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

Material Name: Hydroxyzine Hydrochloride, Ephedrine Sulfate and Theophylline Syrup

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous 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>0.04</td>
</tr>
<tr>
<td>Ephedrine sulfate</td>
<td>134-72-5</td>
<td>205-154-4</td>
<td>0.1</td>
</tr>
<tr>
<td>Theophylline, anhydrous</td>
<td>58-55-9</td>
<td>200-385-7</td>
<td>0.5</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>*</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cherry flavor, artificial</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>*</td>
</tr>
<tr>
<td>Special Fruits Flavor</td>
<td>NOT ASSIGNED</td>
<td>Not listed</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: 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 may cause headache, dizziness, nausea, vomiting, diarrhea, drowsiness, and symptoms of drunkenness.
Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include anxiety, nervousness, dry mouth, headache, flushing, nausea, irritability.

EU Indication of danger: Not classified


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: May generate flammable vapors.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: 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.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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: 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/m³

Theophylline, anhydrous
Pfizer OEL TWA-8 Hr: 1.8mg/m³

Ethanol
OSHA - Final PELS - TWAs: = 1000 ppm TWA
= 1900 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1880 mg/m³ TWA

Hydrogen chloride
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m³ Peak

Sucrose
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 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:

Physical State: Syrup
Odor: Cherry
Molecular Weight: Mixture
Solubility: Soluble: Water
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/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
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 1,600 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
MATERIAL SAFETY DATA SHEET

Material Name: Hydroxyzine Hydrochloride, Ephedrine Sulfate and Theophylline Syrup
Revision date: 21-Feb-2007
Version: 3.0

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)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>Duration</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>10 Day(s)</td>
<td>27370 mg/kg</td>
<td>LOAEL</td>
<td>Liver, Blood</td>
</tr>
<tr>
<td>10 Day(s) Mouse</td>
<td>Oral</td>
<td>45 g/kg</td>
<td>LOAEL</td>
<td>Liver, Kidney, Blood, Ureter, Bladder</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td></td>
<td>300 mg/kg/day</td>
<td>LOEL</td>
<td>Male reproductive system</td>
</tr>
<tr>
<td>13 Week(s) Mouse</td>
<td>Oral</td>
<td>300 mg/kg/day</td>
<td>LOEL</td>
<td>Male reproductive system</td>
<td></td>
</tr>
<tr>
<td>13 Week(s) Rat</td>
<td>Oral</td>
<td>150 mg/kg/day</td>
<td>LOEL</td>
<td>Male reproductive system</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>Duration</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium benzoate</td>
<td>Mouse / Fetal Development</td>
<td>Oral</td>
<td>44 g/kg</td>
<td>LOEL</td>
<td>Developmental toxicity</td>
</tr>
<tr>
<td>Hydroxyzine hydrochloride</td>
<td>Reproductive &amp; Fertility</td>
<td>Oral</td>
<td>400 mg/kg</td>
<td>LOAEL</td>
<td>Developmental toxicity, Reproductive toxicity</td>
</tr>
<tr>
<td>Theophylline, anhydrous</td>
<td>Reproductive &amp; Fertility</td>
<td>Mouse</td>
<td>Oral</td>
<td>125 mg/kg/day</td>
<td>NOEL</td>
</tr>
<tr>
<td>13 Week(s) Mouse</td>
<td>Fetal Development</td>
<td>Mouse Intraperitoneal</td>
<td>100 mg/kg</td>
<td>LOEL</td>
<td>Teratogenic</td>
</tr>
<tr>
<td>13 Week(s) Mouse</td>
<td>Fetal Development</td>
<td>Oral</td>
<td>396 mg/kg/day</td>
<td>NOEL</td>
<td>Fetotoxicity, Not Teratogenic</td>
</tr>
<tr>
<td>13 Week(s) Rat</td>
<td>Fetal Development</td>
<td>Oral</td>
<td>259 mg/kg/day</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Theophylline, anhydrous</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Vivo Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells</td>
</tr>
<tr>
<td>In Vitro Chromosome Aberration Rat Bone Marrow</td>
</tr>
<tr>
<td>In Vitro Sister Chromatid Exchange Human</td>
</tr>
<tr>
<td>In Vitro Chromosome Aberration Human</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Theophylline, anhydrous</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Year(s) Rat</td>
</tr>
<tr>
<td>2 Year(s) Female Mouse</td>
</tr>
<tr>
<td>2 Year(s) Male Mouse</td>
</tr>
</tbody>
</table>

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 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.
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 Substances EPCRA RQs = 500 lb TPQ 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
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