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

Material Name: Phenazopyridine Hydrochloride Tablets

Trade Name: Pyridium
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as analgesic, antispasmodic

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>Phenazopyridine hydrochloride</td>
<td>136-40-3</td>
<td>205-243-8</td>
<td>35-40</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
<td>*</td>
</tr>
<tr>
<td>Kaolin</td>
<td>1332-58-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylcellulose</td>
<td>9004-67-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>*</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethyl Starch</td>
<td>9057-06-1</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sugar</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
<tr>
<td>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</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>FD&amp;C Blue No. 2</td>
<td>860-22-0</td>
<td>212-728-8</td>
<td>*</td>
</tr>
<tr>
<td>White wax</td>
<td>8006-40-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Acacia</td>
<td>9000-01-5</td>
<td>232-519-5</td>
<td>*</td>
</tr>
<tr>
<td>Confectioner's sugar</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Tragacanth</td>
<td>9000-65-1</td>
<td>232-552-5</td>
<td>*</td>
</tr>
<tr>
<td>D&amp;C Red #7 Calcium Lake</td>
<td>52821-04-9</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
Material Name: Phenazopyridine Hydrochloride Tablets
Revision date: 15-Dec-2006

Appearance: Reddish-violet tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed. May cause damage to: liver, kidneys, blood and blood forming organs through prolonged or repeated exposure. Suspected of causing cancer.

Additional Hazard Information:
- **Short Term:** Overexposure may affect the ability of the blood to carry oxygen (methemoglobinemia) with symptoms of headache, dizziness and a blue color to the skin and lips. May be absorbed through the skin and cause systemic effects. May cause allergic reactions in susceptible individuals.
- **Known Clinical Effects:** Adverse effects most commonly reported in clinical use include headache, dizziness, skin rash, gastrointestinal disturbances red discoloration of urine. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. Kidney dysfunction has been seen during clinical use. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Harmful
Carcinogenic: Category 3

EU Hazard Symbols:

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:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention immediately. 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.
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:
If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions:
Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Phenazopyridine hydrochloride
Pfizer OEL TWA-8 Hr: 0.3 mg/m³, Skin

Starch
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

Sugar
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

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

Kaolin
OSHA - Final PELS - TWAs: 15 mg/m³ TWA total
                               = 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) 2 mg/m³ TWA
Australia TWA 10 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
<th>Color: Reddish-violet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight: Mixture</td>
</tr>
</tbody>
</table>

| Physical State: Tablet |

| Molecular Formula: Mixture |

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

<table>
<thead>
<tr>
<th>Starch Mouse</th>
<th>IP LD50 6600 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch Rat Oral LD50 &gt; 4640 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Stearic acid Rabbit Dermal LD50 &gt; 5000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
Sugar
Rat  Oral  LD 50  29700 mg/kg
Mouse  Oral  LD 50  14000 mg/kg

Calcium carbonate
Rat  Oral  LD50  6450 mg/kg

Talc (non-asbestiform)
Rat  Oral  LD50  > 1600 mg/kg

Titanium dioxide
Rat  Oral  LD50  > 7500 mg/kg
Rat  Subcutaneous  LD 50  50 mg/kg

FD&C Blue No. 2
Rat  Oral  LD50  2 g/kg
Mouse  Oral  LD50  2500 mg/kg

FD&C Yellow No. 6; (Sunset yellow)
Rat  Oral  LD50  > 10,000 mg/kg
Mouse  Oral  LD50  > 6,000 mg/kg

Phenazopyridine hydrochloride
Rat  Oral  LD50  472 mg/kg
Mouse  Intravenous  LD 50  180 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)

Stearic acid
Skin Irritation  Rabbit  Mild

Acacia
Eye Irritation  Rabbit  Severe

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

Phenazopyridine hydrochloride
Embryo / Fetal Development  Rat  Oral  50 mg/kg/day  NOEL  Not teratogenic

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

FD&C Blue No. 2
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Phenazopyridine hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella  Positive
Mammalian Cell Mutagenicity  Mouse Lymphoma  Positive
Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Positive
Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive
In Vivo  Drosophila  Equivocal

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

Phenazopyridine hydrochloride
Carcinogen Status: See below

Phenazopyridine hydrochloride
  IARC:  Group 2B
  NTP: Reasonably Anticipated To Be A Carcinogen
  OSHA: Present

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
  Carcinogenic: Category 3

EU Risk Phrases: R22 - Harmful if swallowed.
  R40 - Limited evidence of a carcinogenic effect

EU Safety Phrases:
OSHA Label:
WARNING
Harmful if swallowed.
May cause damage to: liver, kidneys, blood and blood forming organs through prolonged or repeated exposure.
Suspected of causing cancer.

Canada - WHMIS: Classifications

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

Phenazopyridine hydrochloride
   California Proposition 65                  carcinogen, initial date 1/1/88
   Australia (AICS):                        Present
   EU EINECS List                           205-243-8

Starch
   Inventory - United States TSCA - Sect. 8(b)    XU
   Australia (AICS):                            Present
   EU EINECS List                              232-679-6

Lactose hydrous
   Australia (AICS):                          Present

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

Gelatin
   Inventory - United States TSCA - Sect. 8(b)    XU
   Australia (AICS):                            Present
   EU EINECS List                              232-554-6

Stearic acid
   Inventory - United States TSCA - Sect. 8(b)                  Present
   Australia (AICS):                          Present
   EU EINECS List                              200-313-4

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

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

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.
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