SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dexchlorpheniramine Maleate Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone: 908-740-4000
Emergency telephone: 55 19 3758 2000
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 in accordance with ABNT NBR 14725 Standard
Acute toxicity (Oral): Category 5
Eye irritation: Category 2A
Specific target organ toxicity - single exposure: Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms:

Signal Word: Warning
Hazard Statements:
H303 May be harmful if swallowed.
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.
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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.
P337 + P313 If eye irritation persists: Get medical advice/attention.

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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>Acute toxicity (Oral), Category 3 Acute toxicity (Dermal), Category 3 Serious eye damage, Category 1 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure, Category 3 Specific target organ toxicity - repeated exposure (Oral) (Heart), Category 2</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td></td>
<td>&gt;= 1 - &lt; 5</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: May be harmful if swallowed. Causes serious eye irritation. 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.

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 fire fighting: 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 fire-fighters: 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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spills 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.
Wash skin thoroughly after handling.
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 labeled 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

Ingredients 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>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

Hand protection

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : white to off-white
Odor : No data available
Odor 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 : No data available
Evaporation rate : No data available
Flammability (solid, gas) : May form combustible dust concentrations in air.
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor 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
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
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Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: Not applicable
Dust deflagration index (Kst): 16 - 75 m.b./s
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

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 5.000 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5.000 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:
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:**

**Dexchlorphrine 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:**

**Starch:**
- Species: Rabbit
  - Result: No eye irritation
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 sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:
Starch:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Dexchlorpheniramine Maleate:
Remarks : No data available

Magnesium stearate:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:
Starch:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Dexchlorpheniramine Maleate:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
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tion

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 syn-
thesis 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 fetal 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 fetal 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 fetal development
- Test Type: Embryo-fetal 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: $\geq 2.000 \text{ mg/kg}$
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
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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.

Domestic regulation

ANTT
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
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

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

SECTION 16. OTHER INFORMATION

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

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

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...
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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.

BR / Z8