

SAFETY DATA SHEET



Mometasone / Formoterol Metered Dose Inhaler Formulation



Version 2.20 Revision Date: 30.09.2023 SDS Number: 75392-00022 Date of last issue: 04.04.2023
Date of first issue: 16.03.2015

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

Recommended restrictions on use : Not applicable

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 : +1-551-430-6000

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

1.4 Emergency telephone number

+1-215-631-6999

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.

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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.

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

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.

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	1,8
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 100	>= 0,087 - <= 0,17
Formoterol	43229-80-7	Acute Tox. 4; H332 Carc. 2; H351 Repr. 2; H361d STOT SE 1; H370 (Cardio-vascular	>= 0,0009 - <= 0,0087

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		system, Central nervous system) STOT RE 1; H372 (Heart)	
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For explanation of abbreviations see section 16.
#: Voluntarily-disclosed 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.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray

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Alcohol-resistant foam
Carbon dioxide (CO₂)
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.

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. 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 absor-

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bent.

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:
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 |

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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	OEL- RL STEL/C	2.000 ppm	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
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

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 ³
	Consumers	Inhalation	Long-term systemic effects	6533 mg/m ³
Ethanol	Workers	Inhalation	Long-term systemic effects	950 mg/m ³
	Workers	Skin contact	Long-term systemic effects	343 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day

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

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	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.
 Filter type : Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : aerosol
 Colour : white to off-white
 Odour : No data available
 Odour Threshold : No data available
 pH : No data available
 Melting point/freezing point : No data available
 Initial boiling point and boiling range : -16,5 °C
 Flash point : No data available
 Evaporation rate : No data available
 Flammability (solid, gas) : Not applicable
 Upper explosion limit / Upper flammability limit : No data available
 Lower explosion limit / Lower flammability limit : No data available
 Vapour pressure : 3.900 hPa (20 °C)
 Relative vapour density : 5,9
 Relative density : 5,9
 Density : No data available

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Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	: No data available
Molecular weight	: No data available
Particle size	: No data available

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
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of exposure	: Inhalation Skin contact
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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

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

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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

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

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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
 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

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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

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

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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
 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

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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
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

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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)
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

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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
 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

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

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 : NOEC: 9,6 mg/l

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aquatic invertebrates (Chronic toxicity)

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

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

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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

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:

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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.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : 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.

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. 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.

SECTION 14: Transport information

14.1 UN number

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

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IATA : UN 1950

14.2 UN proper shipping name

ADN : AEROSOLS

ADR : AEROSOLS

RID : AEROSOLS

IMDG : AEROSOLS
(Mometasone)

IATA : Aerosols, non-flammable

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 2	2.2
ADR	: 2	2.2
RID	: 2	2.2
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 (passen- : 203

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ger aircraft)
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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**

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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.

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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
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL- RL STEL/C : Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 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; 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

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Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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.

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