

SAFETY DATA SHEET



Mometasone / Formoterol Metered Dose Inhaler Formulation



Version 10.0 Revision Date: 2024/04/06 SDS Number: 75385-00023 Date of last issue: 2023/09/30
Date of first issue: 2015/03/16

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Mometasone / Formoterol Metered Dose Inhaler 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 : +1-551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : +1-215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Aerosols : Category 3

Long-term (chronic) aquatic hazard : Category 2

Hazardous to the ozone layer : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H229 Pressurised container: May burst if heated.
H411 Toxic to aquatic life with long lasting effects.
H420 Harms public health and the environment by destroying ozone in the upper atmosphere.

Precautionary statements : **Prevention:**

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P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251 Do not pierce or burn, even after use.
P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Storage:

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 40 °C/ 104 °F.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.
P502 Refer to manufacturer or supplier for information on recovery or recycling.

Other hazards which do not result in classification

Important symptoms and out- : May displace oxygen and cause rapid suffocation.
lines of the emergency as-
sumed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
1,1,1,2,3,3,3-Heptafluoropropane	431-89-0	>= 98.05 - <= 98.09	2-3763
Ethanol#	64-17-5	1.8	2-202
Mometasone	83919-23-7	>= 0.087 - <= 0.17	
Formoterol	43229-80-7	>= 0.0009 - <= 0.0087	

Voluntarily-disclosed substance

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.

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In case of eye contact : Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

If swallowed : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and 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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

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 products : Fluorine compounds
Carbon oxides

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : 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.

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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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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 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.

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.

Storage

Conditions for safe storage : Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

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Materials to avoid : Do not pierce or burn, even after use.
Keep cool. Protect from sunlight.
Do not store with the following product types:
Oxidizing solids
Oxidizing liquids

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 / Reference concentration / Permissible concentration	Basis
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm ²	Internal
Formoterol	43229-80-7	TWA	0.05 µg/m ³ (OEB 5)	Internal
		Wipe limit	0.5 µg/100 cm ²	Internal

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 : Self-contained breathing apparatus

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : aerosol

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : -16.5 °C

Flammability (solid, gas) : Not applicable

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Flammability (liquids) : No data available

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

Lower explosion limit / : No data available
Lower flammability limit

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n- : Not applicable
octanol/water

Vapour pressure : 3,900 hPa (20 °C)

Density and / or relative density
Relative density : 5.9
Density : No data available

Relative vapour density : 5.9

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
Particle size : No data available

10. STABILITY AND REACTIVITY

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Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-Heptafluoropropane:

Acute inhalation toxicity	:	LC50 (Rat): > 788696 ppm Exposure time: 4 h Test atmosphere: gas Method: OECD Test Guideline 403
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Ethanol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC50 (Rat): 124.7 mg/l Exposure time: 4 h Test atmosphere: vapour

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

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Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg
Application Route: Subcutaneous
Symptoms: Breathing difficulties

Formoterol:

Acute oral toxicity : LD50 (Rat): 3,130 mg/kg
LD50 (Mouse): 6,700 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1,000 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 640 mg/kg
Application Route: Subcutaneous

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

Formoterol:

Species : Rabbit
Result : No skin irritation
Remarks : slight irritation

Serious eye damage/eye irritation

Not classified based on available information.

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Components:**Ethanol:**

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Mometasone:

Species : Rabbit
Result : No eye irritation

Formoterol:

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:**Ethanol:**

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 sensitizer.

Formoterol:

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

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Germ cell mutagenicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-Heptafluoropropane:

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: inhalation (gas) Result: negative

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 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

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		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.

Formoterol:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test
		Result: negative
		Test Type: Chromosomal aberration
		Result: negative
		Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
		Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test
		Species: Mouse
		Application Route: Oral
		Result: negative
		Test Type: Micronucleus test
		Species: Rat
		Application Route: Oral
		Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Mometasone:

Species	:	Rat
Application Route	:	Inhalation
Exposure time	:	2 Years
Dose	:	0.067 mg/kg body weight
Result	:	negative

Species	:	Mouse
Application Route	:	Inhalation
Exposure time	:	19 Months
Dose	:	0.160 mg/kg body weight
Result	:	negative

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Formoterol:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
LOAEL : 0.5 mg/kg body weight
Target Organs : Ovary
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 18 month(s)
LOAEL : 2 mg/kg body weight
Target Organs : Adrenal gland, Liver, Uterus (including cervix)
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Reproductive toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-Heptafluoropropane:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (gas)
Method: OECD Test Guideline 414
Result: negative

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 foetal

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Effects on foetal development	<p>weight Result: No effects on fertility, Effect on reproduction capacity</p> <p>: 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</p> <p>Test Type: Embryo-foetal development Species: Rat Application Route: Dermal Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight Result: Embryo-foetal toxicity</p> <p>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.</p> <p>Test Type: Embryo-foetal development Species: Rat Application Route: Subcutaneous Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight Result: Effects on newborn</p> <p>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.</p>
Reproductive toxicity - Assessment	<p>: 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.</p>

Formoterol:

Effects on fertility	<p>: Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: NOAEL: 3 mg/kg body weight Result: No effects on fertility</p>
Effects on foetal development	<p>: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 0.2 mg/kg body weight Result: Embryo-foetal toxicity, No malformations were observed.</p>

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served.

Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 3 mg/kg body weight
 Result: Malformations were observed.

Test Type: Embryo-foetal development
 Species: Rat
 Application Route: inhalation (dust/mist/fume)
 Developmental Toxicity: NOAEL: 1.2 mg/kg body weight
 Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL: 60 mg/kg body weight
 Result: Embryo-foetal toxicity, No malformations were observed.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, 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.

Formoterol:

Exposure routes : Ingestion, inhalation (dust/mist/fume)
 Target Organs : Cardio-vascular system, Central nervous system
 Assessment : Causes damage to organs.

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.

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Formoterol:

Exposure routes : Ingestion, inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****1,1,1,2,3,3,3-Heptafluoropropane:**

Species : Rat
NOAEL : 731.69 mg/l
Application Route : inhalation (gas)
Exposure time : 13 Weeks
Method : OECD Test Guideline 413

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
NOAEL : 0.0005 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 90 d

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|| Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Formoterol:

|| Species : Dog
 || LOAEL : ≥ 1.5 mg/kg
 || Application Route : Inhalation
 || Exposure time : 13 Weeks
 || Target Organs : Heart

|| Species : Rat
 || NOAEL : 0.14 mg/kg
 || Application Route : Inhalation
 || Exposure time : 13 Weeks
 || Target Organs : Heart

|| Species : Dog
 || LOAEL : 0.003 mg/kg
 || Application Route : Oral
 || Exposure time : 1 yr
 || Target Organs : Heart

|| Species : Rat
 || LOAEL : 0.3 mg/kg
 || Application Route : Oral
 || Exposure time : 1 yr
 || Target Organs : Heart

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

|| Skin contact : Symptoms: Dermatitis, Itching

Formoterol:

|| Inhalation : Target Organs: Heart

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Symptoms: Palpitation, Tremors, Dizziness, Headache, dry mouth, Nausea, Fatigue

Further information

Components:

Mometasone:

Remarks : Dermal absorption possible

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1,1,1,2,3,3,3-Heptafluoropropane:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 200 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 200 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 114 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
		NOEC (Pseudokirchneriella subcapitata (green algae)): 1.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	:	EC50: > 173.1 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

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

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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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9.6 mg/l
Exposure time: 9 d

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 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

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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

Formoterol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 114 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 94 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 30 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability**Components:****1,1,1,2,3,3,3-Heptafluoropropane:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 1 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Mometasone:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %

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Stability in water : Exposure time: 28 d
Method: OECD Test Guideline 314
: 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

Formoterol:

Partition coefficient: n-octanol/water : log Pow: 0.41

Mobility in soil

Components:

Mometasone:

Distribution among environmental compartments : log Koc: 4.02

Hazardous to the ozone layer

Components:

1,1,1,2,3,3,3-Heptafluoropropane:

Ozone-Depletion Potential : Regulation: Japan.Enforcement Ordinance of the Law concerning the Protection of the Ozone Layer through the Control of Specified Substances and other measures (Update: 2018-08-10)
Number: 6
Group: Annex F - Group I

Other adverse effects

No data available

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13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

Contaminated packaging : Please ensure aerosol cans are sprayed completely empty (including propellant)
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 1950
Proper shipping name : AEROSOLS
Class : 2.2
Packing group : Not assigned by regulation
Labels : 2.2
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1950
Proper shipping name : Aerosols, non-flammable
Class : 2.2
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas
Packing instruction (cargo aircraft) : 203
Packing instruction (passenger aircraft) : 203

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.

National Regulations

Refer to section 15 for specific national regulation.

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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.

ERG Code : 126

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Group 4, Alcohols, (400 litre), Hazardous rank II, (Remained chemical in a spray can after degassing falls under this group)

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

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	Concentration (%)	Remarks
1,1,1,2,3,3,3-heptafluoropropane	>=98.05 - <=98.09	From April 1st, 2026
Ethanol	>0 - <10	-

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
1,1,1,2,3,3,3-heptafluoropropane	From April 1st, 2026
Ethanol	-

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Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

|| Not applicable

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

Exempted from application of the High Pressure Gas Safety Act in accordance with Ministry of International Trade and Industry Notification No. 139 of 1997

Explosive Control Law

Not applicable

Vessel Safety Law

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

Aviation Law

Gases (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

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

Not applicable

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International Regulations

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

Further informationSources 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)

ACGIH / STEL : Short-term exposure limit

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

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