SECTION 1. IDENTIFICATION

Product name : Mometasone Metered Dose Inhaler Formulation
Other means of identification : No data available

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 the Hazardous Products Regulations
Gases under pressure : Dissolved gas
Reproductive toxicity : Category 1B
Simple Asphyxiant : Category 1

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H280 Contains gas under pressure; may explode if heated.
                   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:
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formula-
tion

Version 4.3 Revision Date: 09/13/2019 SDS Number: 25977-00014 Date of last issue: 05/31/2019 Date of first issue: 10/28/2014

P405 Store locked up.
P410 + P403 Protect from sunlight. Store in a well-ventilated place.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<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>&gt;= 1.8 - &lt;= 2.5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.08 - &lt;= 0.18</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 (see section 8).

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

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.

Carbon oxides
Fluorine compounds

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.

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

Evacuate personnel to safe areas.
Ventilate the area.
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

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.

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe 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.


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 1,880 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA EV</td>
<td>1,000 ppm 1,880 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</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>
</tbody>
</table>

Further information: Skin

Wipe limit 10 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
Hygiene measures
: Skin should be washed after contact.
: If exposure to chemical is likely during typical use, provide
eye flushing systems and safety showers close to the
working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aerosol containing a dissolved gas</td>
</tr>
<tr>
<td>Color</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>odorless</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>-16 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 reac-
tions : 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

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

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

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.

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

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.

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

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.

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Mometasone:**

Remarks: Based on available data, the classification criteria are not met.

**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
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

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

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 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.

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

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
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formulation

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

TDG
UN number: UN 1950
Proper shipping name: AEROSOLS
Class: 2.2
Packing group: Not assigned by regulation
Labels: 2.2
ERG Code: 126
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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formula-
tion

Version 4.3  Revision Date: 09/13/2019  SDS Number: 25977-00014  Date of last issue: 05/31/2019  Date of first issue: 10/28/2014

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / STEL : Short-term exposure limit
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / STEL : short-term exposure limit
CA QC OEL / TWAERV : Time-weighted average exposure value


Revision Date : 09/13/2019

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.

CA / Z8