



MATERIAL SAFETY DATA SHEET

Revision date: 15-Mar-2012

Version: 4.0

Page 1 of 7

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

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

Trade Name: Unasyn® , UNASYNA; UNACIM; UNACID; UNACIM; BEGALIN-P; DUOCID
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Off-white dry powder - powder may be reconstituted to a pale yellow/yellow solution
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause damage to liver through prolonged or repeated exposure.

Additional Hazard Information:

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.
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®

EU Indication of danger: Irritant
Harmful

EU Hazard Symbols:

Xn



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 15-Mar-2012

Page 2 of 7

Version: 4.0

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 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ampicillin sodium	69-52-3	200-708-1	Xn;R42/43	66
Sulbactam sodium	69388-84-7	273-984-4	Xn;R48/22	44

Additional Information: 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.

MATERIAL SAFETY DATA SHEET

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 15-Mar-2012

Page 3 of 7

Version: 4.0

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 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sulbactam sodium

Pfizer OEL TWA-8 Hr:

3 mg/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.

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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

MATERIAL SAFETY DATA SHEET

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

Revision date: 15-Mar-2012

Page 4 of 7

Version: 4.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	Color:	Off-white
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Solubility:	Soluble: Water
pH:	8 - 10 (reconstituted)

Polymerization: Will not occur

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 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.

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

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

Sulbactam sodium

Rat	Oral	LD50	> 4000 mg/kg
Mouse	Oral	LD50	> 10,000 mg/kg
Rat	IV	LD50	4582 mg/kg
Mouse	IV	LD50	3604 mg/kg

Ampicillin trihydrate

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

Ampicillin

Rat	Oral	LD 50	> 5000 mg/kg
Rat	Sub-tenon injection (eye)	LD 50	4500 mg/kg
Mouse	Oral	LD 50	> 5000 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.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 15-Mar-2012

Page 5 of 7

Version: 4.0

11. TOXICOLOGICAL INFORMATION

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

Sulbactam sodium

6 Month(s) Rat Subcutaneous 20 mg/kg/day NOEL Liver

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

Sulbactam sodium

Reproductive & Fertility Rat Subcutaneous 120 mg/kg/day NOEL Negative

Prenatal & Postnatal Development Mouse Rat Intramuscular 800 mg/kg/day NOEL Not Teratogenic

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Unasyn® (Ampicillin Sodium/Sulbactam Sodium) Powder for Injection
Revision date: 15-Mar-2012

Page 6 of 7

Version: 4.0

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.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Irritant
Harmful

EU Risk Phrases:
R42/43 - May cause sensitization by inhalation and skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

OSHA Label:
WARNING
May cause allergic skin reaction.
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause damage to liver through prolonged or repeated exposure.

Canada - WHMIS: Classifications

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



MATERIAL SAFETY DATA SHEET

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

Revision date: 15-Mar-2012

Page 7 of 7

Version: 4.0

15. REGULATORY INFORMATION

Ampicillin sodium

Australia (AICS):	Present
EU EINECS/ELINCS List	200-708-1

Sulbactam sodium

EU EINECS/ELINCS List	273-984-4
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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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

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