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

Material Name: Cetirizine HCl Film Coated Tablets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>ZYRTEC®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as antihistamine</td>
</tr>
</tbody>
</table>

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


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

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Cetirizine hydrochloride</td>
<td>83881-52-1</td>
<td>Not listed</td>
<td>Xn;R22</td>
<td>5.88</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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/m³ TWA
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA = 10 mg/m³ TWA
- Estonia OEL - TWA = 10 mg/m³ TWA
- France OEL - TWA = 10 mg/m³ VME
- Ireland OEL - TWAs = 10 mg/m³ TWA
  = 4 mg/m³ TWA
- Latvia OEL - TWA = 2 mg/m³ TWA
- OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
- Portugal OEL - TWA = 10 mg/m³ TWA
- Romania OEL - TWA = 10 mg/m³ TWA
- Spain OEL - TWA = 10 mg/m³ VLA-ED

Colloidal silicon dioxide
- Australia TWA = 2 mg/m³ TWA
- Austria OEL - MAKs = 4 mg/m³ MAK
- Czech Republic OEL - TWA = 0.1 mg/m³ TWA
  = 4.0 mg/m³ TWA
- Estonia OEL - TWA = 2 mg/m³ TWA
- Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
- Ireland OEL - TWAs = 2.4 mg/m³ TWA
  = 6 mg/m³ TWA
- Latvia OEL - TWA = 1 mg/m³ TWA containing more than 70% SiO2 (quartz)
  = 2 mg/m³ TWA containing 10-70% SiO2 (granite, mica)
  = 4 mg/m³ TWA containing 2-10% SiO2 (copper sulfate ores)
- OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
- Slovakia OEL - TWA = 4.0 mg/m³ TWA
- Slovenia OEL - TWA = 4 mg/m³ TWA
Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA = 3 mg/m³ IPRV
Portugal OEL - TWA = 10 mg/m³ TWA does not include stearates of toxic metals
Spain OEL - TWA = 10 mg/m³ VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs = 5 mg/m³ LLV

Cetirizine hydrochloride

Pfizer OEL TWA-8 Hr: 150µg/m³

Titanium dioxide

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Austria OEL - MAKs = 6 mg/m³ MAK
Belgium OEL - TWA = 10 mg/m³ TWA
Bulgaria OEL - TWA = 10.0 mg/m³ TWA
Denmark OEL - TWA = 6 mg/m³ TWA
Estonia OEL - TWA = 5 mg/m³ TWA
France OEL - TWA = 10 mg/m³ VME
Greece OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA
Latvia OEL - TWA = 10 mg/m³ TWA
Lithuania OEL - TWA = 5 mg/m³ IPRV
Netherlands OEL - TWA = 10 mg/m³ MAC
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
Poland OEL - TWA = 10.0 mg/m³ NDS <2% free crystalline silica and containing no asbestos
Portugal OEL - TWA = 10 mg/m³ TWA
Romania OEL - TWA = 10 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED
Sweden OEL - TWAs = 5 mg/m³ LLV

Polyethylene glycol

Austria OEL - MAKs = 1000 mg/m³ MAK
Germany - TRGS 900 - TWAs = 1000 mg/m³ TWA
Netherlands OEL - TWA = 1000 mg/m³ MAC
Slovakia OEL - TWA = 1000 mg/m³ TWA
Slovenia OEL - TWA = 1000 mg/m³ TWA

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


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:
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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>White</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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
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
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**

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

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.
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