

# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone Lotion Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48

Pandaan, Jawa Timur - Indonesia

Telephone : +1-551-430-6000

Emergency telephone number: +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

**GHS Classification** 

Flammable liquids : Category 2

Serious eye damage/eye irri-

tation

Category 2A

Specific target organ toxicity - :

single exposure

Category 3

Long-term (chronic) aquatic

hazard

Category 2

**GHS** label elements

Hazard pictograms



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.

H411 Toxic to aquatic life with long lasting effects.



# **Mometasone Lotion Formulation**



Version Revision Date: SDS Number: 4.1 2024/04/06 1288472-00019

Date of last issue: 2023/09/30 Date of first issue: 2017/02/15

Precautionary statements

#### Prevention:

P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P261 Avoid breathing mist or vapours.
P264 Wash skin thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

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/ attention.

P391 Collect spillage.

#### Storage:

P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up.

# Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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

Vapours may form explosive mixture with air.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 60
Mometasone	83919-23-7	>= 0.025 -< 0.25

#### 4. FIRST AID MEASURES

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



# **Mometasone Lotion Formulation**

Date of last issue: 2023/09/30 Version Revision Date: SDS Number: 2024/04/06 1288472-00019 Date of first issue: 2017/02/15 4.1

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 plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

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

May cause drowsiness or dizziness.

Protection of first-aiders

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

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

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



# **Mometasone Lotion Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Remove all sources of ignition.

Ventilate the area.

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions

Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

oarriers).

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

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

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

Avoid breathing mist or vapours.

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

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges.

Materials to avoid



**™**ORGANON

# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

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

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition. Do not store with the following product types:

Colf reactive substances and mixtures

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases Explosives

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Propan-2-ol	67-63-0	NAB	400 ppm 983 mg/m3	ID OEL		
		PSD	500 ppm 1,230 mg/m3	ID OEL		
		TWA	200 ppm	ACGIH		
		STEL	400 ppm	ACGIH		
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal		
	Further information: Skin					
		Wipe limit	t 10 µg/100 cm <sup>2</sup> Internal			

# **Biological occupational exposure limits**

Components	CAS-No.	Control	Biological	Sam-	Permissible	Basis
		parameters	specimen	pling	concentra-	
				time	tion	
Propan-2-ol	67-63-0	Acetone	Urine	End of	40 mg/l	ACGIH
				shift at		BEI
				end of		
				work-		
				week		

**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.



# **Mometasone Lotion Formulation**



Version 4.1

Revision Date: 2024/04/06

SDS Number: 1288472-00019 Date of last issue: 2023/09/30 Date of first issue: 2017/02/15

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.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

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

Filter type Hand protection

Material

Chemical-resistant gloves

Remarks Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

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** lotion

Colour colourless, clear, to, translucent

Odour No data available

Odour Threshold No data available

4.5 pН



# **Mometasone Lotion Formulation**

Version SDS Number: Date of last issue: 2023/09/30 **Revision Date:** 2024/04/06 1288472-00019 Date of first issue: 2017/02/15 4.1

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

18.4 °C Flash point

Method: closed cup

Evaporation rate No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) Ignitable (see flash point)

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

No data available Density

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 Not applicable

Particle characteristics

Particle size Not applicable



# **Mometasone Lotion Formulation**

Version SDS Number: Date of last issue: 2023/09/30 Revision Date: 2024/04/06 1288472-00019 Date of first issue: 2017/02/15 4.1

#### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Possibility of hazardous reac-Highly flammable liquid and vapour.

Vapours may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Propan-2-ol:

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

Acute inhalation toxicity LC50 (Rat): > 25 mg/l

> Exposure time: 6 h Test atmosphere: vapour

Acute dermal toxicity LD50 (Rabbit): > 5,000 mg/kg

Mometasone:

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

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

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

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



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

#### Skin corrosion/irritation

Not classified based on available information.

# **Components:**

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Mometasone:

Species : Rabbit

Result : No skin irritation

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### **Components:**

Propan-2-ol:

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:**

Propan-2-ol:

Test Type : Buehler 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



# **Mometasone Lotion Formulation**



Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

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:** 

Propan-2-ol:

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

Result: negative

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

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



# **Mometasone Lotion Formulation**

p ORGANON

Version SDS Number: Date of last issue: 2023/09/30 Revision Date: 2024/04/06 1288472-00019 Date of first issue: 2017/02/15 4.1

Germ cell mutagenicity -

Weight of evidence does not support classification as a germ

Assessment

cell mutagen.

#### Carcinogenicity

Not classified based on available information.

### **Components:**

Propan-2-ol:

**Species** Rat

Application Route inhalation (vapour)

Exposure time 104 weeks

: OECD Test Guideline 451 Method

Result negative

Mometasone:

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

0.067 mg/kg body weight Dose

Result negative

Species Mouse Application Route Inhalation Exposure time 19 Months

0.160 mg/kg body weight Dose

Result negative

#### Reproductive toxicity

Not classified based on available information.

# Components:

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Mometasone:

Test Type: Fertility Effects on fertility

Species: Rat

Application Route: Subcutaneous

Fertility: NOAEL: 0.015 mg/kg body weight

Symptoms: Reduced embryonic survival, Reduced foetal



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

weight

Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development 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** 

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

May cause drowsiness or dizziness.

# **Components:**

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

Mometasone:

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

#### STOT - repeated exposure

Not classified based on available information.



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

#### **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:**

Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time : 104 Weeks

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.



# **Mometasone Lotion Formulation**

♣ ORGANON

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

**Components:** 

Mometasone:

Not applicable

Experience with human exposure

**Components:** 

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

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h

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



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

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

#### Persistence and degradability

#### Components:

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)

COD: 2,23 BOD/COD: 53 %

Mometasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 28 d



# **Mometasone Lotion Formulation**

Version Date of last issue: 2023/09/30 Revision Date: SDS Number:

1288472-00019

Method: OECD Test Guideline 314

Date of first issue: 2017/02/15

Stability in water Hydrolysis: 50 %(12 d)

Method: OECD Test Guideline 111

**Bioaccumulative potential** 

2024/04/06

Components:

4.1

Propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0.05

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

#### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

# 14. TRANSPORT INFORMATION

# International Regulations

**UNRTDG** 

**UN** number UN 1219

Proper shipping name ISOPROPANOL SOLUTION



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

Class : 3
Packing group : II
Labels : 3
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 1219

Proper shipping name : Isopropanol solution

Class : 3 Packing group : II

Labels : Flammable Liquids

Packing instruction (cargo :

aircraft)

Packing instruction (passen: 353

ger aircraft)

**IMDG-Code** 

UN number : UN 1219

Proper shipping name : ISOPROPANOL SOLUTION

(Mometasone)

Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### Special precautions for user

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

#### 15. REGULATORY INFORMATION

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

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

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

Hazardous substances that must be registered : Not applicable

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

Hazardous substances approved for use : Propan-2-ol

Prohibited substances : Not applicable

# **Mometasone Lotion Formulation**



Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

Restricted substances : Not applicable

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

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

Revision Date : 2024/04/06

**Further information** 

Sources of key data used to compile the Safety Data

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

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
ID OEL : Indonesia. Occupational Exposure Limits

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

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized 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 Chemi-



# **Mometasone Lotion Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 4.1 2024/04/06 1288472-00019 Date of first issue: 2017/02/15

cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

ID / EN