MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME:	**Cetirizine Hydrochloride Syrup 1mg/mL, (OTC)**	**Product :**	51672-2088- **Allergy** 51672-2090 - **Hives**
CAS #:	83881-52-1 (CETIRIZINE DIHYDROCHLORIDE)	**FORMULA:**	$C_{21}H_{25}C_lN_2O_3$•2HCl
SUBSTANCE CLASS:	Selective H_1-Receptor Antagonist	**M.W.:**	461.82

SECTION 2: PHYSICAL/CHEMICAL DATA

Boiling point:	Not Determined
Physical state (liquid/solid/gas):	Liquid
Specific gravity (H_2O=1):	1.100 -1.300
Evaporation rate (Butyl Acetate=1):	Not Determined
Solubility:	Soluble in water.
Appearance:	Cetirizine hydrochloride is a white or almost white powder. Taro Cetirizine Hydrochloride Syrup is colorless to slightly yellow liquid free from any particles.
Odor description:	Grape-Banana Flavor

SECTION 3: FIRE AND EXPLOSION HAZARD DATA

Flash point:	Not Determined
Extinguishing media:	No special requirements needed.
Special fire fighting procedures:	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Unusual fire and explosion hazards:	This product is classified as non-flammable.
Hazardous combustion products:	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

SECTION 4: STABILITY AND REACTIVITY DATA

Chemical stability:	Stable
Physical conditions to avoid:	None for normal handling of this product.
Incompatibility with other materials:	Not Determined
Hazardous decomposition products:	Not Determined
Hazardous polymerization:	Not Determined
Conditions to avoid:	Not Determined
Material to avoid:	Not Determined

SECTION 5: PHARMACOLOGY

Pharmacological Activity:	Cetirizine, a metabolite of hydroxyzine, is an antihistamine; its principal effects are mediated via selective inhibition of H1 receptors. The antihistaminic activity of cetirizine has been clearly documented in a variety of animal and human models. *In vivo* and *Ex vivo* animal models have shown negligible anticholinergic and antiserotonergic activity. In clinical trials, however, dry mouth was more common with cetirizine than with placebo. *In vitro* receptor binding studies have shown no measurable affinity for other than H1 receptors. Autoradiographic studies with radiolabeled cetirizine in the rat have shown negligible penetration into the brain. *Ex vivo* experiments in the mouse have shown that systemically administered cetirizine does not significantly occupy cerebral H1 receptors**.**
Half-life:	7.9 – 8.3 hours
Onset of action:	20 minutes to 1 hour
Time to peak effect:	Not Determined
Metabolism:	Low degree first pass metabolism
Elimination:	Renal (70%)

SECTION 6: HEALTH HAZARD DATA

EMERGENCY OVERVIEW	The risk of health hazards may be reduced when Cetirizine Hydrochloride Syrup is handled as directed in the product description.
Primary Routes of Exposure:	Ingestion
Overdose Effects:	Most common effects are on the CNS, including hallucinations, excitements, ataxia, and convulsions. Get Medical Help or Call Poison Control Center immediately.
Adverse Effects:	The most common adverse reaction in patients aged 12 years and older that occurred more frequently on cetirizine than placebo was

	somnolence. The incidence of somnolence associated with cetirizine was dose related, 6% in placebo, 11% at 5 mg and 14% at 10 mg. Discontinuations due to somnolence for cetirizine were uncommon (1.0% on cetirizine vs. 0.6% on placebo). Fatigue and dry mouth also appeared to be treatment-related adverse reactions. There were no differences by age, race, gender or by body weight with regard to the incidence of adverse reactions.
Acute:	Not Determined
Eye:	Irritation is not expected following direct contact with eyes.
Ingestion:	Not expected to be toxic following ingestion.
Skin:	Irritation is not expected following direct contact.
Inhalation:	Not Determined
Chronic Effects:	Not Determined
Medical Conditions Aggravated by Exposure:	Activities Requiring Mental Alertness: In clinical trials, the occurrence of somnolence has been reported in some patients taking cetirizine; due caution should therefore be exercised when driving a car or operating potentially dangerous machinery. Concurrent use of cetirizine with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur.
Contraindications:	Taro Cetirizine Hydrochloride Syrupis contraindicated in those patients with a known hypersensitivity to it or any of its ingredients or hydroxyzine.

ECTION 7: TOXICOLOGICAL INFORMATION

The risk of health hazards may be reduced when Taro Cetirizine Hydrochloride Syrup is handled as directed in the product description.

Oral Rat:	LD50: 703 mg/kg
Oral Mouse:	LD50: 600 mg/kg (male), 752 mg/kg (female)
Carcinogen:	Not expected to produce cancer in humans under occupational exposure conditions.
Acute Toxicity:	Not Determined
Repeat Dose Toxicity:	Not Determined
Sensitization:	Sensitization (allergic skin reaction) is not expected.
Reproductive Effects:	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

SECTION 8: SPILL OR LEAK PROCEDURES

Routine: Not Determined

Accidental release:

Personal Precautions

Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

Collect and place it in a suitable, properly labeled container for recovery or disposal.

Decontamination Procedures

No specific decontamination or detoxification procedures have been identified for this product.

SECTION 9: HANDLING AND STORAGE

Handling: No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Storage: No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

SECTION 10: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls: Not Determined

Personal protection Safety Glasses, adequate ventilation

Respiratory: Not required under normal conditions of use and storage.

Eye: Workers should wear adequate eye protection to prevent eye contact.

Clothing: Adequate protective clothing should be worn to prevent occupational skin contact.

Gloves: When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn.

Work practices: Not Determined

SECTION 11: OTHER INFORMATION

Environmental effects: No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Waste disposal: Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Observe all local and national regulations when disposing of this product.

SECTION 12: TRANSPORTATION INFORMATION

US Department of Transportation

Proper shipping name: Not regulated in transportation.

IATA/ICAO

Proper shipping name: Not regulated in transportation.

IMDG

Proper shipping name: Not regulated in transportation.

RQ: None

Marine Pollutant: No

SECTION 13: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Pseudoephedrine is not listed under the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations, 1996. However suitable labeling would be:

Indication of Danger (Hazard Symbol): Not Available

Risk Phrases: Not Available

Safety Phrases: Not Available

Other legislation: Not Available

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.

Revised: April 11, 2008