Mometasone Ointment Formulation

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 : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

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  Causes skin irritation.
- H319  Causes serious eye irritation.
- H411  Toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:
- P264  Wash skin thoroughly after handling.
- P273  Avoid release to the environment.
Mometasone Ointment Formulation

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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REA CH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REA CH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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>Index-No. 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 RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; 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 so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions: Avoid release to the environment. 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
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. Wash skin thoroughly after handling. 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: Exposure limits

<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>
</tbody>
</table>

Further information: Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.
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<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>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>49 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>15 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1,5 mg/kg bw/day</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9,33 mg/kg food</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>Fresh water</td>
<td>0,429 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,043 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>4,29 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1,59 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,159 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,066 mg/kg dry weight (d.w.)</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: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: ointment
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flammability (solid, gas): Not classified as a flammability hazard
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: > 93.3 °C
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water
Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : No data available

9.2 Other information
Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : 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 hazard classes as defined in Regulation (EC) No 1272/2008

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:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Mometasone:
Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

Germ cell mutagenicity
Not classified based on available information.

Components:

2-Methyl-2,4-pentanediol:
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

Test Type: Chromosome aberration test in vitro
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
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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
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 and NOAEL

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0,00013 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0,0005 mg/l</td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver</td>
</tr>
</tbody>
</table>

### Aspiration Toxicity
Not classified based on available information.

### Components
- **Mometasone**: Not applicable

### 11.2 Information on other hazards

#### Endocrine disrupting properties

**Product**:
- **Assessment**: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 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 (Ceriodaphnia 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 (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 microorganisms

<table>
<thead>
<tr>
<th>EC50</th>
<th>&gt; 1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC</th>
<th>1.000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>3 h</td>
</tr>
<tr>
<td>Test Type</td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

## Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>NOEC</th>
<th>0.00014 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>32 d</td>
</tr>
<tr>
<td>Species</td>
<td>Pimephales promelas (fathead minnow)</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NOEC</th>
<th>0.34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Species</td>
<td>Daphnia magna (Water flea)</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

## M-Factor (Chronic aquatic toxicity)

| M-Factor | 100 |

### 12.2 Persistence and degradability

#### Components:

#### 2-Methyl-2,4-pentanediol

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>81 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 301F</td>
</tr>
</tbody>
</table>

#### Mometasone

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>50 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 314</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stability in water</th>
<th>Hydrolysis: 50 % (12 d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 111</td>
</tr>
</tbody>
</table>

### 12.3 Bioaccumulative potential

#### Components:

#### 2-Methyl-2,4-pentanediol

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Calculation</td>
</tr>
</tbody>
</table>
Mometasone Ointment Formulation

12.4 Mobility in soil

**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

12.5 Results of PBT and vPvB assessment

**Product:**

- **Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**

- **Endocrine disrupting potential:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

- **ADN:** UN 3077
- **ADR:** UN 3077
Mometasone Ointment Formulation

RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
IATA : Environmentally hazardous substance, solid, n.o.s. (Mometasone)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

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

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

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

IMDG
Packing group : III
Mometasone Ointment Formulation

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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 de- : Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Ointment Formulation

Version 1.8 Revision Date: 09.04.2021 SDS Number: 1758840-00009 Date of last issue: 10.10.2020
Date of first issue: 14.06.2017

To complete the ozone layer
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import
of dangerous chemicals
major-accident hazards involving dangerous substances.

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<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
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA
FOR-2011-12-06-1358 / T : Ceiling

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada);
Further information

Classification of the mixture:
Skin Irrit. 2 H315 Calculation method
Eye Irrit. 2 H319 Calculation method
Aquatic Chronic 2 H411 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