MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Cetirizine HCl/Pseudoephedrine HCl tablets

Trade Name: ZYRTEC-D 12 HOUR™ Extended Release tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihistamine, decongestant

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 EEC No. 418-260-2	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	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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.

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).

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/m^3

Pseudoephedrine hydrochloride
- **Pfizer OEL TWA-8 Hr:** 700µg/m^3

Colloidal silicon dioxide
- **Australia TWA** = 2 mg/m^3 TWA
- **Austria OEL - MAKs** = 4 mg/m^3 MAK
- **Czech Republic OEL - TWA** = 0.1 mg/m^3 TWA
  = 4.0 mg/m^3 TWA
- **Estonia OEL - TWA** = 2 mg/m^3 TWA
- **Germany - TRGS 900 - TWAs** = 4 mg/m^3 TWA
- **Ireland OEL - TWAs** = 2.4 mg/m^3 TWA
  = 6 mg/m^3 TWA
- **Latvia OEL - TWA** = 1 mg/m^3 TWA containing more than 70% SiO_2 (quartz)
  = 2 mg/m^3 TWA containing 10-70% SiO_2 (granite, mica)
  = 4 mg/m^3 TWA containing 2-10% SiO_2 (copper sulfate ores)
- **OSHA - Final PELs - Table Z-3 Mineral D:** (80)/(% SiO_2) mg/m^3 TWA
  = 20 mppcf TWA
- **Slovakia OEL - TWA** = 4.0 mg/m^3 TWA
- **Slovenia OEL - TWA** = 4 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
Belgium OEL - TWA	= 10 mg/m^3 TWA
Ireland OEL - TWAs	= 10 mg/m^3 TWA except lead stearate
Lithuania OEL - TWA	= 3 mg/m^3 IPRV
Portugal OEL - TWA	= 10 mg/m^3 TWA does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m^3 VLA-ED not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m^3 LLV

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Estonia OEL - TWA	= 10 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME
Ireland OEL - TWAs	= 10 mg/m^3 TWA = 4 mg/m^3 TWA
Latvia OEL - TWA	= 2 mg/m^3 TWA
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
Portugal OEL - TWA	= 10 mg/m^3 TWA
Romania OEL - TWA	= 10 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Austria OEL - MAKs	= 6 mg/m^3 MAK
Belgium OEL - TWA	= 10 mg/m^3 TWA
Bulgaria OEL - TWA	= 10.0 mg/m^3 TWA
Denmark OEL - TWA	= 6 mg/m^3 TWA
Estonia OEL - TWA	= 5 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME
Greece OEL - TWA	= 10 mg/m^3 TWA = 5 mg/m^3 TWA
Ireland OEL - TWAs	= 10 mg/m^3 TWA = 4 mg/m^3 TWA
Latvia OEL - TWA	= 10 mg/m^3 TWA
Lithuania OEL - TWA	= 5 mg/m^3 IPRV
Netherlands OEL - TWA	= 10 mg/m^3 MAC
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total
Poland OEL - TWA	= 10.0 mg/m^3 NDS <2% free crystalline silica and containing no asbestos
Portugal OEL - TWA	= 10 mg/m^3 TWA
Romania OEL - TWA	= 10 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED
Sweden OEL - TWAs	= 5 mg/m^3 LLV

Polyethylene glycol

Austria OEL - MAKs	= 1000 mg/m^3 MAK
Germany - TRGS 900 - TWAs	= 1000 mg/m^3 TWA
Netherlands OEL - TWA	= 1000 mg/m^3 MAC

Slovakia OEL - TWA	= 1000 mg/m^3 TWA
Slovenia OEL - TWA	= 1000 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 cetrirzine 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:

Physical State:	Tablet	**Color:**	White
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)

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

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

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

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Pseudoephedrine hydrochloride
Rat Oral LD50 660 mg/kg
Mouse Oral LD50 371 mg/kg
Mouse IP LD50 202 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

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/pseudoepehdrine 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

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 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

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 EEC No. 418-260-2

Croscarmellose sodium

Australia (AICS):	Present

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Lactose NF, monohydrate

Australia (AICS):	Present

Magnesium stearate

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

Microcrystalline cellulose

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

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

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
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet