

Safety Data Sheet (SDS)

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

Printing date 04/01/2015

Reviewed on 04/01/2015

* 1 Identification

- **Product identifier**
- **Trade name:** Diphenhydramine HCl Tablets
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Product description** 25 mg, Film-Coated Clear, Capsule-Shaped: 160R, 241R and 329R
- **Application of the substance / the mixture** Diphenhydramine HCl 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**



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

STOT SE 3 H335 May cause respiratory irritation.

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**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**
Calcium Phosphate Dibasic Dihydrate
Titanium Dioxide
- **Hazard statements**
Causes skin and eye irritation.
May cause respiratory irritation.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area.
Wear protective gloves.
Wash thoroughly after handling.
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 INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Call a poison center/doctor if you feel unwell.

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Trade name: Diphenhydramine HCl Tablets

If skin irritation occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 If on skin: Wash with plenty of water.
 Take off contaminated clothing and wash it before reuse.
 Store locked up.
 Store in a well-ventilated place. Keep container tightly closed.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Unknown acute toxicity:**

40.7 percent of the mixture consists of ingredient(s) of unknown toxicity.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards** None known

* 3 Composition/information on ingredients

9004-65-3	Hypromellose	Combustible Dust	Proprietary%
9004-34-6	Microcrystalline Cellulose		Proprietary%
112945-52-5	Amorphous Silica		Proprietary%
9004-65-3	Hypromellose	Combustible Dust	Proprietary%
9002-89-5	Poly(vinyl alcohol)		Proprietary%
25322-68-3	Polyethylene Glycol		Proprietary%
8015-86-9	Carnauba Wax		Proprietary%
	FD&C Blue No.1		Proprietary%

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous Components:**

CAS: 7789-77-7	Calcium Phosphate Dibasic Dihydrate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 147-24-0 RTECS: KR 7000000	Diphenhydramine Hydrochloride ⚠ Acute Tox. 4, H302	10.10%
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: 13473-26-2	FD&C Red #27 Aluminum Lake ⚠ Eye Irrit. 2A, H319	Proprietary%

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Trade name: Diphenhydramine HCl Tablets

CAS: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	Proprietary%
CAS: 9005-65-6	Polysorbate 80 ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 14807-96-6	Talc ⚠ Carc. 2, H351; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%

• **Additional information:**

160R: Only product version that contains the following ingredient: FD&C Red #27 Aluminum Lake.

160R & 329R: Only product versions that contain the following ingredients: Hypromellose and Polysorbate 80.

241R: Only product version that contains the following ingredients: Poly(vinyl alcohol), FD&C Blue #1 Aluminum Lake and Talc.

160R: Only product version colored Pink.

241R: Only product version colored Blue.

329R: Only product version colored White.

* 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.

• **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.

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

• **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

• **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.

• **Information for doctor:**

Signs and symptoms of Diphenhydramine Hydrochloride overdose may not appear at first, and may occur gradually. Symptoms may include inability to urinate, blurred vision, dry mouth, enlarged pupils, severely dry eyes, ringing in the ears, low blood pressure, rapid heartbeat, agitation, confusion, convulsions (seizures), delirium, depression, drowsiness, hallucinations, nervousness, and dry, flushed, red skin. Treatment should be started as soon as possible after overdose. Possible treatments may include use of activated charcoal, gastric lavage, laxatives or emetics for stomach evacuation and/or use of an antidote like sodium bicarbonate.

• **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.

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

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

· **Advice for firefighters**

Product has a combustible dust hazard. Avoid generating dust while extinguishing any fires.

· **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

Ensure adequate ventilation.

Pick up mechanically.

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.

· **Information about protection against explosions and fires:**

Dust can combine with air to form an explosive mixture.

· **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.

