

SAFETY DATA SHEETS

This SDS packet was issued with item:

078906801

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078850062



1110 W. Lake Cook Rd.
Suite 301
Buffalo Grove, IL 60089
(800) 521-5340

MATERIAL SAFETY DATA SHEET

DATE: 04/07/2011

GENERIC NAME: Cetirizine Hydrochloride Tablets 5mg and 10mg - ALLERGY

BRAND EQUIVILANT: Zyrtec® Allergy

SECTION 1: CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Common Name	Cetirizine Hydrochloride Tablets
Synonyms	N/A
Formula	$C_{21}H_{25}ClN_2O_3 \cdot 2HCl$
CAS Number	83881-52-1
Therapeutic Category	Anti allergic/Antihistamine
Chemical Name	(±) - [2- [4- [(4-chlorophenyl)phenylmethyl] -1-piperazinyl] ethoxy]acetic acid, dihydrochloride
Additional Names	N/A
Manufacturer Name & Address	Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd) Meelam Centre Worli, Mumbai 400016, INDIA
Distributor Name & Address	PACK Pharmaceuticals, LLC 1110 W. Lake Cook Rd., Ste. 301 Buffalo Grove, IL 60089
Emergency Telephone No.	(866) 562-4597
Adverse Reactions/Product Compliant/Inquires	(866) 562-4597

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

This material is not subject to the Federal Occupational Safety and Health Standards (OSHA) Hazard Communication Standard 29 CFR 1910.1200

SECTION 3: HAZARDS IDENTIFICATOIN

N/A



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SECTION 4: FIRST AID MEASURES

General	Use only as directed. See product packaging for further information concerning adverse effects and drug interactions.
Eyes	In case of contact flush with plenty of water for at least 15 minutes. Contact a physician.
Skin	No skin irritation is known. If contact occurs, wash with plenty of water, if persists, contact physician

SECTION 5: FIRE AND EXPLOSION DATA

Flash Point	Not Applicable
Explosion Sensitivity to Impact	None Known
Explosion Sensitivity to Static Electricity	None Known
Combustible Material	Not Applicable
Explosive Material	Not Applicable
Flammable Material	None Known
Pyrophoric Material	Not Applicable
Hazardous Combustion Products	Will not occur

SECTION 6: ACCIDENTAL RELEASE MEASURES

Spills/Leaks	Spills should be swept up and placed in appropriate containers for disposal. Prevent from entering open drains and waterways. Avoid creating dusty conditions.
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SECTION 7: HANDLING & STORAGE

Handling	Keep this and all drugs out of reach of children. Wash thoroughly for handling. Store in a dry place away from excessive heat. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug. Avoid contact with eyes, skin or clothing.
Storage	Store at 20°-25 °C (68°-77° F)



MATERIAL SAFETY DATA SHEET

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Control	Not Applicable
Respiratory Protection	NIOSH approved dust respirator should be worn if inhalation of dust is a problem.
Skin Protection	Lab coat. Employees should wash their hands and face before eating, drinking or using tobacco products. Gloves, long sleeved shirts and pants
Eye Protection	None for normal use.

SECTION 9: PHYSICAL DATA

Melting Point	Not Applicable
Solubility in Water	Soluble
Solubility in org. solvents	Not Established
Molecular Weight	Not Applicable
Appearance	White to slightly yellowish
Odor	Odorless

SECTION 10: STABILITY & REACTIVITY

Stability	Stable
Hazardous Decomposition Products	These products are carbon oxides (CO, CO ₂), halogenated compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

Reproductive Effects	No adequate and well-controlled studies in pregnant women.
Carcinogenicity	Long-term carcinogenicity studies in rats and mice resulted in no carcinogenic or tumorigenic or clastogenic effects due to Cetirizine at daily oral dose levels.
Mutagenicity	Nil
Ecotoxicity	No data available for this product



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SECTION 12: ECOLOGICAL INFORMATION

Acute Aquatic Toxicity	None Known
Degradability	Not Applicable

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method	Incineration is recommended. Waste disposal should be in accordance with existing federal, state and local environment control laws.
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SECTION 14: TRANSPORTATION INFORMATION

This material is not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION

NDCNumber/s:	5mg: 16571-401-10 (100ct)
	10mg: 16571-402-10 (100ct) 16571-402-50 (500ct) 16571-402-00 (10000ct)

SECTION 16: OTHER INFORMATION

MSDS Preparation Information	Created: 02/01/2010 Updated: 02/01/2011 Updated: 10/08/2012
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DISCLAIMER

The above information is believed to be correct but should only be used as a guide. PACK Pharmaceuticals, LLC disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.



October 12, 2015

Subject: SDS Exemption Letter for Cetirizine Hydrochloride Tablets, 5mg and 10mg

To Whom It May Concern:

This communication serves as a Safety Data Sheet (SDS) Exemption Letter for the following product(s) listed below:

NDC	Product
16571-401-10	Cetirizine Hydrochloride Tablets, 5mg, 100ct
16571-402-10	Cetirizine Hydrochloride Tablets, 10mg, 100ct
16571-402-50	Cetirizine Hydrochloride Tablets, 10mg, 500ct

The Hazard Communication regulation, which requires the preparation of Safety Data Sheets (SDS) for hazardous chemicals in the workplace, reads as follows:

Title 29 Section 1910.1200 Hazard communication

(b)(6) This section does not apply to: (vii) Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et. seq.*), when it is in solid, final form for direct administration to the patient (*e.g.*, tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (*e.g.*, over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (*e.g.*, first aid supplies);

The above paragraph exempts solid-dose finished pharmaceuticals (i.e., tablets and capsules) from requirements of the Hazard Communication regulation. For this reason, in compliance with the regulation, an SDS is not required for the subject product(s).

For general information on the handling and storage of product, please refer to the label.

Sincerely,

Rising Quality Assurance