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Function: Regulatory Affairs	Effective Date: November 09, 2020	Version Number: 2.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

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

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment: Antibiotics

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
224-443-4617

[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Acute Tox. 4 (Oral)	H302
Resp. Sens. 1	H334
Skin Sens. 1	H317

Full text of hazard classes and H-statements : see section 16

### 2.2. Label Elements

#### GHS-US Labeling

**Hazard Pictograms (GHS-US)**



**Signal Word (GHS-US)**

: Danger

**Hazard Statements (GHS-US)**

: H302 - Harmful if swallowed  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**Precautionary Statements (GHS-US)**

: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P264 - Wash ... thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P284 - [In case of inadequate ventilation] wear respiratory protection  
P301 + P312 - If swallowed: Call a poison center/doctor if you



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feel unwell  
P302 + P352 - If on skin: Wash with plenty of water  
P304 + P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing  
P330 - Rinse mouth  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention  
P342 + P311 - If experiencing respiratory symptoms: Call a poison center/doctor  
P362+P364 - Take off contaminated clothing and wash it before reuse  
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

### 2.3. Other Hazards

No additional information available

### 2.4. Unknown Acute Toxicity (GHS-US)

Not applicable

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Ampicillin Sodium	(CAS No) 69-52-3	66.66	Resp. Sens. 1, H334 Skin Sens. 1, H317
Sulbactam Sodium	(CAS No) 69388-84-7	33.33	Acute Tox. 4 (Oral), H302

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures After Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.

**First-aid Measures After Skin Contact:** Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.

**First-aid Measures After Eye Contact:** Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

**First-aid Measures After Ingestion:** DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries After Inhalation:** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation on direct contact.



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**Symptoms/Injuries After Ingestion:** Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals

**Chronic Symptoms:** None known.

#### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

No additional information available

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

#### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** None known.

#### 5.3. Advice for Firefighters

**Protection During Firefighting:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** No special measures required.

##### 6.1.1. For Non-Emergency Personnel

No additional information available

##### 6.1.2. For Emergency Personnel

No additional information available

#### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Stop the flow of material, if this is without risk.

**Methods for Cleaning Up:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

#### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

### SECTION 7: HANDLING AND STORAGE

#### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.

#### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Storage Conditions:** Store at controlled room temperature at 20–25 °C (68–77°F). Store away from incompatible Materials.

#### 7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions.

Medical Treatment: Antibiotics

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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Local exhaust and general ventilation must be adequate to meet exposure standards.

#### Personal Protective Equipment

: Wear protective gloves. Wear safety glasses with side shields (or goggles).



#### Materials for Protective Clothing

: Chemically resistant materials and fabrics.

#### Hand Protection

: Wear protective gloves.

#### Eye and Face Protection

: Wear safety glasses with side shields (or goggles).

#### Skin and Body Protection

: Wear suitable working clothes.

#### Respiratory Protection

: If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Use high efficiency particulate respirator with appropriate filter.

#### Other Information

: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Powder
Color	: White to off-white
Odor	: None
Odor Threshold	: No data available
pH	: 8-10
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available



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**Relative Density** : Approx to water  
**Solubility** : Soluble in water  
**Partition Coefficient: N-Octanol/Water** : No data available  
**Viscosity** : No data available

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** No additional available.  
**10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).  
**10.3. Possibility of Hazardous Reactions:** Will not occur.  
**10.4. Conditions to Avoid:** Heat. Water, moisture. Minimize dust generation and accumulation. Contact with incompatible materials.  
**10.5. Incompatible Materials:** Strong oxidizers.  
**10.6. Hazardous Decomposition Products:** Carbon oxides. Nitrogen oxides. Sulfur oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Oral: Harmful if swallowed.

<b>Ampicillin and Sulbactam for Injection</b>	
<b>ATE US (Oral)</b>	1250.000 mg/kg body weight
<b>Ampicillin Sodium (69-52-3)</b>	
<b>LD50 Oral Rat</b>	>5314 mg/kg
<b>Sulbactam Sodium (69388-84-7)</b>	
<b>ATE US (Oral)</b>	500.000 mg/kg body weight

**Skin Corrosion/Irritation:** Not classified.

**Serious Eye Damage/Irritation:** Not classified.

**Respiratory or Skin Sensitization:** May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>Ampicillin Sodium (69-52-3)</b>	
<b>IARC group</b>	3-Not classifiable

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified.

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation on direct contact.



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**Symptoms/Injuries After Ingestion:** Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and Degradability

No additional information available

### 12.3. Bioaccumulative Potential

No additional information available

### 12.4. Mobility in Soil

No additional information available

### 12.5. Other Adverse Effects

**Other Information**

: No known ecological damage caused by this product.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

No additional information available

### 15.2. US State Regulations

No additional information available

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest Revision** : 11/09/2020

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

### GHS Full Text Phrases:

Acute Tox. 4 (Oral)

Acute toxicity (oral) Category 4

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Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

Effective