# MATERIAL SAFETY DATA SHEET



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

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## Material Name: Ampicillin Sodium for Injectable Solution

**Trade Name:** Amplital Powder and Solvent for Injectable Solution
**Chemical Family:** Mixture
**Intended Use:** Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

**Appearance:** Powder plus sterile diluent
**Signal Word:** WARNING

**Statement of Hazard:** May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

**Additional Hazard Information:**
**Short Term:** Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe.
**Known Clinical Effects:** Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug. In sensitive individuals, symptoms might include skin rash, nausea, stomach discomfort, diarrhea, sore or dry mouth or sore tongue.

**EU Indication of danger:** Harmful
Irritant

**EU Hazard Symbols:**


**EU Risk Phrases:**
R42/43 - May cause sensitization by inhalation and skin contact.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Hazardous Substance.

## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|---|---|---|---|---|
| Ampicillin sodium | 69-52-3 | 200-708-1 | Xn;R42/43 | 1000 or 500 mg#### |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|---|---|---|---|---|
| Water for injection | 7732-18-5 | 231-791-2 | Not Listed | 2.5 or 4 ml#### |

**Additional Information:** #### per vial/cartridge/ampule.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases mentioned in this Section, see Section 16**

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 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. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

**Ampicillin sodium**

**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Sensitizer (control exposure to the range of >100ug/$m^3$ to < 1000ug/$m^3$, provide additional precautions to protect from skin contact)

**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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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 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:** | Crystalline powder plus sterile diluent | **Color:** | White |
| **Odor:** | Odorless or practically odorless | **Molecular Formula:** | Mixture |
| **Molecular Weight:** | Mixture | | |

**Solubility:** Slightly Soluble: Water
**Melting/Freezing Point (°C):** 202 (decomposes)

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information in this section describes the hazards of various forms of the active ingredient.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Ampicillin trihydrate**
Rat Oral LD50 10,000 mg/kg
Mouse Oral LD50 15,200 mg/kg

**Ampicillin sodium**
Rat Oral LD50 > 5314 mg/kg
Mouse Oral LD50 > 5314 mg/kg
Rat SC LD50 > 5314 mg/kg
Mouse SC LD50 > 5314 mg/kg
Rat IP LD50 7400 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.

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Ampicillin trihydrate**
103 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal System
103 Week(s) Mouse Oral 1500 mg/kg/day LOEL Gastrointestinal system

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Ampicillin trihydrate**
Fertility and Embryonic Development Rat Oral 2500 mg/kg/day LOEL Fetotoxicity

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

**Ampicillin trihydrate**
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Negative
Sister Chromatid Exchange Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

## 11. TOXICOLOGICAL INFORMATION

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

**Ampicillin trihydrate**
103 Week(s) Mouse Oral 3000 mg/kg/day NOEL Not carcinogenic
103 Week(s) Female Rat Oral 1500 mg/kg/day NOEL Not carcinogenic
103 Week(s) Male Rat Oral 750 mg/kg/day LOEL Malignant tumors, Adrenal gland, Blood

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

**Ampicillin trihydrate**
**IARC:** Group 3

**Ampicillin sodium**
**IARC:** Group 3

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 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
Irritant

**EU Risk Phrases:**
R42/43 - May cause sensitization by inhalation and skin contact.

**EU Safety Phrases:**
S24 - Avoid contact with skin.
S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## 15. REGULATORY INFORMATION

**OSHA Label:**
WARNING
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

**Canada - WHMIS: Classifications**

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

**Water for injection**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Listed |
| **Australia (AICS):** | Listed |
| **REACH - Annex IV - Exemptions from the obligations of Register:** | Present |
| **EU EINECS/ELINCS List** | 231-791-2 |

**Ampicillin sodium**

| | |
|---|---|
| **Australia (AICS):** | Listed |
| **EU EINECS/ELINCS List** | 200-708-1 |

## 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

R42 - May cause sensitization by inhalation.
R43 - May cause sensitization by skin contact.

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties.

**Prepared by:** Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**