MATERIAL SAFETY DATA SHEET

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

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

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

Hazardous

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

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

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/m^3 TWA = 20 mppcf TWA
Australia TWA	= 2 mg/m^3 TWA

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA except stearates of toxic metals
Australia TWA	= 10 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. 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/m^3

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