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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

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

Material Name: Cetirizine Hydrochloride Solution

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>ZYRTEC Syrup</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: Colorless to slightly yellow liquid

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

Additional Hazard Information:

<table>
<thead>
<tr>
<th>Short Term:</th>
<th>Active ingredient may be harmful if swallowed. May cause eye and skin irritation (based on components). Accidental ingestion may cause effects similar to those seen in clinical use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term:</td>
<td>Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.</td>
</tr>
<tr>
<td>Known Clinical Effects:</td>
<td>Sleepiness, dry mouth, fatigue, pharyngitis, dizziness</td>
</tr>
<tr>
<td>EU Indication of danger:</td>
<td>Not classified</td>
</tr>
</tbody>
</table>


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 Name: Cetirizine Hydrochloride Solution
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>Cetirizine hydrochloride</td>
<td>83881-52-1</td>
<td>Not listed</td>
<td>Xn;R22</td>
<td>1</td>
</tr>
<tr>
<td>Acetic acid USP - glacial</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>C;R35 R10</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>*</td>
</tr>
<tr>
<td>Sugar</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
### as required

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:**
Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**
Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:**
Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**
Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 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.

**Fire / Explosion Hazards:**
Fine particles (such as dust and mists) may fuel fires/explosions.
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 spill with absorbent material. 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: Avoid breathing vapor or mist. 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.

Storage Temperature: 15-30°C (59-86°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

Acetic acid USP - glacial
ACGIH Threshold Limit Value (TWA) = 10 ppm TWA
ACGIH Threshold Limit Value (STEL) = 15 ppm STEL
Australia STEL = 15 ppm STEL
= 37 mg/m³ STEL
Australia TWA = 10 ppm TWA
= 25 mg/m³ TWA
Austria OEL - MAKs = 10 ppm MAK
= 25 mg/m³ MAK
Belgium OEL - TWA = 10 ppm TWA
= 25 mg/m³ TWA
Bulgaria OEL - TWA = 25.0 mg/m³ TWA
Cyprus OEL - TWA = 10 ppm TWA
= 25 mg/m³ TWA
Czech Republic OEL - TWA = 25 mg/m³ TWA
Denmark OEL - TWA = 10 ppm TWA
= 25 mg/m³ TWA
Estonia OEL - TWA = 10 ppm TWA
= 25 mg/m³ TWA
Finland OEL - TWA = 13 mg/m³ TWA
= 5 ppm TWA
Greece OEL - TWA = 10 ppm TWA
= 25 mg/m³ TWA
Hungary OEL - TWA = 25 mg/m³ TWA
Ireland OEL - TWAs
= 10 ppm TWA
= 25 mg/m³ TWA

