

SAFETY DATA SHEETS

This SDS packet was issued with item:

078933962

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078927500

1.0 Product Identification:

- 1.1 **Product Name:** **Cyproheptadine Hydrochloride Tablets USP, 4mg**
- 1.2 **CAS #:** Mixture
- 1.3 **Chemical Name:** Mixture
- 1.4 **Chemical Formula:** Mixture
- 1.5 **Manufacturer:** Ingenus Pharmaceuticals NJ, LLC
140 New Dutch Lane
Fairfield, NJ 07004
862-210-8536
www.ingenus.com
- 1.6 **Intended Use:** An antihistaminic and antiserotonergic agent
- 1.7 **Emergency Contact:** 862-250-3243; rsingh@ingenus.com

2.0 Hazard Identification:

- 2.1 **GHS Classification:** Eye irritation: Category 2A
Reproductive toxicity: Category 2

2.2 **GHS Label Elements:**



Signal Word:

WARNING

Hazard Statement:

If small particles are generated during, further processing, handling or by other means, may form combustible dust concentrations in air.

H315: Causes skin irritation

H319: Causes serious eye irritation.

H335: May cause respiratory irritation

H361d: Suspected of damaging the unborn child.

Precautionary Statements: P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P264: Wash skin thoroughly after use.

P280: Wear protective gloves/protective clothing/eye protection/ face protection.

Response: 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.

2.3 Hazards Not Otherwise Classified (HNOC): None

3.0 Composition / Information on Ingredients:

3.1 Hazardous Ingredients: Per 29 CFR 1910.1200

Chemical Name	CAS #	% By Weight
Cyproheptadine Hydrochloride, USP	41354-29-4	< 5%

3.2 Non-Hazardous Ingredients:

Chemical Name	CAS #
Lactose Monohydrate, NF	64044-51-5
Microcrystalline Cellulose, NF	9004-34-6
Sodium Starch Glycolate, NF	9063-38-1
Magnesium Stearate	557-04-0

4.0 First Aid Measures:

- 4.1 **General advice:** This pharmaceutical product is in a tablet form. The most likely route of exposure is ingestion. If unintentionally ingested, immediately consult a physician.
- 4.2 **In case of Eye Contact:** Rinse thoroughly with plenty of water for at least 15 minutes. Consult a physician.
- 4.3 **In case of Skin Contact:** Wash off with soap and plenty of water. Consult a physician.
- 4.4 **If Inhaled:** If inhaled, move person to fresh air. If not breathing, give artificial respiration. Consult a physician.
- 4.5 **If Swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
- 4.6 **Special treatment required:** No specific antidote. Treat symptomatically and supportively.

5.0 Firefighting Measures:

- 5.1 **Extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- 5.2 **Special hazards from fire:** May emit toxic fumes of oxides of carbon, metal oxides and oxides of phosphorus.
- 5.3 **Advice for firefighters:** Wear self-contained breathing apparatus (SCBA) under fire conditions.
- 5.4 **Further information:** May form combustible dust concentrations in air.

6.0 Accidental Release Measures:

- 6.1 **Protective equipment and emergency procedures:** Avoid dust formation. Ensure adequate ventilation. Use personal protective equipment. Avoid breathing dusts.
- 6.2 **Environmental precautions:** Do not let product enter drains, sewers or waterways.
- 6.3 **Containment and clean-up:** Avoid creating dust. Sweep up and place into a suitable container for disposal.
- 6.4 **Reference to other SDS Sections:** See Section 8 for Personal Protective Equipment (PPE). See Section 13 for waste handling and disposal.

7.0 Handling and Storage:

- 7.1 **Precautions for safe handling:** If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

7.2 **Conditions for safe storage:** Store as directed product packaging.

7.3 **Incompatibilities:** None identified.

8.0 **Exposure Controls:**

8.1 **Engineering Controls:** Use local exhaust ventilation when airborne dusts are present.

8.2 **Eye / Face Protection:** Not required for the normal use of this product. Use safety glasses or goggles if eye contact is possible.

