

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Betamethasone (0.05%) Cream Formulation

Version 3.5      Revision Date: 09.04.2021      SDS Number: 1685836-00009      Date of last issue: 10.10.2020  
Date of first issue: 17.05.2017

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### 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

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### 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:**

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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.

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).

Ecological information: 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.

Toxicological information: 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 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	0,1

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		M-Factor (Acute aquatic toxicity): 1	
		Acute toxicity estimate	
		Acute dermal toxicity: 1.100 mg/kg	
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) Aquatic Chronic 1; H410	0,064
		M-Factor (Chronic aquatic toxicity): 1.000	
		specific concentration limit STOT RE 1; H372 >= 0,01 % Repr. 1B; H360D >= 0,01 %	
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.

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- 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.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 meth- : Use extinguishing measures that are appropriate to local cir-

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ods	cumstances 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.
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### 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 determine 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.

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### 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.

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Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
: 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

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	TWA (Vapour)	50 mg/m <sup>3</sup>	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Propylene glycol	57-55-6	TWA	25 ppm 79 mg/m <sup>3</sup>	FOR-2011-12-06-1358
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

#### Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	TWA	0,5 ppm 0,6 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin				

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	T	1 ppm 1,2 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or air-ways or evoking allergies after coming into contact with the skin, Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.			
	STEL	0,6 ppm 0,74 mg/m <sup>3</sup>	2004/37/EC
Further information: Dermal sensitisation, Carcinogens or mutagens			
	TWA	0,3 ppm 0,37 mg/m <sup>3</sup>	2004/37/EC
Further information: Dermal sensitisation, Carcinogens or mutagens			

### 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 <sup>3</sup>	
	Workers	Inhalation	Acute systemic effects	62 mg/m <sup>3</sup>	
	Workers	Inhalation	Long-term local effects	24,2 mg/m <sup>3</sup>	
	Consumers	Inhalation	Long-term systemic effects	17,3 mg/m <sup>3</sup>	
	Consumers	Inhalation	Long-term local effects	4,3 mg/m <sup>3</sup>	
	Consumers	Ingestion	Long-term systemic effects	5 mg/kg bw/day	
	Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
Workers		Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>	
Consumers		Inhalation	Long-term local effects	10 mg/m <sup>3</sup>	
Consumers		Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>	
4-Chloro-3-methylphenol		Workers	Inhalation	Long-term systemic effects	6,289 mg/m <sup>3</sup>
		Workers	Skin contact	Long-term systemic effects	3,567 mg/kg bw/day
		Consumers	Inhalation	Long-term systemic effects	1,551 mg/m <sup>3</sup>
	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

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	Marine sediment	1,1 mg/kg
	Soil	3,77 mg/kg
	Oral (Secondary Poisoning)	13 mg/kg food
Propylene glycol	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
	Marine sediment	57,2 mg/kg
	Soil	50 mg/kg
4-Chloro-3-methylphenol	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, 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.



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Filter type	: Equipment should conform to NS EN 14387 : Combined particulates, inorganic gas/vapour and organic vapour type (AB-P)
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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	: cream
Colour	: white
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not classified as a flammability hazard
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: > 93,3 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity	: No data available
Viscosity, kinematic	: Not applicable
Solubility(ies)	: No data available
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Vapour pressure	: No data available
Relative density	: No data available
Density	: No data available
Relative vapour density	: Not applicable
Particle characteristics	: No data available
Particle size	: Not applicable

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### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

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## 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

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

#### 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

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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:**

Species : Rabbit  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

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

Species : Rabbit

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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

### 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:

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- 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

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

May damage the unborn child.

### Components:

#### 4-Chloro-3-methylphenol:

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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

### **STOT - single exposure**

Not classified based on available information.

### **Components:**

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

Assessment : May cause respiratory irritation.

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### 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

##### **Decamethylcyclopentasiloxane:**

Species : Rat  
NOAEL : 1.000 mg/kg  
LOAEL : > 1.000 mg/kg  
Application Route : Ingestion

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Method : OECD Test Guideline 408

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

Assessment : 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.

#### 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 : EC50 (Daphnia magna (Water flea)): 1,5 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l  
plants : 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 tox- : 1  
icity)

Toxicity to microorganisms : EC50 : 22,86 mg/l  
Exposure time: 60 h

Toxicity to fish (Chronic tox- : NOEC: 0,15 mg/l



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- icity)      Exposure time: 28 d  
Species: *Oncorhynchus mykiss* (rainbow trout)  
Method: OECD Test Guideline 204
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,32 mg/l  
Exposure time: 21 d  
Species: *Daphnia magna* (Water flea)  
Method: OECD Test Guideline 211
- 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: 0,052 mg/l  
Exposure time: 32 d  
Species: *Pimephales promelas* (fathead minnow)  
Method: OECD Test Guideline 210
- NOEC: 0,07 µg/l  
Exposure time: 219 d  
Species: *Oryzias latipes* (Japanese medaka)  
Method: OECD Test Guideline 229
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l  
Exposure time: 21 d  
Species: *Daphnia magna* (Water flea)  
Method: OECD Test Guideline 211
- M-Factor (Chronic aquatic toxicity) : 1.000
- Decamethylcyclpentasiloxane:**
- Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 16 µg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 2,9 µg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility
- Toxicity to algae/aquatic : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): > 12

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plants		µg/l Exposure time: 96 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
		EC10 (Pseudokirchneriella subcapitata (green algae)): > 12 µg/l 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

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### **betamethasone:**

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

### **Decamethylcyclopentasiloxane:**

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

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## **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.

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### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADN	:	UN 3077
ADR	:	UN 3077
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

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

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### RID

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

### IMDG

Packing group	: III
Labels	: 9
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
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### ADR

Environmentally hazardous	: yes
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### RID

Environmentally hazardous	: yes
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### IMDG

Marine pollutant	: yes
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### IATA (Passenger)

Environmentally hazardous	: yes
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### IATA (Cargo)

Environmentally hazardous	: yes
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## 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 Maritime transport in bulk according to IMO instruments

Remarks	: Not applicable for product as supplied.
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## SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Decamethylcyclopentasiloxane (Number on list 70)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Decamethylcyclopentasiloxane

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 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.

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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  
  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
2004/37/EC / STEL : Short term exposure limit  
2004/37/EC / TWA : Long term exposure limit  
FOR-2011-12-06-1358 / TWA : Long term exposure limit  
FOR-2011-12-06-1358 / T : Ceiling

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 - 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;

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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 Bio-accumulative

### 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.

NO / EN