

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



ORGANON

## Betamethasone / Clotrimazole Cream Formulation

Version 7.0      Revision Date: 06.04.2024      SDS Number: 415445-00022      Date of last issue: 30.09.2023  
Date of first issue: 14.12.2015

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Betamethasone / Clotrimazole Cream Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 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 : +1-551-430-6000

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

#### 1.4 Emergency telephone number

+1-215-631-6999

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B

H360D: May damage the unborn child.

Specific target organ toxicity - repeated exposure, Category 1

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

Long-term (chronic) aquatic hazard, Category 1

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

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

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

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

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification  | Concentration<br>(% w/w) |
|---------------|---|---|--------------------------|
| clotrimazole  | 23593-75-1<br>245-764-8                               | Acute Tox. 4; H302<br>Acute Tox. 3; H311<br>Eye Irrit. 2; H319<br>Repr. 2; H361fd<br>STOT RE 2; H373<br>(Liver, Kidney, Ad-renal gland) | >= 1 - < 2.5             |

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|                |                                       |  |                  |
|----------------|---------------------------------------|--|------------------|
|                |                                       | <p>Aquatic Acute 1; H400<br/>Aquatic Chronic 1; H410</p> <hr/> <p>M-Factor (Acute aquatic toxicity): 10<br/>M-Factor (Chronic aquatic toxicity): 10</p> <hr/> <p>Acute toxicity estimate</p> <p>Acute dermal toxicity: 923 mg/kg</p>   |                  |
| Benzyl alcohol | 100-51-6<br>202-859-9<br>603-057-00-5 | <p>Acute Tox. 4; H302<br/>Acute Tox. 4; H332<br/>Eye Irrit. 2; H319</p> <hr/> <p>Acute toxicity estimate</p> <p>Acute oral toxicity: 1,620 mg/kg</p>   | >= 0.1 - < 1     |
| betamethasone  | 378-44-9<br>206-825-4                 | <p>Acute Tox. 2; H330<br/>Repr. 1B; H360D<br/>STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)<br/>Aquatic Chronic 1; H410</p> <hr/> <p>M-Factor (Chronic aquatic toxicity): 1,000</p> <hr/> <p>specific concentration limit<br/>STOT RE 1; H372<br/>&gt;= 0.01 %<br/>Repr. 1B; H360D<br/>&gt;= 0.01 %</p> | >= 0.025 - < 0.1 |

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

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

#### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
- 

### 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.
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### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

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

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

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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.  
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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

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### 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.<br>Do not breathe mist or 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.                              |
| 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.<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. |

### 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:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

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

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### 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                 | OELV - 8 hrs (TWA) (inhalable fraction)           | 5 mg/m <sup>3</sup>              | IE OEL   |
| Propylene glycol              | 57-55-6                   | OELV - 8 hrs (TWA) (particles)                    | 10 mg/m <sup>3</sup>             | IE OEL   |
|                               |                           | OELV - 8 hrs (TWA) (total (vapour and particles)) | 150 ppm<br>470 mg/m <sup>3</sup> | IE OEL   |
| White mineral oil (petroleum) | 8042-47-5                 | OELV - 8 hrs (TWA) (inhalable fraction)           | 5 mg/m <sup>3</sup>              | IE OEL   |
| clotrimazole                  | 23593-75-1                | TWA   | 0.2 mg/m <sup>3</sup> (OEB 2)    | 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 |

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

| Substance name   | End Use   | Exposure routes | Potential health effects   | Value                    |
|------------------|-----------|-----------------|----------------------------|--------------------------|
| 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>     |
| Alcohols, C16-18 | Workers   | Inhalation      | Long-term systemic effects | 237.76 mg/m <sup>3</sup> |
|                  | Workers   | Inhalation      | Acute systemic effects     | 237.76 mg/m <sup>3</sup> |
|                  | Workers   | Inhalation      | Long-term local effects    | 6.52 mg/m <sup>3</sup>   |
|                  | Workers   | Inhalation      | Acute local effects        | 6.52 mg/m <sup>3</sup>   |
|                  | Workers   | Skin contact    | Long-term systemic effects | 200 mg/kg bw/day         |
|                  | Workers   | Skin contact    | Acute systemic effects     | 400 mg/kg bw/day         |
|                  | Workers   | Skin contact    | Long-term local effects    | 1.124 mg/cm <sup>2</sup> |
|                  | Workers   | Skin contact    | Acute local effects        | 1.124 mg/cm <sup>2</sup> |

