# SAFETY DATA SHEET

## Betamethasone Cream Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2020/10/10 |
|---|---|---|---|
| 8.0 | 2021/04/09 | 1841208-00010 | Date of first issue: 2017/07/19 |

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone Cream Formulation

**Supplier's company name, address and phone number**

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

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

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H402 Harmful to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read

and understood.
P260 Do not breathe vapours.
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.

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---|---|---|---|
| Petrolatum | 8009-03-8 | >= 10 - < 20 | |
| Paraffin oil | 8012-95-1 | >= 2.5 - < 10 | |
| Hexadecan-1-ol. Ethoxylated | 9004-95-9 | >= 1 - < 2.5 | |
| 4-Chloro-3-methylphenol | 59-50-7 | >= 0.1 - < 0.25 | 3-900 |
| betamethasone | 378-44-9 | >= 0.025 - < 0.1 | |

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

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

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

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

## 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## 7. HANDLING AND STORAGE

**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.<br>Do not breathe vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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. |

**Storage**

| | | |
|---|---|---|
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |
| Packaging material | : | Unsuitable material: None known. |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Petrolatum | 8009-03-8 | OEL-M (Mist) | 3 mg/m3 | JP OEL JSOH |
| | Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans | | | |
| | | TWA (Inhalable particulate matter) | 5 mg/m3 | ACGIH |
| Paraffin oil | 8012-95-1 | OEL-M (Mist) | 3 mg/m3 | JP OEL JSOH |
| | Further information: Group 1: carcinogenic to humans | | | |
| | | TWA (Inhalable particulate matter) | 5 mg/m3 | ACGIH |
| betamethasone | 378-44-9 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm² | Internal |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : cream

| | | |
|---|---|---|
| Colour | : | No data available |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Boiling point, initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | Not applicable |
| Lower explosion limit and upper explosion limit / flammability limit | | |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | > 93.3 °C |
| Decomposition temperature | : | No data available |
| pH | : | 5 |
| Evaporation rate | : | No data available |
| Auto-ignition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | No data available |
| Density and / or relative density | | |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | No data available |
| Explosive properties | : | Not explosive |

| | | |
|---|---|---|
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics | | |
| Particle size | : | Not applicable |

## 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## 11. TOXICOLOGICAL INFORMATION

| | | |
|---|---|---|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Components:**

**Petrolatum:**

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

**Paraffin oil:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Hexadecan-1-ol. Ethoxylated:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 2,500 mg/kg |

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

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

| | | |
|---|---|---|
| Acute inhalation toxicity | : | LC50 (Rat): > 2.871 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rat): > 5,000 mg/kg |

**betamethasone:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br><br>LD50 (Mouse): > 4,500 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 0.4 mg/l<br>Exposure time: 4 h |

**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 |

**Paraffin oil:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |

**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 |

**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 |

**Paraffin oil:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Hexadecan-1-ol. Ethoxylated:**

| | | |
|---|---|---|
| Result | : | Irritation to eyes, reversing within 21 days |
| Remarks | : | Based on data from similar materials |

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

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

**betamethasone:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Petrolatum:**

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

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

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

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |

**betamethasone:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Oral<br>Result: equivocal |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Skin contact<br>Result: negative<br>Remarks: Based on data from similar materials |

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

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Reproduction/Developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**betamethasone:**

| | | |
|---|---|---|
| Effects on foetal development | : | Species: Rabbit<br>Application Route: Intramuscular<br>Developmental Toxicity: LOAEL: 0.05 mg/kg body weight<br>Result: Fetotoxicity, Malformations were observed.<br><br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 0.42 mg/kg body weight<br>Result: Malformations were observed.<br><br>Species: Mouse<br>Application Route: Intramuscular<br>Developmental Toxicity: LOAEL: 1 mg/kg body weight<br>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 |
| Application Route | : | Ingestion |
| Exposure time | : | 2 yr |

**Paraffin oil:**

| | | |
|---|---|---|
| Species | : | Rat, female |
| LOAEL | : | 161 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

**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 |

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Paraffin oil:**

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**Experience with human exposure**

**Components:**

**betamethasone:**

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

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Petrolatum:**

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

| | | |
|---|---|---|
| | | Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 10 mg/l<br>Exposure time: 21 d<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |

**Paraffin oil:**

| | | |
|---|---|---|
| Toxicity to fish | : | LL50 (Scophthalmus maximus (turbot)): > 100 mg/l<br>Exposure time: 96 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Acartia tonsa): > 100 mg/l<br>Exposure time: 48 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |
| | | NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials |

**Hexadecan-1-ol. Ethoxylated:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50: > 1 - 10 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50: > 1 - 10 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EC50: > 10 - 100 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials |

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

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 1.5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

| | | |
|---|---|---|
| | | EC10 (Chlorella pyrenoidosa (aglae)): 2.3 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Oncorhynchus mykiss (rainbow trout)): 0.15 mg/l<br>Exposure time: 28 d<br>Method: OECD Test Guideline 204 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.32 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: 22.86 mg/l<br>Exposure time: 60 h |

**betamethasone:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): > 50 mg/l<br>Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210<br><br>NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l<br>Exposure time: 219 d<br>Method: OECD Test Guideline 229 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 8 mg/l<br>Exposure time: 21 d<br>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

**Hexadecan-1-ol. Ethoxylated:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 99 %
Exposure time: 19 d

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

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

**Bioaccumulative potential**

**Components:**

**Paraffin oil:**

Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Calculation

**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

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

## 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

## 14. TRANSPORT INFORMATION

### International Regulations

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (passenger aircraft) | : | 964 |
| Environmentally hazardous | : | yes |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**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.

## 15. REGULATORY INFORMATION

### Related Regulations

**Fire Service Law**

Designated Flammable Substances, Flammable liquid, (2 cubic metre)

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

| Chemical name | Number |
|---|---|
| alpha-Alkyl(C=9-11)-omega-hydroxypoly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.) | 188 |
| alpha-Alkyl(C=12-15)-omega-hydroxypoly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.) | 189 |
| [alpha-(Alkyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl) or alpha-(alkenyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl)] | 250 |

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

| Chemical name | Number | Concentration (%) |
|---|---|---|
| Mineral oil | 168 | >=20 - <30 |

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

| Chemical name | Number |
|---|---|
| Mineral oil | 168 |

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

| | | |
|---|---|---|
| Bulk transportation | : | Noxious liquid substance(Category Z) |
| Pack transportation | : | Classified as marine pollutant |

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## 16. OTHER INFORMATION

**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.

| | | |
|---|---|---|
| Date format | : | yyyy/mm/dd |

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| JP OEL JSOH | : | Japan. The Japan Society for Occupational Health. Recom- |

mendation of Occupational Exposure Limits

| | | |
|---|---|---|
| ACGIH / TWA | : | 8-hour, time-weighted average |
| JP OEL JSOH / OEL-M | : | Occupational Exposure Limit-Mean |

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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