SAFETY DATA SHEET

Mometasone Lotion Formulation

Section 1: Identification

Product name : Mometasone Lotion Formulation
Manufacturer or supplier’s details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

Section 2: Hazard identification

GHS Classification
Flammable liquids : Flam. Liq.2
Serious eye damage/eye irritation : 2A
Specific target organ toxicity - single exposure : STOT SE3

GHS label elements
Hazard pictograms
Signal word : Danger
Hazard statements : H225 Highly flammable liquid and vapour.
                    H319 Causes serious eye irritation.
                    H336 May cause drowsiness or dizziness.
Precautionary statements : Prevention:
                           P210 Keep away from heat/sparks/open flames/hot surfaces.
                           No smoking.
                           P233 Keep container tightly closed.
                           P241 Use explosion-proof electrical/ ventilating/ lighting equip-
                           ment.
                           P242 Use only non-sparking tools.
SAFETY DATA SHEET

Mometasone Lotion Formulation

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&lt; 0.3</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with 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.

**Most important symptoms and effects, both acute and delayed:**
- Causes serious eye irritation.
- May cause drowsiness or dizziness.

**Protection of first-aiders:**
- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**Notes to physician:**
- Treat symptomatically and supportively.

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### Section 5: Fire-fighting measures

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

**Unsuitable extinguishing media:**
- High volume water jet

**Specific hazards during firefighting:**
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapours may form explosive mixtures with air.
- 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 firefighters:**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

**Hazchem Code:**
- 2YE

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### Section 6: Accidental release measures

**Personal precautions, protective equipment and emergency procedures:**
- Remove all sources of ignition.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions:**
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- 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:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If dyked 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: If sufficient ventilation is unavailable, use with local exhaust ventilation.
- If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- 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.
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

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 labelled containers.
- Store locked up.
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.  

Materials to avoid:  
Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents  
Flammable gases  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Poisonous gases  
Explosives

Section 8: Exposure controls/personal protection

Components 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>Propan-2-ol</td>
<td>67-63-0</td>
<td>WES-TWA</td>
<td>400 ppm 983 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES- STEL</td>
<td>500 ppm 1,230 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit 10 µg/100 cm² Internal

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 mg/l</td>
<td>ACGIH BEI</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
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 vapour type

Hand protection:

Material: Chemical-resistant gloves

Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

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: lotion

Colour: colourless, clear, to, translucent

Odour: No data available

Odour Threshold: No data available

pH: 4.5

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: 18.4 °C

Method: closed cup

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): Ignitable (see flash point)
SAFETY DATA SHEET

Mometasone Lotion Formulation

Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition 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
Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.

Components:

Propan-2-ol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapour
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Propylene glycol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
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
Not classified based on available information.

Components:

Propan-2-ol:
Species : Rabbit
Result : No skin irritation

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Mometasone:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Propan-2-ol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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:

Propan-2-ol:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
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.

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Propan-2-ol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

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: Intraperitoneal injection Result: negative

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection 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:

Propan-2-ol:  
Species: Rat  
Application Route: inhalation (vapour)  
Exposure time: 104 weeks  
Method: OECD Test Guideline 451  
Result: negative

Propylene glycol:  
Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
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

Reproductive toxicity  
Not classified based on available information.
Components:

Propan-2-ol:
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Result: negative
- Effects on foetal development: Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Ingestion
  Result: negative

Propylene glycol:
- Effects on fertility: Test Type: Three-generation reproduction toxicity study
  Species: Mouse
  Application Route: Ingestion
  Result: negative
- Effects on foetal development: Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Ingestion
  Result: negative

Mometasone:
- Effects on fertility: Test Type: Fertility
  Species: Rat
  Application Route: Subcutaneous
  Fertility: NOAEL: 0.015 mg/kg body weight
  Symptoms: Reduced embryonic survival, Reduced 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
May cause drowsiness or dizziness.

Components:

Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

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:

Propan-2-ol:
Species: Rat
NOAEL: 12.5 mg/l
Application Route: inhalation (vapour)
Exposure time: 104 Weeks

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr
## Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Oral Route</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Oral Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>0.5 mg/kg</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Inhalation Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Inhalation (dust/mist/fume)</td>
<td>0.00013 mg/l</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Inhalation Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Inhalation (dust/mist/fume)</td>
<td>0.0005 mg/l</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:

\[ \text{Not applicable} \]

### Experience with human exposure

#### Components:

### Mometasone:

#### Inhalation

\[ \text{Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion} \]

#### Skin contact

\[ \text{Symptoms: Dermatitis, Itching} \]

### Further information

#### Components:

### Mometasone:

#### Remarks

\[ \text{Dermal absorption possible} \]
Section 12: Ecological information

Ecotoxicity

Components:

Propan-2-ol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h
Toxicity to microorganisms: EC50 (Pseudomonas putida): > 1,050 mg/l
Exposure time: 16 h

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
Toxicity to microorganisms: NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d
NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Mometasone:
Toxicity to fish: LC50 (Menidia beryllina (Silverside)): 0.11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility
LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility
EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2
plants

Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity)

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

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

Toxicity to microorganisms

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Persistence and degradability

Components:

Propan-2-ol:
Biodegradability: Result: rapidly degradable
BOD/COD: BOD: 1.19 (BOD5)/COD: 2.23BOD/COD: 53 %

Propylene glycol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98.3 %
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
Bioaccumulative potential

Components:

Propan-2-ol:
Partition coefficient: n-octanol/water : log Pow: 0.05

Propylene glycol:
Partition coefficient: n-octanol/water : log Pow: -1.07

Mometasone:
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water : log Pow: 4.68

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments : log Koc: 4.02

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG
UN number : UN 1219
Proper shipping name : ISOPROPANOL SOLUTION
Class : 3
Packing group : II
Labels : 3

IATA-DGR
UN/ID No. : UN 1219
Proper shipping name: Isopropanol solution
Class: 3
Packing group: II
Labels: Flammable Liquids
Packing instruction (cargo aircraft): 364
Packing instruction (passenger aircraft): 353

**IMDG-Code**
UN number: UN 1219
Proper shipping name: ISOPROPANOL SOLUTION
(Mometasone)
Class: 3
Packing group: II
Labels: 3
EmS Code: F-E, S-D
Marine pollutant: yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**

**NZS 5433**
UN number: UN 1219
Proper shipping name: ISOPROPANOL SOLUTION
Class: 3
Packing group: II
Labels: 3
Hazchem Code: 2YE

**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**

**HSNO Approval Number**
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

**HSW Controls**
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**
AICS: not determined
SAFETY DATA SHEET

Mometasone Lotion Formulation

Section 16: Other information

Further information


Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA, ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

AICS - Australian Inventory of Chemical Substances; 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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
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.

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