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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxyzine hydrochloride</td>
<td>2192-20-3</td>
<td>218-586-3</td>
<td>3.5</td>
</tr>
<tr>
<td>Ephedrine sulfate</td>
<td>134-72-5</td>
<td>205-154-4</td>
<td>8.9</td>
</tr>
<tr>
<td>Theophylline, anhydrous</td>
<td>58-55-9</td>
<td>200-385-7</td>
<td>45.8</td>
</tr>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
<td>*</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Alginic acid</td>
<td>9005-32-7</td>
<td>232-680-1</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Blue no. 1 aluminum lake</td>
<td>68921-42-6</td>
<td>272-939-6</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
Material Name: Ephedrine/theophylline/hydroxyzine hydrochloride tablets
Revision date: 21-Feb-2007

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):

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.
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:** 1.8 mg/m³

**Calcium carbonate**
- **OSHA - Final PELS - TWAs:**
  - Total = 15 mg/m³ TWA
  - Particulate matter containing no asbestos and <1% crystalline silica = 5 mg/m³ TWA
- **ACGIH Threshold Limit Value (TWA):**
  - Particulate matter containing no asbestos and <1% crystalline silica = 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):**
  - Except stearates of toxic metals = 10 mg/m³ TWA
  - Australia TWA = 10 mg/m³ 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:
**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
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

**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:**
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.
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
Theophylline, anhydrous
  Inventory - United States TSCA - Sect. 8(b) Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
  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