Latvia OEL - TWA
= 10 ppm TWA
= 25 mg/m³ TWA

Lithuania OEL - TWA
= 10 ppm IPRV
= 25 mg/m³ IPRV

Luxembourg OEL - TWA
= 10 ppm TWA
= 25 mg/m³ TWA

OSHA - Final PELS - TWAs:
= 10 ppm TWA
= 25 mg/m³ TWA

Poland OEL - TWA
= 15 mg/m³ NDS

Portugal OEL - TWA
= 10 ppm TWA

Romania OEL - TWA
= 10 ppm TWA
= 25 mg/m³ TWA

Slovakia OEL - TWA
= 10 ppm TWA
= 25 mg/m³ TWA

Slovenia OEL - TWA
= 10 ppm TWA
= 25 mg/m³ TWA

Spain OEL - TWA
= 10 ppm VLA-ED
= 25 mg/m³ VLA-ED

Sweden OEL - TWAs
= 13 mg/m³ LLV
= 5 ppm LLV

Glycerin, USP
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

Finland OEL - TWA
= 20 mg/m³ TWA

France OEL - TWA
= 10 mg/m³ VME

Greece OEL - TWA
= 10 mg/m³ TWA

Ireland OEL - TWAs
= 10 mg/m³ TWA

Netherlands OEL - TWA
= 10 mg/m³ MAC

OSHA - Final PELS - TWAs: total
= 15 mg/m³ TWA
= 5 mg/m³ TWA

Poland OEL - TWA
= 10 mg/m³ NDS

Portugal OEL - TWA
= 10 mg/m³ TWA

Spain OEL - TWA
= 10 mg/m³ VLA-ED

Propylene glycol

Australia TWA
= 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

Ireland OEL - TWAs
= 10 mg/m³ TWA
= 150 ppm TWA
= 470 mg/m³ TWA

Latvia OEL - TWA
= 7 mg/m³ TWA

Lithuania OEL - TWA
= 7 mg/m³ IPRV

Sodium hydroxide
ACGIH Ceiling Threshold Limit:
= 2 mg/m³ Ceiling

Australia PEAK
= 2 mg/m³ Peak

Austria OEL - MAKs
= 2 mg/m³ MAK

Belgium OEL - TWA
= 2 mg/m³ TWA

Bulgaria OEL - TWA
= 2.0 mg/m³ TWA
9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid
Odor: Grape/banana
Molecular Weight: Mixture
Specific Gravity: 1.198

Color: Colorless to Slightly yellow
Molecular Formula: Mixture


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.

Czech Republic OEL - TWA = 1 mg/m³ TWA
Finland OEL - TWA = 2 mg/m³ TWA
France OEL - TWA = 2 mg/m³ VME
Greece OEL - TWA = 2 mg/m³ TWA
Hungary OEL - TWA = 2 mg/m³ TWA
Latvia OEL - TWA = 0.5 mg/m³ TWA
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA = 0.5 mg/m³ NDS
Slovakia OEL - TWA = 2 mg/m³ TWA
Slovenia OEL - TWA = 2 mg/m³ TWA
Sweden OEL - TWAs = 1 mg/m³ LLV

Sugar
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA = 10 mg/m³ TWA
Bulgaria OEL - TWA = 10.0 mg/m³ TWA
Estonia OEL - TWA = 10 mg/m³ TWA
France OEL - TWA = 10 mg/m³ VME
Ireland OEL - TWAs = 10 mg/m³ TWA
Lithuania OEL - TWA = 10 mg/m³ IPRV
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
Portugal OEL - TWA = 10 mg/m³ TWA
Slovakia OEL - TWA = 10 mg/m³ TWA
Spain OEL - TWA = 10 mg/m³ VLA-ED

Physical State: Liquid
Color: Colorless to Slightly yellow
Molecular Formula: Mixture


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.

Physical State: Liquid
Odor: Grape/banana
Molecular Weight: Mixture
Specific Gravity: 1.198
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)

Glycerin, USP
Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD50 > 21.9 g/kg

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

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Methylparaben
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Propylparaben
Mouse Oral LD50 6332 mg/kg
Mouse Intraperitoneal LD50 200 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Sugar
Rat Oral LD50 29700 mg/kg
Mouse Oral LD50 14000 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)

Glycerin, USP
Eye 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

Propylparaben
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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.

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)

Glycerin, USP

- Oncorhynchus mykiss (Rainbow Trout)  
  LD50 96 Hours 50 mg/L
- Daphnia magna (Water Flea)  
  EC50 24 Hours >500 mg/L

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

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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 Name: Cetirizine Hydrochloride Solution
Revision date: 13-Dec-2007

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.

Acetic acid USP - glacial
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
Standard for the Uniform Scheduling for Drugs and Poisons:
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:
EU EINECS/ELINCS List

Glycerin, USP
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
EU EINECS/ELINCS List

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
EU EINECS/ELINCS List

Propylene glycol
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
EU EINECS/ELINCS List

Propylparaben
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
EU EINECS/ELINCS List

Sodium acetate
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
EU EINECS/ELINCS List

Sodium hydroxide
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List

Sugar
Inventory - United States TSCA - Sect. 8(b) Australia (AICS):
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 200-334-9

Purified water
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R10 - Flammable.
R22 - Harmful if swallowed.
R35 - Causes severe burns.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity 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 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet