

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Betamethasone / Clotrimazole Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9372483-00007	Date of first issue: 27.08.2021

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### 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.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

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

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 1B  
Specific target organ toxicity - repeated exposure, Category 1  
Long-term (chronic) aquatic hazard, Category 1

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.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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Hazard pictograms	:		
Signal word	:	Danger	
Hazard statements	:	H360D	May damage the unborn child.
		H372	Causes damage to organs through prolonged or repeated exposure.
		H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b>	
		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.
		<b>Response:</b>	
		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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
clotrimazole	23593-75-1 245-764-8	Acute Tox. 4; H302 Acute Tox. 3; H311 Eye Irrit. 2; H319 Repr. 2; H361fd STOT RE 2; H373 (Liver, Kidney, Adrenal gland) Aquatic Acute 1; H400 Aquatic Chronic 1;	>= 1 - < 2.5

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			H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5		Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	$\geq 0.1 - < 1$
betamethasone	378-44-9 206-825-4		Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1,000  specific concentration limit STOT RE 1; H372 $\geq 0.01\%$ Repr. 1B; H360D $\geq 0.01\%$ STOT RE 1; H372 $\geq 0.01\%$ Repr. 1B; H360D $\geq 0.01\%$	$\geq 0.025 - < 0.1$
Substances with a workplace exposure limit :				
Propylene glycol	57-55-6 200-338-0			$\geq 1 - < 10$

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

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

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- |                            |   |   |
|----------------------------|---|---|
| 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.<br>Get medical attention.  |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

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

- |       |   |   |
|-------|---|---|
| Risks | : | May damage the unborn child.<br>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. |
|-----------|---|---|

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- |                                |   |  |
|--------------------------------|---|--|
| Suitable extinguishing media   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.  |

### 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  |

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### 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. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

### 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
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- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
: If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
: Do not breathe mist or vapours.  
: Do not swallow.  
: Avoid contact with eyes.  
: Wash skin thoroughly after handling.  
: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
: Keep container tightly closed.  
: Do not eat, drink or smoke when using this product.  
: Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
: The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

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

### 7.3 Specific end use(s)

- Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA (Total vapour and parti-	150 ppm 474 mg/m3	GB EH40

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		cles)		
		TWA (particles)	10 mg/m3	GB EH40
clotrimazole	23593-75-1	TWA	0.2 mg/m3 (OEB 2)	Internal
betamethasone	378-44-9	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local effects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Alcohols, C16-18	Workers	Inhalation	Long-term systemic effects	237.76 mg/m3
	Workers	Inhalation	Acute systemic effects	237.76 mg/m3
	Workers	Inhalation	Long-term local effects	6.52 mg/m3
	Workers	Inhalation	Acute local effects	6.52 mg/m3
	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/cm2
	Workers	Skin contact	Acute local effects	1.124 mg/cm2
	Consumers	Inhalation	Long-term systemic effects	118.88 mg/m3
	Consumers	Inhalation	Acute systemic effects	118.9 mg/m3
	Consumers	Inhalation	Long-term local effects	0.652 mg/m3
	Consumers	Inhalation	Acute local effects	0.652 mg/m3
	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/cm2
	Consumers	Skin contact	Acute local effects	0.562 mg/cm2
	Consumers	Ingestion	Long-term systemic effects	75 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	75 mg/kg bw/day

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Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	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/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	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):

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 weight (d.w.)
Alcohols, C16-18	Fresh water	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



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	Soil	0.456 mg/kg
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### 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.<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. |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Remarks                  | : | Consider double gloving.   |
| Skin and body 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.<br>Equipment should conform to BS EN 14387  |
| 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

- |   |   |                    |
|---|---|--------------------|
| Appearance                              | : | cream              |
| Colour                                  | : | white to off-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                             | : | No data available  |

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Evaporation rate	:	No data available
Flammability (solid, gas)	:	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	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	Not applicable

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
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### 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.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

#### Acute toxicity

Not classified based on available information.

#### Product:

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

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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

### Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### clotrimazole:

Species : Rabbit  
Result : No skin irritation

#### Benzyl alcohol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### betamethasone:

Species : Rabbit  
Result : Mild skin irritation

#### Propylene glycol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

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### 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

#### **Propylene glycol:**

Species : Rabbit  
Method : OECD Test Guideline 405  
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

#### **Propylene glycol:**

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

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### clotrimazole:

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

#### Benzyl alcohol:

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

#### betamethasone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo

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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.

### Propylene glycol:

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### 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

#### Propylene glycol:

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

### Reproductive toxicity

May damage the unborn child.

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### 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 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



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### 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.

### Propylene glycol:

- Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative
- Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### 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.

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### 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
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

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

### Propylene glycol:

Species	: Rat, male
NOAEL	: >= 1,700 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr

### Aspiration toxicity

Not classified based on available information.

### 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 Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.02 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l Exposure time: 72 h  NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	: 10

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Toxicity to microorganisms	:	EC50 : > 10,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0.025 mg/l Exposure time: 32 d Species: Oncorhynchus mykiss (rainbow trout) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0.01 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10
<b>Benzyl alcohol:</b>		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l 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
<b>betamethasone:</b>		
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: 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

### Propylene glycol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 13,020 mg/l Exposure time: 7 d Species: Ceriodaphnia dubia (water flea)

## 12.2 Persistence and degradability

### Components:

#### clotrimazole:

Stability in water	:	Hydrolysis: 50 %(242 d)
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#### Benzyl alcohol:

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

### Propylene glycol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

## 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

#### Propylene glycol:

Partition coefficient: n-  
octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

## 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 Other adverse effects

### Product:

Endocrine disrupting poten-  
tial : This substance/mixture does not contain components consid-  
ered to have endocrine disrupting properties for environment  
according to UK REACH Article 57(f).

## 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

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are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in  
discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste han-  
dling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN 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

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Packing group : III  
Classification Code : M6  
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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the following entries should be considered: Number on list 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.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)	:	
E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t      Quantity 2 200 t

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive

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94/33/EC on the protection of young people at work.

### 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
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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

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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; 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

### 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 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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