

**Betamethasone (0.05%) Cream Formulation**

Version 4.0      Revision Date: 06.04.2024      SDS Number: 1682143-00015      Date of last issue: 30.09.2023  
Date of first issue: 17.05.2017

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**Section 1: Identification**

**Product identifier** : Betamethasone (0.05%) Cream Formulation

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

**Manufacturer or supplier's details**


Company : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : +1-551-430-6000  
Emergency telephone number : +1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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**Section 2: Hazard identification****Classification of the substance or mixture**

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

**GHS Label elements, including precautionary statements**

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

Precautionary statements : **Prevention:**

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P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

**Response:**

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

P391 Collect spillage.

**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)
Petrolatum	8009-03-8	>= 20 -<= 30
Glyceryl monostearate	123-94-4	3
4-Chloro-3-methylphenol	59-50-7	0.1
betamethasone	378-44-9	0.064

**Section 4: First-aid measures****Description of necessary 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.

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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**

Risks : 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).

**Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically and supportively.

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**Section 5: Fire-fighting measures****Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**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

**Special protective actions for fire-fighters**

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.

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**Section 6: Accidental release measures****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).

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**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.

**Methods and materials 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.

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**Section 7: Handling and storage****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.  
Do not breathe decomposition products.

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, including any incompatibilities**

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.

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Materials to avoid : Keep tightly closed.  
Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents

## Section 8: Exposure controls/personal protection

## Control parameters

## Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	PEL (long term) (Mist)	5 mg/m <sup>3</sup>	SG OEL
		PEL (short term) (Mist)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Glyceryl monostearate	123-94-4	PEL (long term)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
4-Chloro-3-methylphenol	59-50-7	TWA	200 µg/m <sup>3</sup> (OEB 2)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
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 / Permissible concentration	Basis
Formaldehyde	50-00-0	PEL (short term)	0.3 ppm 0.37 mg/m <sup>3</sup>	SG OEL
		TWA	0.1 ppm	ACGIH
		STEL	0.3 ppm	ACGIH

**Appropriate engineering control 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

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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.

**Individual protection measures, such as personal protective equipment (PPE)**

- |                        |   |  |
|------------------------|---|--|
| Eye/face protection    | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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 protection        | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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  |
| Hand protection        | : |  |
| Material               | : | Chemical-resistant gloves  |
| Remarks                | : | Consider double gloving.   |
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**Section 9: 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    |

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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
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
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.
Particle characteristics	:	
Particle size	:	Not applicable

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**Section 10: Stability and reactivity**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Vapours may form explosive mixture with air. Can react with strong oxidizing agents. Hazardous decomposition products will be formed at elevated temperatures.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents

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## Hazardous decomposition products

Thermal decomposition : Formaldehyde

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## Section 11: Toxicological information

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

### Acute toxicity

Not classified based on available information.

### Components:

#### **Petrolatum:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity Remarks: Based on data from similar materials

#### **Glyceryl monostearate:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials

#### **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	:	LD50 (Rat): > 5,000 mg/kg

#### **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



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**II****Skin corrosion/irritation**

Not classified based on available information.

**Components:****Petrolatum:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Glyceryl monostearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

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

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

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Species : Rabbit  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Petrolatum:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

**Glyceryl monostearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

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

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

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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:****Petrolatum:**

Test Type	: Buehler Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**Glyceryl monostearate:**

Test Type	: Buehler Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

**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
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**betamethasone:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Petrolatum:**

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

**Glyceryl monostearate:**

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

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

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

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

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

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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.

**Carcinogenicity**

Not classified based on available information.

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**Components:****Petrolatum:**

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

**Reproductive toxicity**

May damage the unborn child.

