Dexchlorpheniramine Maleate Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Dexchlorpheniramine Maleate Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
- Eye irritation, Category 2: H319: Causes serious eye irritation.
- Specific target organ toxicity - single exposure, Category 3: H336: May cause drowsiness or dizziness.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
- Signal word: Warning
- Hazard statements:
  - H319: Causes serious eye irritation.
  - H336: May cause drowsiness or dizziness.
- Precautionary statements:
  - Prevention:
    - P261: Avoid breathing dust.
Dexchlorpheniramine Maleate Solid Formula-
tion

Hazardous components which must be listed on the label:
Dexchlorpheniramine Maleate

2.3 Other hazards
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

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>219-450-6</td>
<td></td>
<td>Acute Tox.3; H301 Acute Tox.3; H311 Eye Dam.1; H318 Repr.2; H361d STOT SE3; H336 STOT RE2; H373</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. May cause drowsiness or dizziness. Contact with dust can cause mechanical irritation or drying of the skin.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment: In the event of fire, wear self-contained breathing apparatus.
for firefighters

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>
8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder

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: No data available
Evaporation rate: No data available

Flammability (solid, gas): May form combustible dust concentrations in air.

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: No data available

Explosive properties: Not explosive

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

9.2 Other information
- Flammability (liquids): Not applicable
- 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

10.1 Reactivity
Not classified as a reactivity hazard.
10.2 Chemical stability  
Stable under normal conditions.

10.3 Possibility of hazardous reactions  
Hazardous reactions: May form combustible dust concentrations in air. Can react with strong oxidizing agents.

10.4 Conditions to avoid  
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials  
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products  
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects  
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:  
Dexchlorpheniramine Maleate:  
Acute oral toxicity: LD50 (Rat): 188 - 267 mg/kg  
LD50 (Mouse): 133 - 189 mg/kg

Acute inhalation toxicity: LC50 (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.
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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

Skin corrosion/irritation
Not classified based on available information.

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
Dexchlorpheniramine Maleate:
Species: Rabbit
Result: Severe irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Dexchlorpheniramine Maleate:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of first issue: 09.02.2018

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.

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
## Dexchlorpheniramine Maleate Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue: 13.09.2019</th>
<th>Date of first issue: 09.02.2018</th>
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<td>3.3</td>
<td>23.03.2020</td>
<td>2436178-00008</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

**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:**

**Dexchlorpheniramine Maleate:**

**Species** : Rat
Dexchlorpheniramine Maleate Solid Formulation

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

Species: Monkey
LOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 105 Weeks
Target Organs: Heart
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

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Dexchlorpheniramine Maleate Solid Formulation

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

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<tbody>
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</tr>
<tr>
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<tr>
<td>RID</td>
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<tr>
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<tr>
<td>IATA</td>
<td>UN 3335</td>
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</table>

14.2 UN proper shipping name

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<tbody>
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<tr>
<td>IMDG</td>
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<tr>
<td>IATA</td>
<td>Aviation regulated solid, n.o.s. (Dexchlorpheniramine Maleate)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<p>| | |</p>
<table>
<thead>
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14.4 Packing group

**ADN**: Not regulated as a dangerous good
**ADR**: Not regulated as a dangerous good
**RID**: Not regulated as a dangerous good
**IMDG**: Not regulated as a dangerous good

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**: Not regulated as a dangerous good
**ADR**: Not regulated as a dangerous good
**RID**: Not regulated as a dangerous good
**IMDG**: Not regulated as a dangerous good

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)**: Not applicable
**REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59)**: Not applicable
**REACH - List of substances subject to authorisation (Annex XIV)**: Not applicable
**Regulation (EC) No 1005/2009 on substances that deplete the ozone layer**: Not applicable
**Regulation (EU) 2019/1021 on persistent organic pollu-**

Not applicable
Dexchlorpheniramine Maleate Solid Formulation

SECTION 15: Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-statements

H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H318: Causes serious eye damage.
H336: May cause drowsiness or dizziness.
H361d: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Eye Dam.: Serious eye damage
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Equip-
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Further information


Classification of the mixture:  
Eye Irrit. 2 H319  
STOT SE 3 H336

Classification procedure:  
Calculation method  
Based on product data or assessment

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.

NO / EN