



# MATERIAL SAFETY DATA SHEET

Revision date: 13-Dec-2007

Version: 1.8

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

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

### Material Name: Cetirizine Hydrochloride Solution

<b>Trade Name:</b>	ZYRTEC Syrup
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product used as antihistamine.

## 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:

<b>Short Term:</b>	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.
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
<b>Known Clinical Effects:</b>	Sleepiness, dry mouth, fatigue, pharyngitis, dizziness
<b>EU Indication of danger:</b>	Not classified

**Australian Hazard Classification (NOHSC):** Non-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

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## Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Cetirizine hydrochloride	83881-52-1	Not listed	Xn;R22	1
Acetic acid USP - glacial	64-19-7	200-580-7	C;R35 R10	<1
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	###
Sugar	57-50-1	200-334-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
B&C artificial banana concentrate (SA10)	NOT ASSIGNED	Not listed	Not Listed	*
Grape flavor, artificial	NOT ASSIGNED	Not listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Sodium acetate	127-09-3	204-823-8	Not Listed	*
Purified water	7732-18-5	231-791-2	Not Listed	*

### 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.

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	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.
<b>Storage Conditions:</b>	Store as directed by product packaging.
<b>Storage Temperature:</b>	15-30°C (59-86°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Cetirizine hydrochloride</b>	
Pfizer OEL TWA-8 Hr:	150µg/m <sup>3</sup>
<b>Acetic acid USP - glacial</b>	
ACGIH Threshold Limit Value (TWA)	= 10 ppm TWA
ACGIH Threshold Limit Value (STEL)	= 15 ppm STEL
Australia STEL	= 15 ppm STEL
Australia TWA	= 37 mg/m <sup>3</sup> STEL
Austria OEL - MAKs	= 10 ppm TWA
Belgium OEL - TWA	= 25 mg/m <sup>3</sup> TWA
Bulgaria OEL - TWA	= 10 ppm MAK
Cyprus OEL - TWA	= 25 mg/m <sup>3</sup> MAK
Czech Republic OEL - TWA	= 10 ppm TWA
Denmark OEL - TWA	= 25 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 25 mg/m <sup>3</sup> TWA
Finland OEL - TWA	= 10 ppm TWA
Greece OEL - TWA	= 25 mg/m <sup>3</sup> TWA
Hungary OEL - TWA	= 13 mg/m <sup>3</sup> TWA
	= 5 ppm TWA
	= 10 ppm TWA
	= 25 mg/m <sup>3</sup> TWA
	= 25 mg/m <sup>3</sup> TWA

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Ireland OEL - TWAs	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Lithuania OEL - TWA	= 10 ppm IPRV = 25 mg/m <sup>3</sup> IPRV
Luxembourg OEL - TWA	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
OSHA - Final PELs - TWAs:	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Poland OEL - TWA	= 15 mg/m <sup>3</sup> NDS
Portugal OEL - TWA	= 10 ppm TWA
Romania OEL - TWA	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Slovakia OEL - TWA	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 10 ppm TWA = 25 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 ppm VLA-ED = 25 mg/m <sup>3</sup> VLA-ED
Sweden OEL - TWAs	= 13 mg/m <sup>3</sup> LLV = 5 ppm LLV

### Glycerin, USP

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA
Australia TWA	= 10 mg/m <sup>3</sup> TWA
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Finland OEL - TWA	= 20 mg/m <sup>3</sup> TWA
France OEL - TWA	= 10 mg/m <sup>3</sup> VME
Greece OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA
Netherlands OEL - TWA	= 10 mg/m <sup>3</sup> MAC
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA    total = 5 mg/m <sup>3</sup> TWA
Poland OEL - TWA	= 10 mg/m <sup>3</sup> NDS
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED

### Propylene glycol

Australia TWA	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 474 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 150 ppm TWA = 470 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 7 mg/m <sup>3</sup> TWA
Lithuania OEL - TWA	= 7 mg/m <sup>3</sup> IPRV

### Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m <sup>3</sup> Ceiling
Australia PEAK	= 2 mg/m <sup>3</sup> Peak
Austria OEL - MAKs	= 2 mg/m <sup>3</sup> MAK
Belgium OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Bulgaria OEL - TWA	= 2.0 mg/m <sup>3</sup> TWA

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Czech Republic OEL - TWA	= 1 mg/m <sup>3</sup> TWA
Finland OEL - TWA	= 2 mg/m <sup>3</sup> TWA
France OEL - TWA	= 2 mg/m <sup>3</sup> VME
Greece OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Hungary OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 0.5 mg/m <sup>3</sup> TWA
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	= 0.5 mg/m <sup>3</sup> NDS
Slovakia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Sweden OEL - TWAs	= 1 mg/m <sup>3</sup> LLV

## Sugar

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA
Australia TWA	= 10 mg/m <sup>3</sup> TWA
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Bulgaria OEL - TWA	= 10.0 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 10 mg/m <sup>3</sup> TWA
France OEL - TWA	= 10 mg/m <sup>3</sup> VME
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA
Lithuania OEL - TWA	= 10 mg/m <sup>3</sup> IPRV
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA total
	= 5 mg/m <sup>3</sup> TWA
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Slovakia OEL - TWA	= 6 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED

**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. 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:

<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless to Slightly yellow
<b>Odor:</b>	Grape/banana	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		
<b>Specific Gravity:</b>	1.198		

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### 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/m<sup>3</sup>  
Rat Dermal LD 50 >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 LD 50 6332 mg/kg  
Mouse Intraperitoneal LD 50 200 mg/kg

##### **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

##### **Sugar**

Rat Oral LD 50 29700 mg/kg  
Mouse Oral LD 50 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

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### Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

### Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

### 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.

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### 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



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### 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:	= 2270 kg final RQ = 5000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 40.
EU EINECS/ELINCS List	200-580-7

### Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-289-5

### Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

### Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

### Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

### Sodium acetate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

### Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

### Sugar

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

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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**