcyclpentasiloxane	541-02-6 208-764-9		7

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

SECTION 5: Firefighting measures**5.1 Extinguishing media**

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Silicon oxides
Formaldehyde

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
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-

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe dust, fume, gas, mist, vapours or spray.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

Betamethasone (0.05%) Cream Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA OEL-RL (particulate)	10 mg/m ³	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (Vapour + particulates)	150 ppm 470 mg/m ³	ZA OEL
Further information: Recommended Limit				
betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	STEL OEL-CL	2 ppm 2,5 mg/m ³	ZA OEL
Further information: Control Limit				
		TWA OEL-CL	2 ppm 2,5 mg/m ³	ZA OEL
Further information: Control Limit				
		STEL	0,6 ppm 0,74 mg/m ³	2004/37/EC
		TWA	0,3 ppm 0,37 mg/m ³	2004/37/EC

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Decamethylcyclopentasiloxane	Workers	Inhalation	Long-term systemic effects	97,3 mg/m ³
	Workers	Inhalation	Acute systemic effects	62 mg/m ³
	Workers	Inhalation	Long-term local effects	24,2 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	17,3 mg/m ³
	Consumers	Inhalation	Long-term local effects	4,3 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³

SAFETY DATA SHEET



Betamethasone (0.05%) Cream Formulation



Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
 Date of first issue: 17.05.2017

			fects	
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³
4-Chloro-3-methylphenol	Workers	Inhalation	Long-term systemic effects	6,289 mg/m ³
	Workers	Skin contact	Long-term systemic effects	3,567 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,551 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	1,783 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,892 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9,33 mg/kg food
Decamethylcyclopentasiloxane	Sewage treatment plant	10 mg/l
	Fresh water sediment	11 mg/kg
	Marine sediment	1,1 mg/kg
	Soil	3,77 mg/kg
Propylene glycol	Oral (Secondary Poisoning)	13 mg/kg food
	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
4-Chloro-3-methylphenol	Marine sediment	57,2 mg/kg
	Soil	50 mg/kg
	Fresh water	0,015 mg/l
	Intermittent use/release	0,015 mg/l
	Marine water	0,002 mg/l
	Sewage treatment plant	2,286 mg/l
	Fresh water sediment	13,981 mg/kg dry weight (d.w.)
	Marine sediment	13,981 mg/kg dry weight (d.w.)
	Soil	6,399 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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.

Personal protective equipment

Eye protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions,

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

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, inorganic gas/vapour and organic vapour type (AB-P)

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

Appearance	: cream
Colour	: white
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	: > 93,3 °C
Evaporation rate	: Not applicable
Flammability (solid, gas)	: Not classified as a flammability hazard
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	: Not applicable
Relative density	: No data available
Density	: No data available

SAFETY DATA SHEET



Betamethasone (0.05%) Cream Formulation



Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.
Hazardous decomposition products will be formed at elevated temperatures.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

Thermal decomposition : Formaldehyde

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Skin contact
Ingestion
Eye contact

Betamethasone (0.05%) Cream Formulation

Version Revision Date: SDS Number: Date of last issue: 10.10.2020
3.5 09.04.2021 1682110-00009 Date of first issue: 17.05.2017

Acute toxicity

Not classified based on available information.

Components:**4-Chloro-3-methylphenol:**

Acute oral toxicity : LD50 (Mouse): 600 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2,871 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Acute toxicity estimate: 1.100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

Decamethylcyclopentasiloxane:

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

Acute inhalation toxicity : LC50 (Rat): 8,67 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:**4-Chloro-3-methylphenol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure

betamethasone:

Species : Rabbit
Result : Mild skin irritation

Decamethylcyclopentasiloxane:

Betamethasone (0.05%) Cream Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**4-Chloro-3-methylphenol:**

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

betamethasone:

Species : Rabbit
Result : No eye irritation

Decamethylcyclopentasiloxane:

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:**4-Chloro-3-methylphenol:**

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

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

betamethasone:

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

Decamethylcyclopentasiloxane:

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

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Germ cell mutagenicity

Not classified based on available information.

Components:

4-Chloro-3-methylphenol:

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

betamethasone:

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: equivocal

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Decamethylcyclopentasiloxane:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: inhalation (vapour)
Method: OECD Test Guideline 474
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 486
Result: negative

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

May damage the unborn child.

Components:**4-Chloro-3-methylphenol:**

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

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

betamethasone:

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

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

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

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

Decamethylcyclopentasiloxane:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Method: OPPTS 870.3800
Result: negative

Effects on foetal development : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Method: OPPTS 870.3800
Result: negative

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

STOT - single exposure

Not classified based on available information.

Components:**4-Chloro-3-methylphenol:**

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Causes damage to organs 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:****4-Chloro-3-methylphenol:**

Species : Rat
 NOAEL : 200 mg/kg
 LOAEL : 400 mg/kg
 Application Route : Ingestion
 Exposure time : 28 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

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Decamethylcyclopentasiloxane:

Species	:	Rat
NOAEL	:	1.000 mg/kg
LOAEL	:	> 1.000 mg/kg
Application Route	:	Ingestion
Method	:	OECD Test Guideline 408

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**12.1 Toxicity****Components:****4-Chloro-3-methylphenol:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC10 (Chlorella pyrenoidosa (aglae)): 2,3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50 : 22,86 mg/l Exposure time: 60 h
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,15 mg/l Exposure time: 28 d Species: Oncorhynchus mykiss (rainbow trout) Method: OECD Test Guideline 204
Toxicity to daphnia and other aquatic invertebrates (Chronic)	:	NOEC: 0,32 mg/l Exposure time: 21 d

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Exposure time: 96 h
 Method: OECD Test Guideline 201
 Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 2.000 mg/l
 Exposure time: 3 h
 Method: 88/302/EC

Toxicity to fish (Chronic toxicity) : NOEC: 14 µg/l
 Exposure time: 90 d
 Species: Oncorhynchus mykiss (rainbow trout)
 Method: OECD Test Guideline 210
 Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 15 µg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)
 Method: OECD Test Guideline 211
 Remarks: No toxicity at the limit of solubility

12.2 Persistence and degradability**Components:****4-Chloro-3-methylphenol:**

Biodegradability : Result: Readily biodegradable.
 Biodegradation: 78 %
 Exposure time: 15 d
 Method: OECD Test Guideline 301

Decamethylcyclopentasiloxane:

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 0,14 %
 Exposure time: 28 d
 Method: OECD Test Guideline 310

12.3 Bioaccumulative potential**Components:****4-Chloro-3-methylphenol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)
 Bioconcentration factor (BCF): 5,5 - 13

Partition coefficient: n-octanol/water : log Pow: 0,477

betamethasone:

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

Decamethylcyclopentasiloxane:

Bioaccumulation : Species: Pimephales promelas (fathead minnow)
 Bioconcentration factor (BCF): 7.060 - 13.300

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 8,023

12.4 Mobility in soil

No data available

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

Assessment : This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

Components:**Decamethylcyclopentasiloxane:**Assessment :
: This substance is considered to be persistent, bioaccumulating and toxic (PBT).
: This substance is considered to be very persistent and very bioaccumulating (vPvB).**12.6 Other adverse effects****Product:**

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

SECTION 13: Disposal considerations**13.1 Waste treatment methods**Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**ADN : UN 3077
ADR : UN 3077

SAFETY DATA SHEET



Betamethasone (0.05%) Cream Formulation



Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
IATA : Environmentally hazardous substance, solid, n.o.s. (betamethasone)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9

SAFETY DATA SHEET



Betamethasone (0.05%) Cream Formulation



Version 3.5 Revision Date: 09.04.2021 SDS Number: 1682110-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302 : Harmful if swallowed.
 H312 : Harmful in contact with skin.
 H314 : Causes severe skin burns and eye damage.
 H317 : May cause an allergic skin reaction.
 H318 : Causes serious eye damage.
 H330 : Fatal if inhaled.
 H335 : May cause respiratory irritation.
 H360D : May damage the unborn child.
 H372 : Causes damage to organs through prolonged or repeated exposure.
 H400 : Very toxic to aquatic life.
 H410 : Very toxic to aquatic life with long lasting effects.
 H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
 Aquatic Acute : Short-term (acute) aquatic hazard
 Aquatic Chronic : Long-term (chronic) aquatic hazard
 Eye Dam. : Serious eye damage
 Repr. : Reproductive toxicity
 Skin Corr. : Skin corrosion
 Skin Sens. : Skin sensitisation
 STOT RE : Specific target organ toxicity - repeated exposure
 STOT SE : Specific target organ toxicity - single exposure
 2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
 2004/37/EC / STEL : Short term exposure limit
 2004/37/EC / TWA : Long term exposure limit
 ZA OEL / TWA OEL-CL : Long term occupational exposure limits - control limit
 ZA OEL / STEL OEL-CL : Short term occupational exposure limits - control limit
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP -

Betamethasone (0.05%) Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	1682110-00009	Date of first issue: 17.05.2017

Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Repr. 1B	H360D
STOT RE 1	H372
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method

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

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