

Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	1699488-00017	Date of first issue: 21.05.2017

SECTION 1. IDENTIFICATION

Product name : Mometasone Cream Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd 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**

Reproductive toxicity : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :  

Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5	>= 50 -< 70
2-Methyl-2,4-pentanediol	107-41-5	>= 10 -< 20
Titanium dioxide	13463-67-7	>= 1 -< 5
Mometasone	83919-23-7	>= 0,1 -< 0,25

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 soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Suspected of damaging the unborn child.
- 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.

SECTION 5. FIRE-FIGHTING MEASURES

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- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Vapors may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
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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.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapors.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

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- assessment
Keep container tightly closed.
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.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	CMP (Mist)	5 mg/m ³	AR OEL
		CMP - CPT (Mist)	10 mg/m ³	AR OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
2-Methyl-2,4-pentanediol	107-41-5	CMP-C	25 ppm	AR OEL
		TWA (Vapor)	25 ppm	ACGIH
		STEL (Vapor)	50 ppm	ACGIH
		STEL (Inhalable fraction, Aerosol only)	10 mg/m ³	ACGIH
Titanium dioxide	13463-67-7	CMP	10 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Respirable particulate matter)	2,5 mg/m ³ (Titanium dioxide)	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

- Engineering measures** : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of

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the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Essentially no open handling permitted.
 Use closed processing systems or containment technologies.

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 vapor type |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Eye protection | : | Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, 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 | : | cream |
| Color | : | white to off-white |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |

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Initial boiling point and boiling range : No data available

Flash point : > 93,3 °C

Evaporation rate : Not applicable

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

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

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Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:**White mineral oil (petroleum):**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

2-Methyl-2,4-pentanediol:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 420

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Mometasone:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

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LD50 (Mouse): > 2.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3,3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

LC50 (Mouse): > 3,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg
Application Route: Subcutaneous
Symptoms: Breathing difficulties

Skin corrosion/irritation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species : Rabbit
Result : No skin irritation

2-Methyl-2,4-pentanediol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Titanium dioxide:

Species : Rabbit
Result : No skin irritation

Mometasone:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species : Rabbit
Result : No eye irritation

2-Methyl-2,4-pentanediol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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Titanium dioxide:

Species : Rabbit
Result : No eye irritation

Mometasone:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**White mineral oil (petroleum):**

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

2-Methyl-2,4-pentanediol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
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.

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Components:**White mineral oil (petroleum):**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Titanium dioxide:

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
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

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Test Type: Chromosomal aberration
 Species: Rat
 Cell type: Bone marrow
 Result: negative

Test Type: unscheduled DNA synthesis assay
 Species: Rat
 Cell type: Liver cells
 Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species : Rat
 Application Route : Ingestion
 Exposure time : 24 Months
 Result : negative

Titanium dioxide:

Species : Rat
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 2 Years
 Method : OECD Test Guideline 453
 Result : positive
 Remarks : The mechanism or mode of action may not be relevant in humans.
 This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

Mometasone:

Species : Rat
 Application Route : Inhalation
 Exposure time : 2 Years
 Dose : 0.067 mg/kg body weight
 Result : negative

Species : Mouse
 Application Route : Inhalation
 Exposure time : 19 Months
 Dose : 0.160 mg/kg body weight
 Result : negative

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Reproductive toxicity

Suspected of damaging the unborn child.

Components:**White mineral oil (petroleum):**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

2-Methyl-2,4-pentanediol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: negative

Effects on fetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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.

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Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Dermal
 Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
 Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Subcutaneous
 Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
 Result: Effects on newborn.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 Embryo-fetal toxicity.: LOAEL: 0,7 mg/kg body weight
 Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - 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

Not classified based on available information.

Components:**Mometasone:**

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

STOT-repeated exposure

Not classified based on available information.

Components:**Mometasone:**

Routes of exposure : inhalation (dust/mist/fume)
 Target Organs : Immune system, Liver, Kidney, Skin
 Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****White mineral oil (petroleum):**

Species : Rat
 LOAEL : 160 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days

Species : Rat
 LOAEL : >= 1 mg/l
 Application Route : inhalation (dust/mist/fume)

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Exposure time : 4 Weeks
Method : OECD Test Guideline 412

2-Methyl-2,4-pentanediol:

Species : Rat
NOAEL : ≥ 450 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Method : OECD Test Guideline 408

Titanium dioxide:

Species : Rat
NOAEL : 24.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat
NOAEL : 10 mg/m³
Application Route : inhalation (dust/mist/fume)
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
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

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Components:**Mometasone:**

Not applicable

Experience with human exposure**Components:****2-Methyl-2,4-pentanediol:**

Eye contact : Target Organs: Eyes
Symptoms: Irritation

Mometasone:

Inhalation : Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory 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:****White mineral oil (petroleum):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.000 mg/l
Exposure time: 21 d

2-Methyl-2,4-pentanediol:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 8.510 mg/l

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Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 2.800 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 429 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Raphidocelis subcapitata (freshwater green alga)): > 429 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 25 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : NOEC (Bacteria): 200 mg/l
Exposure time: 10 d

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Mometasone:

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0,11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035

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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:****White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 31 %
 Exposure time: 28 d

2-Methyl-2,4-pentanediol:

Biodegradability : Result: Readily biodegradable.
 Biodegradation: 81 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301F

Mometasone:

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 50 %
 Exposure time: 28 d
 Method: OECD Test Guideline 314

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Stability in water : Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

Bioaccumulative potential**Components:****2-Methyl-2,4-pentanediol:**

Partition coefficient: n-octanol/water : log Pow: < 4
Remarks: Calculation

Mometasone:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107,1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,68

Mobility in soil**Components:****Mometasone:**

Distribution among environmental compartments : log Koc: 4,02

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077

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Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Mometasone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

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Further information

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 Agency, <http://echa.europa.eu/>

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
AR OEL	: Argentina. Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
AR OEL / CMP	: TLV (Threshold Limit Value)
AR OEL / CMP - CPT	: STEL (Short Term Limit Value)
AR OEL / CMP-C	: Ceiling value

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; TECl - 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

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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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