· **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

13463-67-7 Titanium Dioxide

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

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REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³ withdrawn from NIC
557-04-0 Magnesium Stearate	
TLV	Long-term value: 10 mg/m ³
112945-52-5 Amorphous Silica	
ACGIH-TLV	Short-term value: 3 mg/m ³ Long-term value: 4 E mg/m ³
OSHA-PEL	Short-term value: 5 mg/m ³ Long-term value: 4 E mg/m ³
25322-68-3 Polyethylene Glycol	
WEEL	Long-term value: 10 mg/m ³ (H); MW>200
14807-96-6 Talc	
REL	Long-term value: 20 mppcf ppm (containing <1% Quartz)
REL	Long-term value: 2* mg/m ³ *respirable dust
TLV	Long-term value: 2* mg/m ³ *as respirable fraction; E

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Wash hands before breaks and at the end of work.

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:

Pink, Blue or White

· **Odor:**

Odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

Melting point/Melting range:

Not determined.

Boiling point/Boiling range:

Not determined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gaseous):**

Not determined.

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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 applicable.

· **Density:**

Relative density Not determined.

Vapor density Not applicable.

Evaporation rate Not applicable.

· **Solubility in / Miscibility with**

Water: Partly soluble.

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

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Solvent content:**

Organic solvents: 0.0 %

Solids content: 99.4 %

· **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, Calcium, Silicon, Magnesium, Nitrogen (NO_x), Sodium, Titanium 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)

147-24-0 Diphenhydramine Hydrochloride

Oral	LD50	500 mg/kg (rat)
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13463-67-7 Titanium Dioxide		
Oral	LD50	>10000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (rat)
112945-52-5 Amorphous Silica		
Oral	LD50	10000 mg/kg (rat)
9004-65-3 Hypromellose		
Oral	LD50	2000 mg/kg (rat)
	Intravenous	5200 mg/kg (rat)
9002-89-5 Poly(vinyl alcohol)		
Oral	LD50	20000 mg/kg (rat)
25322-68-3 Polyethylene Glycol		
Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)
9005-65-6 Polysorbate 80		
Oral	LD50	25000 mg/kg (mouse)

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **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:

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

13463-67-7	Titanium Dioxide	2B
112945-52-5	Amorphous Silica	3
14807-96-6	Talc	2B
	FD&C Blue No.1	3

· **NTP (National Toxicology Program)**

None of the ingredients are listed.

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

None of the ingredients are listed.

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* 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

13463-67-7 Titanium Dioxide

EC50 >1000 mg/l (Water flea)

· **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:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

· **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.

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 MARPOL73/78 and the IBC Code**

Not applicable.

· **UN "Model Regulation":**

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* 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):**

9004-34-6 Microcrystalline Cellulose

9004-65-3 Hypromellose

13463-67-7 Titanium Dioxide

25322-68-3 Polyethylene Glycol

557-04-0 Magnesium Stearate

112945-52-5 Amorphous Silica

14807-96-6 Talc

9005-65-6 Polysorbate 80

FD&C Blue No.1

8015-86-9 Carnauba Wax

· **Proposition 65**

· **Chemicals known to cause cancer:**

13463-67-7 Titanium Dioxide

· **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.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

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

13463-67-7 Titanium Dioxide

A4

14807-96-6 Talc

A4

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

13463-67-7 Titanium Dioxide

· **GHS label elements**

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

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· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

Calcium Phosphate Dibasic Dihydrate

Titanium Dioxide

· **Hazard statements**

Causes skin and eye irritation.

May cause respiratory irritation.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area.

Wear protective gloves.

Wash thoroughly after handling.

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 INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Call a poison center/doctor if you feel unwell.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

If on skin: Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

Store locked up.

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

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: 9004-34-6	Microcrystalline Cellulose	Proprietary%
CAS: 7789-77-7	Calcium Phosphate Dibasic Dihydrate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	Proprietary%
CAS: 147-24-0 RTECS: KR 7000000	Diphenhydramine Hydrochloride ⚠ Acute Tox. 4, H302	10.10%
CAS: 9004-65-3	Hypromellose Combustible Dust	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: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	Proprietary%
All ingredients are listed.		

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- **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** 04/01/2015 / -

- **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. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B

Carc. 2: Carcinogenicity, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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

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