SAFETY DATA SHEET

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

Product Identifier

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection

Trade Name: Unasyn®, UNASYN; UNACIM; UNACID; UNACIM; BEGALIN-P; DUOCID

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
H373 - May cause damage to organs through prolonged or repeated exposure. May form combustible dust concentrations in air

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

Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com
Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P311 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sulbactam sodium</td>
<td>69388-84-7</td>
<td>273-984-4</td>
<td>STOT RE 2 (H373)</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>Ampicillin sodium</td>
<td>69-52-3</td>
<td>200-708-1</td>
<td>Resp. Sens.1 (H334)</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1 (H317)</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure:  None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician:  None

5. FIRE FIGHTING MEASURES

Extinguishing Media:  Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products:  Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
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.

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

Precautions for Safe 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 thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities
SAFETY DATA SHEET

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 23-Jun-2017

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Sulbactam sodium
Pfizer OEL TWA-8 Hr: 3000 µg/m³, (as free acid)

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/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Analytical Method: Analytical method available for sulbactam; ampicillin. Contact Pfizer Inc for further information.

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Powder
Odor: Odorless
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: 8 - 10 (reconstituted)
Melting/Freezing Point (°C): No data available

Color: Off-white
Odor Threshold: No data available.
Molecular Weight: Mixture
9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
- Ampicillin sodium: No data available
- Sulbactam sodium: No data available
- Ampicillin trihydrate: No data available
- Ampicillin: No data available

Decomposition Temperature (°C): No data available
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions:
- Oxidizing Properties: No data available
- 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
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of various forms of the active ingredient. The toxicities of the two materials can be expected to be similar.

Short Term: Accidental ingestion may cause effects similar to those seen in clinical use. Ampicillin is reported to induce environmental or occupational asthma. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe (anaphylactic).

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

Known Clinical Effects: Adverse effects seen during clinical use are infrequent (<3%) and include diarrhea and skin rash. Pseudomembranous colitis has been reported following the use of Unasyn®

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

Ampicillin sodium
11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>LD50</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulbactam sodium</td>
<td>Oral</td>
<td>&gt; 5314 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>&gt; 5314mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5314mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SC</td>
<td>LD50</td>
<td>&gt; 5314mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>IP</td>
<td>LD50</td>
<td>7400mg/kg</td>
<td></td>
</tr>
<tr>
<td>Ampicillin trihydrate</td>
<td>Oral</td>
<td>10,000 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>15,200mg/kg</td>
<td></td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Oral</td>
<td>&gt; 5000 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sub-tenon injection (eye)</td>
<td>LD 50</td>
<td>4500mg/kg</td>
<td></td>
<td></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.

**Skin Irritation / Sensitization**

Hypersensitivity reactions can occur in individuals sensitive to penicillin, streptomycin, and/or other aminoglycosides. Mild irritation was seen in 3-day venous irritation studies in rabbits with sulbactam/ampicillin. Ampicillin is reported to induce environmental or occupational asthma.

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Duration</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulbactam sodium</td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>20 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Ampicillin trihydrate</td>
<td>103 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>750 mg/kg/day</td>
<td>LOEL</td>
</tr>
<tr>
<td></td>
<td>103 Week(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>1500 mg/kg/day</td>
<td>LOEL</td>
</tr>
</tbody>
</table>

**Reproduction & Developmental Toxicity:** (Study Type, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulbactam sodium</td>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>120 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Prenatal &amp; Postnatal Development</td>
<td>Mouse Rat</td>
<td>Intramuscular</td>
<td>800 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Ampicillin trihydrate</td>
<td>Fertility and Embryonic Development</td>
<td>Rat</td>
<td>Oral</td>
<td>2500 mg/kg/day</td>
<td>LOEL</td>
<td>Fetotoxicity</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicillin trihydrate</td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Mammalian Cell Mutagenicity</td>
<td>Mouse Lymphoma</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Sister Chromatid Exchange Chromosome Aberration</td>
<td>Chinese Hamster Ovary (CHO) cells</td>
<td>Negative</td>
</tr>
</tbody>
</table>
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 sodium
IARC: Group 3 (Not Classifiable)

Ampicillin trihydrate
IARC: Group 3 (Not Classifiable)

Ampicillin
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
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Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 23-Jun-2017

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Sulbactam sodium

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List 273-984-4

Ampicillin sodium

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 200-708-1

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-Jun-2017


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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet