SAFETY DATA SHEET

Mometasone Dry Powder Inhaler Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Dry Powder 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: EHSDATASEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Inhalation): Category 2 (Immune system, Liver, Kidney, Skin)
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal Word: Danger

Hazard Statements:
H360Df May damage the unborn child. Suspected of damaging fertility.
H373 May cause damage to organs (Immune system, Liver, Kidney, Skin) through prolonged or repeated exposure if inhaled.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 10 -&lt; 20</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 : If in eyes, rinse well with water.
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 : May damage the unborn child. Suspected of damaging fertility.
delayed May cause damage to organs through prolonged or repeated exposure if inhaled. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides Chlorine compounds

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: 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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust. 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents Organic peroxides 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>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></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
</tr>
</tbody>
</table>

Further information: Skin

Engineering measures: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from
stationary container, ventilated enclosure, etc.).
All engineering controls should be implemented by facility
design and operated in accordance with GMP principles to
protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.

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 : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions,
mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a
potential for direct contact to the face with dusts, mists, or
aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the
task being performed (e.g., sleevelets, apron, gauntlets,
disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially
contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide
eye flushing systems and safety showers close to the
working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of
engineering controls, proper personal protective equipment,
appropriate degowning and decontamination procedures,
industrial hygiene monitoring, medical surveillance and the
use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : white
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : 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 : May form explosive dust-air mixture during processing, handling or other means. 
Can react with strong oxidizing agents.
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Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.

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:

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:

Mometasone:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation:
Not classified based on available information.

Components:

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:

Mometasone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Assessment</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Does not cause skin sensitization.</td>
<td>negative</td>
<td>The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Mometasone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Chromosomal aberration</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster lung cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
<td>Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Mouse Lymphoma</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity - Weight of evidence does not support classification as a germ
Assessment  cell mutagen.

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Mometasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Dose</td>
<td>0.067 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Exposure time</td>
<td>19 Months</td>
</tr>
<tr>
<td>Dose</td>
<td>0.160 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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

**Components:**

**Mometasone:**

**Effects on fertility**

<table>
<thead>
<tr>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td>Fertility: NOAEL: 0,015 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms: Reduced embryonic survival, Reduced fetal weight.</td>
</tr>
<tr>
<td>Result: No effects on fertility., Effect on reproduction capacity.</td>
</tr>
</tbody>
</table>

**Effects on fetal development**

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
</tr>
<tr>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td>Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryotoxic effects., Teratogenicity and developmental toxicity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Dermal</td>
</tr>
<tr>
<td>Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryo-fetal toxicity.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Dermal</td>
</tr>
<tr>
<td>Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryo-fetal toxicity., Malformations were observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
</table>

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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
May cause damage to organs (Immune system, Liver, Kidney, Skin) through prolonged or repeated exposure if inhaled.

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.

Repeated dose toxicity

Components:
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:
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: EC50 (Daphnia magna (Water flea)): > 5 mg/l
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- **aquatic invertebrates**  
  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.

- **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.

**Persistence and degradability**

**Components:**

**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:**

**Mometasone:**

Bioaccumulation:

Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107,1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water

*Bioconcentration factor (BCF): 107.1*

**Mobility in soil**

**Components:**

**Mometasone:**

Distribution among environmental compartments

*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.

SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**

- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Mometasone)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes
IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
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 : Not applicable

International Regulations

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
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