

# SAFETY DATA SHEET



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

Version 9.0 Revision Date: 03.12.2024 SDS Number: 808837-00024 Date of last issue: 28.09.2024  
Date of first issue: 22.07.2016

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### SECTION 1. IDENTIFICATION

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

Other means of identification : OTOMAX OINTMENT (51104)

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-

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

#### : Storage:

P405 Store locked up.

### Other hazards which do not result in classification

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5		>= 90 -< 100
clotrimazole	23593-75-1	Acute Tox. (Oral), 4 Acute Tox. (Dermal), 3 Eye Irrit., 2B Repr., 2 STOT RE, (Oral)(Liver, Kidney, Adrenal gland) , 2 Aquatic Acute, 1 Aquatic Chronic, 1	>= 1 -< 2,5
Gentamicin	1403-66-3	Repr., 1A STOT RE, (Oral)(Kidney, inner ear) , 1 Aquatic Acute, 1 Aquatic Chronic, 1	>= 0,3 -< 1
Betamethasone	378-44-9	Acute Tox. (Inhalation), 2 Repr., 1B STOT RE, (Pituitary gland, Immune sys- tem, muscle, thymus gland, Blood, Adrenal	>= 0,1 -< 0,25

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### 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 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.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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 so. Evacuate area.

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

### 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 diking or other appropriate containment to keep material from spreading. If diked 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.

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### 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 vapors. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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

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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 labeled containers.  
Store locked up.  
Keep tightly closed.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
clotrimazole	23593-75-1	TWA	0.2 mg/m <sup>3</sup> (OEB 2)	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
	Further information: OTO			
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

### Engineering measures

: The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne

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levels as low as reasonably achievable.  
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 Hand protection	: Combined particulates and organic vapor type
Material	: Chemical-resistant gloves
Remarks Eye protection	: Consider double gloving. : 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**

Physical state	: liquid
Color	: No data available
Odor	: No data available
Odor 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

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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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition 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

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## SECTION 10. STABILITY AND REACTIVITY

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

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

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exposure	Skin contact Ingestion Eye contact
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## Acute toxicity

Not classified based on available information.

### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method

## **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 inhalation 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

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Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous  
  
LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular  
  
LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

### **Betamethasone:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
  
LD50 (Mouse): > 4.500 mg/kg  
  
Acute inhalation toxicity : LC50 (Rat): 0,4 mg/l  
Exposure time: 4 h

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **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

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Result : No eye irritation

## **clotrimazole:**

Species : Rabbit  
Result : Mild eye irritation

## Gentamicin:

Species : Rabbit  
Result : Mild eye irritation

## Betamethasone:

Species : Rabbit  
Result : No eye irritation

### **Respiratory or skin sensitization**

## Skin sensitization

Not classified based on available information.

## Respiratory sensitization

Not classified based on available information

## Components:

### White mineral oil (petroleum):

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

## Gentamicin:

Remarks : No data available

## **Betamethasone:**

Routes of exposure : 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

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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  
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.

**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

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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:****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 - Assessment : 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 fetal development : Test Type: Embryo-fetal 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

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Result: Effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 200 mg/kg body weight  
Result: No effects on fetal development.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 180 mg/kg body weight  
Result: No effects on fetal 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.

**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 fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight  
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: Fetal mortality., No malformations were observed.

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Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: Fetal mortality., No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

**Betamethasone:**

Effects on fetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight  
Result: Fetotoxicity., Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight  
Result: Malformations were observed.

Species: Mouse  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

**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
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

**clotrimazole:**

Species	:	Rabbit
LOAEL	:	5 - 40 mg/kg
Application Route	:	Skin contact
Exposure time	:	3 Weeks
Target Organs	:	Skin
Symptoms	:	Edema, 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

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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
<b>Betamethasone:</b>		
Species	:	Rabbit
LOAEL	:	0.05 %
Application Route	:	Skin contact
Exposure time	:	10 - 30 d
Target Organs	:	Pituitary gland, Immune system
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

## Aspiration toxicity

Not classified based on available information

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**Experience with human exposure****Components:****clotrimazole:**

Skin contact : Symptoms: Rash, Itching, Blistering, Edema, Redness  
Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

**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

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**SECTION 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 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l  
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.000 mg/l  
Exposure time: 21 d

**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 : EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l

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plants	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
<b>Gentamicin:</b>	
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

**Clotrimazole / Gentamicin / Betamethasone  
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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 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:****White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

**clotrimazole:**

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

**Gentamicin:**

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

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Partition coefficient: n-octanol/water : log Pow: &lt; -2

**Betamethasone:**

Partition coefficient: n-octanol/water : log Pow: 2,11

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**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.  
(clotrimazole, Gentamicin)

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.  
(clotrimazole, Gentamicin)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

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### IMDG-Code

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

### Domestic regulation

#### ANTT

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(clotrimazole, Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

### 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.

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## SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined  
DSL : not determined  
IECSC : not determined

## SECTION 16. OTHER INFORMATION

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Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <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.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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; KECL - 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

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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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