SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexchlorpheniramine Maleate Solid Formulation

Manufacturer or supplier's details
Company : MSD
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park
          New South Wales, 2113 Australia
Telephone : (61)-02-8988-8000
Emergency telephone number : (61)-02-8988-8000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation : Category 2A
Specific target organ toxicity - single exposure : Category 3

GHS label elements
Hazard pictograms : !
Signal word : Warning
Hazard statements : H319 Causes serious eye irritation.
                   H336 May cause drowsiness or dizziness.
Precautionary statements : Prevention:
                          P261 Avoid breathing dust.
                          P264 Wash skin thoroughly after handling.
                          P271 Use only outdoors or in a well-ventilated area.
                          P280 Wear eye protection/ face protection.
Response:
           P304 + P340 + P312 IF INHALED: Remove victim to fresh air
and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: 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**
Contact with dust can cause mechanical irritation or drying of the skin.
May form combustible dust concentrations in air.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</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. Contact with dust can cause mechanical irritation or drying of
## SECTION 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Protection of first-aiders</th>
<th>Notes to physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td>Treat symptomatically and supportively.</td>
</tr>
</tbody>
</table>

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

### Unsuitable extinguishing media
- High volume water jet

### Specific hazards during firefighting
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Do not use a solid water stream as it may scatter and spread fire.
- Exposure to combustion products may be a hazard to health.

### Hazardous combustion products
- Carbon oxides
- Metal 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.

## 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.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- 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 in a cool, well-ventilated place.
- 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>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no
asbestos and < 1% crystalline silica

<table>
<thead>
<tr>
<th>Component</th>
<th>TWA (Inhalable fraction)</th>
<th>TWA (Respirable fraction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>10 mg/m³</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica

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

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles.

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: powder

Colour: white to off-white
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form combustible dust concentrations in air.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</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>Not applicable</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>Not applicable</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>
<tr>
<td>Molecular weight</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Dust deflagration index (Kst)</td>
<td>16 - 75 m.b_/s</td>
</tr>
</tbody>
</table>
Minimum ignition energy: > 10 mJ
Particle size: 10 - 220 µm

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- May form combustible dust concentrations in air.
- Can react with strong oxidizing agents.
Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.
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.

Product:
Acute oral toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method
Acute dermal toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:

Starch:
Acute oral toxicity:
- LD50 (Mouse): > 5,000 mg/kg

Dexchlorpheniramine Maleate:
Acute oral toxicity:
- LD50 (Rat): 188 - 267 mg/kg
  LD50 (Mouse): 133 - 189 mg/kg
Acute inhalation toxicity:
- LClO (Rat): 0.52 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity:
- LD50 (Rat): 365 mg/kg
  Remarks: Information given is based on data obtained from similar substances.
Acute toxicity (other routes of administration):
- LD50 (Rat): 84 mg/kg
  Application Route: Intraperitoneal
- LD50 (Mouse): 82 mg/kg
  Application Route: Intraperitoneal
- LD50 (Mouse): 20 mg/kg
  Application Route: Intravenous

Magnesium stearate:
- Acute oral toxicity:
  - LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity
  - Remarks: Based on data from similar materials
- Acute dermal toxicity:
  - LD50 (Rabbit): > 2,000 mg/kg
  - Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Dexchlorpheniramine Maleate:
- Species: Rabbit
  Result: Mild skin irritation

Magnesium stearate:
- Species: Rabbit
  Result: No skin irritation
  Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Dexchlorpheniramine Maleate:
- Species: Rabbit
  Result: Severe irritation

Magnesium stearate:
- Species: Rabbit
  Result: No eye irritation
  Remarks: Based on data from similar materials
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Dexchlorpheniramine Maleate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

<table>
<thead>
<tr>
<th>Dexchlorpheniramine Maleate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
</tr>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse Lymphoma</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sister chromatid exchange assay</td>
<td></td>
</tr>
<tr>
<td>Test system</td>
<td>Chinese hamster ovary cells</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td></td>
</tr>
<tr>
<td>Test system</td>
<td>rat hepatocytes</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

Magnesium stearate:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
</tr>
</tbody>
</table>
### Carcinogenicity
Not classified based on available information.

### Components:

#### Dexchlorpheniramine Maleate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>30 - 60 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>NOAEL</td>
<td>20 - 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Reproductive toxicity
Not classified based on available information.

### Components:

#### Dexchlorpheniramine Maleate:

**Effects on fertility**
- Test Type: One-generation reproduction toxicity study
- Species: Rat
- Application Route: Oral
- Early Embryonic Development: NOAEL: 20 mg/kg body weight
- Result: No effects on fertility
- Remarks: Based on data from similar materials

**Effects on foetal development**
- Test Type: Development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: LOAEL: 20 mg/kg body weight
- Result: Reduced offspring weight gain, No malformations were observed.
- Remarks: Based on data from similar materials
Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 15 mg/kg body weight
Result: No effects on foetal development
Remarks: Based on data from similar materials

Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 20 mg/kg body weight
Result: Reduced embryonic survival, No malformations were observed.
Remarks: Based on data from similar materials

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

Magnesium stearate:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

STOT - single exposure
May cause drowsiness or dizziness.

Product:
Assessment: May cause drowsiness or dizziness.

Components:
Dexchlorpheniramine Maleate:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Components:
Dexchlorpheniramine Maleate:
Target Organs: Heart
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Dexchlorpheniramine Maleate:
Species: Rat
NOAEL: 30 mg/kg
LOAEL: 60 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Symptoms: Reduced body weight, Lethargy
Remarks: Based on data from similar materials

Components:
Species: Rat
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Remarks: Based on data from similar materials

Components:
Species: Monkey
LOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 105 Weeks
Target Organs: Heart
Remarks: Based on data from similar materials

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Product:
Ingestion: Symptoms: sedation, Dizziness, tinnitus, Lack of coordination, Fatigue, Blurred vision, dry mouth, urinary retention, Tremors, insomnia, nervousness

Components:
Dexchlorpheniramine Maleate:
Inhalation: Symptoms: May cause, central nervous system effects, Headache, dry mouth, Increased heart rate
Remarks: May cause respiratory tract irritation.
Skin contact: Remarks: May irritate skin.
Eye contact: Remarks: May cause irreversible eye damage.
Ingestion: Symptoms: sedation, dizziness, tinnitus, lack of coordination, fatigue, blurred vision, dry mouth, urinary retention, tremors, insomnia, nervousness

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Magnesium stearate:
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials
Bioaccumulative potential

Components:

Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4
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

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
UN/ID No.: UN 3335
Proper shipping name: Aviation regulated solid, n.o.s.
(Dexchlorpheniramine Maleate)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956

IMDG-Code
Not regulated as a dangerous good

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

National Regulations

ADG
Not regulated as a dangerous good

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Further information

Revision Date: 09/13/2019

Sources of key data used to compile the Safety Data Sheet:

- 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 Chemi-
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.