SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

SECTION 1. IDENTIFICATION

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Reproductive toxicity: Category 1B
Simple Asphyxiant

GHS label elements

Hazard pictograms: 

Signal Word: Danger

Hazard Statements: H360Df May damage the unborn child. Suspected of damaging fertility.
May displace oxygen and cause rapid suffocation.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
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Version 7.0  Revision Date: 05/29/2019  SDS Number: 75391-00012  Date of last issue: 04/24/2019

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
</tr>
<tr>
<td></td>
<td>Formoterol</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

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.

Most important symptoms and effects, both acute and delayed: May damage the unborn child. Suspected of damaging fertility.

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.

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health. If the temperature rises there is danger of the vessels bursting
due to the high vapor pressure.

Hazardous combustion products: Fluorine compounds
Carbon oxides

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Evacuate personnel to safe areas.
Ventilate the area.
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSOanal PROTECTION section.

Local/Total ventilation:
Use with local exhaust ventilation.

Advice on safe handling:
Do not get on skin or clothing.
Do not breathe vapors or spray mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Do not pierce or burn, even after use.
- Keep cool. Protect from sunlight.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>1,000 ppm 1,900 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
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<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Personal protective equipment

Respiratory protection: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air
supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Skin and body protection**
- Skin should be washed after contact.

**Hygiene measures**
- Ensure that eye flushing systems and safety showers are located close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>aerosol</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>white to off-white</td>
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<tr>
<td><strong>Odor</strong></td>
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<tr>
<td><strong>Odor Threshold</strong></td>
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<tr>
<td><strong>pH</strong></td>
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<tr>
<td><strong>Melting point/freezing point</strong></td>
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<td><strong>Initial boiling point and boiling range</strong></td>
<td>2.3 °F / -16.5 °C</td>
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<td><strong>Flash point</strong></td>
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<tr>
<td><strong>Evaporation rate</strong></td>
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<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable</td>
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<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
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<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
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</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>3,900 hPa (68 °F / 20 °C)</td>
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<tr>
<td><strong>Relative vapor density</strong></td>
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</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>5.9</td>
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<tr>
<td><strong>Density</strong></td>
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<td><strong>Solubility(ies)</strong></td>
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<tr>
<td><strong>Water solubility</strong></td>
<td>No data available</td>
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<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
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<tr>
<td><strong>Autoignition temperature</strong></td>
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<tr>
<td><strong>Decomposition temperature</strong></td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.
- 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
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

Mometasone:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 3.3 mg/l
Exposure time: 4 h
### Test atmosphere:
- 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

### 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
  - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Genotoxicity in vivo:
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: equivocal

**Mometasone:**
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosomal aberration
    - Test system: Chinese hamster lung cells
    - Result: negative
  - Test Type: Chromosomal aberration
    - Test system: Chinese hamster ovary cells
    - Result: positive
  - Test Type: Mouse Lymphoma
    - Result: negative
- Genotoxicity in vivo:
  - Test Type: Micronucleus test
    - Species: Mouse
    - Application Route: Oral
    - Result: negative
  - Test Type: Chromosomal aberration
    - Species: Rat
    - Cell type: Bone marrow
    - 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
IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage the unborn child. Suspected of damaging fertility.

Components:

Ethanol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Mometasone:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced fetal weight.
Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0.06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development
Species: Rat
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0.3 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight
Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0.15 mg/kg body weight
Result: Effects on newborn.
Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Embryo-fetal toxicity: LOAEL: 0.7 mg/kg body weight
Result: Embryo-fetal toxicity, Malformations were observed.

Reproductive toxicity - 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.
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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
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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
       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
      Exposure time: 96 h

   Toxicity to daphnia and other aquatic invertebrates
   : EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
      Exposure time: 48 h

   Toxicity to algae/aquatic plants
   : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
      Exposure time: 72 h
      EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
      Exposure time: 72 h

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

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

Mometasone:
   Toxicity to fish
   : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l
      Exposure time: 96 h
      Remarks: No toxicity at the limit of solubility.

   LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
      Exposure time: 7 d
      Remarks: No toxicity at the limit of solubility.

   Toxicity to daphnia and other aquatic invertebrates
   : EC50 (Daphnia magna (Water flea)): > 5 mg/l
      Exposure time: 48 h
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Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity)

NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 0.34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

Formoterol:

Toxicity to fish

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

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 114 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

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

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

Components:

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

Mometasone:
Biodegradability: Result: Not readily biodegradable.
   Biodegradation: 50 %
   Exposure time: 28 d
   Method: OECD Test Guideline 314

Stability in water:
   Hydrolysis: 50 %(12 d)
   Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Ethanol:
   Partition coefficient: n-octanol/water: log Pow: -0.35

Mometasone:
   Bioaccumulation:
      Species: Lepomis macrochirus (Bluegill sunfish)
      Bioconcentration factor (BCF): 107.1
      Method: OECD Test Guideline 305

   Partition coefficient: n-octanol/water: log Pow: 4.68

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.
  If not otherwise specified: Dispose of as unused product.
  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 (passenger aircraft): 203

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

**49 CFR**
- UN/ID/NA number: UN 1950
- Proper shipping name: Aerosols
- Class: 2.2
- Packing group: Not assigned by regulation
- Labels: NON-FLAMMABLE GAS
- ERG Code: 126
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version: 7.0
Revision Date: 05/29/2019
SDS Number: 75391-00012
Date of last issue: 04/24/2019
Date of first issue: 03/16/2015

Marine pollutant: yes (Mometasone)

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

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

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
Simple Asphyxiant
Reproductive toxicity

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
1,1,1,2,3,3,3-Heptafluoropropane 431-89-0
Ethanol 64-17-5

California List of Hazardous Substances
Ethanol 64-17-5

California Permissible Exposure Limits for Chemical Contaminants
Ethanol 64-17-5

International Regulations

Montreal Protocol (Ozone Depleting Substances):
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
Further information

**NFPA 704:**
- Health: 0
- Flammability: 1
- Reactivity: 0
- Special hazard.

**HMIS® IV:**
- HEALTH: *
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

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

**Full text of other abbreviations**
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / STEL: Short-term exposure limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version    Revision Date:    SDS Number:    Date of last issue: 04/24/2019
7.0         05/29/2019         75391-00012    Date of first issue: 03/16/2015

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


Revision Date: 05/29/2019

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

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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