**Components:****Petrolatum:**

Effects on fertility	:	Test Type: Reproduction/Developmental toxicity screening test
		Species: Rat
		Application Route: Ingestion
		Result: negative
		Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development
		Species: Rat
		Application Route: Skin contact
		Result: negative
		Remarks: Based on data from similar materials

**Glyceryl monostearate:**

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
		Species: Rat
		Application Route: Ingestion
		Method: OECD Test Guideline 422
		Result: negative
		Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
		Species: Rat
		Application Route: Ingestion
		Method: OECD Test Guideline 422
		Result: negative
		Remarks: Based on data from similar materials

**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

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||| ment

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.

**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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

**Components:****betamethasone:**

||| Target Organs

: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland

||| Assessment

: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Petrolatum:**

||| Species

: Rat

||| NOAEL

: 5,000 mg/kg

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Application Route	: Ingestion
Exposure time	: 2 yr

**Glyceryl monostearate:**

Species	: Rat
NOAEL	: >= 12,500 mg/kg
Application Route	: Ingestion
Exposure time	: 84 Days
Remarks	: Based on data from similar materials

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

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

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Species	: Rabbit
LOAEL	: 0.05 %
Application Route	: Skin contact
Exposure time	: 10 - 30 d
Target Organs	: Pituitary gland, Immune system, muscle

Species	: Rat
LOAEL	: 0.05 %
Application Route	: Skin contact
Exposure time	: 8 Weeks
Target Organs	: thymus gland

Species	: Mouse
LOAEL	: 0.1 %
Application Route	: Skin contact
Exposure time	: 8 Weeks
Target Organs	: thymus gland

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

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****betamethasone:**

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

**Section 12: Ecological information****Toxicity****Components:****Petrolatum:**

Toxicity to fish	:	LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

**Glyceryl monostearate:**

Toxicity to fish	:	LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 32 mg/l Exposure time: 47 h Method: Directive 67/548/EEC, Annex V, C.2. Remarks: No toxicity at the limit of solubility Based on data from similar materials
Toxicity to algae/aquatic plants	:	EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility

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		NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): > 0.22 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility Based on data from similar materials
	Toxicity to microorganisms	: EC10 (Pseudomonas putida): > 1 mg/l Exposure time: 18 h Remarks: Based on data from similar materials

**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 (algae)): 15 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	M-Factor (Acute aquatic toxicity)	: 1
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.32 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
	Toxicity to microorganisms	: EC50: 22.86 mg/l Exposure time: 60 h

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	Toxicity to daphnia and other aquatic invertebrates	: EC50 (Americamysis): > 50 mg/l Exposure time: 96 h
	Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility



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		NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility
	Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
		NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l Exposure time: 219 d Method: OECD Test Guideline 229
	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
	M-Factor (Chronic aquatic toxicity)	: 1,000

**Persistence and degradability****Components:****Petrolatum:**

	Biodegradability	: Result: Not readily biodegradable. Biodegradation: 31 % Exposure time: 28 d Method: OECD Test Guideline 301F Remarks: Based on data from similar materials
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**Glyceryl monostearate:**

	Biodegradability	: Result: Readily biodegradable. Remarks: Based on data from similar materials
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**4-Chloro-3-methylphenol:**

	Biodegradability	: Result: Readily biodegradable. Biodegradation: 78 % Exposure time: 15 d Method: OECD Test Guideline 301
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**Bioaccumulative potential****Components:****Glyceryl monostearate:**

	Partition coefficient: n-octanol/water	: log Pow: 6.1
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**4-Chloro-3-methylphenol:**

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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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information****International Regulations****UNRTDG**

UN number : UN 3077

UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone)

Transport hazard class(es) : 9

Packing group : III

Labels : 9

Environmental hazards : yes

**IATA-DGR**

UN/ID No. : UN 3077

UN proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(betamethasone)

Transport hazard class(es) : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

Environmentally hazardous : yes

**IMDG-Code**

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UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)  
Transport hazard class(es) : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

### Special precautions for user

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

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## Section 15: Regulatory information

### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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## Section 16: Other information

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### 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/>

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

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Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term  
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

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

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

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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.

SG / EN