SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Suspension Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil B-2220
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Short-term (acute) aquatic hazard: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms: 

Hazard Statements: H402 Harmful to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements: Prevention:
P273 Avoid release to the environment.
Response:
P391 Collect spillage.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
**SAFETY DATA SHEET**

Mometasone Suspension Formulation

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Reproductive toxicity, Category 1B, Specific target organ toxicity - repeated exposure (Inhalation), (Immune system, Liver, Kidney, Skin), Category 2, Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Acute toxicity (Oral), Category 3, Acute toxicity (Inhalation), Category 2, Acute toxicity (Dermal), Category 3, Skin corrosion, Category 1, Serious eye damage, Category 1, Short-term (acute) aquatic hazard, Category 1, Long-term (chronic) aquatic hazard, Category 2</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
</tbody>
</table>

**SECTION 4. FIRST AID MEASURES**

- **If inhaled**: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
- **In case of skin contact**: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
- **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 if symptoms occur. Rinse mouth thoroughly with water.
- **Most important symptoms and effects, both acute and delayed**: None known.
- **Protection of first-aiders**: No special precautions are necessary for first aid responders.
- **Notes to physician**: Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

- **Suitable extinguishing media**: Water spray, Alcohol-resistant foam
SAFETY DATA SHEET
Mometasone Suspension Formulation

Unsuitable extinguishing media: None known.

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- 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:
- Wear self-contained breathing apparatus for firefighting if necessary.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- 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/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure.
SAFETY DATA SHEET

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Version 3.1  Revision Date: 16.10.2020  SDS Number: 23585-00017  Date of last issue: 23.03.2020
Date of first issue: 21.10.2014

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.

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

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

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>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
</tr>
</tbody>
</table>

Engineering measures: 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. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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: Combined particulates and organic vapor type

Hand protection: Chemical-resistant gloves

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid
Color: white to off-white, opaque
Odor: odorless
Odor Threshold: No data available
pH: 4.3 - 4.9
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
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: No data available
Relative vapor density: No data available
Relative density: No data available
Density: 1 g/cm³
Solubility(ies):
- Water solubility: soluble
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature : No data available

Viscosity
  Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : 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:

Cellulose:
Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

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

Benzalkonium chloride:
Acute oral toxicity: LD50 (Rat): 240 mg/kg
Acute inhalation toxicity: LC50 (Rat, male): > 0.05 - 0.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
Mometasone:
Species: Rabbit
Result: No skin irritation

Benzalkonium chloride:
Species: Human
Result: Corrosive after 4 hours or less of exposure

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

Components:
Mometasone:
Species: Rabbit
Result: No eye irritation

Benzalkonium chloride:
Species: Rabbit
Result: Irreversible effects on the eye

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

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.

Benzalkonium chloride:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Mometasone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vitro: Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Genotoxicity in vitro: Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Genotoxicity in vitro: 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.

Benzalkonium chloride:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
  - Remarks: Based on data from similar materials

- Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative
  - Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

Carcinogenicity:
Not classified based on available information.

Components:

Cellulose:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 72 weeks
- Result: negative

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

Benzalkonium chloride:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Species: Mouse
Application Route: Skin contact
Exposure time: 80 weeks
Result: negative

Species: Rabbit
Application Route: Skin contact
Exposure time: 90 weeks
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
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.

Benzalkonium chloride:

Effects on fertility:
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development:
Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

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 exposure.

Benzalkonium chloride:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: >= 9.000 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

**Benzalkonium chloride:**
- **Species:** Rat
- **NOAEL:** \( \geq 100 \text{ mg/kg} \)

**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:**
- **Cellulose:**
  - Toxicity to fish:
    - LC50 (Oryzias latipes (Japanese medaka)): \( > 100 \text{ mg/l} \)
    - Exposure time: 48 h
    - Remarks: Based on data from similar materials

- **Mometasone:**
  - Toxicity to fish:
    - LC50 (Menidia beryllina (Silverside)): 0,11 mg/l
    - Exposure time: 96 h
    - Remarks: No toxicity at the limit of solubility.
<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50</td>
<td>(Cyprinodon variegatus (sheepshead minnow))</td>
<td>&gt; 5 mg/l (7 d)</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

| EC50    | (Daphnia magna (Water flea)) | > 5 mg/l (48 h) |
| Remarks | No toxicity at the limit of solubility. |

| EC50    | (Americamysis) | > 5 mg/l (96 h) |
| Remarks | No toxicity at the limit of solubility. |

**Toxicity to algae/aquatic plants**

| EC50    | (Pseudokirchneriella subcapitata (green algae)) | > 3.2 mg/l (72 h) |
| Remarks | No toxicity at the limit of solubility. |

**Toxicity to fish (Chronic toxicity)**

| NOEC    | (Pimephales promelas (fathead minnow)) | 0,00014 mg/l (32 d) |
| Remarks | No toxicity at the limit of solubility. |

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

| NOEC    | (Daphnia magna (Water flea)) | 0,34 mg/l (21 d) |
| Remarks | No toxicity at the limit of solubility. |

**M-Factor (Chronic aquatic toxicity)**

| EC50    | > 1.000 mg/l (3 h) |
| Test Type: | Respiration inhibition |
| Method: | OECD Test Guideline 209 |
| Remarks: | No toxicity at the limit of solubility. |

| NOEC    | 1.000 mg/l (3 h) |
| Test Type: | Respiration inhibition |
| Method: | OECD Test Guideline 209 |
| Remarks: | No toxicity at the limit of solubility. |

**Benzalkonium chloride:**

**Toxicity to fish**

| LC50    | (Pimephales promelas (fathead minnow)) | 0,28 mg/l (96 h) |

**Toxicity to daphnia and other aquatic invertebrates**

| EC50    | (Daphnia magna (Water flea)) | 0,0056 mg/l (48 h) |

**Toxicity to algae/aquatic plants**

| ErC50   | (Chlorella pyrenoidosa) | 0,09 mg/l (72 h) |
**SAFETY DATA SHEET**

**Mometasone Suspension Formulation**

Version 3.1  
Revision Date: 16.10.2020  
SDS Number: 23585-00017  
Date of last issue: 23.03.2020  
Date of first issue: 21.10.2014

**M-Factor (Acute aquatic toxicity):** 100

**Toxicity to fish (Chronic toxicity):** NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l  
Exposure time: 34 d

**Persistence and degradability**

**Components:**

**Cellulose:**  
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

**Benzalkonium chloride:**  
Biodegradability: Result: Readily biodegradable.  
Method: OECD Test Guideline 301D  
Remarks: Based on data from similar materials

**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: log Pow: 4.68

**Benzalkonium chloride:**  
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): < 500  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: 1.692  
Remarks: Calculation

**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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Benzalkonium chloride)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.
(Mometasone, Benzalkonium chloride)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Benzalkonium chloride)
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.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
SAFETY DATA SHEET

Mometasone Suspension Formulation

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Date of first issue: 21.10.2014

N.O.S. (Mometasone, Benzalkonium chloride)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations
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)
ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
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.

BR / Z8