

# SAFETY DATA SHEET



## Mometasone Cream Formulation



Version 4.5      Revision Date: 04/09/2021      SDS Number: 1688391-00011      Date of last issue: 10/10/2020  
Date of first issue: 05/21/2017

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### SECTION 1. IDENTIFICATION

Product name : Mometasone Cream Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 551-430-6000  
Emergency telephone : 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. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Eye irritation : Category 2A  
Reproductive toxicity : Category 1B

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H319 Causes serious eye irritation.  
H360Df May damage the unborn child. Suspected of damaging fertility.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
**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.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.

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### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
White mineral oil (petroleum)	Paraffinum liquidum	8042-47-5	$\geq 60 - < 80$ *
2-Methyl-2,4-pentanediol	Hexylene glycol	107-41-5	$\geq 10 - < 30$ *
Titanium dioxide	No data available	13463-67-7	$\geq 1 - < 5$ *
Mometasone	No data available	83919-23-7	$\geq 0.1 - < 1$ *

\* Actual concentration or concentration range is withheld as a trade secret

## 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.  
May 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 : Vapors may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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

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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 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.

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Do not breathe vapors.  
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.

Conditions for safe storage : Keep in properly labeled containers.  
Keep tightly closed.

Materials to avoid : Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
White mineral oil (petroleum)	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL		
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL		
		TWAEV (Mist)	5 mg/m <sup>3</sup>	CA QC OEL		
		STEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL		
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL		
2-Methyl-2,4-pentanediol	107-41-5	TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH		
		(c)	25 ppm 121 mg/m <sup>3</sup>	CA AB OEL		
		C	25 ppm	CA BC OEL		
		C	25 ppm 121 mg/m <sup>3</sup>	CA QC OEL		
		TWA (Vapor)	25 ppm	ACGIH		
		STEL (Vapor)	50 ppm	ACGIH		
		STEL (Inhalable fraction, Aerosol only)	10 mg/m <sup>3</sup>	ACGIH		
		Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
				TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
				TWA (respirable dust)	3 mg/m <sup>3</sup>	CA BC OEL

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		fraction)		
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	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

**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 vapor type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Eye protection** : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

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use of administrative controls.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Color	:	white to off-white
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	> 93.3 °C
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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

#### Information on likely routes of exposure

Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

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

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

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

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

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toxicity

**Titanium dioxide:**

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

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
 Exposure time: 4 h  
 Test atmosphere: dust/mist  
 Assessment: The substance or mixture has no acute inhalation toxicity

**Mometasone:**

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



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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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

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

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

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

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

**Titanium dioxide:**

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

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**Mometasone:**

Test Type	:	Maximization Test
Routes of exposure	:	Dermal
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Result	:	negative
Remarks	:	The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

**Germ cell mutagenicity**

Not classified based on available information.

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

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

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

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

**Titanium dioxide:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Result: negative

**Mometasone:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster lung cells Result: negative

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	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.
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**Mometasone:**

Species	: Rat
Application Route	: Inhalation
Exposure time	: 2 Years

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

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
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Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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**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
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Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative
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**Mometasone:**

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Subcutaneous Fertility: NOAEL: 0.015 mg/kg body weight Symptoms: Reduced embryonic survival, Reduced fetal weight. Result: No effects on fertility., Effect on reproduction capacity.
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Effects on fetal development	:	Test Type: Embryo-fetal development Species: Mouse Application Route: Subcutaneous Embryo-fetal toxicity.: LOAEL: 0.06 mg/kg body weight Result: Embryotoxic effects., Teratogenicity and
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developmental toxicity

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Dermal  
 Embryo-fetal toxicity.: LOAEL: 0.3 mg/kg body weight  
 Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Dermal  
 Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight  
 Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Subcutaneous  
 Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight  
 Result: Effects on newborn.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Embryo-fetal toxicity.: LOAEL: 0.7 mg/kg body weight  
 Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

**STOT-single exposure**

Not classified based on available information.

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

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

**STOT-repeated exposure**

Not classified based on available information.

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

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

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

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

Species	:	Rat
LOAEL	:	>= 1 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	4 Weeks
Method	:	OECD Test Guideline 412

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

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

**Mometasone:**

Species	:	Rat
NOAEL	:	0.005 mg/kg
LOAEL	:	0.3 mg/kg
Application Route	:	Oral
Exposure time	:	30 d
Target Organs	:	Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

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

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

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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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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****White mineral oil (petroleum):**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
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Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
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Toxicity to algae/aquatic	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100
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plants		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
<b>2-Methyl-2,4-pentanediol:</b>		
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
<b>Titanium dioxide:</b>		
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
<b>Mometasone:</b>		
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.



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- 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.
- Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: No toxicity at the limit of solubility.
- NOEC: 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: No toxicity at the limit of solubility.

**Persistence and degradability****Components:****White mineral oil (petroleum):**

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

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

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

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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

**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

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**SECTION 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.

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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

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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.

### Domestic regulation

#### TDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Mometasone)  
Class : 9  
Packing group : III  
Labels : 9  
ERG Code : 171  
Marine pollutant : yes(Mometasone)

### 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

### The ingredients 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

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA AB OEL / STEL	:	15-minute occupational exposure limit
CA AB OEL / (c)	:	ceiling occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA BC OEL / C	:	ceiling limit
CA QC OEL / TWAEV	:	Time-weighted average exposure value
CA QC OEL / STEV	:	Short-term exposure value
CA QC OEL / C	:	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; 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

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

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Date format : mm/dd/yyyy

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.

CA / Z8