SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: CYPROHEPTADINE ORAL SUSPENSION

DESCRIPTION: Cyproheptadine Oral Suspension Inhalation Solution
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: 4-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-1-methylpiperidine hydrochloride sesquihydrate
CHEMICAL FAMILY: For Active Ingredient: Dibenzocycloheptene
HOW SUPPLIED: 2 mg as oral solution
OTHER DESIGNATIONS: NDC 00472-1400
FORMULA: For Active Ingredient: $C_{21}H_{21}N \bullet HCl \bullet 1.5H_2O$

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**ACTAVIS, INC.**
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NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This compound has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: June 13, 2013 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product is white to off-white powder in aqueous suspension.

Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin from prolonged contact. Eye contact and inhalation of mists or sprays may cause irritation. In therapeutic use, this product may cause adverse effects on the central nervous and cardiovascular systems, fatigue, chills, headache, increased appetite/weight gain. Antihistamines may diminish mental alertness. More information on adverse effects from is described in Section 11 (Toxicological Information).

Reactivity Hazards: This product is not reactive.

Flammability Hazards: This product is not flammable or combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides, hydrogen chloride).

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect due to active ingredient toxicity in marine organisms. This product has not been tested for toxicity in the marine or terrestrial environments.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Cyproheptadine Hydrochloride Sesquihydrate	41354-29-4	For Non-Hydrate: 213-535-1	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrase Codes: R33 Hazard Symbols: Xn GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, Respiratory Sensitization Cat. 1, STOT (Inhalation/Ingestion) RE Cat. 2, Aquatic Chronic Toxicity Cat. 3 Hazard Codes: H303, H315, H334, H373, H412 Hazard Symbol/Pictogram: GHS07, GHS08
Citric Acid, Anhydrous	77-92-9	201-069-1	Proprietary	SELF-CLASSIFICATION EU 67/548 Classification: Not Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: None Applicable
D&C Yellow No. 10	8004-92-0	Not Listed	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful Risk Phrase Codes: R22 Hazard Symbols: Xn GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4 Hazard Codes: H302 Hazard Symbol/Pictogram: GHS07
Ethyl Alcohol	64-17-5	200-578-5	Proprietary	EU 67/548 Classification: Highly Flammable Risk Phrases: R11 Hazard Symbol: F EU/GHS 1272/2008 Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbol/Pictogram: GHS02
Sodium Citrate	68-04-2	200-675-3	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Sorbic Acid	110-44-1	203-768-7	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrase Codes: R36/37/38 Hazard Symbols: Xi GHS & EU 1272/2008 Classification: Skin Irritation Cat. 2, Eye Irritation Cat. 2A, STOT (Inhalation-Respiratory Irritation) SE Cat. 3 Hazard Codes: H315, H319, H335 Hazard Symbol/Pictogram: GHS07
Sucrose	57-50-1	200-334-9	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Water	7732-18-5	231-791-2	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable

See Section 16 for full classification information for components.

4. FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of SDS to physician or other health professional with victim(s).

INHALATION: If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

EYE EXPOSURE: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

INGESTION EXPOSURE: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

4. FIRST-AID MEASURES (Continued)

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, hepatic, angle-closure glaucoma, peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, duodenal obstruction, bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or high blood pressure may be aggravated. Persons with these conditions may also have aggravation of these disorders. Workplace exposure may also aggravate these conditions.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. General supportive measures and symptomatic treatment should be followed in all cases of overdosage. Persons developing hypersensitivity reactions should receive medical attention. The following information is recommended in event of serious overdose or ingestion exposure to this product.

If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac. If patient is unable to vomit, perform gastric lavage followed by activated charcoal. Isotonic or 1/2 isotonic saline is the lavage of choice.

When life-threatening central nervous system 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. 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.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): LEL/UEL: Not applicable.

