# SAFETY DATA SHEET

# Mometasone / Formoterol Metered Dose Inhaler Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 10.10.2020 |
|---|---|---|---|
| 5.2 | 09.04.2021 | 75375-00016 | Date of first issue: 16.03.2015 |

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone / Formoterol Metered Dose Inhaler Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil B-2220

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification in accordance with ABNT NBR 14725 Standard**

Aerosols : Category 3

Long-term (chronic) aquatic hazard : Category 2

**GHS label elements in accordance with ABNT NBR 14725 Standard**

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/ sparks/ open flames/ hot surfaces. 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 tempera-

tures exceeding 50 °C/ 122 °F.

**Other hazards which do not result in classification**

May displace oxygen and cause rapid suffocation.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---|---|---|---|
| Ethanol# | 64-17-5 | Flammable liquids, Category 2<br>Eye irritation, Category 2A | 1,8 |
| Mometasone | 83919-23-7 | Reproductive toxicity, Category 1B<br>Specific target organ toxicity - repeated exposure (Inhalation) (Immune system, Liver, Kidney, Skin), Category 2<br>Long-term (chronic) aquatic hazard, Category 1 | >= 0,087 -<= 0,17 |
| Formoterol | 43229-80-7 | Acute toxicity (Inhalation), Category 4<br>Carcinogenicity, Category 2<br>Reproductive toxicity, Category 2<br>Specific target organ toxicity - single exposure (Cardio-vascular system, Central nervous system), Category 1<br>Specific target organ toxicity - repeated exposure (Heart), Category 1<br>Short-term (acute) aquatic hazard, Category 3 | >= 0,0009 -<= 0,0087 |

# Voluntarily-disclosed non-hazardous substance

## SECTION 4. FIRST AID MEASURES

| | | |
|---|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention immediately. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>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. |

## SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health.<br>If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. |
| Hazardous combustion products | : | Fluorine compounds<br>Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Evacuate personnel to safe areas.<br>Ventilate the area.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe vapors or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use. |
| Conditions for safe storage | : | Keep tightly closed.<br>Keep in a cool, well-ventilated place. |

Store in accordance with the particular national regulations.
Do not pierce or burn, even after use.
Keep cool. Protect from sunlight.

Materials to avoid : Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Ethanol | 64-17-5 | LT | 780 ppm<br>1.480 mg/m³ | BR OEL |
| | Further information: Degree of harmfulness: minimum | | | |
| | | STEL | 1.000 ppm | ACGIH |
| Mometasone | 83919-23-7 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm² | Internal |
| Formoterol | 43229-80-7 | TWA | 0.05 µg/m3 (OEB 5) | Internal |
| | | Wipe limit | 0.5 µg/100 cm² | 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : aerosol

Color : white to off-white

Odor : No data available

Odor 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 |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapor pressure | : | 3.900 hPa (20 °C) |
| Relative vapor density | : | 5,9 |
| Relative density | : | 5,9 |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Autoignition 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. |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

## SECTION 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:**

**Ethanol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5.000 mg/kg<br>Method: OECD Test Guideline 401 |
| Acute inhalation toxicity | : | LC50 (Rat): 124,7 mg/l<br>Exposure time: 4 h<br>Test atmosphere: vapor |

**Mometasone:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2.000 mg/kg<br><br>LD50 (Mouse): > 2.000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 3,3 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose.<br><br>LC50 (Mouse): > 3,2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 300 mg/kg<br>Application Route: Subcutaneous<br>Symptoms: Breathing difficulties |

**Formoterol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 3.130 mg/kg<br><br>LD50 (Mouse): 6.700 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 1,5 mg/l |

| | | |
|---|---|---|
| | | Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | Remarks: No data available |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 1.000 mg/kg<br>Application Route: Subcutaneous<br><br>LD50 (Mouse): 640 mg/kg<br>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 |
| 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 sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**Ethanol:**

| | | |
|---|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| Routes of exposure | : | Skin contact |
| Species | : | Mouse |
| Result | : | negative |

