



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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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Ephedrine/theophylline/hydroxyzine hydrochloride tablets

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydroxyzine hydrochloride	2192-20-3	218-586-3	3.5
Ephedrine sulfate	134-72-5	205-154-4	8.9
Theophylline, anhydrous	58-55-9	200-385-7	45.8
Calcium carbonate	471-34-1	207-439-9	*
Sodium lauryl sulfate	151-21-3	205-788-1	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Alginate acid	9005-32-7	232-680-1	*
FD&C Blue no. 1 aluminum lake	68921-42-6	272-939-6	*

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

3. HAZARDS IDENTIFICATION

Appearance: White to off-white scored tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Suspected of damaging fertility or the unborn child.

Additional Hazard Information:

Short Term: May cause nervous system and cardiovascular system effects.
Known Clinical Effects: Ingestion of large amounts of this material may cause effects similar to those seen in clinical use including irregular heart rate, fear, anxiety, restlessness, tremor, insomnia, confusion, high blood pressure, nausea, vomiting and loss of appetite.

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EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

EU Hazard Symbols:



EU Risk Phrases: R22 - Harmful if swallowed.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.
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 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

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. If irritation occurs or persists, get 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 and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May include oxides of carbon, sulfur and products of chlorine.

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.

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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). Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydroxyzine hydrochloride

Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Theophylline, anhydrous

Pfizer OEL TWA-8 Hr: 1.8mg/m³

Calcium carbonate

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA particulate matter containing no asbestos and <1% crystalline silica

ACGIH OELs - Notice of Intended Changes Listed

Australia TWA = 10 mg/m³ TWA

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Pfizer STEL 0.75 mg/m³

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.

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:

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Physical State:	Tablet	Color:	White to off-white
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Alginic acid

Rat Oral LD50 > 5 g/kg

Calcium carbonate

Rat Oral LD50 6450 mg/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

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

Ephedrine sulfate

Mouse Oral LD50 812 mg/kg

Rat Oral LD50 404 mg/kg

Theophylline, anhydrous

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)

Sodium lauryl sulfate

Eye Irritation Rabbit Severe

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Skin Irritation Rabbit Severe

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

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))

Hydroxyzine hydrochloride

Reproductive & Fertility Rat Oral 400 mg/kg LOAEL 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

<i>In Vivo</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vitro</i> Chromosome Aberration	Rat Bone Marrow	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Human	Positive
<i>In Vitro</i> 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: Not listed as a carcinogen by IARC, NTP or US OSHA.

Theophylline, anhydrous

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

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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 Symbol: Xn
EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R62 - Possible risk of impaired fertility.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



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

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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

Alginic acid

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-680-1

Calcium carbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	207-439-9

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Magnesium stearate

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

FD&C Blue no. 1 aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	272-939-6

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