

## **Mometasone Ointment Formulation**

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 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.03.2020

 2.1
 10.10.2020
 1751222-00008
 Date of first issue: 14.06.2017

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone Ointment Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

## 2. HAZARDS IDENTIFICATION

**GHS Classification** 

Serious eye damage/eye irri-

tation

Category 2

Long-term (chronic) aquatic

hazard

Category 2

**GHS** label elements

Hazard pictograms

<u>(!</u>)



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P391 Collect spillage.



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#### Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)	
Petrolatum	8009-03-8	>= 70 -< 90	
2-Methyl-2,4-pentanediol	107-41-5	>= 10 -< 20	
Propylene glycol monostearate	1323-39-3	>= 1 -< 10	
Mometasone	83919-23-7	>= 0.1 -< 0.25	

#### 4. FIRST AID MEASURES

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

vice 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 In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

Causes serious eye irritation.

delayed

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

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

Notes to physician Treat symptomatically and supportively.

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)



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Dry chemical

Unsuitable extinguishing

media

: None known.

Specific hazards during fire-

fighting

Vapours may form explosive mixtures with air.

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 firefighters

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

Use personal protective equipment.

#### 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 pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not swallow. Do not get in 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.

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



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environment.

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Petrolatum	8009-03-8	PEL (long term) (Mist)	5 mg/m3	SG OEL	
		PEL (short term) (Mist)	10 mg/m3	SG OEL	
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH	
2-Methyl-2,4-pentanediol	107-41-5	PEL (short term)	25 ppm 121 mg/m3	SG OEL	
		TWA (Va- pour)	25 ppm	ACGIH	
		STEL (Va- pour)	50 ppm	ACGIH	
		STEL (Inhalable fraction, Aerosol only)	10 mg/m3	ACGIH	
Propylene glycol monostearate	1323-39-3	PEL (long term)	10 mg/m3	SG OEL	
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH	
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH	
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal	
	Further information: Skin				
		Wipe limit	10 μg/100 cm <sup>2</sup>	Internal	

**Engineering measures** 

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from

stationary container, ventilated enclosure, etc.).

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.



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Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

: Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

eye flushing systems and safety showers close to the work-

ing place.

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

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

use of administrative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flash point : > 93.3 °C

Evaporation rate : No data available





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Flammability (solid, gas) : Not classified as a flammability hazard

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

#### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- : Vapours ma

tions

Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

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

Hazardous decomposition

No hazardous decomposition products are known.

products

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Skin contact



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exposure Ingestion
Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Petrolatum:

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

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

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

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Propylene glycol monostearate:

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

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.



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#### **Components:**

Petrolatum:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

2-Methyl-2,4-pentanediol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Propylene glycol monostearate:

Result : No skin irritation

Mometasone:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

Petrolatum:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

2-Methyl-2,4-pentanediol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Mometasone:

Species : Rabbit

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:** 

Petrolatum:

Test Type : Buehler Test



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Exposure routes : Skin contact Species : Guinea pig Result : negative

Remarks : Based on data from similar materials

2-Methyl-2,4-pentanediol:

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

Method : OECD Test Guideline 406

Result : negative

Mometasone:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Result : negative

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

be a weak skin sensitiser.

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Petrolatum:

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

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Mometasone:

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



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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:**

#### Petrolatum:

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

## 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



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## Reproductive toxicity

Not classified based on available information.

## **Components:**

Petrolatum:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

**Application Route: Ingestion** 

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 421

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

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 foetal

weight

Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Mouse

Application Route: Subcutaneous

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

tal toxicity

Test Type: Embryo-foetal development

Species: Rat

Application Route: Dermal



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Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight

Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Dermal

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

Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight

Result: Effects on newborn

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight Result: Embryo-foetal 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.

## STOT - repeated exposure

Not classified based on available information.

#### **Components:**

#### Mometasone:

Exposure routes : 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:**

#### Petrolatum:

Species : Rat

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



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2-Methyl-2,4-pentanediol:

Species : Rat

NOAEL : >= 450 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

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 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:

2-Methyl-2,4-pentanediol:

Eye contact : Target Organs: Eyes

Symptoms: Irritation

Mometasone:

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

piratory tract infection, sinusitis, oral candidiasis, Back pain,



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musculoskeletal pain, immune system effects, indigestion

Skin contact Symptoms: Dermatitis, Itching

**Further information** 

**Components:** 

Mometasone:

Remarks Dermal absorption possible

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

Components:

Petrolatum:

Toxicity to fish LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

NOEL (Pseudokirchneriella subcapitata (green algae)): >=

100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 10 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

Toxicity to fish LC50 (Gambusia affinis (Mosquito fish)): 8,510 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 2,800 mg/l

Toxicity to algae/aquatic

plants

Exposure time: 48 h

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 429

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): > 429

mg/l



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Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC: 200 mg/l

Exposure time: 10 d

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

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2

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/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)): 0.34 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

100

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



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Persistence and degradability

**Components:** 

Petrolatum:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 31 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 81 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Mometasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 28 d

Method: OECD Test Guideline 314

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

Method: OECD Test Guideline 111

**Bioaccumulative potential** 

**Components:** 

2-Methyl-2,4-pentanediol:

Partition coefficient: n- : log Pow: 0

octanol/water Remarks: Calculation

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



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#### 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

#### International Regulations

**UNRTDG** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

Class 9 Ш Packing group Labels 9

**IATA-DGR** 

UN/ID No. UN 3077

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

(Mometasone)

9 Class Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 956

aircraft)

Packing instruction (passen-

956

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

UN 3077 **UN** number

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

Class 9 Packing group Ш 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.

#### 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.

# Public ORGANON

## **Mometasone Ointment Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 23.03.2020

 2.1
 10.10.2020
 1751222-00008
 Date of first issue: 14.06.2017

#### 15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials)

Regulations

: Not applicable

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

## **Further information**

Sources of key data used to compile the Safety Data

Sheet

Sneet

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

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SG OEL : Singapore. Workplace Safety and Health Act - First Schedule

Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

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



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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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN