

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/05/16 6.0 2024/07/06 808844-00022 Date of first issue: 2016/07/22

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Other means of identification : OTOMAX OINTMENT (51104)

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 1A

Specific target organ toxicity - :

repeated exposure

Category 1 (Pituitary gland, Immune system, muscle, thymus

gland, Blood, Adrenal gland)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

Hazard pictograms

¥2

Signal word : Danger

Hazard statements : H360D May damage the unborn child.



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H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-

longed or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours. P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 60 -<= 100
clotrimazole	23593-75-1	>= 0.25 -< 2.5
Gentamicin	1403-66-3	>= 0.3 -< 1
betamethasone	378-44-9	>= 0.025 -< 0.25

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.



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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.

: Flush eyes with water as a precaution.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

: May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

nedia

None known.

Specific hazards during fire-

fighting

110110 1111011111

Hazardous combustion prod- :

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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



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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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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 as-

sessment

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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components CAS-No.	Value type C	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration		
White mineral oil (petroleum)	8042-47-5	NAB (Mist)	5 mg/m3	ID OEL	
		PSD (Mist)	10 mg/m3	ID OEL	
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH	
clotrimazole	23593-75-1	TWA	0.2 mg/m3 (OEB 2)	Internal	
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB 2)	Internal	
	Further information: OTO				
betamethasone	378-44-9	TWA	1 μg/m3 (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter 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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-



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ing 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.

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

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



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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

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- :

tions

: Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation
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



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Components:

White mineral oil (petroleum):

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

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

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

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



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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:

White mineral oil (petroleum):

Species : Rabbit

Result : No skin irritation

clotrimazole:

Species : Rabbit

Result : No skin irritation

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:

White mineral oil (petroleum):

Species : Rabbit

Result : No eye irritation

clotrimazole:

Species : Rabbit

Result : Mild eye irritation

Gentamicin:

Species : Rabbit

Result : Mild eye irritation

betamethasone:

Species : Rabbit



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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:

White mineral oil (petroleum):

Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
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:

White mineral oil (petroleum):

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

clotrimazole:

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

Result: negative

Test Type: Chromosome aberration test in vitro



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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 -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

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 - : Weight of evidence does not support classification as a germ



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Assessment cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

White mineral oil (petroleum):

Species : Rat
Application Route : Ingestion
Exposure time : 24 Months
Result : negative

clotrimazole:

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

Gentamicin:

Carcinogenicity - Assess-

nent

No data available

Reproductive toxicity

May damage the unborn child.

Components:

White mineral oil (petroleum):

Effects on fertility: Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral



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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 - As-

sessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experi-

ments.

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 develop-

ment

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



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Species: Rat

Application Route: Intraperitoneal

Developmental Toxicity: LOAEL: 50 mg/kg body weight Result: foetal mortality, No malformations were observed.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

betamethasone:

Effects on foetal develop-

ment

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 - As-

sessment

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.

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



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Assessment Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

White mineral oil (petroleum):

Species Rat LOAEL 160 mg/kg Application Route Ingestion Exposure time 90 Days

Species Rat LOAEL >= 1 mg/l

LOAEL
Application Route
Exposure time inhalation (dust/mist/fume)

Exposure time 4 Weeks

Method **OECD Test Guideline 412**

clotrimazole:

Species Rabbit 5 - 40 mg/kg LOAEL Exposure time
Target Organs Skin contact 3 Weeks 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

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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LOAEL 50 mg/kg Application Route : Subcutaneous Exposure time 3 Weeks

Target Organs : Kidney, inner ear

Species Monkey LOAEL :
Application Route :
Exposure time :
Target Organs : 6 mg/kg Intramuscular 3 Weeks

Target Organs Blood, Kidney, inner ear, Liver

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

LOAEL
Application Route
Exposure time
Target Organs Rat : 12.5 mg/kg : 50 mg/kg : Intramuscular : 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 LÖAEL 0.05 % Application Route Skin contact Exposure time 8 Weeks thymus gland Target Organs

Mouse Species 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.

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): 100

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l

Exposure time: 28 d

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

NOEC (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 21 d

ic toxicity)

clotrimazole:

LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203



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aquatic invertebrates

Toxicity to daphnia and other : 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 tox-

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.01 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

10

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

EC50: > 10,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 100

icity)

M-Factor (Chronic aquatic : 1

toxicity)

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 :

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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 8 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

Michiod. OLOD 163t Galdeline 2

Persistence and degradability

Components:

White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.

: 1,000

Biodegradation: 31 % Exposure time: 28 d



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clotrimazole:

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

Gentamicin:

Biodegradability : Result: rapidly degradable

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

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

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

Class : 9
Packing group : III
Labels : 9



Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(clotrimazole, Gentamicin)

Class q Packing group Ш

Miscellaneous Labels

Packing instruction (cargo 964

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous **IMDG-Code**

UN number UN 3082

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, Proper shipping name

N.O.S.

964

yes

(clotrimazole, Gentamicin)

Class 9 Ш Packing group Labels **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.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Sub-

Hazardous substances approved for use Not applicable



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Prohibited substances Not applicable

Restricted substances Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous **Materials**

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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

AICS not determined

DSL not determined

IECSC not determined

16. OTHER INFORMATION

Revision Date 2024/07/06

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-

Sheet cy, http://echa.europa.eu/

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

Date format yyyy/mm/dd

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV) **ID OEL** Indonesia. Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average ID OEL / NAB Long term exposure limit ID OEL / PSD 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 Sys-



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tem; 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 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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