



NFPA	HMIS	PPE	Transport Symbol						
	<table border="1"> <tr> <td>Health Hazard</td> <td align="center">2</td> </tr> <tr> <td>Fire Hazard</td> <td align="center">0</td> </tr> <tr> <td>Reactivity</td> <td align="center">0</td> </tr> </table>	Health Hazard	2	Fire Hazard	0	Reactivity	0		
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Fire Hazard	0								
Reactivity	0								

Issuing Date 24-Aug-2006

Revision Date NOT AUTHORIZED

Revision Number 0

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name** Ampicillin and Sulbactam for Injection, USP

**Product Code(s)**  
**10139-070-12** - 1.5 g Vial  
**10139-070-11** - Shelf Pack (1.5 g Vials x 10)  
**10139-071-18** - 3 g Vial  
**10139-071-10** - Shelf Pack (3 g Vials x 10)

**Recommended Use** Anti-infective

**Supplier Address**  
 GeneraMedix Inc.  
 150 Allen Road  
 Liberty Corner, NJ 07938, USA  
 TEL: 908-504-1300

**Chemical Emergency Phone Number** Chemtrec 1-800-424-9300

## 2. HAZARDS IDENTIFICATION

### WARNING!

#### Emergency Overview

May be harmful if swallowed, inhaled, or absorbed through skin.

May produce an allergic reaction.

May cause skin irritation and/or dermatitis.

May cause sensitization by skin contact.

PRODUCT INTENDED FOR THERAPEUTIC USE ONLY AS PRESCRIBED BY A PHYSICIAN.

**Appearance** White to off-white

**Physical State** Powder

**Odor** Odorless

### Potential Health Effects

**Principle Routes of Exposure** Skin contact, Ingestion.

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<b>Acute Toxicity</b>	
<b>Eyes</b>	May cause eye irritation with susceptible persons.
<b>Skin</b>	May be harmful in contact with skin. May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.
<b>Inhalation</b>	May be harmful if inhaled. May cause allergic respiratory reaction.
<b>Ingestion</b>	May be harmful if swallowed. May cause additional affects as listed under "Inhalation".
<b>Chronic Effects</b>	Repeated contact may cause allergic reactions in very susceptible persons. Avoid repeated exposure. See Section 11 for additional Toxicological Information.
<b>Aggravated Medical Conditions</b>	Allergies. Allergies to penicillin, penicillin derivatives, penicillamine, or cephalosporins. Skin disorders. Respiratory disorders. Blood disorders. Gastrointestinal tract. Liver disorders. Kidney disorders.
<b>Interactions with Other Chemicals</b>	Irritants. Sensitizers. Note: Penicillin-sensitive individuals may experience an allergic cross-reaction upon exposure to this product.
<b>Environmental Hazard</b>	See Section 12 for additional Ecological information.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Ampicillin Sodium	69-52-3	66-67%
Sulbactam Sodium	69388-84-7	33-34%

### 4. FIRST AID MEASURES

<b>General Advice</b>	Immediate medical attention is not required. Show this safety data sheet to the doctor in attendance.
<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician. Wash off immediately with soap and plenty of water.
<b>Inhalation</b>	Move to fresh air. If symptoms persist, call a physician.
<b>Ingestion</b>	Immediate medical attention is not required. Rinse mouth. Drink plenty of water. Do not induce vomiting.
<b>Notes to Physician</b>	May cause sensitization of susceptible persons. Use of epinephrine may be indicated.
<b>Protection of First-aiders</b>	Use personal protective equipment.

### 5. FIRE-FIGHTING MEASURES

<b>Flammable Properties</b>	Not flammable.
<b>Flash Point</b>	N/A
<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Explosion Data**

Sensitivity to mechanical impact None.  
 Sensitivity to static discharge None.

**Specific Hazards Arising from the Chemical**

Thermal decomposition can lead to release of irritating gases and vapors. In the event of fire and/or explosion do not breathe fumes. May cause sensitization by inhalation and skin contact.

**Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

<b>NFPA</b>	<b>Health Hazard 2</b>	<b>Flammability 0</b>	<b>Stability 0</b>	<b>Physical and Chemical Hazards N/A</b>
<b>HMIS</b>	<b>Health Hazard 2</b>	<b>Flammability 0</b>	<b>Stability 0</b>	<b>Personal Precautions N/A</b>

**6. ACCIDENTAL RELEASE MEASURES**

<b>Personal Precautions</b>	Use personal protective equipment. Avoid contact with the skin and the eyes.
<b>Methods for Containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for Cleaning Up</b>	Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically and collect in suitable container for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

<b>Handling</b>	Ensure adequate ventilation. Wear personal protective equipment.
<b>Storage</b>	Keep containers tightly closed in a cool, well-ventilated place. Keep out of the reach of children.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
<b>Engineering Measures</b>	Showers, eyewash stations, and ventilation systems.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Tightly fitting safety goggles.
<b>Skin and body protection</b>	Impervious gloves. Long sleeved clothing.
<b>Respiratory Protection</b>	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
<b>Hygiene Measures</b>	When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance</b>	White to off-white	<b>Odor</b>	Odorless
<b>Physical State</b>	Powder	<b>pH</b>	No data available.
<b>Flash Point</b>	N/A	<b>Autoignition Temperature</b>	N/A
<b>Boiling Point/Range</b>	No data available.	<b>Melting Point/Range</b>	215°C / 419°F
<b>Flammability Limits in Air</b>	No data available.		
<b>Solubility</b>	Soluble in water.	<b>VOC Content</b>	N/A

**10. STABILITY AND REACTIVITY**

<b>Stability</b>	Stable under recommended storage conditions.
<b>Conditions to Avoid</b>	None known based on information supplied.
<b>Incompatible Products</b>	None known based on information supplied.
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), carbon dioxide (CO <sub>2</sub> ), nitrogen oxides (NO <sub>x</sub> ), sulfur oxides.
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity**

**Product Information** Product does not present an acute toxicity hazard based on known or supplied information.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ampicillin Sodium	5314 mg/kg (Rat)	N/A	N/A
Sulbactam Sodium	>4000 mg/kg (Rat) >10000 mg/kg (Mouse)	>4000 mg/kg (Rat)	6500 mg/kg (Rat) 8.1 mg/kg (Mouse)

**Subchronic Toxicity (28 days)** N/A

**Chronic Toxicity**

**Chronic Toxicity** Repeated contact may cause allergic reactions in very susceptible persons. Avoid repeated exposure. See Section 11 for additional Toxicological Information.

**Carcinogenicity** There are no known carcinogenic chemicals in this product.

**Mutagenicity**

**Reproductive Toxicity** This product does not contain any known or suspected reproductive hazards.

**Target Organ Effects** Skin.

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**Endocrine Disruptor Information**      This product does not contain any known or suspected endocrine disruptors.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**      Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

**13. DISPOSAL CONSIDERATIONS**

**Waste Disposal Method**      This material, as supplied, is not a hazardous waste according to state and federal regulations (40 CFR 261).

**Contaminated Packaging**      Dispose of in accordance with local regulations.

**14. TRANSPORT INFORMATION**

<b><u>DOT</u></b>	Not regulated
<b><u>TDG</u></b>	Not regulated
<b><u>MEX</u></b>	Not regulated
<b><u>ICAO</u></b>	Not regulated
<b><u>IATA</u></b>	Not regulated
<b><u>IMDG/IMO</u></b>	Not regulated
<b><u>RID</u></b>	Not regulated
<b><u>ADR</u></b>	Not regulated
<b><u>ADN</u></b>	Not regulated

15. REGULATORY INFORMATION

**International Inventories**

TSCA	Complies
DSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	Does not Comply
CHINA	Does not Comply
KECL	Complies
PICCS	Does not Comply
AICS	Does not Comply

**U.S. Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

**Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**U.S. State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

**International Regulations**

**Mexico - Grade** Moderate risk, Grade 2

**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

**WHMIS Hazard Class**

D2B Toxic materials



16. OTHER INFORMATION

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Issuing Date	24-Aug-2006
Revision Date	NOT AUTHORIZED.
Revision Note	NO DATA AVAILABLE.

**Disclaimer**

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of MSDS**