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|                |           |              |                            |                          |
|----------------|-----------|--------------|----------------------------|--------------------------|
|                | Consumers | Inhalation   | Long-term systemic effects | 118.88 mg/m <sup>3</sup> |
|                | Consumers | Inhalation   | Acute systemic effects     | 118.9 mg/m <sup>3</sup>  |
|                | Consumers | Inhalation   | Long-term local effects    | 0.652 mg/m <sup>3</sup>  |
|                | Consumers | Inhalation   | Acute local effects        | 0.652 mg/m <sup>3</sup>  |
|                | Consumers | Skin contact | Long-term systemic effects | 100 mg/kg bw/day         |
|                | Consumers | Skin contact | Acute systemic effects     | 200 mg/kg bw/day         |
|                | Consumers | Skin contact | Long-term local effects    | 0.562 mg/cm <sup>2</sup> |
|                | Consumers | Skin contact | Acute local effects        | 0.562 mg/cm <sup>2</sup> |
|                | Consumers | Ingestion    | Long-term systemic effects | 75 mg/kg bw/day          |
|                | Consumers | Ingestion    | Acute systemic effects     | 75 mg/kg bw/day          |
| Benzyl alcohol | Workers   | Inhalation   | Long-term systemic effects | 22 mg/m <sup>3</sup>     |
|                | Workers   | Inhalation   | Acute systemic effects     | 110 mg/m <sup>3</sup>    |
|                | Workers   | Skin contact | Long-term systemic effects | 8 mg/kg bw/day           |
|                | Workers   | Skin contact | Acute systemic effects     | 40 mg/kg bw/day          |
|                | Consumers | Inhalation   | Long-term systemic effects | 5.4 mg/m <sup>3</sup>    |
|                | Consumers | Inhalation   | Acute systemic effects     | 27 mg/m <sup>3</sup>     |
|                | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day           |
|                | Consumers | Skin contact | Acute systemic effects     | 20 mg/kg bw/day          |
|                | Consumers | Ingestion    | Long-term systemic effects | 4 mg/kg bw/day           |
|                | Consumers | Ingestion    | Acute systemic effects     | 20 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              |
| Propylene glycol | Fresh water                | 260 mg/l                     |
|                  | Freshwater - intermittent  | 183 mg/l                     |
|                  | Marine water               | 26 mg/l                      |
|                  | Sewage treatment plant     | 20000 mg/l                   |
|                  | Fresh water sediment       | 572 mg/kg dry weight (d.w.)  |
|                  | Marine sediment            | 57.2 mg/kg dry weight (d.w.) |
|                  | Soil                       | 50 mg/kg dry                 |



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|                  |                            |                               |
|------------------|----------------------------|-------------------------------|
| Alcohols, C16-18 | Fresh water                | weight (d.w.)<br>0.13 mg/l    |
|                  | Marine water               | 0.12 mg/l                     |
|                  | Sewage treatment plant     | 1000 mg/l                     |
|                  | Fresh water sediment       | 13.61 mg/kg dry weight (d.w.) |
|                  | Marine sediment            | 1.361 mg/kg dry weight (d.w.) |
|                  | Soil                       | 100 mg/kg dry weight (d.w.)   |
|                  | Oral (Secondary Poisoning) | 86.7 mg/kg food               |
| Benzyl alcohol   | Fresh water                | 1 mg/l                        |
|                  | Marine water               | 0.1 mg/l                      |
|                  | Intermittent use/release   | 2.3 mg/l                      |
|                  | Sewage treatment plant     | 39 mg/l                       |
|                  | Fresh water sediment       | 5.27 mg/kg                    |
|                  | Marine sediment            | 0.527 mg/kg                   |
|                  | Soil                       | 0.456 mg/kg                   |

### 8.2 Exposure controls

#### 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

Eye/face 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.  
Equipment should conform to I.S. EN 14387

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Filter type : Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

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

Physical state : cream

Colour : white to off-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 applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

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Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

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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 : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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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 :  
Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

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Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

### Components:

#### **clotrimazole:**

Acute oral toxicity : LD50 (Rat): 708 mg/kg  
LD50 (Mouse): 761 mg/kg  
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.73 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Mouse): 923 mg/kg

#### **Benzyl alcohol:**

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

#### **betamethasone:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

### **Skin corrosion/irritation**

Not classified based on available information.

### Components:

#### **clotrimazole:**

Species : Rabbit  
Result : No skin irritation

#### **Benzyl alcohol:**

Species : Rabbit  
Method : OECD Test Guideline 404

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||Result : No skin irritation

### betamethasone:

||Species : Rabbit  
||Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### clotrimazole:

||Species : Rabbit  
||Result : Mild eye irritation

#### Benzyl alcohol:

||Species : Rabbit  
||Method : OECD Test Guideline 405  
||Result : Irritation to eyes, reversing within 21 days

### 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:

#### Benzyl alcohol:

||Test Type : Maximisation Test  
||Exposure routes : Skin contact  
||Species : Guinea pig  
||Method : OECD Test Guideline 406  
||Result : negative

### betamethasone:

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

### Germ cell mutagenicity

Not classified based on available information.

