

SAFETY DATA SHEET



Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation



Version 9.0 Revision Date: 06.04.2024 SDS Number: 610547-00021 Date of last issue: 30.09.2023
Date of first issue: 29.04.2016

Section 1: Identification

Product name : Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Manufacturer or supplier's details

Company : Organon & Co.

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

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Skin sensitisation : Category 1

Reproductive toxicity : Category 1

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

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Kidney, Adrenal gland)

Hazardous to the aquatic environment - chronic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

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Hazard statements	:	<p>H317 May cause an allergic skin reaction. H360Df May damage the unborn child. Suspected of damaging fertility. H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure. H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects.</p>
Precautionary statements	:	<p>Prevention: P201 Obtain special instructions before use. P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>Response: P302 + P352 IF ON SKIN: Wash with plenty of water. P308 + P313 IF exposed or concerned: Get medical advice/ attention. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention. P391 Collect spillage.</p> <p>Storage: P405 Store locked up.</p> <p>Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.</p>

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 10 -< 20
Propylene glycol	57-55-6	>= 10 -< 20
Paraffin oil	8012-95-1	>= 2.5 -< 10
Hexadecan-1-ol. Ethoxylated	9004-95-9	>= 1 -< 10
clotrimazole	23593-75-1	>= 1 -< 2.5

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Benzyl alcohol	100-51-6	≥ 1 -< 10
Gentamicin	1403-66-3	≥ 0.1 -< 0.25
betamethasone	378-44-9	≥ 0.025 -< 0.1

Section 4: First-aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
May damage the unborn child. Suspected of damaging fertility.
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do

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so.
Evacuate area.

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

Hazchem Code : 3Z

Section 6: Accidental release measures

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

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

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

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 assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.

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- Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	WES-TWA (Mist)	5 mg/m ³	NZ OEL
		WES-STEL (Mist)	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m ³	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL
Paraffin oil	8012-95-1	WES-TWA (Mist)	5 mg/m ³	NZ OEL
		WES-STEL (Mist)	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
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				

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betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

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

Personal protective equipment

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

Filter type : Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

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

Section 9: 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

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Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : 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

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 : 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.

Particle characteristics
Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

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Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : 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 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:

Petrolatum:

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

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

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

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Assessment: The substance or mixture has no acute dermal toxicity

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

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.

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.

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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:**Petrolatum:**

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

Propylene glycol:

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

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

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Gentamicin:

Species : Rabbit
Result : Mild skin irritation

betamethasone:

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Petrolatum:**

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

Propylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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

Gentamicin:

Species : Rabbit
Result : Mild eye irritation

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betamethasone:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:**Petrolatum:**

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

Propylene glycol:

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

Benzyl alcohol:

Assessment : Probability or evidence of skin sensitisation in humans
Remarks : Based on national or regional regulation.

Gentamicin:

Remarks : No data available

betamethasone:

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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Petrolatum:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

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

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

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.

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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:

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:**Petrolatum:**

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

Propylene glycol:

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

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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Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:**Petrolatum:**

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

Propylene glycol:

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

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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

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

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

May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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:

Petrolatum:

Species : Rat
NOAEL : 5,000 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Propylene glycol:

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

Paraffin oil:

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

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

Gentamicin:

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

Species	: Monkey
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Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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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

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

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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

betamethasone:

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

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

|| Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
 Exposure time: 96 h
 Test substance: Water Accommodated Fraction
 Method: OECD Test Guideline 203
 Remarks: Based on data from similar materials

|| Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
 Exposure time: 48 h
 Test substance: Water Accommodated Fraction
 Remarks: Based on data from similar materials

|| Toxicity to algae/aquatic plants : NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
 Exposure time: 72 h
 Test substance: Water Accommodated Fraction
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

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

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 daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Paraffin oil:

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

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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 fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms : EC50: > 10,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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

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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 (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d 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 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
M-Factor (Chronic aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50: 288.7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

betamethasone:

Toxicity to daphnia and other	: EC50 (Americamysis): > 50 mg/l
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aquatic invertebrates	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 (Pimephales promelas (fathead minnow)): 0.052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l Exposure time: 219 d Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 1,000

Persistence and degradability

Components:

Petrolatum:

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

Biodegradability	: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Hexadecan-1-ol. Ethoxylated:

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

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

Bioaccumulative potential

Components:

Propylene glycol:

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

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

Mobility in soil

No data available

Other adverse effects

No data available

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Section 13: Disposal considerations

Disposal methods

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

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

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(betamethasone, clotrimazole)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(betamethasone, clotrimazole)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

National Regulations

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NZS 5433

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	3Z
Marine pollutant	:	no

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.

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

Further information

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only

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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.

NZ / EN