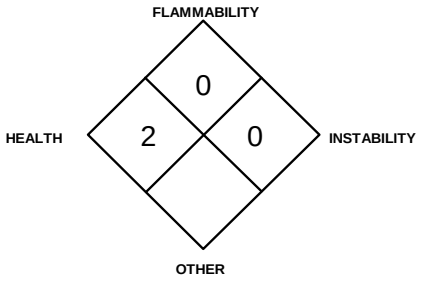
FIRE EXTINGUISHING MEDIA: In the event of a fire, use suppression methods for surrounding materials, including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: This product is not flammable or combustible, but may ignite if heated for a prolonged period and the water evaporates. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact/Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Contaminated protective equipment should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Spills may be slippery.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.**

METHODS FOR CLEANUP AND CONTAINMENT: Eliminate all sources of ignition before cleanup begins. Use non-sparking tools.

Small Spills: Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of mists or sprays onto polypads or other non-reactive absorption.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep container tightly closed when not in use. Use non-sparking tools. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Material should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity). Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Material should be stored in secondary containers or in a diked area, as appropriate. Store containers away from incompatible chemicals (see Section 10, Stability and Reactivity). Empty containers may contain residual liquid or vapors which are flammable; therefore, empty containers should be handled with care.

SPECIFIC END USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

OCCUPATIONAL/WORKPLACE EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA ppm	STEL ppm	TWA ppm	STEL ppm	TWA ppm	STEL ppm	IDLH ppm	ppm
Cyproheptadine Hydrochloride Sesquihydrate	41354-29-4	NE	NE	NE	NE	NE	NE	NE	NE
Citric Acid, Anhydrous	77-92-9	NE	NE	NE	NE	NE	NE	NE	NE
D&C Yellow No. 10	8004-92-0	NE	NE	NE	NE	NE	NE	NE	NE
Ethyl Alcohol	64-17-5	NE	1000	1000	NE	1000	NE	3300 (10% of LEL)	DFG MAKs: TWA = 500 PEAK = 2•MAK, 15 min. average value, 1-hr interval, 4 per shift DFG Germ Cell Mutagen Category: 5 DFG MAK Pregnancy Risk Classification: C Carcinogen: MAK-5, TLV-A3
Sorbic Acid	110-44-1	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Citrate	68-04-2	NE	NE	NE	NE	NE	NE	NE	NE
Sucrose	57-50-1	10	NE	15 (total dust), 5 (resp. fraction)	NE	10 (total dust), 5 (respirable fraction)	NE	NE	Carcinogen: TLV-A4
Water	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently the following international exposure limits are in place for some components of this product. Limits may added; consult appropriate authorities for currency.

CITRIC ACID:
Russia: STEL = 1 mg/m^3, JUN 2003

ETHANOL:
Australia: TWA = 1000 ppm (1880 mg/m^3), JUL 2008
AUSTRIA: MAK-TMW = 1000 ppm (1900 mg/m^3); KZW = 2000 ppm (3800 mg/m^3), 2007
Belgium: TWA = 1000 ppm (1907 mg/m^3), MAR 2002
Denmark: TWA = 1000 ppm (1900 mg/m^3), MAY 2011
Finland: TWA = 1000 ppm (1900 mg/m^3), STEL = 1300 ppm (2500 mg/m^3), NOV2011
France: VME = 1000 ppm (1900 mg/m^3), VLE = 5000 ppm (9500), FE B2006
Germany: MAK = 960 mg/m^3 (500 mL/m^3), 2005

ETHANOL (continued):
Hungary: TWA = 1900 mg/m^3, STEL = 7600 mg/m^3, SEP 2000
Iceland: TWA = 1000 ppm (1900 mg/m^3), NOV 2011
Korea: TWA = 1000 ppm (1900 mg/m^3), 2006
Mexico: TWA = 1000 ppm (1900 mg/m^3), 2004
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003
New Zealand: TWA = 1000 ppm (1880 mg/m^3), JAN 2002
Norway: TWA = 500 ppm (950 mg/m^3), JAN 1999
Peru: TWA = 1000 ppm (1884 mg/m^3), JUL2005
The Philippines: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Poland: MAC(TWA) = 1000 mg/m^3, MAC(STEL) = 3000 mg/m^3, JAN 1999