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### Components:

#### **clotrimazole:**

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

#### **Benzyl alcohol:**

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

#### **betamethasone:**

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

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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:**

#### **clotrimazole:**

Species : Rat  
Application Route : Oral  
Exposure time : 78 weeks  
Result : negative

#### **Benzyl alcohol:**

Species : Mouse  
Application Route : Ingestion  
Exposure time : 103 weeks  
Method : OECD Test Guideline 451  
Result : negative

### **Reproductive toxicity**

May damage the unborn child.

### **Components:**

#### **clotrimazole:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 50 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Oral

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Developmental Toxicity: NOAEL: 200 mg/kg body weight  
Result: No effects on foetal development

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### betamethasone:

Effects on foetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
Result: Fetotoxicity, Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
Result: Malformations were observed.

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

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

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.



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### Components:

#### **clotrimazole:**

Target Organs : Liver, Kidney, Adrenal gland  
Assessment : May cause damage to organs through prolonged or repeated exposure.

#### **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:

#### **clotrimazole:**

Species : Rabbit  
LOAEL : 5 - 40 mg/kg  
Application Route : Skin contact  
Exposure time : 3 Weeks  
Target Organs : Skin  
Symptoms : Oedema, Fissuring, Necrosis, Redness

Species : Rat  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 18 Months  
Target Organs : Liver, Kidney, Adrenal gland

Species : Dog  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 6 - 12 Months  
Target Organs : Adrenal gland  
Symptoms : Salivation, Lachrymation, Vomiting

#### **Benzyl alcohol:**

Species : Rat  
NOAEL : 1.072 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 28 Days  
Method : OECD Test Guideline 412

#### **betamethasone:**

Species : Rabbit  
LOAEL : 0.05 %  
Application Route : Skin contact

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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.

## 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:

##### **clotrimazole:**

Skin contact : Symptoms: Rash, Itching, Blistering, Oedema, Redness  
Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

##### **betamethasone:**

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

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### **clotrimazole:**

|  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203  |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): 0.02 mg/l<br>Exposure time: 48 h  |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l<br>Exposure time: 72 h |
| M-Factor (Acute aquatic toxicity)                                      | : | 10   |
| Toxicity to microorganisms   | : | EC50 : > 10,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209   |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: 0.025 mg/l<br>Exposure time: 32 d<br>Species: Oncorhynchus mykiss (rainbow trout)<br>Method: OECD Test Guideline 210   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0.01 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211   |
| M-Factor (Chronic aquatic toxicity)                                    | : | 10   |

##### **Benzyl alcohol:**

|   |   |   |
|---|---|---|
| Toxicity to fish                                    | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h                          |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l  |

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Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 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

## 12.2 Persistence and degradability

### Components:

**clotrimazole:**

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Stability in water : Hydrolysis: 50 %(242 d)

### Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

### 12.3 Bioaccumulative potential

#### Components:

#### Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

#### betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2.11

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 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.

### 12.7 Other adverse effects

No data available

## 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

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Contaminated packaging : discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.  
: Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADN : UN 3082  
ADR : UN 3082  
RID : UN 3082  
IMDG : UN 3082  
IATA : UN 3082

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

|      | Class | Subsidiary risks |
|------|-------|------------------|
| ADN  | : 9   |                  |
| ADR  | : 9   |                  |
| RID  | : 9   |                  |
| IMDG | : 9   |                  |
| IATA | : 9   |                  |

#### 14.4 Packing group

ADN  
Packing group : III  
Classification Code : M6

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Hazard Identification Number : 90  
Labels : 9

### ADR

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

### RID

Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

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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.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75, 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : 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 (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : 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<br>100 t | Quantity 2<br>200 t |
|----|-----------------------|---------------------|---------------------|

Other regulations:



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

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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.   |
| H311   | : | Toxic in contact with skin.   |
| H319   | : | Causes serious eye irritation.  |
| H330   | : | Fatal if inhaled.   |
| H332   | : | Harmful if inhaled.   |
| H360D  | : | May damage the unborn child.  |
| H361fd | : | Suspected of damaging fertility. Suspected of damaging the unborn child.        |
| H372   | : | Causes damage to organs through prolonged or repeated exposure.                 |
| H373   | : | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400   | : | Very toxic to aquatic life.   |
| H410   | : | Very toxic 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 Irrit.                  | : | Eye irritation  |
| Repr.                       | : | Reproductive toxicity   |
| STOT RE                     | : | Specific target organ toxicity - repeated exposure  |
| IE OEL                      | : | Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2 |
| IE OEL / OELV - 8 hrs (TWA) | : | Occupational exposure limit value (8-hour reference period)   |

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

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

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

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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 mate-

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rial 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.

IE / EN