1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Dexchlorpheniramine Maleate Solid Formulation

Supplier's company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Serious eye damage/eye irritation : Category 2
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 person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Dexchlorpheniramine Maleate</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td>8-98</td>
</tr>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>&gt;= 1 - &lt; 3</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
</tbody>
</table>

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: Causes serious eye irritation.
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

Version 3.0  Revision Date: 2020/03/23  SDS Number: 2426303-00008  Date of last issue: 2019/09/13
Date of first issue: 2018/02/09

and effects, both acute and delayed
May cause drowsiness or dizziness. Contact with dust can cause mechanical irritation or drying of the skin.

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.

5. FIREFIGHTING 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:
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.

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.

7. HANDLING AND STORAGE

Handling
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.

Avoidance of contact: Oxidizing agents
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.

Storage
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
Packaging material: Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</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>ACGIH</td>
</tr>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>TWA</td>
<td>6 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>60 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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>
</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

Material: 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.
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>2020/03/23</td>
<td>2426303-00008</td>
<td>2019/09/13</td>
<td>2018/02/09</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: powder
- **Colour**: white to off-white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Boiling point, initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: May form combustible dust concentrations in air.
- **Flammability (liquids)**: Not applicable
- **Lower explosion limit and upper explosion limit / flammability limit**
  - **Upper explosion limit / Upper flammability limit**: No data available
  - **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: No data available
- **Decomposition temperature**: No data available
- **pH**: No data available
- **Evaporation rate**: No data available
- **Auto-ignition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Vapour pressure**: No data available
- **Density and / or relative density**
  - **Relative density**: No data available
  - **Density**: No data available
  - **Relative vapour density**: Not applicable
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Dexchlorpheniramine Maleate Solid Formulation

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.
**SAFETY DATA SHEET**

**Dexchlorpheniramine Maleate Solid Formula-**

tion

---

**Version** 3.0  
**Revision Date:** 2020/03/23  
**SDS Number:** 2426303-00008  
**Date of last issue:** 2019/09/13  
**Date of first issue:** 2018/02/09

---

**Components:**

<table>
<thead>
<tr>
<th>Starch:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species:</strong> Rabbit</td>
</tr>
<tr>
<td><strong>Result:</strong> No eye irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dexchlorpheniramine Maleate:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species:</strong> Rabbit</td>
</tr>
<tr>
<td><strong>Result:</strong> Severe irritation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Magnesium stearate:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species:</strong> Rabbit</td>
</tr>
<tr>
<td><strong>Result:</strong> No eye irritation</td>
</tr>
<tr>
<td><strong>Remarks:</strong> Based on data from similar materials</td>
</tr>
</tbody>
</table>

---

**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>Starch:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Type:</strong> Maximisation Test</td>
</tr>
<tr>
<td><strong>Exposure routes:</strong> Skin contact</td>
</tr>
<tr>
<td><strong>Species:</strong> Guinea pig</td>
</tr>
<tr>
<td><strong>Result:</strong> negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dexchlorpheniramine Maleate:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Remarks:</strong> No data available</td>
</tr>
</tbody>
</table>

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

---

**Germ cell mutagenicity**  
Not classified based on available information.

---

**Components:**

<table>
<thead>
<tr>
<th>Starch:</th>
</tr>
</thead>
</table>
| **Genotoxicity in vitro:**  
| **Test Type:** Bacterial reverse mutation assay (AMES)  
| **Result:** negative |
Dexchlorpheniramine Maleate Solid Formulation

**SAFETY DATA SHEET**

**Version**: 3.0  
**Revision Date**: 2020/03/23  
**SDS Number**: 2426303-00008  
**Date of last issue**: 2019/09/13  
**Date of first issue**: 2018/02/09

---

**Dexchlorpheniramine Maleate**:

**Genotoxicity in vitro**

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Mouse Lymphoma  
Result: negative  
Remarks: Based on data from similar materials

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster ovary cells  
Result: positive  
Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: rat hepatocytes  
Result: negative  
Remarks: Based on data from similar materials

**Germ cell mutagenicity - Assessment**

Weight of evidence does not support classification as a germ cell mutagen.

---

**Magnesium stearate**:

**Genotoxicity in vitro**

Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

---

**Carcinogenicity**

Not classified based on available information.

---

**Components**:

**Dexchlorpheniramine Maleate**:

**Species**: Rat  
**Application Route**: Oral  
**Exposure time**: 2 Years  
**NOAEL**: 30 - 60 mg/kg body weight  
**Result**: negative  
**Remarks**: Based on data from similar materials

**Species**: Mouse
Application Route: Oral
Exposure time: 2 Years
NOAEL: 20 - 50 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials

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
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

Version 3.0  Revision Date: 2020/03/23  SDS Number: 2426303-00008  Date of last issue: 2019/09/13
Date of first issue: 2018/02/09

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

Repeated dose toxicity

Components:
Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

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

Species: Rat
NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 6 Weeks
Remarks: Based on data from similar materials
No significant adverse effects were reported

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Magnesium stearate:
### Toxicity to fish
: \( LC_{50} \) (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
: \( EL_{50} \) (Daphnia magna (Water flea)): > 1 mg/l
  Exposure time: 47 h
  Remarks: Based on data from similar materials
  No toxicity at the limit of solubility

### Toxicity to algae/aquatic plants
: \( EL_{50} \) (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
: \( EC_{10} \) (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

### Hazardous to the ozone layer
Not applicable
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.

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
Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.
Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law
Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formula-
tion

Version 3.0  Revision Date: 2020/03/23  SDS Number: 2426303-00008  Date of last issue: 2019/09/13  Date of first issue: 2018/02/09

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

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 : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

Version 3.0 | Revision Date: 2020/03/23 | SDS Number: 2426303-00008 | Date of last issue: 2019/09/13

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 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; 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; 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.

JP / EN