



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc	Emergency telephone	212-573-2222
Pfizer Pharmaceuticals Group	Hours of operation	24 hours
235 E 42nd Street	Telephone	212-573-2222
New York, NY 10017		

Product name	Ampicillin sodium/Sulbactam sodium parenteral
Synonyms	UNASYN® parenteral; Ampicillin sodium/sulbactam sodium parenteral
Chemical family	Penicillin
Therapeutic use	Antibacterial.
Description	White to off-white powder reconstituted to a pale yellow to yellow solution.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Hazardous Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Ampicillin sodium	69-52-3	Trade Secret
Sulbactam sodium	69388-84-7	Trade Secret

SECTION 3 - HAZARDS IDENTIFICATION

CERCLA ratings (scale 0-3) Health=1 Fire=0 Reactivity=0

NFPA ratings (scale 0-4) Health=1 Fire=0 Reactivity=0

Signal word CAUTION!

Statements of hazard MAY CAUSE EYE, SKIN AND RESPIRATORY TRACT IRRITATION.

MAY CAUSE HYPERSENSITIVITY REACTIONS IN SUSCEPTIBLE INDIVIDUALS.

Eye

Short term effects None known; however, direct contact with any foreign material may cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.

Long term effects None known; see short-term effects above.

Skin

Short term effects May cause skin irritation. May cause allergic reactions in susceptible individuals.

Long term effects None known; see short term-effects above.

Inhalation

Short term effects May cause respiratory tract and mucous membrane irritation. May cause hypersensitivity reactions in susceptible individuals.

SECTION 3 - HAZARDS IDENTIFICATION continued

Long term effects	Not known; see short-term effects above.
Ingestion	
Short term effects	Ingestion of this material may cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Persons sensitive to this material or other materials in its chemical class may develop allergic reactions.
Long term effects	Symptoms of chronic exposure to this material include redness and swelling of the skin, rash, chills, tooth discoloration (tetracyclines), yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes, convulsion or shock may also occur.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
Skin	Wash skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing and shoes before reuse. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion	If swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

General hazard	Toxic or corrosive emissions may be given off in a fire. See Hazardous combustion products, below, and Hazardous decomposition products in Section 10 - STABILITY AND REACTIVITY.
Fire fighting instructions	Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
Extinguisher to use	Use carbon dioxide, dry chemical, or water spray.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides and other sulfur-containing compounds.
Flash point	Not known
Autoignition	Not known
Minimum explosive concentration for dust/vapor	Not known
Flammability limits	Not known

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Occupational spill	Contain the source of spill or leak. Scoop spilled material into a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.
Clean up - large spill	Review Section 3 and 8 before proceeding with clean up. Scoop or shovel spilled material into a labeled container for recovery or disposal. Close

SECTION 6 - ACCIDENTAL RELEASE MEASURES continued

container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash water with a non-combustible absorbent material and transfer to labeled container for treatment and disposal.

SECTION 7 - HANDLING AND STORAGE

General handling	Keep away from heat. Use with adequate ventilation. Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. Avoid breathing vapor or mist. When handling, use proper personal protective equipment specified in Section 8.
Storage	Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at ambient temperature.
Temperature range	15 - 30 °C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits	Hazardous Ingredient	OEL	Type	Value
	Ampicillin sodium	Pfizer	TWA-8	Not established
	Subactam sodium	Pfizer	TWA-8	3 mg/m ³
Exposure information	No Occupational Exposure Limit (OEL) established by Pfizer for this mixture or the active ingredient it contains.			
Ventilation	General room ventilation is adequate unless the process generates airborne dust or fumes.			
Eye protection	None required under normal and foreseeable conditions of use.			
Skin protection	None required under normal and foreseeable conditions of use.			
Hand protection	None required under normal and foreseeable conditions of use.			
Respiratory protection	None required under normal and foreseeable conditions. Use dust mask for dusty conditions.			

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Powder
Color	White to off-white or pale yellow.
Odor	Odorless.
Molecular weight	Not applicable
Molecular formula	Not applicable
pH	8 - 10
Melting point	215 °C
Pour point	Not applicable
Vapor pressure	Not applicable
Water solubility	Soluble in water.
Solvent solubility	No data available.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable.
Conditions to avoid	None known.
Incompatibilities	Strong alkalies, strong acids.
Hazardous decomposition products	No data available. See Section 5 - under Hazardous combustion products.
Hazardous polymerization	Will not occur.
Oxidizing properties	No data available.
Explosive properties	None known or expected.

SECTION 11 - TOXICOLOGY INFORMATION

	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Acute toxicity	LD50	Oral	Rat	> 5314 mg/kg
	LD50	Oral	Rat	> 4000 mg/kg
Eye	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Skin	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Inhalation	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Ingestion	Acute oral LD50s for the active ingredient are listed above in the table. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient in the mixture.			
Mutagenicity	Ampicillin was not mutagenic in the Ames test using <i>S. typhimurium</i> and did not induce differential toxicity in <i>E. coli</i> strains. It did not induce chromosomal aberrations in Chinese hamster cells, mutations in mouse lymphoma cells or sister chromatid exchange in human lymphocytes or in Chinese hamster cells. Ampicillin, however, did induce chromosomal aberrations in <i>V. faba</i> . It also increased the frequency of chromosomal aberrations in human lymphocytes but not in human fibroblasts in vitro.			
Subchronic effects	Subchronic oral toxicity studies for ampicillin were conducted in rats (180 mg/kg) and mice (2000-3000 mg/kg) five days per week for 13 weeks. No compound-related pathology or histopathology was observed grossly in either species.			
Chronic toxicity	Chronic oral toxicity studies for ampicillin were performed in rats at doses of 750 or 1500 mg/kg and in mice at doses of 1500 or 3000 mg/kg 5 days per week for 103 weeks. Signs of toxicity observed in rats included diarrhea, excessive urination and colored tears (chromodacryorrhea); those in treated mice included increased salivation and decreased activity. In rats, the incidence of C-cell hyperplasia of the thyroid gland was increased in low-dose males and high-dose females. An increased incidences of hypertrophy of the epidermis of the skin and the forestomach were observed in the high-dose male rats. In male and female mice, an increased incidence of forestomach lesions, including ulcers, inflammation, hypertrophy of the epidermis of the skin and forestomach, and evidence of fungal infection, was observed in treated animals.			
Chronic effects/ Carcinogenicity	No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.			
OSHA carcinogen	No			
NTP carcinogen	Not classified			
IARC carcinogen	Not classified			

SECTION 11 - TOXICOLOGY INFORMATION continued

Reproductive effects	Reproduction studies have been performed in mice, rats, and rabbits at doses up to ten times the human dose to reveal no evidence of impaired fertility or harm to the fetus.
Teratogenicity	No data available.
At increased risk from exposure	Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.
Additional data	FDA PREGNANCY CATEGORY B. No adequate and well-controlled studies in pregnant women. However, animal studies failed to demonstrate a risk to the fetus or adequate and well-controlled studies in pregnant women failed to demonstrate a risk to the fetus.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.
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SECTION 13 - DISPOSAL INFORMATION

Disposal procedure	Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal options.
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SECTION 14 - TRANSPORTATION INFORMATION

Proper shipping name	Ampicillin sodium/sulbactam sodium parenteral
General shipping instructions	Non-regulated

SECTION 15 - REGULATORY INFORMATION

TSCA status	No
SARA section 302	No
SARA section 313	No
California proposition 65	No
Summary	Not applicable

SECTION 16 - OTHER

Summary	Not applicable
Disclaimer	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 a warranty of any kind, expressed or implied.