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



## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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

1.1 Product identifier

Trade name : Clotrimazole / Gentamicin / Betamethasone (0.1%) Formula-

tion

Other means of identification : OTOMAX OINTMENT (51104)

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions : Not applicable

on use

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 1A H360D: May damage the unborn child.

Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

exposure, Category 1 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate- H400: Very toxic to aquatic life.

orv 1

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1 effects.

#### 2.2 Label elements

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

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Hazard pictograms

¥2>

Signal word : Danger

Hazard statements : H360D May damage the unborn child.

H372 Causes damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : 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:

Gentamicin betamethasone

#### 2.3 Other hazards

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

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

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

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

Components

CAS-No. EC-No.	Classification	Concentration (% w/w)
Index-No.		(70 W/W)
Registration number		

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



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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 aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10  Acute toxicity esti-	>= 1 - < 2.5
Gentamicin	1403-66-3 215-765-8	mate  Acute dermal toxicity: 923 mg/kg  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	>= 0.3 - < 1
betamethasone	378-44-9 206-825-4	aquatic toxicity): 1  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	>= 0.1 - < 0.25

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 Specific concentration limit

 STOT RE 1; H372
 >= 0.01 %

 Repr. 1B; H360D
 >= 0.01 %

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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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

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

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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

Risks : May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

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

Treatment : Treat symptomatically and supportively.

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### **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

fighting

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

Hazardous combustion prod- : Carbon oxides

ucts

#### 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 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.

#### **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 pro-

tective 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.

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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-

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.

mine 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-

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.

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 contami-

nated 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:

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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	
White mineral oil (petroleum)	8042-47-5	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m3	IE OEL	
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 <sup>2</sup>	Internal	

#### 8.2 Exposure controls

#### **Engineering measures**

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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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.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387

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

#### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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### **SECTION 11: Toxicological information**

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

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:** 

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

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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:** 

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:** 

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:**

#### 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 aberra-

tion test (in vivo) Species: Hamster Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

#### Gentamicin:

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



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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- As-

sessment

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

Gentamicin:

Carcinogenicity - Assess-

ment

: No data available

## Reproductive toxicity

May damage the unborn child.

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#### **Components:**

clotrimazole:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Oral

Fertility: LOAEL: 50 mg/kg body weight

Result: Effects on fertility

Effects on foetal develop-

ment

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 - 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

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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 - 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 through prolonged or repeated exposure.

Components:

clotrimazole:

Target Organs : Liver, Kidney, Adrenal gland

Assessment : May cause damage to organs through prolonged or repeated

exposure.

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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:** 

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

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

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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

#### **Aspiration toxicity**

Not classified based on available information.

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



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#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

**Product:** 

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### **Experience with human exposure**

**Components:** 

clotrimazole:

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

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**

#### 12.1 Toxicity

#### Components:

clotrimazole:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.02 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l

Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

10

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



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Toxicity to microorganisms : EC50 : > 10,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

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 tox- :

icity)

100

Toxicity to microorganisms : EC50 : 288.7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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



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M-Factor (Chronic aquatic

toxicity)

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: 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 (Chron-

ic toxicity)

NOEC: 8 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1,000

#### 12.2 Persistence and degradability

#### **Components:**

clotrimazole:

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

**Gentamicin:** 

Biodegradability Result: rapidly degradable

> Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 314

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



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#### 12.3 Bioaccumulative potential

#### Components:

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:**

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

### 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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



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### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

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

14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(clotrimazole, Gentamicin)

#### 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

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



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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 : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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



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## **SECTION 15: Regulatory information**

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

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

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not. Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

E1 ENVIRONMENTAL

**HAZARDS** 

Quantity 1 100 t

Quantity 2 200 t

#### Other regulations:

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

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

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

AICS : not determined

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



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DSL : not determined : 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
H311
Toxic in contact with skin.
H319
Causes serious eye irritation.

H330 : Fatal 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.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration

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



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associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

## **Further information**

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

#### Classification of the mixture:

#### Classification procedure:

Repr. 1A H360D Calculation method STOT RE 1 H372 Calculation method Aquatic Acute 1 H400 Calculation method Aquatic Chronic 1 H410 Calculation method

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.

IE / EN