SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Ointment Formulation

Version 1.5  Revision Date: 09/13/2019  SDS Number: 1758840-00006  Date of last issue: 24.04.2019
Date of first issue: 14.06.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Mometasone Ointment Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Skin irritation, Category 2 : H315: Causes skin irritation.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Long-term (chronic) aquatic hazard, Category 2 : H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Warning
   Hazard statements : H315 Caused skin irritation.
                      H319 Causes serious eye irritation.
                      H411 Toxic to aquatic life with long lasting effects.
   Precautionary statements : Prevention:
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Mometasone Ointment Formulation**

**Version** 1.5  
**Revision Date:** 09/13/2019  
**SDS Number:** 1758840-00006  
**Date of last issue:** 24.04.2019  
**Date of first issue:** 14.06.2017

P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.

**Response:**  
P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P391 Collect spillage.

### 2.3 Other hazards
None known.

**SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>203-489-0</td>
<td>603-053-00-3</td>
<td></td>
<td>Skin Irrit.2; H315 Eye Irrit.2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td></td>
<td></td>
<td></td>
<td>Repr.1B; H360Df STOT RE2; H373 Aquatic Chronic1; H410</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 100</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures**

#### 4.1 Description of 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.

**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).

**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: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes skin irritation. Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

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

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
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures

See Engineering measures under EXPOSURE CONTROLS/PERSOAL 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 swallow. Do not get in 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>T</td>
<td>20 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.</td>
<td></td>
<td></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>Further information</td>
<td>Skin</td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>44,4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>49 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>98 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>42 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>7,8 mg/m3</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves

Remarks

Skin and body protection

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-
Mometasone Ointment Formulation

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour 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>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 93,3 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Ointment Formulation

Flammability (liquids) : Not applicable
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure : Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

2-Methyl-2,4-pentanediol:
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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
Causes skin irritation.

Components:

2-Methyl-2,4-pentanediol:

Result: Skin irritation
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

Mometasone:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

2-Methyl-2,4-pentanediol:

Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Mometasone:

Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

2-Methyl-2,4-pentanediol:
Mometasone Ointment Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Test Type: Maximisation Test</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
</tr>
<tr>
<td></td>
<td>Test Type: OECD Test Guideline 406</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Species: Guinea pig</td>
<td>Test Type: Chromosomal aberration test in vitro</td>
</tr>
<tr>
<td></td>
<td>Assessment: Does not cause skin sensitisation.</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Test Type: Mouse Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.</td>
<td>Result: negative</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Micronucleus test</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 476</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chinese hamster lung cells</td>
<td>Test Type: Mouse Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.
Mometasone Ointment Formulation

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
Not classified based on available information.

Components:

2-Methyl-2,4-pentanediol:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 421  
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

Mometasone:
Effects on fertility: Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous
Mometasone Ointment Formulation

Fertility: NOAEL: 0,015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced foetal weight
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development:

- Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Subcutaneous
  Embryo-foetal toxicity: LOAEL: 0,06 mg/kg body weight
  Result: Embryotoxic effects, Teratogenicity and developmental toxicity

- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Dermal
  Embryo-foetal toxicity: LOAEL: 0,3 mg/kg body weight
  Result: Embryo-foetal toxicity

- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Dermal
  Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight
  Result: Embryo-foetal toxicity, Malformations were observed.

- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Subcutaneous
  Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight
  Result: Effects on newborn

- Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Oral
  Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight
  Result: Embryo-foetal 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:
Exposure routes: 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:

2-Methyl-2,4-pentanediol:
Species: Rat
NOAEL: >= 450 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408

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.
Mometasone Ointment 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>1.5</td>
<td>09/13/2019</td>
<td>1758840-00006</td>
<td>24.04.2019</td>
<td>14.06.2017</td>
</tr>
</tbody>
</table>

**Components:**

**Mometasone:**
Not applicable

**Experience with human exposure**

**Components:**

**2-Methyl-2,4-pentanediol:**
Eye contact: Target Organs: Eyes
Symptoms: Irritation

**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**

**12.1 Toxicity**

**Components:**

**2-Methyl-2,4-pentanediol:**
Toxicity to fish: LC50 (Gambusia affinis (Mosquito fish)): 8.510 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceridaphnia dubia (water flea)): 2.800 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 429 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): > 429 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: NOEC : 200 mg/l
Exposure time: 10 d

**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 (sheephead 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 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

Toxicity to fish (Chronic toxicity):

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

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

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

M-Factor (Chronic aquatic toxicity): 100

12.2 Persistence and degradability

Components:

2-Methyl-2,4-pentanediol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

12.3 Bioaccumulative potential

Components:

2-Methyl-2,4-pentanediol:
Partition coefficient: n-octanol/water: log Pow: 0
Remarks: Calculation

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

12.4 Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste han-
SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>Code</th>
<th>UN number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3077</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3077</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Code</th>
<th>Proper Shipping Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Mometasone)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Code</th>
<th>Hazard Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Code</th>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>M7</td>
<td>90</td>
<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>III</td>
<td>M7</td>
<td>90</td>
<td>9</td>
</tr>
</tbody>
</table>
Mometasone Ointment Formulation

Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Ointment Formulation

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H360DF : May damage the unborn child. Suspected of damaging fertility.
H373 : May cause damage to organs through prolonged or repeated exposure if inhaled.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Mometasone Ointment Formulation


classification: H315, H319, H315, H411

Further information

Sources of key data used to compile the Safety Data Sheet

Classification of the mixture:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method
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.

NO / EN