

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Printing date 04/15/2015

Reviewed on 04/15/2015

* 1 Identification

- **Product identifier**
- **Trade name: Chlorpheniramine Maleate Tablets**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product description** Un-Coated, Round, Bi-Convex: 242R
- **Application of the substance / the mixture** Chlorpheniramine Maleate Tablets
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735
Phone: (631) 753-9090
Fax: (631) 753-2220
- **Emergency telephone number:** (631) 753-9090

* 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS06 Skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.

Eye Irrit. 2B H320 Causes eye irritation.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS06

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Chlorphenamine Hydrogen Maleate
Croscarmellose Sodium
- **Hazard statements**
Toxic if swallowed.
Causes eye irritation.
- **Precautionary statements**
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
If swallowed: Immediately call a poison center/doctor.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
If eye irritation persists: Get medical advice/attention.
Rinse mouth.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Unknown acute toxicity:**
60 percent of the mixture consists of ingredient(s) of unknown toxicity.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Hazard(s) not otherwise classified (HNOC):** None known

* 3 Composition/information on ingredients

63-42-3	Lactose	Proprietary.%
9004-34-6	Microcrystalline Cellulose	Proprietary%
112945-52-5	Amorphous Silica	Proprietary%

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous Components:**

CAS: 113-92-8	Chlorphenamine Hydrogen Maleate ⚠ Acute Tox. 3, H301	2.4%
CAS: 57-11-4 RTECS: WI 2800000	Stearic Acid, pure ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 74811-65-7	Croscarmellose Sodium ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 557-04-0	Magnesium Stearate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 68814-04-0	FD&C Yellow #10 Lake Eye Irrit. 2B, H320; Combustible Dust	Proprietary%

* 4 First-aid measures

- **Description of first aid measures**
- **General information:**
First aid is generally not required if product is used correctly and according to the recommended dosages established by this manufacturer.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
Product generally does not present an inhalation hazard unless it is in powder form. Take care not to crush tablet and inhale powder.
In case of unconsciousness, place patient securely on side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation occurs, consult a doctor.

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· **After eye contact:**

Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Product generally does not present an ingestion hazard is used correctly and according to the recommended dosages established by this manufacturer.

If large quantities are ingested, seek medical advice.

· **Information for doctor:**

Signs and symptoms of Chlorpheniramine Hydrogen Maleate overdose may include somnolence, anticholinergic effects (mydriasis, flushing, fever, dry mouth, and decreased bowel sounds), tachycardia, mild hypertension, nausea, vomiting, agitation, confusion, hallucinations, agitated delirium, psychosis, seizures, coma, hypotension, QRS widening, ventricular dysrhythmias rhabdomyolysis and renal failure.

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

* 5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture**

If incinerated, product may release the following toxic gases: Oxides of Carbon, Magnesium, Nitrogen (NO_x), Sodium, Silicon, Aluminum and Hydrochloric acid gas.

· **Advice for firefighters**

· **Protective equipment:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

* 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Avoid breathing dust.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:**

Avoid the formation of dust

Pick up mechanically.

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

* 7 Handling and storage

· **Handling:**

· **Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

No special precautions are necessary if used correctly.

· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**

Store away from strong acids, strong bases, strong oxidizing agents and strong reducing agents.

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

* 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

· **Components with occupational exposure limits:**

9004-34-6 Microcrystalline Cellulose

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV Long-term value: 10 mg/m³

557-04-0 Magnesium Stearate

TLV Long-term value: 10 mg/m³

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing and wash before reuse.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not necessary under normal conditions.

· **Protection of hands:** Not necessary under normal conditions.

· **Eye protection:** Not necessary under normal conditions.

* 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Tablet

Color: Yellow

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

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· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not determined.

· **Density:**

Relative density Not determined.

Vapor density Not determined.

Evaporation rate Not determined.

· **Solubility in / Miscibility with**

Water: Partly soluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not determined.

Kinematic: Not determined.

· **Solvent content:**

Organic solvents: 0.0 %

Solids content: 97.6 %

· **Other information** No further relevant information available.

* 10 Stability and reactivity

· **Reactivity** No further relevant information available.

· **Chemical stability** Stable under normal conditions.

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** Strong acids, strong bases, strong oxidizing agents and strong reducing agents.

· **Hazardous decomposition products:**

Oxides of Carbon, Magnesium, Nitrogen (NO_x), Sodium, Silicon, Aluminum and Hydrochloric acid gas.

* 11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

9004-34-6 Microcrystalline Cellulose

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)

113-92-8 Chlorphenamine Hydrogen Maleate

Oral	LD50	188 mg/kg (rat)
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57-11-4 Stearic Acid, pure		
Dermal	LD50	>5000 mg/kg (rabbit)
112945-52-5 Amorphous Silica		
Oral	LD50	10000 mg/kg (rat)

- **Primary irritant effect:**

- **on the skin:** No irritating effect.

- **on the eye:**

Irritating effect.

Causes serious eye irritation.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Toxic

Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

Group 1 - Carcinogenic to humans

Group 2A - Probably carcinogenic to humans

Group 2B - Possibly carcinogenic to humans

Group 3 - Not classifiable as to its carcinogenicity to humans

Group 4 - Probably not carcinogenic to humans

112945-52-5	Amorphous Silica	3
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- **NTP (National Toxicology Program)**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients are listed.

* 12 Ecological information

- **Toxicity** The hazards for the aquatic environment are unknown.

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:** Not known to be hazardous to water.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

* 13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packagings:**

- **Recommendation:**

Disposal must be made according to official regulations.

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Dispose of as unused product.

* 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

* 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

63-42-3	Lactose
9004-34-6	Microcrystalline Cellulose
113-92-8	Chlorphenamine Hydrogen Maleate
57-11-4	Stearic Acid, pure
557-04-0	Magnesium Stearate
112945-52-5	Amorphous Silica
68814-04-0	FD&C Yellow #10 Lake

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients are listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS06

· **Signal word** Danger

· **Hazard-determining components of labeling:**

Chlorphenamine Hydrogen Maleate

Croscarmellose Sodium

· **Hazard statements**

Toxic if swallowed.

Causes eye irritation.

· **Precautionary statements**

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

If swallowed: Immediately call a poison center/doctor.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

If eye irritation persists: Get medical advice/attention.

Rinse mouth.

Store locked up.

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

· **National regulations:**

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

· **State Right to Know**

CAS: 63-42-3	Lactose	Proprietary%
CAS: 9004-34-6	Microcrystalline Cellulose	Proprietary%
CAS: 113-92-8	Chlorphenamine Hydrogen Maleate	2.4%
	 Acute Tox. 3, H301	
CAS: 57-11-4	Stearic Acid, pure	Proprietary%
RTECS: WI 2800000	 Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	

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Trade name: Chlorpheniramine Maleate Tablets

CAS: 74811-65-7	Croscarmellose Sodium ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2B, H320; Combustible Dust	Proprietary%
CAS: 557-04-0	Magnesium Stearate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
All ingredients are listed.		

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision** 04/15/2015 / -

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Acute Tox. 3: Acute toxicity, Hazard Category 3
Acute Tox. 4: Acute toxicity, Hazard Category 4
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**

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