SAFETY DATA SHEET

Betamethasone (0.05%) Ointment Formulation

Version 3.0  Revision Date: 23.03.2020  SDS Number: 1681974-00007  Date of last issue: 13.09.2019  Date of first issue: 18.05.2017

Section 1: Identification

Product name: Betamethasone (0.05%) Ointment 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

Reproductive toxicity: Repr.1B
Specific target organ toxicity - repeated exposure: STOT RE1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements

Hazard pictograms:

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td></td>
<td>8009-03-8</td>
<td>&gt;= 60 &lt;= 100</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
<td>57-55-6</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td></td>
<td>1323-39-3</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Betamethasone</td>
<td></td>
<td>378-44-9</td>
<td>&gt;= 0.01 &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 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 : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

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

Most important symptoms and effects, both acute and delayed : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

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

Notes to physician : Treat symptomatically and supportively.
Section 5: Fire-fighting measures

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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: 2Z

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
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.

Advice on safe handling: Do not get on skin or clothing.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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.
- Store in accordance with the particular national regulations.

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

### Section 8: Exposure controls/personal protection

#### 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>Petrolatum</td>
<td>8009-03-8</td>
<td>WES-TWA (Mist)</td>
<td>5 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method that does not collect vapour.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-STEEL (Mist)</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</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></td>
<td></td>
<td></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>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>WES-TWA</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
</tbody>
</table>
Engineering measures: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

Personal protective equipment:

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

Remarks: Consider double gloving.

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

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

Section 9: Physical and chemical properties

Appearance: ointment

Colour: white to off-white

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: > 93.3 °C
Evaporation rate : Not applicable

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
Vapour pressure : No data available

Relative vapour density : Not applicable
Relative density : No data available
Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

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
Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.
Section 11: Toxicological information

Exposure routes:
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**Petrolatum:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
  - Remarks: Based on data from similar materials

- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity
  - Remarks: Based on data from similar materials

**Propylene glycol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

**Propylene glycol monostearate:**
- Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg

**betamethasone:**
- Acute oral toxicity:
  - LD50 (Rat): > 5,000 mg/kg
  - LD50 (Mouse): > 4,500 mg/kg

- Acute inhalation toxicity:
  - LC50 (Rat): 0.4 mg/l
  - Exposure time: 4 h

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Petrolatum:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
Remarks: Based on data from similar materials

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

Propylene glycol monostearate:
- Result: No skin irritation

Betamethasone:
- Species: Rabbit
- Result: Mild skin irritation

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

Components:

Petrolatum:
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
- Remarks: Based on data from similar materials

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

Betamethasone:
- 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:

Petrolatum:
- Test Type: Buehler Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative
- Remarks: Based on data from similar materials
Propylene glycol:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative

betamethasone:
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Weak sensitizer

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

betamethasone:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Test Type: Chromosome aberration test in vitro
  Result: positive
- Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
cytogenetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

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

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

### Components:

**Petrolatum:**
- **Species:** Rat  
- **Application Route:** Ingestion  
- **Exposure time:** 2 Years  
- **Result:** negative

**Propylene glycol:**
- **Species:** Rat  
- **Application Route:** Ingestion  
- **Exposure time:** 2 Years  
- **Result:** negative

**Reproductive toxicity**  
May damage the unborn child.

### Components:

**Petrolatum:**
- **Effects on fertility**  
  - **Test Type:** Reproduction/Developmental toxicity screening test  
  - **Species:** Rat  
  - **Application Route:** Ingestion  
  - **Result:** negative  
  - **Remarks:** Based on data from similar materials

- **Effects on foetal development**  
  - **Test Type:** Embryo-foetal development  
  - **Species:** Rat  
  - **Application Route:** Skin contact  
  - **Result:** negative  
  - **Remarks:** Based on data from similar materials

**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
betamethasone:

Effects on foetal development:
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.
Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:

betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Petrolatum:
Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr
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- **Species**: Rabbit
  - **LOAEL**: 0.05 %
  - **Application Route**: Skin contact
  - **Exposure time**: 10 - 30 d
  - **Target Organs**: Pituitary gland, Immune system, muscle

- **Species**: Rat
  - **LOAEL**: 0.05 %
  - **Application Route**: Skin contact
  - **Exposure time**: 8 Weeks
  - **Target Organs**: thymus gland

- **Species**: Mouse
  - **LOAEL**: 0.1 %
  - **Application Route**: Skin contact
  - **Exposure time**: 8 Weeks
  - **Target Organs**: thymus gland

- **Species**: Dog
  - **LOAEL**: 0.05 mg/kg
  - **Application Route**: Oral
  - **Exposure time**: 28 d
  - **Target Organs**: Blood, thymus gland, Adrenal gland

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

- **betamethasone**:
  - **Inhalation**: Target Organs: Adrenal gland
  - **Skin contact**: Symptoms: Redness, pruritis, Irritation

**Section 12: Ecological information**

**Ecotoxicity**

**Components:**

- **Petrolatum**:
  - **Toxicity to fish**:
    - LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
    - Exposure time: 96 h
    - Test substance: Water Accommodated Fraction
    - Method: OECD Test Guideline 203
    - Remarks: Based on data from similar materials
  - **Toxicity to daphnia and other aquatic invertebrates**:
    - EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
    - Exposure time: 48 h
    - Test substance: Water Accommodated Fraction
    - Remarks: Based on data from similar materials
  - **Toxicity to algae/aquatic plants**:
    - NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
### Propylene glycol:

<table>
<thead>
<tr>
<th>Test endpoint</th>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Onchorhynchus mykiss (rainbow trout)): 40,613 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (chronic toxicity)</td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l</td>
<td>7 d</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>NOEC (Pseudomonas putida): &gt; 20,000 mg/l</td>
<td>18 h</td>
<td></td>
</tr>
</tbody>
</table>

### betamethasone:

<table>
<thead>
<tr>
<th>Test endpoint</th>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l</td>
<td>32 d</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (chronic toxicity)</td>
<td>NOEC (Daphnia magna (water flea)): 8 mg/l</td>
<td>21 d</td>
<td></td>
</tr>
</tbody>
</table>

**Test substance:** Water Accommodated Fraction  
**Method:** OECD Test Guideline 201
Persistence and degradability

**Components:**

**Petrolatum:**
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 31%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F
  - Remarks: Based on data from similar materials

**Propylene glycol:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 98.3%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F

Bioaccumulative potential

**Components:**

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

**betamethasone:**
- Partition coefficient: n-octanol/water: log Pow: 2.11

Mobility in soil
No data available

Other adverse effects
No data available

Section 13: Disposal considerations

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging:
  - Empty containers should be taken to an approved waste handling site for recycling or disposal.
  - If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

**UNRTDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
- Class: 9
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Date of first issue: 18.05.2017

Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (betamethasone)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class: 9
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
EmS Code: F-A, S-F
Marine pollutant: yes

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

National Regulations

NZS 5433
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class: 9
Packing group: III
Labels: 9
Hazchem Code: 2Z

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
HSG 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
- DSL: not determined
- IECSC: not determined

Section 16: Other Information

Further information

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

Date format: dd.mm.yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- 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 Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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.
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