



MATERIAL SAFETY DATA SHEET

Revision date: 13-Dec-2007

Version: 1.4

Page 1 of 9

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

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Material Name: Cetirizine HCl Film Coated Tablets

Trade Name:	ZYRTEC®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antihistamine

2. HAZARDS IDENTIFICATION

Appearance: White, film-coated tablet

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Active ingredient may be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: Sleepiness, dry mouth, fatigue, pharyngitis, dizziness

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 2 of 9
Version: 1.4

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Cetirizine hydrochloride	83881-52-1	Not listed	Xn;R22	5.88
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Croscarmellose sodium	74811-65-7	Not listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Hypromellose	9004-65-3	Not listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 3 of 9
Version: 1.4

- Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

- General Handling:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided.
- Storage Conditions:** Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
Latvia OEL - TWA	= 2 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

Colloidal silicon dioxide

Australia TWA	= 2 mg/m ³ TWA
Austria OEL - MAKs	= 4 mg/m ³ MAK
Czech Republic OEL - TWA	= 0.1 mg/m ³ TWA
	= 4.0 mg/m ³ TWA
Estonia OEL - TWA	= 2 mg/m ³ TWA
Germany - TRGS 900 - TWAs	= 4 mg/m ³ TWA
Ireland OEL - TWAs	= 2.4 mg/m ³ TWA
	= 6 mg/m ³ TWA
Latvia OEL - TWA	= 1 mg/m ³ TWA containing more than 70% SiO ₂ (quartz)
	= 2 mg/m ³ TWA containing 10-70% SiO ₂ (granite, mica)
	= 4 mg/m ³ TWA containing 2-10% SiO ₂ (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(%) SiO ₂) mg/m ³ TWA
	= 20 mppcf TWA
Slovakia OEL - TWA	= 4.0 mg/m ³ TWA
Slovenia OEL - TWA	= 4 mg/m ³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 4 of 9
Version: 1.4

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA	
Belgium OEL - TWA	= 10 mg/m ³ TWA	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m ³ IPRV	
Portugal OEL - TWA	= 10 mg/m ³ TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m ³ VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m ³ LLV	

Cetirizine hydrochloride

Pfizer OEL TWA-8 Hr:	150µg/m ³
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Titanium dioxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	
Australia TWA	= 10 mg/m ³ TWA	
Austria OEL - MAKs	= 6 mg/m ³ MAK	
Belgium OEL - TWA	= 10 mg/m ³ TWA	
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA	
Denmark OEL - TWA	= 6 mg/m ³ TWA	
Estonia OEL - TWA	= 5 mg/m ³ TWA	
France OEL - TWA	= 10 mg/m ³ VME	
Greece OEL - TWA	= 10 mg/m ³ TWA	
	= 5 mg/m ³ TWA	
Ireland OEL - TWAs	= 10 mg/m ³ TWA	
	= 4 mg/m ³ TWA	
Latvia OEL - TWA	= 10 mg/m ³ TWA	
Lithuania OEL - TWA	= 5 mg/m ³ IPRV	
Netherlands OEL - TWA	= 10 mg/m ³ MAC	
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA	total
Poland OEL - TWA	= 10.0 mg/m ³ NDS	<2% free crystalline silica and containing no asbestos
	= 10 mg/m ³ TWA	
Portugal OEL - TWA	= 10 mg/m ³ TWA	
Romania OEL - TWA	= 10 mg/m ³ TWA	
Spain OEL - TWA	= 10 mg/m ³ VLA-ED	
Sweden OEL - TWAs	= 5 mg/m ³ LLV	

Polyethylene glycol

Austria OEL - MAKs	= 1000 mg/m ³ MAK
Germany - TRGS 900 - TWAs	= 1000 mg/m ³ TWA
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
Slovakia OEL - TWA	= 1000 mg/m ³ TWA
Slovenia OEL - TWA	= 1000 mg/m ³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method:

Analytical method available for cetirizine hydrochloride. Contact Pfizer Inc for further information.

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.

Personal Protective Equipment:

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 5 of 9
Version: 1.4

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Heat, sparks, and flame
Incompatible Materials: Bases, strong oxidizers
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Cetirizine hydrochloride

Rat (M) Oral LD50 703 mg/kg
Rat (F) Oral LD50 865 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Lactose

Rat Oral LD50 > 10 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 6 of 9
Version: 1.4

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Cetirizine hydrochloride

6 Month(s) Dog Oral 8 mg/kg/day NOEL None identified
1 Month(s) Dog Oral 45 mg/kg/day NOEL None identified
6 Month(s) Rat Oral 8 mg/kg/day NOEL Liver
1 Year(s) Monkey Oral 45 mg/kg/day NOAEL None identified
1 Year(s) Dog Oral 60 mg/kg/day NOAEL None identified

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cetirizine hydrochloride

Reproductive & Fertility Mouse Oral 64 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Mouse Oral 96 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rat Oral 225 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 135 mg/kg/day NOAEL Not Teratogenic
Peri-/Postnatal Development Mouse No route specified 24 mg/kg/day NOEL Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Cetirizine hydrochloride

Bacterial Mutagenicity (Ames) Bacteria Negative
Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Rat Negative
Chromosome Aberration Mouse Lymphoma Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cetirizine hydrochloride

2 Year(s) Rat Oral 20 mg/kg/day NOEL Not carcinogenic
2 Year(s) Mouse Oral 4 mg/kg/day NOEL Not carcinogenic, Benign tumors

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Colloidal silicon dioxide

IARC: Group 3

Titanium dioxide

IARC: Group 2B
OSHA: Present

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 7 of 9
Version: 1.4

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Cetirizine hydrochloride

<i>Pseudokirchneriella subcapitata</i> (Green Alga)	NPDES	EC50	96 Hours	96.9 mg/L
<i>Daphnia magna</i> (Water Flea)	NPDES	LC50	48 Hours	14 mg/L
<i>Cyprinodon variegatus</i> (Sheepshead Minnow)	NPDES	LC50	48 Hours	> 100 mg/L
<i>Mysidopsis bahia</i> (Mysid Shrimp)	NPDES	LC50	48 Hours	44.7 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	48 Hours	> 100 mg/L

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Cetirizine hydrochloride

Activated sludge MIC 100 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 8 of 9
Version: 1.4

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Croscarmellose sodium

Australia (AICS):	Present
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Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 EEC No. 418-260-2

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-559-2

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

MATERIAL SAFETY DATA SHEET

Material Name: Cetirizine HCl Film Coated Tablets
Revision date: 13-Dec-2007

Page 9 of 9
Version: 1.4

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet