SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

SECTION 1. IDENTIFICATION

Product name: Dexchlorpheniramine Maleate Solid Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Combustible dust
Eye irritation: Category 2A
Reproductive toxicity: Category 2
Specific target organ toxicity - single exposure: Category 3
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Heart)

GHS label elements
Hazard pictograms: 

Signal Word: Warning

Hazard Statements: May form combustible dust concentrations in air. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Heart) through prolonged or repeated exposure if swallowed.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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
Contact with dust can cause mechanical irritation or drying of the skin.

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; 20</td>
</tr>
<tr>
<td>Dexchlorpheniramine Maleate</td>
<td>2438-32-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

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.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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 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.

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>
</table>
Starch  9005-25-8  TWA  10 mg/m³  ACGIH
  TWA (Respirable)  5 mg/m³  NIOSH REL
  TWA (Total)  10 mg/m³  NIOSH REL
  TWA (Total dust)  15 mg/m³  OSHA Z-1
  TWA (Respirable fraction)  5 mg/m³  OSHA Z-1

Dexchlorpheniramine Maleate  2438-32-6  TWA  6 µg/m³ (OEB 4)  Internal
  Wipe limit  60 µg/100 cm²  Internal

Magnesium stearate  557-04-0  TWA (Inhalable particulate matter)  10 mg/m³  ACGIH
  TWA (Respirable particulate matter)  3 mg/m³  ACGIH

**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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

- **Hand protection**: Chemical-resistant gloves

- **Remarks**: Consider double gloving.

- **Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: white to off-white
Odor: No data available
OdorThreshold: 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

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
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: 5,000 mg/kg
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

<table>
<thead>
<tr>
<th>Method: Calculation method</th>
</tr>
</thead>
</table>

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:**

**Dexchlorpheniramine Maleate:**

Species  :  Rabbit
**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>3.3</td>
<td>03/23/2020</td>
<td>2426287-00008</td>
<td>09/13/2019</td>
<td>02/09/2018</td>
</tr>
</tbody>
</table>

**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
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

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
Remarks: Based on data from similar materials

**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

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Suspected of damaging the unborn child.

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**
May cause damage to organs (Heart) through prolonged or repeated exposure if swallowed.

**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

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.
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formula-
tion

Version 3.3  Revision Date: 03/23/2020  SDS Number: 2426287-00008  Date of last issue: 09/13/2019
Date of first issue: 02/09/2018

Domestic regulation

49 CFR
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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Combustible dust
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Serious eye damage or eye irritation

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate  64044-51-5
Starch  9005-25-8

California Permissible Exposure Limits for Chemical Contaminants
Starch  9005-25-8
Magnesium stearate  557-04-0

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

AICS: not determined
DSL: not determined
IECSC: not determined

---

16 / 18
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

- Flammability: 2
- Health: 2
- Instability: 0

HMIS® IV:

- Health: *2
- Flammability: 2
- Physical Hazard: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA: 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; KECl - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)
SAFETY DATA SHEET

Dexchlorpheniramine Maleate Solid Formulation

Version: 3.3
Revision Date: 03/23/2020
SDS Number: 2426287-00008
Date of last issue: 09/13/2019
Date of first issue: 02/09/2018

Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date: 03/23/2020

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.

US / Z8