**Mometasone:**

| | | |
|---|---|---|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Dermal |
| Species | : | Guinea pig |
| Assessment | : | Does not cause skin sensitization. |
| Result | : | negative |
| Remarks | : | The results of a test on guinea pigs showed this substance to be a weak skin sensitizer. |

**Formoterol:**

| | | |
|---|---|---|
| Test Type | : | Maximization Test |
| Routes of exposure | : | 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<br>Result: negative<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: equivocal |

**Mometasone:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>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
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 |

**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<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Mometasone:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0,015 mg/kg body weight<br>Symptoms: Reduced embryonic survival, Reduced fetal weight. |

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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development
Species: Rat
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
Result: Effects on newborn.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 0,7 mg/kg body weight
Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - 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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,2 mg/kg body weight
Result: Embryo-fetal toxicity., No malformations were observed.

Test Type: Embryo-fetal development
Species: Rat

Application Route: Oral
Developmental Toxicity: LOAEL: 3 mg/kg body weight
Result: Malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Developmental Toxicity: NOAEL: 1,2 mg/kg body weight
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Result: Embryo-fetal 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:**

Routes of exposure : 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:**

Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Immune system, Liver, Kidney, Skin
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Formoterol:**

Routes of exposure : 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 |
| 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 | : | >= 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 y |
| Target Organs | : | Heart |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 0,3 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 1 y |
| 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<br>Symptoms: Palpitation, Tremors, Dizziness, Headache, dry mouth, Nausea, Fatigue |

**Further information**

**Components:**

**Mometasone:**

| | | |
|---|---|---|
| Remarks | : | Dermal absorption possible |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Ethanol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other | : | EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l |

| | | |
|---|---|---|
| aquatic invertebrates | | Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l<br>Exposure time: 72 h<br><br>EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l<br>Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 9,6 mg/l<br>Exposure time: 9 d |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): 6.500 mg/l<br>Exposure time: 16 h |

**Mometasone:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Menidia beryllina (Silverside)): 0,11 mg/l<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility.<br><br>LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l<br>Exposure time: 7 d<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility.<br><br>EC50 (Americamysis): > 5 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0,00014 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0,34 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility. |
| M-Factor (Chronic aquatic toxicity) | : | 100 |
| Toxicity to microorganisms | : | EC50: > 1.000 mg/l<br>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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 114 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 94 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 30 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

**Persistence and degradability**

**Components:**

**Ethanol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 84 %<br>Exposure time: 20 d |

**Mometasone:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
| Stability in water | : | Hydrolysis: 50 %(12 d)<br>Method: OECD Test Guideline 111 |

**Bioaccumulative potential**

**Components:**

**Ethanol:**

| | | |
|---|---|---|
| Partition coefficient: n- | : | log Pow: -0,35 |

octanol/water

**Mometasone:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Lepomis macrochirus (Bluegill sunfish)<br>Bioconcentration factor (BCF): 107,1<br>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 |

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.<br>Please ensure aerosol cans are sprayed completely empty (including propellant) |

## SECTION 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 |

**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 (passen- | : | 203 |

ger aircraft)

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 1950 |
| Proper shipping name | : | AEROSOLS (Mometasone) |
| Class | : | 2.2 |
| Packing group | : | Not assigned by regulation |
| Labels | : | 2.2 |
| EmS Code | : | F-D, S-U |
| Marine pollutant | : | yes |

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation**

**ANTT**

| | | |
|---|---|---|
| UN number | : | UN 1950 |
| Proper shipping name | : | AEROSOLS |
| Class | : | 2.2 |
| Packing group | : | Not assigned by regulation |
| Labels | : | 2.2 |

**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.

## SECTION 15. REGULATORY INFORMATION

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

| | | |
|---|---|---|
| National List of Carcinogenic Agents for Humans - (LINACH) | : | Not applicable |
| Brazil. List of chemicals controlled by the Federal Police | : | Not applicable |

**International Regulations**

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

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

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

### Further information

| | | |
|---|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

### Full text of other abbreviations

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| BR OEL | : | Brazil. NR 15 - Unhealthy activities and operations |
| ACGIH / STEL | : | Short-term exposure limit |
| BR OEL / LT | : | Up to 48 hours /week |

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific

context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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