

Mometasone Cream Formulation

Version 5.0 Revision Date: 2021/04/09 SDS Number: 1688400-00010 Date of last issue: 2020/10/10
Date of first issue: 2017/05/21

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Mometasone Cream Formulation

Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

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.

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.

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Disposal:

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

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)	ENCS No.
White mineral oil (petroleum)	8042-47-5	>= 60 - < 70	9-1700
2-Methyl-2,4-pentanediol	107-41-5	>= 10 - < 20	2-240
Titanium dioxide	13463-67-7	>= 1 - < 10	1-558, 5-5225
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.
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.
- 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

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|---|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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. |
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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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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. |
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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
 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.

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**Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	OEL-M (Mist)	3 mg/m ³	JP OEL JSOH
	Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans			
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
2-Methyl-2,4-pentanediol	107-41-5	TWA (Vapour)	25 ppm	ACGIH
		STEL (Vapour)	50 ppm	ACGIH
		STEL (Inhalable fraction, Aerosol only)	10 mg/m ³	ACGIH
Titanium dioxide	13463-67-7	OEL-M (Respirable dust)	1 mg/m ³ (Titanium)	JP OEL JSOH
	Further information: Class 2 Dust			
		OEL-M (Total)	4 mg/m ³	JP OEL

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		dust)	(Titanium)	JSOH
	Further information: Class 2 Dust			
		TWA	10 mg/m ³ (Titanium dioxide)	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal

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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : cream

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

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Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

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

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : > 93.3 °C

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics
Particle size : No data available

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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

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

Not classified based on available information.

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

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

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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.
Acute toxicity (other routes of administration)	:	LC50 (Mouse): > 3.2 mg/l
		Exposure time: 4 h
		Test atmosphere: dust/mist
Acute toxicity (other routes of administration)	:	LD50 (Rat): 300 mg/kg
		Application Route: Subcutaneous
		Symptoms: Breathing difficulties

Skin corrosion/irritation

Not classified based on available information.

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

Species	:	Rabbit
Result	:	No skin irritation

2-Methyl-2,4-pentanediol:

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

Titanium dioxide:

Species	:	Rabbit
Result	:	No skin irritation

Mometasone:

Species	:	Rabbit
Result	:	No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

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

Species	:	Rabbit
Result	:	No eye irritation

2-Methyl-2,4-pentanediol:

Species	:	Rabbit
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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

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.

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

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

2-Methyl-2,4-pentanediol:

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

Titanium dioxide:

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

Mometasone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	:	Test Type: Chromosomal aberration Test system: Chinese hamster lung cells Result: negative
	:	Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive
	:	Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative

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	Test Type: Chromosomal aberration
	Species: Rat
	Cell type: Bone marrow
	Result: negative
	Test Type: unscheduled DNA synthesis assay
	Species: Rat
	Cell type: Liver cells
	Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

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

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

Titanium dioxide:

Species	: Rat
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 Years
Method	: OECD Test Guideline 453
Result	: positive
Remarks	: The mechanism or mode of action may not be relevant in humans.

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
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.

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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
 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.

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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:****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:

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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/m3
 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
 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

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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
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Skin contact	:	Symptoms: Dermatitis, Itching
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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
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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 plants	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
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Toxicity to fish (Chronic toxicity)	:	NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d
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2-Methyl-2,4-pentanediol:

Toxicity to fish	:	LC50 (Gambusia affinis (Mosquito fish)): 8,510 mg/l Exposure time: 96 h
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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
	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

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	Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.34 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	: 100
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
	NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility

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

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

2-Methyl-2,4-pentanediol:

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

Mometasone:

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

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

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

Distribution among environmental compartments	:	log Koc: 4.02
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Hazardous to the ozone layer

Not applicable

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.

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)

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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

Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Designated Flammable Substances, Flammable solid, (3000 kilogram)

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

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Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Number	Concentration (%)
Mineral oil	168	>=60 - <70
2-Methyl-2,4-pentanediol	593	>=10 - <20
Titanium(IV) oxide	191	>=1 - <10

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Number
Mineral oil	168
2-Methyl-2,4-pentanediol	593
Titanium(IV) oxide	191

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

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Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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 Con-

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centration 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

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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