



# MATERIAL SAFETY DATA SHEET

Revision date: 21-Feb-2007

Version: 3.0

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## 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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**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: Hydroxyzine Hydrochloride, Ephedrine Sulfate and Theophylline Syrup**

**Trade Name:** MARAX(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as bronchospasmolytic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydroxyzine hydrochloride	2192-20-3	218-586-3	0.04
Ephedrine sulfate	134-72-5	205-154-4	0.1
Theophylline, anhydrous	58-55-9	200-385-7	0.5
Ethanol	64-17-5	200-578-6	*
Hydrogen chloride	7647-01-0	231-595-7	*
Sucrose	57-50-1	200-334-9	*

Ingredient	CAS Number	EU EINECS List	%
Cherry flavor, artificial	NOT ASSIGNED	Not listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Purified water	7732-18-5	231-791-2	*
Sodium benzoate	532-32-1	208-534-8	*
Special Fruits Flavor	NOT ASSIGNED	Not listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear, orange liquid  
**Signal Word:** WARNING

**Statement of Hazard:** May cause eye irritation  
May cause drowsiness or dizziness.

**Additional Hazard Information:**  
**Short Term:** Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication. Ingestion of large quantities may cause headache, dizziness, nausea, vomiting, diarrhea, drowsiness, and symptoms of drunkenness.

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<b>Long Term:</b>	Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.
<b>Known Clinical Effects:</b>	Adverse effects most commonly reported in clinical use include anxiety, nervousness, dry mouth, headache, flushing, nausea, irritability.
<b>EU Indication of danger:</b>	Not classified
<b>Australian Hazard Classification (NOHSC):</b>	Non-Hazardous Substance. Non-Dangerous Goods.
<b>Note:</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	May include oxides of carbon, sulfur and products of chlorine.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	May generate flammable vapors.

### 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. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.
<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

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**General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Keep away from heat, sparks, flame and all other sources of ignition.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Hydroxyzine hydrochloride

Pfizer OEL TWA-8 Hr: 0.3 mg/m<sup>3</sup>

### Theophylline, anhydrous

Pfizer OEL TWA-8 Hr: 1.8mg/m<sup>3</sup>

### Ethanol

OSHA - Final PELs - TWAs: = 1000 ppm TWA  
= 1900 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA  
Australia TWA = 1000 ppm TWA  
= 1880 mg/m<sup>3</sup> TWA

### Hydrogen chloride

ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling  
Australia PEAK = 5 ppm Peak  
= 7.5 mg/m<sup>3</sup> Peak

### Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

**Analytical Method:** Analytical method available for theophylline. 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:** Syrup  
**Odor:** Cherry  
**Molecular Weight:** Mixture  
**Color:** Orange  
**Molecular Formula:** Mixture

**Solubility:** Soluble: Water

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pH: 2.7 - 3.5  
Specific Gravity: 1.245 - 1.265

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** Avoid contact with strong oxidizers, such as bleach, direct sunlight, excessive heat, spark, or open flame.  
**Incompatible Materials:** Strong acids and oxidizers . May react with potassium hydroxide.  
**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)**

##### **Ethanol**

Mouse Oral LD50 3,450 g/m<sup>3</sup>  
Rat Oral LD50 7,060 mg/kg  
Mouse Inhalation LC50 4h 39 g/m<sup>3</sup>  
Rat Inhalation LC50 10h 20,000 ppm

##### **Hydrogen chloride**

Rat Inhalation LC50 1H 3,124 ppm  
Mouse Inhalation LC50 1H 1,108 ppm  
Mouse Oral LD50 900 mg/kg

##### **Sucrose**

Rat Oral LD50 29.7 g/kg

##### **FD&C Yellow No. 6; (Sunset yellow)**

Rat Oral LD50 > 10,000 mg/kg  
Mouse Oral LD50 > 6,000 mg/kg

##### **Sodium benzoate**

Rat Oral LD50 4,070 mg/kg  
Mouse Oral LD50 1600 mg/kg

##### **Ephedrine sulfate**

Mouse Oral LD50 812 mg/kg  
Rat Oral LD50 404 mg/kg

##### **Hydroxyzine hydrochloride**

Rat Oral LD50 840 mg/kg  
Mouse IP LD50 81 mg/kg  
Rat IP LD50 160 mg/kg  
Mouse IV LD50 137 mg/kg  
Rat IV LD50 45 mg/kg

##### **Theophylline, anhydrous**

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Mouse Oral LD50 235 mg/kg  
Rat Oral LD50 225 mg/kg  
Rabbit Oral LD50 350 mg/kg  
Guinea Pig Oral LD50 183 mg/kg  
Rat IP LD50 188 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)

#### **Ethanol**

Eye Irritation Rabbit Severe

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### **Sodium benzoate**

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood  
10 Day(s) Mouse Oral 45 g/kg LOEL Liver, Kidney, Blood, Ureter, Bladder

#### **Theophylline, anhydrous**

75 Week(s) Rat Oral 300 mg/kg/day LOEL Male reproductive system  
13 Week(s) Mouse Oral 300 mg/kg/day LOEL Male reproductive system  
13 Week(s) Rat Oral 150 mg/kg/day LOEL Male reproductive system

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Sodium benzoate**

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

#### **Hydroxyzine hydrochloride**

Reproductive & Fertility Rat Oral 400 mg/kg LOEL Developmental toxicity, Reproductive toxicity

#### **Theophylline, anhydrous**

Reproductive & Fertility Mouse Oral 125 mg/kg/day NOEL Embryotoxicity  
Embryo / Fetal Development Mouse Intraperitoneal 100 mg/kg LOEL Teratogenic  
Embryo / Fetal Development Mouse Oral 396 mg/kg/day NOEL Fetotoxicity, Not Teratogenic  
Embryo / Fetal Development Rat Oral 259 mg/kg/day NOEL Not Teratogenic  
Reproductive system

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### **Theophylline, anhydrous**

*In Vivo* Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive  
*In Vitro* Chromosome Aberration Rat Bone Marrow Negative  
*In Vitro* Sister Chromatid Exchange Human Positive  
*In Vitro* Chromosome Aberration Human Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Theophylline, anhydrous**

2 Year(s) Rat Oral 75 mg/kg/day NOEL Not carcinogenic  
2 Year(s) Female Mouse Oral 75 mg/kg/day NOEL Not carcinogenic  
2 Year(s) Male Mouse Oral 150 mg/kg/day NOEL Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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Hydrogen chloride  
IARC: Group 3

FD&C Yellow No. 6; (Sunset yellow)  
IARC: Group 3

Theophylline, anhydrous  
IARC: Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
Rainbow Trout	NPDES	LC50	96 Hours	12,900 mg/L
Fathead minnow	NPDES	LC50	96 Hours	14,200 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 cause eye irritation

May cause drowsiness or dizziness.

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## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision B



### Hydroxyzine hydrochloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	218-586-3

### Ephedrine sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-154-4

### Theophylline, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS List	200-385-7

### Ethanol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-578-6

### Hydrogen chloride

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

### Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

### FD&C Yellow No. 6; (Sunset yellow)

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

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EU EINECS List	220-491-7
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### Purified water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

### Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	208-534-8

## 16. OTHER 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**