according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

SECTION 1. IDENTIFICATION

Product name : Mometasone Lotion Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor

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

Telephone : 1-551-430-6000 Emergency telephone : 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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids : Category 2

Eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity

- single exposure

Category 3

GHS label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.

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

H360Df May damage the unborn child. Suspected of damaging

fertility.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P210 Keep away from heat, sparks, open flame and hot surfac-

es. No smoking.

P233 Keep container tightly closed.

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

P241 Use explosion-proof electrical, ventilating and lighting equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

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

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

P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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.

P308 + P313 IF exposed or concerned: Get medical attention. P337 + P313 If eye irritation persists: Get medical attention.

Storage:

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

Disposal:

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

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 - < 50
Propylene glycol	57-55-6	>= 20 - < 30
Mometasone	83919-23-7	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 04/06/2024 1288481-00019 Date of first issue: 02/15/2017 4.1

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. Causes serious eye irritation.

Most important symptoms

and effects, both acute and delayed

May cause drowsiness or dizziness.

May damage the unborn child. Suspected of damaging

fertility.

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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING 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. Vapors 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 fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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 protective equipment recommendations (see section 8).

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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

Non-sparking tools should be used. Soak up with inert absorbent material.

Suppress (knock down) gases/vapors/mists with a water spray

jet.

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.

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 vapors.

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

assessment

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.

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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up.

Keep tightly closed.

Keep in a cool, well-ventilated place.

Materials to avoid

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures which in contact with water emit

flammable gases

Explosives Gases

Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH		
		STEL	400 ppm	ACGIH		
		ST	500 ppm 1,225 mg/m ³	NIOSH REL		
		TWA	400 ppm 980 mg/m ³	NIOSH REL		
		TWA	400 ppm 980 mg/m ³	OSHA Z-1		
Propylene glycol	57-55-6	TWA	10 mg/m ³	US WEEL		
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4) Internal			
	Further information: Skin					
			10 μg/100 cm ²	Internal		

Biological occupational exposure limits

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

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

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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 : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is

flammable, 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

erosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to evoid expected skip surfaces.

disposable 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

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : lotion

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Color : colorless, clear, to, translucent

Odor : No data available

Odor Threshold : No data available

pH : 4.5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 65.1 °F / 18.4 °C

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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

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.

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 04/06/2024 1288481-00019 Date of first issue: 02/15/2017 4.1

Molecular weight Not applicable

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-Highly flammable liquid and vapor.

Vapors may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation 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: vapor

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

Propylene glycol:

Acute oral toxicity LD50 (Rat): 22,000 mg/kg

LC50 (Rat): > 44.9 mg/lAcute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

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

Assessment: The substance or mixture has no acute dermal

toxicity

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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:

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

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

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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:

Propan-2-ol:

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

Method : OECD Test Guideline 406

Result : negative

Propylene glycol:

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

Mometasone:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitization.

Result : negative

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:

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

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Result: negative

Propylene glycol:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

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

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Components:

Propan-2-ol:

Species : Rat

Application Route : inhalation (vapor)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

Propylene glycol:

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

Components:

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

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

Species: Rat

Application Route: Ingestion

Result: negative

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Propylene glycol:

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

Species: Mouse

Application Route: Ingestion

Result: negative

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

Species: Mouse

Application Route: Ingestion

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 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.

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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.

Components:

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:

Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

Application Route : inhalation (vapor) Exposure time : 104 Weeks

Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 y

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

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propan-2-ol:

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

Exposure time: 96 h

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 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.

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

ma/l

Exposure time: 32 d

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 04/06/2024 1288481-00019 Date of first issue: 02/15/2017 4.1

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.

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

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 %**

Propylene glycol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Mometasone:

Result: Not readily biodegradable. Biodegradability

> 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:

Propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0.05

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

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

Other adverse effects

No data available

: log Koc: 4.02

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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

handling 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1219

Proper shipping name : ISOPROPANOL SOLUTION

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

IATA-DGR

UN/ID No. : UN 1219

Proper shipping name : Isopropanol solution

Class : 3

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 04/06/2024 1288481-00019 Date of first issue: 02/15/2017 4.1

364

Packing group Ш

Flammable Liquids Labels

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 Ш 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.

Domestic regulation

49 CFR

UN/ID/NA number UN 1219

Proper shipping name Isopropanol SOLUTION

Class 3 Packing group Ш

FLAMMABLE LIQUID Labels

ERG Code 129

Marine pollutant yes(Mometasone)

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

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards Flammable (gases, aerosols, liquids, or solids)

Reproductive toxicity

Serious eye damage or eye irritation

Specific target organ toxicity (single or repeated exposure)

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

SARA 313 : The following components are subject to reporting levels

established by SARA Title III, Section 313:

Propan-2-ol 67-63-0 >= 30 - < 50 %

US State Regulations

Pennsylvania Right To Know

 Propan-2-ol
 67-63-0

 Water
 7732-18-5

 Propylene glycol
 57-55-6

 Phosphoric acid
 7664-38-2

California List of Hazardous Substances

Propan-2-ol 67-63-0

California Permissible Exposure Limits for Chemical Contaminants

Propan-2-ol 67-63-0

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

AICS : not determined

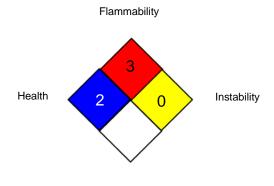
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

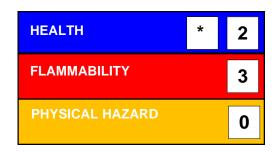
Further information

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

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

 4.1
 04/06/2024
 1288481-00019
 Date of first issue: 02/15/2017

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

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

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded

at any time during a workday

OSHA Z-1 / TWA : 8-hour time weighted average

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

Sources of key data used to compile the Material Safety

Data Sheet

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

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

Revision Date : 04/06/2024

according to the OSHA Hazard Communication Standard



Mometasone Lotion Formulation

Version Revision Date: SDS Number: Date of last issue: 09/30/2023 4.1 04/06/2024 1288481-00019 Date of first issue: 02/15/2017

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.

US / Z8