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

Material Name: Cetirizine HCl/Pseudoephedrine HCl tablets

<table>
<thead>
<tr>
<th>Material Name: Cetirizine HCl/Pseudoephedrine HCl tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name:</strong> ZYRTEC-D 12 HOUR™ Extended Release tablets</td>
</tr>
<tr>
<td><strong>Chemical Family:</strong> Mixture</td>
</tr>
<tr>
<td><strong>Intended Use:</strong> Pharmaceutical product used as antihistamine, decongestant</td>
</tr>
</tbody>
</table>

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

**Appearance:** White, round, biconvex, bilayer tablets

**Signal Word:** WARNING

**Statement of Hazard:** Harmful if swallowed.

**Additional Hazard Information:**
- **Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use. High doses of pseudoephedrine hydrochloride have been reported to cause increased blood pressure and/or heart rate.
- **Known Clinical Effects:** Accidental or incidental ingestion of cetirizine hydrochloride may cause sleepiness, dry mouth and fatigue. Adverse effects associated with the therapeutic use of pseudoephedrine hydrochloride include anxiety, restlessness, confusion, irritability, weakness, and gastrointestinal disturbances.

**EU Indication of danger:** Harmful

**EU Hazard Symbols:**

**EU Risk Phrases:** R22 - Harmful if swallowed.

**Australian Hazard Classification (NOHSC):** 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

| Hazardous Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | %  
|----------------------|------------|------------------------|----------------|------
| Cetirizine hydrochloride | 83881-52-1 | Not listed | Xn;R22 | 5***
| Pseudoephedrine hydrochloride | 345-78-8 | 206-462-1 | Not Listed | 120 mg***
| Colloidal silicon dioxide | 7631-86-9 | 231-545-4 | Not Listed | *
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | *
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | *
| Titanium dioxide | 13463-67-7 | 236-675-5 | Not Listed | *
| Croscarmellose sodium | 74811-65-7 | Not listed | Not Listed | *
| Hypromellose | 9004-65-3 | Not listed | Not Listed | *
| Lactose NF, monohydrate | 64044-51-5 | Not listed | Not Listed | *
| Polyethylene glycol | 25322-68-3 | Not listed | Not Listed | *

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
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. If not breathing, give artificial respiration. Get 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: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
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).

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Storage Temperature:** 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

- **Cetirizine hydrochloride**
  - Pfizer OEL TWA-8 Hr: 150µg/m³
- **Pseudoephedrine hydrochloride**
  - Pfizer OEL TWA-8 Hr: 700µg/m³
- **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:**
  - (80)/(% SiO₂) mg/m³ TWA
  - = 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)
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA except stearates of toxic metals
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

Microcrystalline cellulose

ACGIH Threshold Limit Value (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

Titanium dioxide

ACGIH Threshold Limit Value (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 = 5 mg/m³ TWA
Ireland OEL - TWAs = 10 mg/m³ TWA = 4 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 = 10.0 mg/m³ NDS <2% free crystalline silica and containing no asbestos
Poland OEL - TWA
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
Material Name: Cetirizine HCl/Pseudoephedrine HCl tablets
Revision date: 18-Dec-2007

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

Analytical Method: Analytical method available for cetirizine hydrochloride; pseudoephedrine 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:

- 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
- Hazardous Decomposition Products: No data available
- 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)

- **Microcrystalline cellulose**
  - Rat Oral LD50 > 5000 mg/kg
  - Rabbit Dermal LD50 > 2000 mg/kg

- **Magnesium stearate**
  - Rat Oral LD50 > 2000 mg/kg
  - Rat Inhalation LC50 > 2000 mg/m³

- **Hyromellose**
Subchronic Effects
In subchronic oral studies, clinical signs observed in rats given cetirizine/pseudoephedrine for up to 4 or 26 weeks at doses up to 250 mg/kg or 240 mg/kg, respectively, included hair loss, salivation, hyperactivity, decreased food consumption, decreased body weight gain, and evidence of metabolic enzyme induction. The treatment-related clinical signs and decreased food consumption are those associated with the sympathomimetic activity of pseudoephedrine and not in themselves evidence of toxicity. These were reversible at the high dose after cessation of treatment and a 6 week recovery period following the 26 week exposure period.

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

Pseudoephedrine hydrochloride
Embryo / Fetal Development Rat Oral 50 times human dose NOAEL Not teratogenic
Embryo / Fetal Development Rabbit Oral 35 times human dose NOAEL Not Teratogenic
Reproductive Effects
Cetirizine/pseudoephedrine had no effect on fertility when administered to rats.

Teratogenicity
In reproduction studies with cetirizine/pseudoephedrine, conducted at doses where maternal effects were observed, there was no evidence of either teratogenicity in the rat or rabbit or decreased fertility in the rat. However, there was an increase in early pup mortality during lactation at 40 mg/kg and 160 mg/kg, doses at which maternal effects were observed. At 160 mg/kg there was a reduced body weight gain and an associated delay in the attainment of some developmental indices.

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
Mutagenicity  Cetirizine/pseudoephedrine was not mutagenic in vitro or in vivo.

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 present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen. 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
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 Symbol: Xn
EU Indication of danger: Harmful
EU Risk Phrases: R22 - Harmful if swallowed.
EU Safety Phrases: S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.

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.

Pseudoephedrine hydrochloride

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 206-462-1
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
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End of Safety Data Sheet