SAFETY DATA SHEET

1. Identification

Product identifier Chlorpheniramine Maleate

Other means of identification

Catalog number 1123000

Chemical name 2-Pyridinepropanamine, gamma-(4-chlorophenyl)-N,N-dimethyl-,(Z)-2-butenedioate(1:1)

Synonym(s) Chlorphenamine hydrogen maleate

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway

Rockville

MD

20852-1790

US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US &

Canada 1-800-424-9300

CHEMTREC outside US &

Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral Category 3

Acute toxicity, dermal Category 3

Serious eye damage/eye irritation Category 2

Specific target organ toxicity, single exposure Category 3 narcotic effects

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Toxic if swallowed. Toxic in contact with skin. Causes serious eye irritation. May cause drowsiness or dizziness.

Precautionary statement

Prevention Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing. Wear eye/face protection.

Response Rinse mouth. Call a poison center/doctor/medical professional. If on skin: Wash with plenty of water/soap. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance
4. First-aid measures

**Inhalation**
Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.

**Skin contact**
Wash off with soap and plenty of water. Call a POISON CENTER or doctor/physician if you feel unwell.

**Eye contact**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

**Most important symptoms/effects, acute and delayed**
Irritation of eyes and mucous membranes.

**Indication of immediate medical attention and special treatment needed**
Treatment of antihistamine overdose should be symptomatic and supportive and may include the following:
1. Administer activated charcoal as a slurry.
2. For severe tachycardia, use beta blocking agents such as esmolol as a temporizing measure.
3. For Torsades de Pointes: Administer magnesium, isoproterenol, and/or atrial overdrive pacing to stable patients. Hemodynamically unstable patients may require electrical cardioversion. Correct electrolyte abnormalities.
4. For seizures, administer intravenous benzodiazepines. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
5. For hypotension: Infuse 10 to 20 mL/kg isotonic fluid. If hypotension persists, administer dopamine or norepinephrine.
6. For agitation or dystonia, administer oral or intravenous benzodiazepines.
7. Hemodialysis, hemoperfusion, peritoneal dialysis, and repeat-dose activated charcoal are not effective in removing antihistamines. [Meditext 2007; Poisoning and Drug Overdose, 4th edition]

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>TWA</td>
<td>10 micrograms/m³</td>
</tr>
</tbody>
</table>

Industrial Use

Exposure limit values

No biological exposure limits noted for the ingredient(s).

Biological limit values

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely irritating. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

266 - 275 °F (130 - 135 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

< 0.0000001 kPa at 25 °C

Vapor density

Not available.
Relative density
Not available.
Solubility in water
Freely soluble.
Partition coefficient (n-octanol/water)
Not available.
Auto-ignition temperature
Not available.
Decomposition temperature
Not available.
Viscosity
Not available.
Other information
Chemical family
Propylamine derivative.
Dust explosion properties
Minimum ignition energy (MIE) - dust cloud
5 - 10 mJ
Molecular formula
C16H19ClN2 . C4H4O4
Molecular weight
390.86
pH in aqueous solution
4 - 5 (2% aqueous solution)
Solubility (other)
Soluble in alcohol and in chloroform; slightly soluble in ether and in benzene.

10. Stability and reactivity
Reactivity
No reactivity hazards known.
Chemical stability
Stable at normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.
Conditions to avoid
None known.
Incompatible materials
Hazardous decomposition products
NOx, Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Ingestion
Toxic if swallowed.
Inhalation
Due to lack of data the classification is not possible.
Skin contact
Toxic in contact with skin.
Eye contact
Causes serious eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics
Delayed and immediate effects of exposure
Hepatotoxicity. Dystonic reactions.
Chronic effects
Possible hypersensitization
Cross sensitivity
Persons sensitive to other antihistamines may be sensitive to this material also.
Medical conditions aggravated by exposure
Acute toxicity
Toxic if swallowed. Toxic in contact with skin.

<table>
<thead>
<tr>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material name: Chlorpheniramine Maleate 6391 Version #: 02 Revision date: 05-01-2013 Issue date: 05-13-2008</td>
</tr>
<tr>
<td>Product</td>
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<tr>
<td>--------------------------</td>
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<td></td>
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</tbody>
</table>

**Skin corrosion/irritation**
- Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation**
- Causes serious eye irritation.

**Local effects**
- **Eye irritation test**
  - Result: Severe/corrosive
  - Species: Rabbit
- **Skin irritation test**
  - Result: Slight
  - Species: Rabbit

**Respiratory sensitization**
- Due to lack of data the classification is not possible.

**Skin sensitization**
- Due to lack of data the classification is not possible.
- There have been reports of allergic reactions and contact dermatitis following therapeutic exposure to this material.

**Germ cell mutagenicity**
- Based on available data, the classification criteria are not met.

**Mutagenicity**
- **Ames Salmonella typhimurium assay**
  - Result: Negative
- **In vitro tests in Chinese hamster ovary cells**
  - Result: Weakly positive for sister chromatid exchanges and chromosomal aberrations
- **In vitro unscheduled DNA synthesis in rat hepatocytes**
  - Result: Negative
- **Mouse lymphoma L5178Y/TK+/- forward mutation assay**
  - Result: Negative

**Carcinogenicity**
- Based on available data, the classification criteria are not met.
- This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
- Epidemiological studies have not show a causal relationship between this material and cancer in humans.
- **0 - 200 mg/kg Long-term carcinogenicity studies, administered by gavage 5 times a week**
  - Result: No evidence of carcinogenicity; proliferative effect on the thyroid glands of females
  - Species: Mouse
  - Test Duration: 2 years
- **Long-term carcinogenicity studies, administered by gavage 5 times a week**
  - Result: No evidence of carcinogenicity
  - Species: Rat
  - Test Duration: 2 years

**Reproductive toxicity**
- Based on available data, the classification criteria are not met.
- Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.
- **15 mg/kg/day Reproductivity and development, administered during gestation**
  - Result: No adverse reproductive effects
  - Species: Rabbit
- **20 - 200 mg/kg Reproductivity and development, administered during gestation**
  - Result: 100% abortion or resorption (high dose); decreased offspring survival (low dose)
  - Species: Mouse
  - **20 - 25 mg/kg Reproductivity and development**
  - Result: No adverse reproductive effects (low dose); decreased body weights in offspring (high dose)
  - Species: Rat

**Specific target organ toxicity - single exposure**
- Narcotic effects.

**Specific target organ toxicity - repeated exposure**
- Based on available data, the classification criteria are not met.

**Aspiration hazard**
- Based on available data, the classification criteria are not met.
12. Ecological information

Ecotoxicity
No ecotoxicity data noted for the ingredient(s).

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations

Disposal instructions
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

Local disposal regulations
Not available.

Hazardous waste code
Not regulated.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number
UN2811

UN proper shipping name
Toxic solid, organic, n.o.s. (Chlorpheniramine Maleate)

Transport hazard class(es)
6.1

Subsidiary class(es)
Not available.

Packing group
III

IATA

UN number
UN2811

UN proper shipping name
Toxic solid, organic, n.o.s. (Chlorpheniramine Maleate)

Transport hazard class(es)
6.1

Subsidiary class(es)
-

Packing group
III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

DOT; IATA

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No
Other federal regulations
Safe Drinking Water Act (SDWA) Not regulated.
Food and Drug Administration (FDA) Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

| Issue date          | 05-13-2008 |
| Revision date       | 05-01-2013 |
| Version #           | 02         |
| Further information | Not available. |

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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.

Material name: Chlorpheniramine Maleate

6391  Version #: 02  Revision date: 05-01-2013  Issue date: 05-13-2008

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