SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier's details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Aerosols: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms:

Signal Word: Warning
Hazard Statements: H229 Pressurised container: May burst if heated. H411 Toxic to aquatic life with long lasting effects.
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.
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

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

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
May displace oxygen and cause rapid suffocation.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>1,8</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0,087 - &lt;= 0,17</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>&gt;= 0,0009 - &lt;= 0,0087</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: None known.

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.
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL 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>CMP</td>
<td>1.000 ppm AR OEL</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories., Irritation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1.000 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm² Internal</td>
<td></td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5) Internal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 µg/100 cm² Internal</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 5.7   Revision Date: 05/29/2019   SDS Number: 76084-00012   Date of last issue: 24.04.2019
Date of first issue: 16.03.2015

Personal protective equipment

Respiratory protection: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Filter type: Self-contained breathing apparatus

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

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
SAFETY DATA SHEET

**Mometasone / Formoterol Metered Dose Inhaler Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7</td>
<td>05/29/2019</td>
<td>76084-00012</td>
<td>24.04.2019</td>
<td>16.03.2015</td>
</tr>
</tbody>
</table>

- 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.
  - 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: 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

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 months
- 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 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
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**: 90d
- **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**: \( \geq 1.5 \text{ mg/kg} \)
- **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
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

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
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 : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2
plants

Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity):

NOEC (Pimephales promelas (fathead minnow)): 0,00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 0,34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity):

100

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.
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

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.

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
Argentina. Carcinogenic Substances and Agents Registry : Not applicable

Control of precursors and essential chemicals for the preparation of drugs : Ethanol

International Regulations
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Montreal Protocol (Ozone Depleting Substances) : 1,1,1,2,3,3,3-Heptfluoropropane

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

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits
ACGIH / STEL : Short-term exposure limit
AR OEL / CMP : TLV (Threshold Limit Value)

AICS - Australian Inventory of Chemical Substances; 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; CPR - Controlled Products Regulations; 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.

AR / Z8