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS (continued):

ETHANOL (continued):

Russia: TWA = 1000 mg/m^3, STEL = 2000 mg/m^3, JUN 2003
Sweden: TWA = 500 ppm (1000 mg/m^3); STEL = 1000 ppm (1900 mg/m^3), JUN 2005
Switzerland: MAK-W =500 ppm (960 mg/m^3), KZG-W = 1000 ppm (1920 mg/m^3), DEC 2006
Thailand: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Turkey: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
United Kingdom: TWA = 1000 ppm (1920 mg/m^3), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

SUCROSE:

Belgium: TWA = 10 mg/m^3, MAR 2002
France: VME = 10 mg/m^3, FEB 2006
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Peru: TWA = 10 mg/m^3, JUL 2005
United Kingdom: TWA = 10 mg/m^3; STEL = 20 mg/m^3, OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Singapore, Vietnam check ACGIH TLV

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations. The following are NIOSH respiratory protection guidelines for the alcohol component and are being provided to assist in selection respiratory equipment, should it be needed.

ETHANOL

CONCENTRATION	**RESPIRATORY PROTECTION**
Up to 3300 ppm:	Any Supplied-Air Respirator (SAR), or any Self-Contained Breathing Apparatus (SCBA) with a full facepiece.
Emergency or Planned Entry into Unknown Concentrations or IDLH Conditions:	Any SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any SAR that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in pressure-demand or other positive-pressure mode.
Escape:	Any appropriate escape-type, SCBA.

EYE PROTECTION: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

HAND PROTECTION: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Liquid.
COLOR: White suspension in clear liquid.
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following values are available for the active ingredient, Cyproheptadine Hydrochloride Sesquihydrate:

FORM: Powdered, crystalline.
COLOR: White.
MOLECULAR FORMULA: $C_{21}H_{21}N \bullet HCl \bullet 1.5H_2O$
MOLECULAR WEIGHT: 701.763977 Da (average weight)
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
VAPOR PRESSURE (air = 1) @ 25°C: 6.03E-08 mmHg [predict.]
VAPOR DENSITY (air = 1): Not available.
BOILING POINT @ 760 mmHg: ~ 440.1°C (~ 824.2°F) [predict.]
EVAPORATION RATE (nBuAc = 1): Not applicable.
MELTING POINT: 169-170.5°C (336-339°F)
% VOLATILITY: No data available.
pH: Not available.
DENSITY @ 21°C: Not available.
FLASH POINT: ~ 194.5°C (~ 382.1°F) [predict.]
FLAMMABILITY: Combustible.
UPPER EXPLOSIVE LIMIT: No data available.
LOWER EXPLOSIVE LIMIT: No data available.
AUTOIGNITION TEMPERATURE: No data available.
DECOMPOSITION TEMPERATURE: No data available.
SOLUBILITY IN WATER: Soluble.
COEFFICIENT OF WATER/OIL DISTRIBUTION: Log P: 6.407 (predict.)
OTHER SOLUBILITIES: Freely soluble in methanol, sparingly soluble in ethanol, soluble in chloroform, and practically insoluble in ether.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon and nitrogen oxides, hydrogen chloride). *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility.

POSSIBILITY OF HAZARDOUS REACTIONS OR POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE (continued):

INHALATION: If vapors, mists, or sprays of the product are inhaled, they may cause coughing and respiratory irritation. No other specific symptoms are known.

CONTACT WITH SKIN or EYES: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged skin contact may cause dermatitis (dry, red, cracked skin). Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.

SKIN ABSORPTION: The Ethyl Alcohol component can be absorbed via intact skin. Although no information is available on possible adverse effects by this route of exposure, all skin contact should be avoided.

INGESTION: ingestion caused by poor hygiene practices may cause adverse symptoms as described under 'Other Potential Health Effects'.

