



SAFETY DATA SHEET

1. Identification

Product identifier	Chlorpheniramine Maleate	
Other means of identification		
Catalog number	1123000	
CAS number	113-92-8	
Synonyms	Chlorphenamine hydrogen maleate	
Chemical name	2-[p-Chloro- α -[2-(dimethylamino)ethyl]benzyl] pyridine maleate (1:1)	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	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
Environmental hazards	Not classified.	
OSHA defined hazards	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	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear eye protection/face protection. Wear protective gloves/protective clothing. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Call a poison center/doctor if you feel unwell. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. 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)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Chlorpheniramine Maleate	Chlorphenamine hydrogen maleate	113-92-8	100

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not use mouth-to-mouth method if the substance is inhaled. Call a poison center or doctor/physician if you feel unwell.
Skin contact	Take off immediately all contaminated clothing. Wash off with soap and water. Get medical advice/attention if you feel unwell. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. 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. Do not use mouth-to-mouth method if substance is ingested.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Treatment of antihistamine overdose may include the following: Administer activated charcoal as a slurry. For severe tachycardia, use beta blocking agents such as esmolol as a temporizing measure. 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. 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. For hypotension: Infuse 10 to 20 mL/kg isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For agitation or dystonia, administer oral or intravenous benzodiazepines. Hemodialysis, hemoperfusion, peritoneal dialysis, and repeat-dose activated charcoal are not effective in removing antihistamines.

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.
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5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: 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.
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. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, 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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material	Type	Value
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Chlorpheniramine Maleate (CAS 113-92-8)	TWA	10 micrograms/m ³
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Biological limit values

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

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White.

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 available.
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 (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Freely soluble.
Solubility (other)	Ether: Slightly soluble. Chloroform: Soluble. Alcohol: Soluble. Benzene: Slightly soluble.
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)

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.
Incompatible materials	Acids. Bases. Strong oxidizing agents. Strong reducing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, Cl-.

11. Toxicological information

Information on likely routes of exposure	
Inhalation	May cause drowsiness or dizziness.
Skin contact	Toxic in contact with skin.
Eye contact	Causes serious eye irritation.

Ingestion Toxic if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics For antihistamines: Gastrointestinal disturbances. Drowsiness. Dizziness. Weakness. Trouble sleeping. Clumsiness. Blurred vision. Confusion. Dry mouth. Irregular heart beat. Urination problems.

Information on toxicological effects

Acute toxicity Toxic in contact with skin. Toxic if swallowed.

Product	Species	Test Results
Chlorpheniramine Maleate (CAS 113-92-8)		
Acute		
Dermal		
LD50	Rat	365 mg/kg
Inhalation		
LC50		> 0.61 mg/l, 4 hours
Oral		
LD50	Mouse	162 mg/kg
		130 mg/kg
	Rat	306 mg/kg
		118 mg/kg

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 or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about sensitization hazard is incomplete.
There have been reports of allergic reactions and contact dermatitis following therapeutic exposure to this material.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

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.
Epidemiological studies have not shown 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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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.

Reproductivity

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 May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

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

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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)	
Class	6.1
Subsidiary risk	-
Packing group	III

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Chlorpheniramine Maleate)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

DOT; IATA



General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

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

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

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 05-13-2008

Revision date 02-17-2021

Version # 04

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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