

SAFETY DATA SHEET



Mometasone Lotion Formulation



Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
Date of first issue: 2017/02/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Mometasone Lotion Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Flammable liquids : Category 2

Serious eye damage/eye irritation : 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.

Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equip-

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

ment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
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.
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

Important symptoms and outlines of the emergency assumed : Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propan-2-ol	67-63-0	>= 30 - < 40	2-207
Propylene glycol	57-55-6	>= 20 - < 30	2-234
Mometasone	83919-23-7	>= 0.1 - < 0.25	

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

SAFETY DATA SHEET



Mometasone Lotion Formulation



Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
Date of first issue: 2017/02/15

- 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 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 delayed : Causes serious eye irritation.
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.
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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
fire.
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 products : Carbon oxides
- Specific extinguishing methods : 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.
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6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Ventilate the area.
Use personal protective equipment.
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Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : 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 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.

7. HANDLING AND STORAGE

Handling

- 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 equipment.
- 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 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.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

SAFETY DATA SHEET



Mometasone Lotion Formulation



Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
 Date of first issue: 2017/02/15

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.

Storage

- 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.
- Materials to avoid : Do not store with the following product types:
 Oxidizing solids
 Oxidizing liquids
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	ACL	200 ppm	JP OEL ISHL
		OEL-C	400 ppm 980 mg/m ³	JP OEL JSOH
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
		Further information: Skin		
		Wipe limit	10 µg/100 cm ²	Internal

Biological occupational exposure limits

Components	CAS-No.	Target substance	Biological specimen	Sampling 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

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapour type
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 aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	lotion
Colour	:	colourless, clear, to, translucent
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Ignitable (see flash point)
Lower explosion limit and upper explosion limit / flammability limit		
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

SAFETY DATA SHEET



Mometasone Lotion Formulation



Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
Date of first issue: 2017/02/15

flammability limit

Flash point : 18.4 °C
Method: closed cup

Decomposition temperature : No data available

pH : 4.5

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : 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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : 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.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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

Propylene glycol:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	: LC50 (Rabbit): > 159 mg/l 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

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.

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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

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 Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

Propylene glycol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
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:**Propan-2-ol:**

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

Propylene glycol:

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

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

		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:**Propan-2-ol:**

Species	:	Rat
Application Route	:	inhalation (vapour)
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

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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 development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Propylene glycol:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal 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 foetal 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 developmental 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

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

	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 - Assessment	: 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.
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Mometasone:

Remarks	: Based on available data, the classification criteria are not met.
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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:****Propan-2-ol:**

Species	: Rat
NOAEL	: 12.5 mg/l
Application Route	: inhalation (vapour)
Exposure time	: 104 Weeks

Propylene glycol:

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

Species	: Rat, male
NOAEL	: 1,700 mg/kg
Application Route	: Ingestion
Exposure time	: 2 yr

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:****Mometasone:**

Inhalation	: Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion
Skin contact	: Symptoms: Dermatitis, Itching

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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

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 (Chronic 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

Mometasone Lotion Formulation

Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
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 toxicity)	: 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 (Chronic 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: 2.23BOD/COD: 53 %

Propylene glycol:

Biodegradability	: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Mometasone:

Biodegradability	: Result: Not readily biodegradable.
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Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

Stability in water	Biodegradation: 50 %
	Exposure time: 28 d Method: OECD Test Guideline 314
	Hydrolysis: 50 %(12 d)
	Method: OECD Test Guideline 111

Bioaccumulative potential**Components:****Propan-2-ol:**

Partition coefficient: n-octanol/water	: log Pow: 0.05
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Propylene glycol:

Partition coefficient: n-octanol/water	: log Pow: -1.07
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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
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Mobility in soil**Components:****Mometasone:**

Distribution among environmental compartments	: log Koc: 4.02
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Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

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

Mometasone Lotion Formulation

Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
Date of first issue: 2017/02/15

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 1219
Proper shipping name : ISOPROPANOL SOLUTION
Class : 3
Packing group : II
Labels : 3

IATA-DGR

UN/ID No. : UN 1219
Proper shipping name : Isopropanol solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

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.

National Regulations

Refer to section 15 for specific national regulation.

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**Related Regulations****Fire Service Law**

Group 4, Type 1 petroleum, Water insoluble liquid, (200 litre), Hazardous rank II

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
Isopropyl alcohol	102
Propane-1,2-diol	106

Mometasone Lotion Formulation

Version 4.0 Revision Date: 2021/04/09 SDS Number: 1288475-00012 Date of last issue: 2020/10/05
Date of first issue: 2017/02/15

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Number	Concentration (%)
Propyl alcohol	494	>=30 - <40

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Number
Propyl alcohol	494

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Inflammable Substance

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Mometasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

Vessel Safety Law

Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law

Specially Controlled Industrial Waste

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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

JP OEL ISHL : Japan. Administrative Control Levels

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

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

ACGIH / STEL : Short-term exposure limit

JP OEL ISHL / ACL : Administrative Control level

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

SAFETY DATA SHEET



Mometasone Lotion Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/05
4.0	2021/04/09	1288475-00012	Date of first issue: 2017/02/15

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

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