INJECTION: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

INJECTION: Local pain and inflammation may result from subcutaneous injection.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, this product may cause adverse effects on the central nervous and cardiovascular systems, fatigue, chills, headache and increased appetite/weight gain. Antihistamines may diminish mental alertness. Therapeutic effects may not be relevant to occupational exposure; they are presented to provide the most detailed information available the product. Additional effects described by body system are provided below.

- ***Blood:*** Hemolytic anemia, decrease in the number of white blood cells, other white blood cell levels, blood platelet decrease.
- ***Body as a Whole:*** Fatigue, chills, headache, increased appetite/weight gain.
- ***Cardiovascular System:*** High blood pressure, palpitation, tachycardia, extrasystoles, anaphylactic shock.
- ***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.
- ***Ears:*** Inflammation of the inner ear, vertigo, ringing in the ears.
- ***Eyes:*** Blurred vision, double vision.
- ***Gastrointestinal System:*** Cholestasis, hepatic failure, hepatitis, hepatic function abnormality, dryness of mouth, epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation, jaundice.
- ***Genitourinary System:*** Urinary frequency, difficult urination, urinary retention, early menses.
- ***Respiratory System:*** Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.
- ***Skin:*** Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is irritation of contaminated skin or eyes.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin) or other effects described under 'Ingestion'.

TARGET ORGANS:

Acute: *Industrial Exposure*: Skin, eyes, respiratory system. *Therapeutic Doses*: Central nervous system and other target organs as described under 'Other Potential Health Effects'.

Chronic: *Industrial Exposure*: Skin. *Therapeutic Doses*: Central nervous and cardiovascular systems.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue, especially if contact is prolonged.

SENSITIZATION OF PRODUCT: The Ethanol component is not a clear occupational skin sensitizer. Approximately 20 cases of Ethanol allergic skin reactions confirmed by positive patch tests have been identified; however, other testing has not clearly established Ethanol as a human skin sensitizer. Some effects of sensitization have been described for Cyproheptadine, as indicated under 'Other Potential Health Effects'.

TOXICITY DATA: Currently, no toxicity data are available for the active ingredient, Cyproheptadine HCl Sesquihydrate. For the non-hydrated form of Cyproheptadine HCl, the oral LD_{50} of Cyproheptadine is 123 mg/kg, and 295 mg/kg in the mouse and rat, respectively. The relevance of this toxicity level is not known for the form of Cyproheptadine HCl in this product. Additional data are available for the excipient components of this product, but are not presented in this SDS. Contact Actavis for more information.

CARCINOGENIC POTENTIAL OF COMPONENTS: Long-term carcinogenic studies have not been done with Cyproheptadine.

The excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

Ethanol: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

Sucrose: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION: This product is rated Pregnancy Risk Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester). 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.

Mutagenicity: Cyproheptadine did not produce chromosome damage in human lymphocytes or fibroblasts in vitro; high doses (10-4M) were cytotoxic. Cyproheptadine did not have any mutagenic effect in the Ames microbial mutagen test; concentrations of above 500 mcg/plate inhibited bacterial growth. Ethanol is considered a very toxic mutagen, because it has caused mutations in both the germ cells and somatic cells of live animals. These effects were observed following exposure of the animals to very high, oral doses of Ethanol.

Embryotoxicity/Teratogenicity: Cyproheptadine has been shown to be fetotoxic in rats when given by intraperitoneal injection in doses four times the maximum recommended human oral dose.

