

# SAFETY DATA SHEET



## Mometasone Ointment Formulation



Version 5.1      Revision Date: 30.09.2023      SDS Number: 1751221-00014      Date of last issue: 04.04.2023  
Date of first issue: 14.06.2017

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### Section 1: Identification

Product name : Mometasone Ointment 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 number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Reproductive toxicity : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360Df May damage the unborn child. Suspected of damaging fertility.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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**Response:**

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)
Petrolatum	8009-03-8	>= 70 -< 90
2-Methyl-2,4-pentanediol	107-41-5	>= 10 -< 20
Propylene glycol monostearate	1323-39-3	>= 1 -< 10
Mometasone	83919-23-7	>= 0.1 -< 0.25

**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 : May damage the unborn child. Suspected of damaging fertility.
- Protection of first-aiders : First Aid responders should pay attention to self-protection,

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Notes to physician : and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

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**Section 5: Fire-fighting measures**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Hazchem Code : 2Z

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**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

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- CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.
- Conditions for safe storage : Keep in properly labelled 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

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	WES-TWA (Mist)	5 mg/m <sup>3</sup>	NZ OEL
		WES-STEL (Mist)	10 mg/m <sup>3</sup>	NZ OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
2-Methyl-2,4-pentanediol	107-41-5	WES-Ceiling	25 ppm 121 mg/m <sup>3</sup>	NZ OEL
		TWA (Vapour)	25 ppm	ACGIH
		STEL (Vapour)	50 ppm	ACGIH
		STEL (Inhalable fraction,	10 mg/m <sup>3</sup>	ACGIH

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		Aerosol only)		
Propylene glycol monostearate	1323-39-3	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**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.

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.

**Section 9: Physical and chemical properties**

Appearance : ointment

Colour : white to off-white

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Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : > 93.3 °C

Evaporation rate : No data available

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

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

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Molecular weight : No data available

Particle size : No data available

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**Section 10: Stability and reactivity**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Petrolatum:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

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

**Propylene glycol monostearate:**

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

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**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:****Petrolatum:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

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

**Propylene glycol monostearate:**

Result : No skin irritation

**Mometasone:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Petrolatum:**

Species : Rabbit  
Result : No eye irritation



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Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

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:****Petrolatum:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**Mometasone:**

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative  
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

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**Components:****Petrolatum:**

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

**2-Methyl-2,4-pentanediol:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: negative

**Mometasone:**

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

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

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

**Carcinogenicity**

Not classified based on available information.

**Components:****Petrolatum:**

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

**Mometasone:**

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

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

**Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

**Components:****Petrolatum:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Skin contact  
 Result: negative  
 Remarks: Based on data from similar materials

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**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 foetal 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 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  
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

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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**

Not classified based on available information.

**Components:****Mometasone:**

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

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Mometasone:**

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

**Repeated dose toxicity****Components:****Petrolatum:**

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

**2-Methyl-2,4-pentanediol:**

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

**Mometasone:**

Species : Rat  
 NOAEL : 0.005 mg/kg  
 LOAEL : 0.3 mg/kg  
 Application Route : Oral

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Exposure time : 30 d  
Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog  
LOAEL : 0.5 mg/kg  
Application Route : Oral  
Exposure time : 30 d  
Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat  
NOAEL : 0.00013 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 90 d  
Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species : Dog  
NOAEL : 0.0005 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 90 d  
Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

**Aspiration toxicity**

Not classified based on available information.

**Components:****Mometasone:**

Not applicable

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

Eye contact : Target Organs: Eyes  
Symptoms: Irritation

**Mometasone:**

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

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**Section 12: Ecological information**
**Ecotoxicity****Components:****Petrolatum:**

- Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 21 d  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

- Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 8,510 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 2,800 mg/l  
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

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

**Mometasone:**

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l  
Exposure time: 96 h  
Remarks: No toxicity at the limit of solubility

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

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

EC50 (Americamysis): > 5 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic 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



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**Persistence and degradability****Components:****Petrolatum:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

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

**Mometasone:**

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

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

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

Partition coefficient: n-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

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**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.

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**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
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.

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**National Regulations****NZS 5433**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class	:	9
Packing group	:	III
Labels	:	9
Hazchem Code	:	2Z
Marine pollutant	:	no

**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.

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**Section 16: Other information**

Revision Date : 30.09.2023

**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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

# SAFETY DATA SHEET



## Mometasone Ointment Formulation



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ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL	:	Workplace Exposure Standard - Short-Term Exposure Limit
NZ OEL / WES-Ceiling	:	Workplace Exposure Standard - Ceiling

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

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

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