Safety Data Sheet
Cyproheptadine Hydrochloride Oral Solution USP
Strength: 2mg/5mL Pack Size: 473mL

Revision No.: 00

EMERGENCY OVERVIEW
Each Cyproheptadine Hydrochloride Oral Solution USP intended for oral administration contains Cyproheptadine HCL and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

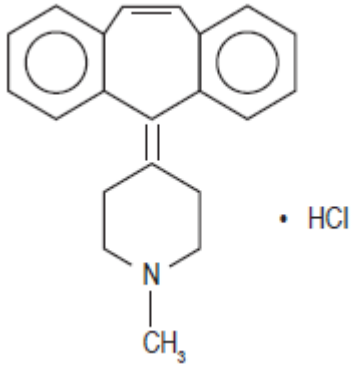
Section 1. Identification

Identification of the product

Product Name: Cyproheptadine Hydrochloride Oral Solution USP

Formula: $C_{21}H_{21}N$• HCL

Chemical Name: 4-(5H-dibenzo [a, d] cyclohepten-5-ylidene)-1-methylpiperidine hydrochloride



Manufacturer / supplier identification

Company: **InvaTech Pharma Solutions LLC**

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USA

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Recommended use / Therapeutic Category Antihistaminic and Antiserotonergic Agent.

Restriction on Use / Contraindications:	**Newborn or Premature Infants** This drug should not be used in newborn or premature infants. **Nursing Mothers** Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers. **Other Conditions** Hypersensitivity to cyproheptadine and other drugs of similar chemical structure. Monoamine oxidase inhibitor therapy Angle-closure glaucoma Stenosing peptic ulcer Symptomatic prostatic hypertrophy Bladder neck obstruction Pyloroduodenal obstruction Elderly, debilitated patients

Section 2. Hazard(s) Identification

Dose and Administration	DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT. Although intended primarily for administration to children, the syrup is also used for administration to adults who cannot swallow tablets. **Children:** The total daily dosage for children may be calculated on the basis of body weight or body area using approximately 0.25 mg/kg/day (0.11 mg/lb/day) or 8 mg per square meter of body surface (8 mg/m2). *Age 2 to 6 years:* The usual dose is 2 mg (one teaspoonful) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 12 mg a day. *Age 7 to 14 years:* The usual dose is 4 mg (two teaspoonsful) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 16 mg a day. **Adults:** The total daily dose for adults should not exceed 0.5 mg/kg/day (0.23 mg/lb/day). The therapeutic range is 4 to 20 mg a day, with the majority of patients requiring 12 to 16 mg a day. An occasional patient may require as much as 32 mg a day for adequate relief. It is suggested that dosage be initiated with 4 mg (two teaspoonsful) three times a day and adjusted according to the size and response of the patient.

Adverse Effects	Adverse reactions which have been reported with the use of antihistamines are as follows: **Central Nervous System:** Sedation and sleepiness (often transient), dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paresthesias, neuritis, convulsions, euphoria, hallucinations, hysteria, faintness. **Integumentary:** Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity. **Special Senses:** Acute labyrinthitis, blurred vision, diplopia, vertigo, tinnitus. **Cardiovascular:** Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock. **Hematologic:** Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia. **Digestive System:** Dryness of mouth, epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation, jaundice. **Genitourinary:** Urinary frequency, difficult urination, urinary retention, early menses. **Respiratory:** Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness. **Miscellaneous:** Fatigue, chills, headache, increased appetite/weight gain. To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.
Overdosage	Antihistamine overdosage reactions may vary from central nervous system depression to stimulation especially in children. Also, atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing, etc.) as well as gastrointestinal symptoms may occur. *If vomiting has not occurred spontaneously*, the patient should be induced to vomit with syrup of ipecac. *If the patient is unable to vomit*, perform gastric lavage followed by activated charcoal. Isotonic or 1/2 isotonic saline is the lavage of choice. Precautions against aspiration must be taken especially in infants and children. When life-threatening CNS signs and symptoms are present, intravenous physostigmine salicylate may be considered. Dosage and frequency of administration are dependent on age, clinical response and recurrence after response. (See package circulars for physostigmine products.) *Saline cathartics*, as milk of magnesia, by osmosis draw water into the bowel and, therefore, are valuable for their action in rapid dilution of bowel content. *Stimulants* should *not* be used. Vasopressors may be used to treat hypotension. The oral LD50 of cyproheptadine is 123 mg/kg, and 295 mg/kg in the mouse and rat, respectively.

Pregnancy Comments	Reproduction studies have been performed in rabbits, mice, and rats at oral or subcutaneous doses up to 32 times the maximum recommended human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to cyproheptadine. Cyproheptadine has been shown to be fetotoxic in rats when given by intraperitoneal injection in doses four times the maximum recommended human oral dose. Two studies in pregnant women, however, have not shown that cyproheptadine increases the risk of abnormalities when administered during the first, second and third trimesters of pregnancy. No teratogenic effects were observed in any of the newborns. Nevertheless, because the studies in humans cannot rule out the possibility of harm, cyproheptadine should be used during pregnancy only if clearly needed.
Pregnancy Category	B

Section 3. Composition / Information on Ingredients		
Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Cyproheptadine HCL	Not Found	41354-29-4
Inactive Ingredients:		
Alcohol	Not Found	64-17-5
Citric Acid	Not Found	77-92-9
Yellow	Not Found	8004-92-0
Purified Water	Not Found	7732-18-5
Sodium Citrate	Not Found	6132-04-3
Sorbic Acid	Not Found	110-44-1
Sugar	Not Found	57-50-1

Section 4. First-Aid Measures

General

- **After inhalation:**
  Move to fresh air in case of accidental inhalation. assure fresh air breathing.
- **After skin contact:**
  Rinse skin with water/shower
- **After eye contact:**
  Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:**
  Rinse mouth out with water
- **Information for doctor:**
- **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.

Overdose Treatment: Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.

Section 5. Fire-Fighting Measures	
Specific hazards arising from the chemical	**Extinguishing media** • **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. • **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not • **Protective equipment:** Hand protection : Gloves Skin Body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140) No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted

Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

Section 7. Handling and Storage	
Storage:	Store at 20° to 25°C (68° to 77°F) **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.

Section 8. Exposure Controls / Personal Protection

Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and Chemical Properties

Appearance	Yellow, peppermint-flavored vehicle supplied in a pint container		
Solubility	Not available	**Odor**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapor density**	Not available.
Reactivity in water	Not available.	**Vapor pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent

Section 11. Toxicological Information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available

Information on toxicological effects

Acute toxicity	Oral (rat) LD50: 295 mg/kg Intraperitoneal (Rat) LD50: 52.4 mg/kg Subcutaneous (rat) LD50: > 1000 mg/kg Oral (mouse) LD50 : 69 mg/kg Subcutaneous (mouse) LD 50: 74.2 mg/kg Intravenous (mouse) LD 50:23 mg/kg
Further information	Not available

Section 12. Ecological information

Poorly soluble in water. No data available on ecotoxicity.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN

Section 15. Regulatory Information

Generic Medicine. Under Approval by USFDA & the ANDA Number is 209108

Section 16. Other information

None

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