

## Mometasone / Clotrimazole / Gentamicin Formulation

Version Revision Date: SDS Number: Date of last issue: 29.05.2024 7.0 06.07.2024 412823-00024 Date of first issue: 14.12.2015

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Mometasone / Clotrimazole / Gentamicin Formulation

Other means of identification : MOMETAMAX OINTMENT (52269)

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

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

## **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity : Category 1A

Specific target organ toxicity :

- repeated exposure (Oral)

Category 2 (Liver, Kidney, Adrenal gland)

**GHS** label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H360Df May damage the unborn child. Suspected of damaging

fertility.

H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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 vapors.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

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

attention.



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Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
White mineral oil (petroleum)	8042-47-5	> 90 -<= 100	
clotrimazole	23593-75-1	1	
Gentamicin	1403-66-3	0.3	
Mometasone	83919-23-7	0.1	

#### **SECTION 4. FIRST AID MEASURES**

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled, remove to fresh air. If inhaled

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 eves with water as a precaution.

In case of eye contact 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. Suspected of damaging

fertility.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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

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

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**



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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

: None known.

Specific hazards during fire

fiahtina

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

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 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 emer-

gency 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.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.



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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.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Take care to prevent spills, waste and minimize release to the

environment.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled 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

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 parameters / Permissible concentration	Basis	
White mineral oil (petroleum)	8042-47-5	VLE-PPT (Mist)	5 mg/m³	NOM-010- STPS-2014	
		TWA (Inhalable particulate 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				
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal	



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Further information: Skin 10 µg/100 cm<sup>2</sup> Wipe limit Internal

**Engineering measures** All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not

exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection. Combined particulates and organic vapor 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.

Work uniform or laboratory coat. Skin and body protection

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** suspension

Color white to off-white

Odor oily

Odor Threshold No data available

No data available pΗ

Melting point/freezing point No data available

Initial boiling point and boiling : No data available

range



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Flash point No data available

No data available **Evaporation rate** 

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

No data available Vapor pressure

Relative vapor density No data available

Relative density No data available

No data available Density

Solubility(ies)

No data available Water solubility

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

## **SECTION 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.



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#### **SECTION 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: > 5,000 mg/kg

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 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



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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

Mometasone:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3.3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Remarks: No mortality observed at this dose.

LC50 (Mouse): > 3.2 mg/l Exposure time: 4 h

Test atmosphere: dust/mist

Acute toxicity (other routes of :

administration)

LD50 (Rat): 300 mg/kg

Application Route: Subcutaneous Symptoms: Breathing difficulties

## 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

#### Mometasone:



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Species : Rabbit

Result : No 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

Mometasone:

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

Mometasone:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitization.

Result : negative



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Remarks : The results of a test on guinea pigs showed this substance to

be a weak skin 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

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



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cytogenetic assay) Species: Mouse

Application Route: Intravenous injection

Result: negative

Mometasone:

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

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells

Result: positive

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat Cell type: Liver cells Result: negative

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: RatApplication Route: IngestionExposure time: 24 MonthsResult: negative

clotrimazole:

Species : Rat Application Route : Oral



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Exposure time : 78 weeks Result : negative

Gentamicin:

Carcinogenicity - Assess-

ment

No data available

Mometasone:

Species : Rat
Application Route : Inhalation
Exposure time : 2 Years

Dose : 0.067 mg/kg body weight

Result : negative

Species : Mouse
Application Route : Inhalation
Exposure time : 19 Months

Dose : 0.160 mg/kg body weight

Result : negative

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

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

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



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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 - 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

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.

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 - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.



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Mometasone:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Subcutaneous

Fertility: NOAEL: 0.015 mg/kg body weight

Symptoms: Reduced embryonic survival, Reduced fetal

weight.

Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Subcutaneous

Embryo-fetal toxicity.: LOAEL: 0.06 mg/kg body weight Result: Embryotoxic effects., Teratogenicity and

developmental toxicity

Test Type: Embryo-fetal development

Species: Rat

Application Route: Dermal

Embryo-fetal toxicity.: LOAEL: 0.3 mg/kg body weight

Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Dermal

Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Subcutaneous

Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight

Result: Effects on newborn.

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Oral

Embryo-fetal toxicity.: LOAEL: 0.7 mg/kg body weight Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - As-

sessment

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

#### STOT-single exposure

Not classified based on available information.

#### **Components:**

#### Mometasone:

Remarks : Based on available data, the classification criteria are not met.



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### STOT-repeated exposure

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

#### **Components:**

clotrimazole:

Target Organs : Liver, Kidney, Adrenal gland

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Gentamicin:

Target Organs : Kidney, inner ear

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Mometasone:

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Immune system, Liver, Kidney, Skin

Assessment : May cause 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



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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

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

Mometasone:

Species : Rat

NOAEL : 0.005 mg/kg LOAEL : 0.3 mg/kg Application Route : Oral Exposure time : 30 d

Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog LOAEL : 0.5 mg/kg



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Application Route : Oral Exposure time : 30 d

Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat

NOAEL : 0.00013 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 90 d

Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow,

Kidney, Liver, thymus gland

Species : Dog

NOAEL : 0.0005 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 90 d

Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow,

Kidney, thymus gland, Liver

## **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

#### Mometasone:

Not applicable

#### **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

Mometasone:

Inhalation : Symptoms: allergic rhinitis, Headache, pharyngitis, upper res-

piratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion

Skin contact : Symptoms: Dermatitis, Itching

**Further information** 

**Components:** 

Mometasone:

Remarks : Dermal absorption possible



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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 tox-

icity)

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

Exposure time: 28 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic 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

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

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

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

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209



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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

Toxicity to microorganisms : EC50: 288.7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Mometasone:

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility.

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l

Exposure time: 7 d

Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 5 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility.

EC50 (Americamysis): > 5 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2



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plants 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)): 0.00014

mg/

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.34 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility.

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Remarks: No toxicity at the limit of solubility.

### 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

Mometasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 28 d

Method: OECD Test Guideline 314



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Stability in water : Hydrolysis: 50 %(12 d)

Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Gentamicin:

Partition coefficient: n-

octanol/water

log Pow: < -2

Mometasone:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 107.1 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 4.68

Mobility in soil

**Components:** 

Mometasone:

Distribution among environ-

mental compartments

log Koc: 4.02

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** 



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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 : 964

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(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**

NOM-002-SCT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(clotrimazole, Gentamicin)

Class : 9
Packing group : III
Labels : 9

Special precautions for user

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

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for

producing capsules, tablets and pills.

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

AICS : not determined



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DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 06.07.2024 Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

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

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-



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Data 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.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8