It is well documented that exposure to Ethanol through the ingestion of alcoholic beverages during pregnancy can cause significant harmful effects in unborn children. There are no reports of adverse effects on pregnancy following occupational exposures of Ethanol. The harmful effects of ethanol administration to pregnant animals are well documented. Effects have included fetotoxicity (e.g. delayed growth), embryotoxicity (e.g. increased prenatal mortality). The minimum dose required to produce these effects varies and determination of this dose is complicated by factors such as the duration and route of exposure and the stage of pregnancy during which the Ethanol is administered. For example, long-term exposure during pregnancy produces effects at lower doses than short-term exposure. Most studies involving oral exposure to Ethanol have involved very large doses that have also produced significant maternal toxicity. The Ethanol component has shown significant teratogenic effects in animal tests (e.g. malformations of the central nervous system, facial structures, heart, limbs and urogenital system). The lowest reported dose which caused teratogenicity in rats is approximately 316 mg/kg (cited as 0.4 mL/kg). No firm conclusions can be drawn from this study since the authors did not conduct a full evaluation of maternal toxicity. Inhalation exposure to levels as high as 20,000 ppm has not produced any statistically significant teratogenic effects despite severe maternal toxicity (unconsciousness). In a related study, male and female rats were exposed to 16,000 or 10,000 ppm for 6 weeks before mating with untreated rats. Pregnant rats were exposed throughout pregnancy. Despite the presence of measurable neuro-chemical effects, there were no behavioral effects observed in the offspring of exposed male or female rats. There are no reports of adverse effects on pregnancy following occupational exposures.

Reproductive Toxicity: Cyproheptadine had no effect on fertility in a two-litter study in rats or a two generation study in mice at about 10 times the human dose. Reproductive effects have been observed in people who have consumed large amounts of alcoholic beverages which contain Ethanol. In tests involving Ethanol, effects on reproductive organs, including decreased testicular weight, decreased numbers of motile sperm, decreased ovarian function and irregular fertility cycles, have been observed in animals given large oral doses of ethanol. However, no confirmed effects on fertility or reproductive capability have been observed. In a well-conducted continuous breeding stud involving Ethanol, mice were exposed to 5, 10 or 15% ethanol in water (approximately 8,500, 16,000 and 20,000 mg/kg/day). No effects on fertility and only minor reproductive effects were observed (reduced sperm motility and increased time between litters). Male and female rats with inhalation exposure to 10,000 or 16,000 ppm ethanol for 6 weeks prior to mating showed no effect on fertility. It is not known if Cyproheptadine is excreted in human milk.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, no ACGIH Biological Exposure Indices (BEIs) have been determined for any component of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil; it is expected to be somewhat mobile due to its composition. The following information is available for the Ethanol component.

ETHYL ALCOHOL: Using a structure estimation method based on molecular connectivity indices, the Koc can be estimated to be 1. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known. The following information is available for the Ethanol component.

ETHYL ALCOHOL: If released to the atmosphere, an extrapolated vapor pressure of 59.3 mm Hg at 25°C indicates that this compound will exist solely in the vapor phase. Vapor phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 days. If released to soil, this compound is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 5X10-6 atm-cu m/mole. This material may also volatilize from dry soils based upon it vapor pressure. Biodegradation is expected to occur rapidly in the environment based on numerous screening tests using different types of inocula and incubation periods. This compound was degraded with half-lives on the order of a few days using microcosms constructed with a low organic sandy soil and groundwater, indicating it is unlikely to be persistent in the environment. If released into water, this material is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 3 and 39 days, respectively. Hydrolysis and photolysis in sunlit surface waters are not expected since this compound lacks functional groups that are susceptible to hydrolysis or photolysis under environmental conditions.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bioaccumulation potential. The Ethyl Alcohol component has a BCF of 3, which suggest the bioconcentration potential of this product is low.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product. The following data are available for the Ethyl Alcohol component.

ETHANOL:

Toxicity Threshold (Cell Multiplication Inhibition Test) (*Microcystis aeruginosa* algae) 1450 mg/L

Toxicity Threshold (Cell Multiplication Inhibition Test) (*Entosiphon sulcatum* protozoa) 65 mg/L

EC_{50} (*Chlorella pyrenoidosa* Green algae; growth inhibition) 48 hours = 9310 mg/L; static

EC_{50} (*Pimephales promelas* fathead minnows) 96 hours = 12.9 g/L

LC_{50} (*Palaemonetes*) 96 hours = > 250 mg/L at 21°C, mature/Static bioassay

LC_{50} (*Salmo gairdnerii* Rainbow trout) 96 hours = 13,000 mg/L

ETHANOL (continued):

LC_{50} (*Pimephales promelas* fathead minnows) 96 hours = 14.2 g/L (95% confidence limit 13.4-15.1 g/L)

