

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Mometasone Cream Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

E-mail address of person
responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation. 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. P264 Wash skin thoroughly after handling. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. P391 Collect spillage.

Hazardous components which must be listed on the label:

2-Methyl-2,4-pentanediol

EUH212 Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-Methyl-2,4-pentanediol	107-41-5 203-489-0 603-053-00-3	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d	>= 10 - < 20
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1;	>= 0.1 - < 0.25

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

		H410	
		M-Factor (Chronic aquatic toxicity): 100	
Substances with a workplace exposure limit :			
Titanium dioxide	13463-67-7 236-675-5 022-006-00-2		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes skin irritation.
Causes serious eye irritation.
Suspected of damaging the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for 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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe vapours.
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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-Methyl-2,4-pentanediol	107-41-5	TWA	25 ppm 123 mg/m ³	GB EH40
		STEL	25 ppm 123 mg/m ³	GB EH40
Titanium dioxide	13463-67-7	TWA (inhalable dust)	10 mg/m ³	GB EH40
		TWA (Respirable dust)	4 mg/m ³	GB EH40
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

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Methyl-2,4-pentanediol	Workers	Inhalation	Long-term systemic effects	44.43 mg/m ³
	Workers	Inhalation	Long-term local effects	49 mg/m ³
	Workers	Inhalation	Acute local effects	98 mg/m ³
	Workers	Skin contact	Long-term systemic effects	63 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	7.83 mg/m ³
	Consumers	Inhalation	Long-term local effects	25 mg/m ³
	Consumers	Inhalation	Acute local effects	49 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	22.5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.25 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
2-Methyl-2,4-pentanediol	Fresh water	0.429 mg/l
	Freshwater - intermittent	4.29 mg/l
	Marine water	0.0429 mg/l
	Sewage treatment plant	20 mg/l
	Fresh water sediment	1.59 mg/kg dry

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

		weight (d.w.)
	Marine sediment	0.159 mg/kg dry weight (d.w.)
	Soil	0.066 mg/kg dry weight (d.w.)

8.2 Exposure controls

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

- Eye/face 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.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 14387
- Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : cream
- Colour : white to off-white
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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.

9.2 Other information

Flammability (liquids)	:	Not applicable
Particle size	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

10.3 Possibility of hazardous reactions

Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Components:

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

||

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

Skin corrosion/irritation

Causes skin irritation.

Components:

2-Methyl-2,4-pentanediol:

|| Result : Skin irritation
|| Remarks : Based on national or regional regulation.

Mometasone:

|| Species : Rabbit
|| Result : No skin irritation

Titanium dioxide:

|| Species : Rabbit
|| Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-Methyl-2,4-pentanediol:

|| Result : Irritation to eyes, reversing within 21 days
|| Remarks : Based on national or regional regulation.

Mometasone:

|| Species : Rabbit
|| Result : No eye irritation

Titanium dioxide:

|| Species : Rabbit
|| Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

Respiratory sensitisation

Not classified based on available information.

Components:

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.

Titanium dioxide:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Result	: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

Genotoxicity in vivo	: Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive
	: Test Type: Mouse Lymphoma Result: negative
	: 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.

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

Carcinogenicity

Not classified based on available information.

Components:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

	Result: Embryo-foetal toxicity
	Test Type: Embryo-foetal development
	Species: Rabbit
	Application Route: Dermal
	Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
	Result: Embryo-foetal toxicity, Malformations were observed.
	Test Type: Embryo-foetal development
	Species: Rat
	Application Route: Subcutaneous
	Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
	Result: Effects on newborn
	Test Type: Embryo-foetal development
	Species: Rabbit
	Application Route: Oral
	Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight
	Result: Embryo-foetal toxicity, Malformations were observed.
Reproductive toxicity - 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:

2-Methyl-2,4-pentanediol:

Species	: Rat
NOAEL	: >= 450 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

|| Method : OECD Test Guideline 408

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

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 yr

Aspiration toxicity

Not classified based on available information.

Components:

Mometasone:

|| Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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

12.1 Toxicity

Components:

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

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 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
Toxicity to fish (Chronic toxicity)	: NOEC: 0.00014 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0.34 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	: 100

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 9373258-00007 Date of last issue: 30.09.2023
Date of first issue: 27.08.2021

	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

12.2 Persistence and degradability

Components:

2-Methyl-2,4-pentanediol:

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

12.3 Bioaccumulative potential

Components:

2-Methyl-2,4-pentanediol:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

12.4 Mobility in soil

Components:

Mometasone:

|| Distribution among environmental compartments : log Koc: 4.02

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

|| Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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

14.1 UN number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

(Mometasone)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Mometasone)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	: Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	: Not applicable
GB Export and import of hazardous chemicals - Prior	: Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

Informed Consent (PIC) Regulation
Control of Major Accident Hazards Regulations 2015 (COMAH)

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
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Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H360Df : May damage the unborn child. Suspected of damaging fertility.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure if inhaled.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



ORGANON

Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Classification of the mixture:

Skin Irrit. 2	H315
Eye Irrit. 2	H319
Repr. 2	H361d
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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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 mate-

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373258-00007	Date of first issue: 27.08.2021

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.

GB / EN