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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

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

Material Name: Bacampicillin hydrochloride tablets

Trade Name: SPECTROBID(R) Tablets  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as Antibacterial

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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Bacampicillin hydrochloride</td>
<td>37661-08-8</td>
<td>253-580-4</td>
<td>400 mg***</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</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:  
* Proprietary  
*** per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance:  
400 mg: White, film-coated, oblong, unscored, engraved "SPECTROBID" on one side and "ROERIG 035" on other side

Signal Word:  
WARNING

Statement of Hazard:  
May cause allergic reaction in sensitive individuals.  
Symptoms of chronic exposure to this material include redness and swelling of the skin, rash, chills, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Sensitization reactions as severe as anaphylaxis or delayed reactions may also occur in susceptible individuals.

Long Term:  
May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects:  
May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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. Get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. 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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. Use only in a well-ventilated area. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: 15 - 30 °C
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA)
= 10 mg/m³ TWA except stearates of toxic metals

Australia TWA
= 10 mg/m³ TWA

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Bacampicillin hydrochloride

Pfizer Occupational Exposure Band (OEB):
OEB 2 - Sensitizer (control exposure to the range of >100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Analytical Method:

Analytical method available for Bacampicillin hydrochloride. Contact Pfizer Inc for further information.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

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: None required under normal conditions of use. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablet
Odor: Odorless
Molecular Weight: Mixture

Color: White
Molecular Formula: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: Heat and oxidizers
Hazardous Decomposition Products: No data available
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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Species</th>
<th>Route</th>
<th>LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 10 g/kg</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>&gt; 2000 mg/m³</td>
</tr>
</tbody>
</table>

#### 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.

#### Ingestion Acute Toxicity
The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient it contains.

#### Irritation / Sensitization: (Study Type, Species, Severity)

<table>
<thead>
<tr>
<th>Material</th>
<th>Species</th>
<th>Route</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
<td></td>
</tr>
</tbody>
</table>

#### Reproductive Effects
No impairment of fertility and no significant effect on general reproductive performance were observed in rats administered oral doses of bacampicillin hydrochloride at up to 750 mg/kg/day prior to and during mating and gestation. No drug-related effects were noted on the reproductive organs of rats and dogs receiving daily oral doses of up to 800 and 650 mg/kg of bacampicillin hydrochloride for 6 months, respectively.

#### Teratogenicity
Teratogenic toxicity studies of bacampicillin hydrochloride were conducted in rats and rabbits at maximum doses of 3000 and 250 mg/kg, respectively, before mating and during the first week of gestation. No drug-related adverse effects or increase in birth defects were seen in rat or rabbit fetuses. In rabbits, abortion and maternal death occurred in some dams at the high dose group. In rats, treatment on days 17-21 at 3000 mg/kg, produced some maternal deaths and an increase in stillbirths.

#### Carcinogen Status:
Not listed as a carcinogen by IARC, NTP or US OSHA.

#### At increase risk from exposure:
Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

#### Additional Information:
FDA PREGNANCY CATEGORY B. No adequate and well-controlled studies in pregnant women. Animal studies failed to demonstrate a risk to the fetus. No adequate and well-controlled studies in pregnant women. However, animal studies failed to demonstrate a risk to the fetus or adequate and well-controlled studies in pregnant women failed to demonstrate a risk to the fetus.
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 Indication of danger: Not classified

OSHA Label: WARNING
May cause allergic reaction in sensitive individuals.

Canada - WHMIS: Classifications

WHMIS hazard class: None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Microcrystalline cellulose
- Inventory - United States TSCA - Sect. 8(b) XU
- Australia (AICS): Present
- EU EINECS List: 232-674-9

Lactose
- Inventory - United States TSCA - Sect. 8(b) Present
- Australia (AICS): Present
- EU EINECS List: 200-559-2

Magnesium stearate
- Inventory - United States TSCA - Sect. 8(b) Present
- Australia (AICS): Present
- EU EINECS List: 209-150-3
MATERIAL SAFETY DATA SHEET

Material Name: Bacampicillin hydrochloride tablets
Revision date: 02-Jan-2007

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory 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