

SAFETY DATA SHEET



Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation



Version 10.0 Revision Date: 06.04.2024 SDS Number: 610550-00021 Date of last issue: 30.09.2023
Date of first issue: 29.04.2016

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

1.1 Product identifier

Trade name : Clotrimazole / Gentamicin / Betamethasone (0.05%) 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

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)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.

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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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 2,5 - < 10
Hexadecan-1-ol. Ethoxylated	9004-95-9	Eye Irrit. 2; H319	>= 1 - < 10
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; H410 M-Factor (Acute	>= 1 - < 2,5

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		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	$\geq 1 - < 10$
Gentamicin	1403-66-3 215-765-8	Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	$\geq 0,1 - < 0,25$
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	$\geq 0,025 - < 0,1$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.

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

4.2 Most important symptoms and effects, both acute and delayed

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

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 (CO₂)
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

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

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so.
Evacuate area.

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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe 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 as-

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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
clotrimazole	23593-75-1	TWA	0.2 mg/m ³ (OEB 2)	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m ³ (OEB 2)	Internal
Further information: OTO				
betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	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 ³
	Workers	Inhalation	Long-term systemic	168 mg/m ³

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	Consumers	Inhalation	effects 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
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m3
	Workers	Inhalation	Short-term exposure	5 mg/m3
	Workers	Inhalation	Long-term local effects	5 mg/m3
	Workers	Inhalation	Acute local effects	5 mg/m3
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	5,4 mg/m3

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			effects	
	Consumers	Inhalation	Acute systemic effects	27 mg/m ³
	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.)
Alcohols, C16-18	Soil	50 mg/kg dry weight (d.w.)
	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.)
Benzyl alcohol	Soil	100 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	86,7 mg/kg food
	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.

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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.
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	:	liquid
Colour	:	No data available
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
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

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Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
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

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.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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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	:	Inhalation
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exposure

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 inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:**Paraffin oil:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Hexadecan-1-ol. Ethoxylated:

Acute oral toxicity : LD50 (Rat): 2.500 mg/kg

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

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Gentamicin:

Acute oral toxicity	:	LD50 (Rat): 8.000 - 10.000 mg/kg
		LD50 (Mouse): 10.000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 0,2 mg/l
		Exposure time: 4 h
		Test atmosphere: dust/mist
		Remarks: No mortality observed at this dose.
Acute toxicity (other routes of administration)	:	LD50 (Rat): 67 - 96 mg/kg
		Application Route: Intravenous
		LD50 (Rat): 371 - 384 mg/kg
		Application Route: Intramuscular
		LDLo (Monkey): 30 mg/kg
		Application Route: Intravenous

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:

Paraffin oil:

Species	:	Rabbit
Result	:	No skin irritation

clotrimazole:

Species	:	Rabbit
Result	:	No skin irritation

Benzyl alcohol:

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

Gentamicin:

Species	:	Rabbit
Result	:	Mild skin irritation

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betamethasone:

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit
Result : No eye irritation

Hexadecan-1-ol. Ethoxylated:

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

clotrimazole:

Species : Rabbit
Result : Mild eye irritation

Benzyl alcohol:

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

Gentamicin:

Species : Rabbit
Result : Mild eye irritation

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

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||Result : negative

Gentamicin:

||Remarks : No data available

betamethasone:

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

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

Gentamicin:

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

Carcinogenicity

Not classified based on available information.

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

Gentamicin:

Carcinogenicity - Assessment	:	No data available
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||ment

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
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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Gentamicin:

- Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight
Result: No significant adverse effects were reported
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight
Result: No embryo-foetal toxicity
- Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-foetal toxicity
- Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: foetal mortality, No malformations were observed.
- Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: foetal mortality, No malformations were observed.
- Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

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.

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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.

Gentamicin:

Target Organs	:	Kidney, inner ear
Assessment	:	Causes 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:****Paraffin oil:**

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

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

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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

Gentamicin:

Species	: Dog
LOAEL	: 3 mg/kg
Application Route	: Intramuscular
Exposure time	: 12 Months
Target Organs	: Kidney
Symptoms	: Vomiting, Salivation

Species	: Monkey
LOAEL	: 50 mg/kg
Application Route	: Subcutaneous
Exposure time	: 3 Weeks
Target Organs	: Kidney, inner ear

Species	: Monkey
LOAEL	: 6 mg/kg
Application Route	: Intramuscular
Exposure time	: 3 Weeks
Target Organs	: Blood, Kidney, inner ear, Liver

Species	: Rat
NOAEL	: 5 mg/kg
LOAEL	: 10 mg/kg
Application Route	: Intramuscular
Exposure time	: 52 Weeks
Target Organs	: Kidney, Blood

Species	: Rat
NOAEL	: 12,5 mg/kg
LOAEL	: 50 mg/kg
Application Route	: Intramuscular
Exposure time	: 13 Weeks
Target Organs	: Kidney

betamethasone:

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

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

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

Species	: Dog
LOAEL	: 0,05 mg/kg
Application Route	: Oral
Exposure time	: 28 d
Target Organs	: Blood, thymus gland, Adrenal gland

Aspiration toxicity

Not classified based on available information.

Components:

Paraffin oil:

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

Experience with human exposure

Components:

clotrimazole:

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

Gentamicin:

Ingestion	: Target Organs: Kidney Target Organs: inner ear Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness
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betamethasone:

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

Paraffin oil:

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Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Hexadecan-1-ol. Ethoxylated:

Toxicity to fish : LC50 : > 1 - 10 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 : > 1 - 10 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 : > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

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

Toxicity to microorganisms : EC50 : > 10.000 mg/l
Exposure time: 3 h

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		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

Benzyl alcohol:

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

Gentamicin:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 86 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
		LC50 (Americamysis): 30 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5

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		µg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
		EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l
		Exposure time: 72 h
		Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	100
Toxicity to microorganisms	:	EC50 : 288,7 mg/l
		Exposure time: 3 h
		Test Type: Respiration inhibition
		Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	:	1
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

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|| M-Factor (Chronic aquatic toxicity) : 1.000

12.2 Persistence and degradability

Components:

Hexadecan-1-ol. Ethoxylated:

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

clotrimazole:

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

Benzyl alcohol:

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

Gentamicin:

|| Biodegradability : Result: rapidly degradable
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 314

12.3 Bioaccumulative potential

Components:

Paraffin oil:

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

Benzyl alcohol:

|| Partition coefficient: n-octanol/water : log Pow: 1,05

Gentamicin:

|| Partition coefficient: n-octanol/water : log Pow: < -2

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:

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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 potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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

SECTION 14: Transport information

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.
(betamethasone, clotrimazole)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)

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IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(betamethasone, clotrimazole)

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
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

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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

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

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.

H304 : May be fatal if swallowed and enters airways.

H311 : Toxic in contact with skin.

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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.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
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.
H413	:	May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Asp. Tox.	:	Aspiration hazard
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure

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 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 -

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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.

ZA / EN