8.3 **Hand / Skin Protection:** Wear chemical resistant gloves. Additional body garments should be used based upon the task being performed to avoid exposed skin surfaces.

8.4 **Body Protection:** Work uniform or lab coat.

8.5 **Respiratory Protection:** Particle respirator or dust mask. Use only approved respiratory protection.

9.0 **Physical and Chemical Properties:**

9.1 State:	Solid
9.2 Appearance:	Tablet
9.3 Color:	White to off-white
9.4 Odor:	No data available
9.5 pH:	No data available
9.6 Melting Point:	No data available
9.7 Freezing Point:	No data available
9.8 Boiling Point:	No data available
9.9 Flash Point:	No data available
9.10 Lower Explosive Limit (LEL):	No data available
9.11 Upper Explosive Limit (UEL):	No data available
9.12 Vapor Pressure:	No data available
9.13 Vapor Density:	No data available
9.14 Water Solubility:	No data available
9.15 Auto-Ignition Temperature:	No data available
9.16 Viscosity:	No data available

10.0 Stability and Reactivity:

- 10.1 **Reactivity:** Not classified as a reactivity hazard.
- 10.2 **Chemical stability:** Stable under recommended storage conditions.
- 10.3 **Possibility of hazardous reactions:** Minimal risk of hazardous reactions.
- 10.4 **Conditions to avoid:** Heat, flames and sparks. Avoid dust formation.
- 10.5 **Incompatible materials:** Oxidizing agents.
- 10.6 **Hazardous decomposition products:** No hazardous decomposition products are known.

11.0 Toxicological Information:

- 11.1 **Toxicological effects:** Not acute toxic.
- 11.2 **Skin corrosion / irritation:** Not skin corrosive/ irritation.
- 11.3 **Serious eye damage / irritation:** Causes serious eye irritation.
- 11.4 **Respiratory or Skin Sensitization:** Not a known sensitizer.
- 11.5 **Germ Cell Mutagenicity:** Not expected to be mutagenic.
- 11.6 **Carcinogenicity:** Not expected to be carcinogenic.
- 11.7 **Reproductive toxicity:** Suspect of damaging the unborn child.
- 11.8 **Specific Target Organ Toxicity (STOT) – Single Exposure:** Not classified based on available information.
- 11.9 **Specific Target Organ Toxicity (STOT) – Repeated Exposure:** Not classified based on available information.
- 11.10 **Aspiration Hazard:** Not an aspiration hazard.
- 11.11 **Additional Information:** See package insert.

12.0 Ecological Information:

- 12.1 **Ecotoxicity:** The product is not classified as environmentally hazardous. Avoid release into the environment.
- 12.2 **Persistence and degradability:** No data available.
- 12.3 **Possibility of hazardous reactions:** No data available.
- 12.4 **Bioaccumulative potential:** No data available.

12.5 **Mobility in soil:** No data available.

12.6 **Results of PBT and vPvB assessment:** No data available.

12.7 **Other adverse effects:** No data available.

13.0 Disposal Consideration:

13.1 **Waste Classification:** Not classified as RCRA Hazardous Waste.

13.2 **Waste treatment methods:** Incineration at a licensed waste handling facility.

14.0 Transportation Information:

14.1 **DOT (US):** Not classified as a Hazardous Material for ground transport.

14.2 **IATA:** Not classified as a Dangerous Good for air transport.

14.3 **IMDG:** Not classified as a Dangerous Good for maritime transport.

15.0 Regulatory Information:

15.1 **SARA 302 Components:** No data available.

15.2 **SARA 313 Components:** No data available.

15.3 **SARA 311 / 312 Hazards:** Combustible dust.
Serious eye damage or eye irritation
Reproductive toxicity

16.0 Other Information:

SDS Preparation Information: Ingenus Environmental, Health and Safety Department

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or the product for any particular purpose.

Ingenus shall not be liable for any damage resulting from handling or from contact with the above product.