MATERIAL SAFETY DATA SHEET

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

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Material Name: Cetirizine HCl chewable tablets
Trade Name: Zyrtec™ chewable tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihistamine.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-cyclodextrin</td>
<td>7585-39-9</td>
<td>231-493-2</td>
<td>*</td>
</tr>
<tr>
<td>Cetirizine hydrochloride</td>
<td>83881-52-1</td>
<td>Not listed</td>
<td>2.22</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma Sweet Flavor Powder</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Grape flavor, artificial</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carmine</td>
<td>1328-60-5</td>
<td>215-527-3</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 2, Aluminum lake</td>
<td>16521-38-3</td>
<td>240-589-3</td>
<td>*</td>
</tr>
<tr>
<td>Acesulfame potassium salt</td>
<td>55589-62-3</td>
<td>259-715-3</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</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.

3. HAZARDS IDENTIFICATION

Appearance: Mottled purple tablet
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May cause central nervous system effects

Additional Hazard Information:
Short Term: May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use.

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.

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 immediately. 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: 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 determined

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store out of direct sunlight in a well ventilated area at room temperature.
Storage Temperature: 20-25°C (68-77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Beta-cyclodextrin
Pfizer OEL TWA-8 Hr: 3 mg/m³

Cetirizine hydrochloride
Pfizer OEL TWA-8 Hr: 0.15 mg/m³

Colloidal silicon dioxide
OSHA - Final PELs - Table Z-3 Mineral D: (80)(% SiO2) mg/m³ TWA
= 20 mppcf TWA
Australia TWA
= 2 mg/m³ TWA

Microcrystalline cellulose
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 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

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. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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: Purple
Molecular Formula: Mixture
Molecular Weight: Mixture

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)

Mannitol
- Rat Oral LD 50 13500 mg/kg
- Mouse Oral LD 50 22 g/kg

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

Beta-cyclodextrin
- Rat Oral LD50 > 2000 mg/kg

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

Inhalation Acute Toxicity: No data available
Ingestion Acute Toxicity: See Acute toxicity table.

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

Microcrystalline cellulose
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

Beta-cyclodextrin
- Eye Irritation Rabbit Non-irritating
- Skin Irritation Rabbit Non-irritating

Eye Irritation / Sensitization: No data available
Skin Irritation / Sensitization: No data available

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
Subchronic Effects
Liver toxicity of cetirizine HCl seen in rodents was considered to be predominantly the result of induction, and was transient and reversible. Similar effects were not observed in dogs or monkeys and, therefore, are thought to be species-specific.

Chronic Toxicity
Chronic oral studies of cetirizine HCl revealed dose-related increases in vomiting in dogs and salivation in monkeys.

Chronic Effects/Carcinogenicity
In 2-year carcinogenicity studies in rats and mice, an increase in benign liver tumors was seen in male mice at the high-dose of 16 mg/kg/day only.

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

Reproductive Effects
No reproductive or developmental toxicity associated with cetirizine oral administration at doses up to 16 mg/kg/day was observed in mice.

Teratogenicity
No evidence of teratogenicity for cetirizine HCl was observed in mice, rats and rabbits at oral doses up to 225 mg/kg.

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

Mutagenicity
No evidence of mutagenicity was observed in vivo or in vitro.

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

Additional Information:
FDA PREGNANCY CATEGORY B

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
Daphnia Magna LC50 48 Hours 14 mg/L
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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:
WARNING
May be harmful if swallowed.
May cause central nervous system effects

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.

Beta-cyclodextrin
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 231-493-2

Carmine
- Inventory - United States TSCA - Sect. 8(b): Present
- EU EINECS List: 215-527-3

Colloidal silicon dioxide
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 231-545-4

FD & C Blue No. 2, Aluminum lake
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 240-589-3

Acesulfame potassium salt
- Australia (AICS): Present
EU EINECS List 259-715-3

**Mannitol**
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS List**: 200-711-8

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

**Lactose NF, monohydrate**
- **Australia (AICS)**: Present

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

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. 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