

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 1. PRODUCT AND COMPANY 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 : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Appearance	: cream
Colour	: white to off-white
Odour	: No data available

Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

#### GHS Classification

Serious eye damage/eye irritation : Category 2A

Long-term (chronic) aquatic hazard : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear eye protection/ face protection.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P391 Collect spillage.

### Disposal:

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

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

Causes serious eye irritation.

### Environmental hazards

Toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification

None known.

## 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 -< 10
Mometasone	83919-23-7	>= 0.1 -< 0.25

## 4. FIRST AID MEASURES

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical 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	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

If swallowed	: Get medical attention. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: Causes serious eye irritation.
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.

### 5. FIREFIGHTING 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 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 firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

certain local or national requirements.

### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapours.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

#### Storage

- Conditions for safe storage : Keep in properly labelled containers.  
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
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
2-Methyl-2,4-pentanediol	107-41-5	MAC	100 mg/m <sup>3</sup>	CN OEL
		TWA (Vapour)	25 ppm	ACGIH
		STEL (Vapour)	50 ppm	ACGIH
		STEL (Inhalable fraction, Aerosol only)	10 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	PC-TWA (Total dust)	8 mg/m <sup>3</sup>	CN OEL
Further information: G2B - Possibly carcinogenic to humans				

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version 3.8      Revision Date: 2021/04/09      SDS Number: 1688394-00011      Date of last issue: 2020/10/10  
Date of first issue: 2017/05/21

		TWA	10 mg/m3 (Titanium dioxide)	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm²	Internal

**These substance(s) are inextricably bound in the product and therefore do 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 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

**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.

**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.

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 9. 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
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
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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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

Particle size : No data available

### 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.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : 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  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 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  
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



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

##### White mineral oil (petroleum):

Species	:	Rabbit
Result	:	No eye irritation

##### 2-Methyl-2,4-pentanediol:

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days

##### Titanium dioxide:

Species	:	Rabbit
Result	:	No eye irritation

##### 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:

##### White mineral oil (petroleum):

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

##### 2-Methyl-2,4-pentanediol:

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

##### Titanium dioxide:

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### Mometasone:

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

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 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
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#### 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
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# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

Result: negative

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: positive

Test Type: Mouse Lymphoma  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

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

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

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

### Carcinogenicity

Not classified based on available information.

### 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.

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

### Mometasone:

Species : Rat

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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

Not classified based on available information.

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

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

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 421  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

#### **Mometasone:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 0.015 mg/kg body weight  
Symptoms: Reduced embryonic survival, Reduced foetal weight  
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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  
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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### Repeated dose toxicity

#### Components:

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

Species	: Rat
LOAEL	: 160 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Species	: Rat
LOAEL	: $\geq 1$ mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 4 Weeks
Method	: OECD Test Guideline 412

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

Species	: Rat
NOAEL	: $\geq 450$ mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
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/m <sup>3</sup>
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 yr

##### **Mometasone:**

Species	: Rat
NOAEL	: 0.005 mg/kg
LOAEL	: 0.3 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
Species	: Dog
LOAEL	: 0.5 mg/kg
Application Route	: Oral
Exposure time	: 30 d
Target Organs	: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
Species	: Rat
NOAEL	: 0.00013 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 90 d

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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
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##### **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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## 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
3.8	2021/04/09	1688394-00011	2020/10/10
			Date of first issue: 2017/05/21

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

Toxicity to microorganisms : NOEC: 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



# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
3.8	2021/04/09	1688394-00011	2020/10/10
			Date of first issue: 2017/05/21

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

### Persistence and degradability

#### Components:

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

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 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: 0  
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

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 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

##### 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.

#### National Regulations

##### GB 6944/12268

UN number	: UN 3077
Proper shipping name	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class	: 9
Packing group	: III
Labels	: 9

#### 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

### 15. REGULATORY INFORMATION

#### National regulatory information

##### Law on the Prevention and Control of Occupational Diseases

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

### 16. OTHER INFORMATION

#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
CN OEL / PC-TWA : Permissible concentration - time weighted average  
CN OEL / MAC : Maximum allowable concentration

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Mometasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
3.8	2021/04/09	1688394-00011	Date of first issue: 2017/05/21

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Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

### Disclaimer

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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