

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 2.14      Revision Date: 09.04.2021      SDS Number: 76095-00016      Date of last issue: 10.10.2020  
Date of first issue: 16.03.2015

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Mometasone / Formoterol Metered Dose Inhaler Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Aerosols, Category 3      H229: Pressurised container: May burst if heated.  
Long-term (chronic) aquatic hazard, Category 2      H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H229 Pressurised container: May burst if heated.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
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.

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P273    Avoid release to the environment.

### Response:

P391    Collect spillage.

### Storage:

P410 + P412    Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

### Additional Labelling

Contains fluorinated greenhouse gases. (HFC-227ea)  
1.8 % by mass of the contents are flammable.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May displace oxygen and cause rapid suffocation.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319  specific concentration limit Eye Irrit. 2; H319 >= 50 %	1.8
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410	>= 0.087 - <= 0.17

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		M-Factor (Chronic aquatic toxicity): 100	
Formoterol	43229-80-7	Acute Tox. 4; H332 Carc. 2; H351 Repr. 2; H361d STOT SE 1; H370 (Cardio-vascular system, Central nervous system) STOT RE 1; H372 (Heart)	$\geq 0.0009 - \leq 0.0087$

For explanation of abbreviations see section 16.

# Voluntarily-disclosed non-hazardous substance

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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.
- In case of eye contact : 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : Gas reduces oxygen available for breathing.

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### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

### 5.3 Advice for firefighters

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

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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : 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).

### 6.2 Environmental precautions

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.

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Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe 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.

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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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.

Advice on common storage : Do not store with the following product types:

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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

### 7.3 Specific end use(s)

Specific use(s) : No data available

No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	OELV - 15 min (STEL)	1,000 ppm	IE OEL
Mometasone	83919-23-7	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal
Formoterol	43229-80-7	TWA	0.05 µg/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	0.5 µg/100 cm <sup>2</sup>	Internal

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
1,1,1,2,3,3,3-Heptafluoropropane	Workers	Inhalation	Long-term systemic effects	61279 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	6533 mg/m <sup>3</sup>
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day

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### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
1,1,1,2,3,3,3-Heptafluoropropane	Fresh water	0.1 mg/l
	Intermittent use/release	1 mg/l
	Sewage treatment plant	1.73 mg/l
	Fresh water sediment	1.3 mg/kg
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry weight (d.w.)
	Marine sediment	2.9 mg/kg dry weight (d.w.)
	Soil	0.63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food

### 8.2 Exposure controls

#### Personal protective equipment

Skin and body protection : Skin should be washed after contact.  
Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 137  
Filter type : Self-contained breathing apparatus

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic 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  
  
Initial boiling point and boiling range : -16.5 °C  
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  
  
Flash point : No data available

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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	3,900 hPa (20 °C)
Relative density	:	5.9
Density	:	No data available
Relative vapour density	:	5.9
Particle characteristics	:	No data available
Particle size	:	No data available

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

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.
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### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
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### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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  
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  
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

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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.

#### Components:

##### Ethanol:

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

##### Mometasone:

Species : Rabbit  
Result : No eye irritation

##### Formoterol:

Species : Rabbit  
Result : No eye irritation

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### 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.

### 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

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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  
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

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### 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

##### **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:

##### **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

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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.

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.

### Formoterol:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 3 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight

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Result: Embryo-foetal toxicity, No malformations were observed.

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.

##### **Formoterol:**

Exposure routes : Ingestion, inhalation (dust/mist/fume)

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Target Organs : Heart  
Assessment : Causes 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  
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

##### **Formoterol:**

Species : Dog  
LOAEL :  $\geq 1.5$  mg/kg  
Application Route : Inhalation  
Exposure time : 13 Weeks  
Target Organs : Heart

Species : Rat



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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

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

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### Further information

#### Components:

#### **Mometasone:**

Remarks : Dermal absorption possible

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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 microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l  
Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.6 mg/l  
Exposure time: 9 d  
Species: Daphnia magna (Water flea)

#### **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

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- 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 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
- Toxicity to fish (Chronic toxicity) : NOEC: 0.00014 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.34 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility
- M-Factor (Chronic aquatic toxicity) : 100
- 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

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### 12.2 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

### 12.3 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

### 12.4 Mobility in soil

#### Components:

##### **Mometasone:**

Distribution among environmental compartments : log Koc: 4.02

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

**Global warming potential**

Regulation (EU) No 517/2014 on fluorinated greenhouse gases

**Product:**

100-year global warming potential: 3,158

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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 (including propellant)

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## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : UN 1950  
ADR : UN 1950  
RID : UN 1950  
IMDG : UN 1950  
IATA : UN 1950

### 14.2 UN proper shipping name

ADN : AEROSOLS  
ADR : AEROSOLS  
RID : AEROSOLS

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**IMDG** : AEROSOLS  
(Mometasone)

**IATA** : Aerosols, non-flammable

### 14.3 Transport hazard class(es)

**ADN** : 2

**ADR** : 2

**RID** : 2

**IMDG** : 2.2

**IATA** : 2.2

### 14.4 Packing group

**ADN**  
Packing group : Not assigned by regulation  
Classification Code : 5A  
Labels : 2.2

**ADR**  
Packing group : Not assigned by regulation  
Classification Code : 5A  
Labels : 2.2  
Tunnel restriction code : (E)

**RID**  
Packing group : Not assigned by regulation  
Classification Code : 5A  
Hazard Identification Number : 20  
Labels : 2.2

**IMDG**  
Packing group : Not assigned by regulation  
Labels : 2.2  
EmS Code : F-D, S-U

**IATA (Cargo)**  
Packing instruction (cargo aircraft) : 203  
Packing instruction (LQ) : Y203  
Packing group : Not assigned by regulation  
Labels : Non-flammable, non-toxic Gas

**IATA (Passenger)**  
Packing instruction (passenger aircraft) : 203  
Packing instruction (LQ) : Y203  
Packing group : Not assigned by regulation  
Labels : Non-flammable, non-toxic Gas

### 14.5 Environmental hazards

**ADN**  
Environmentally hazardous : yes

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### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
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### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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### SECTION 16: Other information

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

#### Full text of H-Statements

H225 : Highly flammable liquid and vapour.  
H319 : Causes serious eye irritation.  
H332 : Harmful if inhaled.  
H351 : Suspected of causing cancer.  
H360Df : May damage the unborn child. Suspected of damaging fertility.  
H361d : Suspected of damaging the unborn child.  
H370 : Causes damage to organs.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H373 : May cause damage to organs through prolonged or repeated exposure if inhaled.  
H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Carc. : Carcinogenicity  
Eye Irrit. : Eye irritation  
Flam. Liq. : Flammable liquids  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1  
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Stand-



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ardization; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Aerosol 3	H229
Aquatic Chronic 2	H411

### Classification procedure:

Based on product data or assessment
Calculation method

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.

IE / EN