LC_{50} (*Artemia franchiscana* Brine shrimp) 96 hours = 7.00 mg/L; static

LC_{50} (*Leuciscus idus melanotus* Golden orfe) 48 hours = 8140 mg/L; static

LC_{50} (*Danio rerio* Zebrafish) 24 hours = >100 mg/L; static

LC_{50} (*Daphnia magna* Water flea) 48 hours = 11,853-13248 mg/L; static, 20°C

LC_{50} (*Artemia salina* Crustacean) 24 hours = >10,000 mg/L; static, 24.5°C

LC_{50} (*Oryzias latipes* Medaka) 48 hours = 1350 mg/L; static

12. ECOLOGICAL INFORMATION (Continued)

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.
RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.
ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.
PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.
U.S. EPA WASTE NUMBER: Not applicable.
EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.
TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.
INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.
EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.
TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.
ENVIRONMENTAL HAZARDS: The active ingredient of this product can cause harm to aquatic organisms, according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); the active ingredient is not a listed marine pollutant, under the to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL UNITED STATES REGULATIONS:
U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.
U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.
U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 Lists. In the form of alcoholic beverages to be consumed, the Ethanol component of this product is on the California Proposition 65 lists as a compound that is known to cause developmental harm. This does not apply to Ethanol that is not consumed as a beverage.
CANADIAN REGULATIONS:
CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.
CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.
CANADIAN WHMIS CLASSIFICATION AND SYMBOL: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.
EUROPEAN REGULATIONS:
SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.
CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! ACCIDENTAL INGESTION MAY CAUSE ADVERSE EFFECTS ON CENTRAL NERVOUS AND CARDIOVASCULAR SYSTEMS. MAY CAUSE EYE AND RESPIRATORY TRACT IRRITATION. Keep away from heat, sparks, and flame. Avoid contact with skin, eyes, and clothing. Avoid breathing vapors. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, do NOT induce vomiting. If vomiting occurs, have person lean forward. Call physician or poison control center immediately. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residue in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Cyproheptadine Hydrochloride Sesquihydrate: This is a self-classification.
- Classification: Acute Oral Toxicity Category 5, Eye Irritation Category 2A, Specific Target Organ Toxicity (Ingestion) Repeated Exposure Category 2
- Hazard Statements: H303: May be harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

Citric Acid: This is a self-classification.
- Classification: Acute Oral Toxicity Category 5
- Hazard Statements: H303: May be harmful if swallowed.

D&C Yellow # 10: Self-Classification
- Classification: Acute Toxicity Oral Category 4
- Hazard Statements: H302: May be harmful if swallowed.

Ethyl Alcohol: This is a published classification.
- Classification: Flammable Liquid Category 2
- Hazard Statements: H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness.

Sorbic Acid: This is a self-classification.
- Classification: Skin Irritation Category 2, Eye Irritation Category 2A, Specific Target Organ Toxicity (Inhalation-Respiratory Irritation) Single Exposure Category 3
- Hazard Statements: H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation.

All Other Components:

An official classification for these substances has not been published in the CLP 1272: 2008 and a self-classification is not applicable.

67/548/EEC:

Cyproheptadine Hydrochloride Sesquihydrate: This is a self-classification.
- Hazard Classification: Irritant
- Risk Phrases: R36/37/38: Irritating to eyes, respiratory system and skin

D&C Yellow # 10: Self-Classification
- Classification: Harmful
- Risk Phrases: R22: Harmful if ingested.

Ethyl Alcohol: This is a published classification.
- Hazard Classification: Highly Flammable
- Risk Phrases: R11: Highly flammable. R36: Irritating to eyes. R67: Vapours may cause drowsiness and dizziness.

Sorbic Acid: This is a self-classification.
- Hazard Classification: Irritant
- Risk Phrases: R36/37/38: Irritating to eyes, respiratory system and skin.

All Other Components:

An official classification for these substances has not been published in Commission Directives and a self-classification is not applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.
REVISION DETAILS: New.

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