

# Mometasone Metered Dose Inhaler Formulation



Version Revision Date: SDS Number: Date of last issue: 10/16/2020 5.6 04/09/2021 26005-00017 Date of first issue: 10/28/2014

#### **SECTION 1. IDENTIFICATION**

Product name : Mometasone Metered Dose Inhaler Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd 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

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Gases under pressure : Dissolved gas

Reproductive toxicity : Category 1B

Simple Asphyxiant

**GHS label elements** 

Hazard pictograms :





Signal Word : Danger

Hazard Statements : H280 Contains gas under pressure; may explode if heated.

H360Df May damage the unborn child. Suspected of damaging

fertility.

May displace oxygen and cause rapid suffocation.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

P410 + P403 Protect from sunlight. Store in a well-ventilated

place.



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#### 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	CAS-No.	Concentration (% w/w)
Ethanol#	64-17-5	>= 1.8 - <= 2.5
Mometasone	83919-23-7	>= 0.08 - <= 0.18

<sup>#</sup> Voluntarily-disclosed non-hazardous substance

#### **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.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

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. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

In case of eye contact

May damage the unborn child. Suspected of damaging fertili-

ty.

delayed Gas reduces oxygen available for breathing.

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.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)







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> Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting

due to the high vapor pressure.

Hazardous combustion prod-

Carbon oxides

Fluorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emergency procedures

Evacuate personnel to safe areas.

Ventilate the area.

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.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

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 Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

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.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.



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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 vapors or spray mist.

Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Do not pierce or burn, even after use. Keep cool. Protect from sunlight.

Materials to avoid : Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures which in contact with water emit

flammable gases 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	
Ethanol	64-17-5	TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	NIOSH REL	
		STEL	1,000 ppm	ACGIH	
		TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	OSHA Z-1	
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal	
	Further information: Skin				
		Wipe limit	10 μg/100 cm <sup>2</sup>	Internal	

## Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where

concentrations are above recommended limits or are



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unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Skin and body protection Hygiene measures : Skin should be washed after contact.

: 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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aerosol containing a dissolved gas

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

3 °F / -16 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1 g/cm<sup>3</sup>





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No data available

No data available

No data available

No data available

Not explosive

Solubility(ies)

Water solubility insoluble

Partition coefficient: n-

octanol/water

Autoignition temperature

Decomposition temperature

Viscosity

Viscosity, kinematic

Explosive properties

Oxidizing properties

Molecular weight

Particle size

The substance or mixture is not classified as oxidizing.

No data available

No data available

# **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

If the temperature rises there is danger of the vessels bursting

due to the high vapor pressure.

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

# Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

## **Acute toxicity**

Not classified based on available information.

## Components:

## **Ethanol:**

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

Method: OECD Test Guideline 401

Acute inhalation toxicity LC50 (Rat): 124.7 mg/l





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Exposure time: 4 h
Test atmosphere: vapor

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:**

**Ethanol:** 

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Mometasone:

Species : Rabbit

Result : No skin irritation

# Serious eye damage/eye irritation

Not classified based on available information.

Components:

**Ethanol:** 

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Mometasone:

Species : Rabbit

Result : No eye irritation



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# Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

## Respiratory sensitization

Not classified based on available information.

#### **Components:**

**Ethanol:** 

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse Result : negative

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:**

**Ethanol:** 

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

**Application Route: Ingestion** 

Result: equivocal

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







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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:**

#### 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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

#### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.



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### **Components:**

**Ethanol:** 

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

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 fetal

weight.

Result: No effects on fertility., Effect on reproduction capacity.

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

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 - As-

sessment

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.



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## 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.

#### Repeated dose toxicity

#### Components:

#### **Ethanol:**

Species : Rat

NOAEL : 1,280 mg/kg LOAEL : 3,156 mg/kg Application Route : Ingestion Exposure time : 90 Days

#### 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







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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:** 

Mometasone:

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

piratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion

Skin contact : Symptoms: Dermatitis, Itching

**Further information** 

**Components:** 

Mometasone:

Remarks : Dermal absorption possible

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

**Ethanol:** 

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 9 d





→ ORGANON

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Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l

Exposure time: 16 h

Mometasone:

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility.

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l

Exposure time: 7 d

Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 5 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility.

EC50 (Americamysis): > 5 mg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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.





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# Persistence and degradability

**Components:** 

**Ethanol:** 

Biodegradability : Result: Readily biodegradable.

Biodegradation: 84 % Exposure time: 20 d

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:** 

**Ethanol:** 

Partition coefficient: n-

octanol/water

log Pow: -0.35

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 environ-

mental compartments

: log Koc: 4.02

Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Dispose of in acco

: 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. Please ensure aerosol cans are sprayed completely empty







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(including propellant)

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

UN 1950 UN number Proper shipping name **AEROSOLS** 

Class 2.2

Packing group Not assigned by regulation

Labels 2.2

IATA-DGR

UN 1950 UN/ID No.

Proper shipping name Aerosols, non-flammable

Class

Packing group Not assigned by regulation Labels Non-flammable, non-toxic Gas

Packing instruction (cargo 203

aircraft)

Packing instruction (passen-203

ger aircraft)

**IMDG-Code** 

**UN** number UN 1950 Proper shipping name **AEROSOLS** 

(Mometasone)

Class 2.2

Packing group Not assigned by regulation

Labels 2.2 **EmS Code** F-D, S-U 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**

**49 CFR** 

UN/ID/NA number UN 1950 Proper shipping name Aerosols Class 2.2

Packing group Not assigned by regulation **NON-FLAMMABLE GAS** Labels

**ERG Code** 126

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**

# **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

# SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Gases under pressure

Simple Asphyxiant Reproductive toxicity

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### **US State Regulations**

Pennsylvania Right To Know

1,1,1,2,3,3,3-Heptafluoropropane 431-89-0 Ethanol 64-17-5

**California List of Hazardous Substances** 

Ethanol 64-17-5

California Permissible Exposure Limits for Chemical Contaminants

Ethanol 64-17-5

International Regulations

Montreal Protocol : 1,1,1,2,3,3,3-Heptafluoropropane

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**



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# NFPA 704:

# Flammability Health Instability

Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants Short-term exposure limit

ACGIH / STEL : Short-term exposure limit

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-



# **Mometasone Metered Dose Inhaler Formulation**

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stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 Agen-

cy, http://echa.europa.eu/

Revision Date : 04/09/2021

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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