



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 2.2

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

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**Pfizer Pharmaceuticals Group**  
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CHEMTREC (24 hours): 1-800-424-9300

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

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*
Bacampicillin hydrochloride	37661-08-8	253-580-4	400 mg***

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*

**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.  
**Long Term:** 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.

**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

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**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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> 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/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, 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	Color:	White
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** None known  
**Incompatible Materials:** Heat and oxidizers

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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)

##### Lactose

Rat Oral LD50 > 10 g/kg

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

**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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

#### **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.

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## 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

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Bacampicillin hydrochloride  
EU EINECS List

253-580-4

### 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

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**End of Safety Data Sheet**