AMPICILLIN FOR INJECTION, USP

Steriscience Specialties Pvt Ltd

Chemwatch Hazard Alert Code: **2**

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Safety Data Sheet

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S.GHS.IND.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	AMPICILLIN FOR INJECTION, USP
Chemical Name	ampicillin
Synonyms	C16-H19-N3-O4-S; (D)-(-)-6-(2-amino)-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; aminobenzylpenicillin; (D)-(-)-alpha-aminobenzylpenicillin; (D)-()alpha-aminopenicillin; 6-((D)-alpha-aminophenylacetamido)penicillanic acid; D-ampicillin; D-(-)-ampicillin; ampicillin B; ampicillin acid; ampicillin anhydrate; penicillin, (aminophenylmethyl)-; L-(+)-ampicillin CAS RN: 19379-33-0; (2S,5R,6R)-6-(2-amino-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; L-6-(2-amino-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic Acid;; [2S-[2a,5a,6beta(R*)]]-6-[(Aminophenylacetyl)amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; (2S,5R,6R)-6-[[(2S)-aminophenylacetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-; carboxylic acid; ampicillin, anhydrous impurity B [EP]; ampicillin trihydrate impurity B [EP];; for anhydrous form:; AB-PC Acillin Adobacillin Alpen Amblosin Amcill Amfipen Amipenix S Amperil Ampi-Bol Ampicin Ampikel Ampimed Ampipenin Amplisom Amplital Ampy-Penyl Austrapen AY-6108 Binotal Bonapicillin Britacil BRL BRL-1341 Copharcilin Cymbi Divercillin Doktacillin Grampenil Guicitrina Guicitrine Lifeampil Marisilan NSI-C528986 Nuvapen Omnipen P-50 Penbristol Penbritin Penbrock Penicline Pentrex Pentrexyl Pfizerpen A Polycillin Ponecil Principen Qidamp Ro-Ampen Semicillin SK-Ampicillin Synpenin Tokiocillin Tolomol Totacillin; Totalciclina Totapen Ultrabion Ultrabron Viccillin Vicillin WY-5013; for trihydrate:; ampicillin A; Amcap Ampichel Ampikel Ampinova Amplin Morepan NCI-56086; Pen A Pensyn Princillin Trafarbiot Ukopen Vidopen; for monohydrate:; Redicilin; antibiotic; Alphacin; ampicillin trihydrate
Chemical formula	C16-H19-N3-O4-S|C16H19N3O4S|C16H19N3O4S.3H2O
Other means of identification	Not Available
CAS number	69-53-4

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Ampicillin is an antibiotic used to prevent and treat a number of bacterial infections, such as respiratory tract infections, urinary tract infections, meningitis, salmonellosis, and endocarditis. It may also be used to prevent group B streptococcal infection in newborns. It is used by mouth, by injection into a muscle, or intravenously Ampicillin acts as an irreversible inhibitor of the enzyme transpeptidase, which is needed by bacteria to make the cell wall. It inhibits the third and final stage of bacterial cell wall synthesis in binary fission, which ultimately leads to cell lysis; therefore, ampicillin is usually bacteriolytic. Therapeutic or pharmacologically-active agent. The aminopenicillins are a group of antibiotics in the penicillin family that are structural analogs of ampicillin (which is the 2-amino derivative of benzylpenicillin, hence the name. Like other penicillins and beta-lactam antibiotics, they contain a beta-lactam ring that is crucial to its antibacterial activity. Aminopenicillins feature a positively charged amino group that enhances their uptake through bacterial porin channels. This does not, however, prevent resistance conferred by bacterial beta-lactamases. Penicillins are derivative of an antimicrobial acid produced by certain strains of Penicillium notatum or related moulds. Used in the treatment of a variety of infections due to susceptible organisms, including wound infections, abscesses, boils, diphtheria, acute tonsillitis etc. Has bacteriostatic and bactericidal actions against most Gram-positive bacteria and Gram-negative cocci. thought to act by inhibiting transpeptidase, the enzyme responsible for the cross-linking of peptidoglycan during the final stages of synthesis of the bacterial cell wall. Given by deep intramuscular injection or by mouth. Penicillins (P, PCN or PEN) are a group of antibiotics originally obtained from Penicillium moulds, principally P. chrysogenum and P. rubens. Most penicillins in clinical use are chemically synthesised from naturally-produced penicillins. Penicillins were among the first medications to be effective against many bacterial infections caused by staphylococci and streptococci. They are members of the beta-lactam antibiotics. They are still widely used today for different bacterial infections, though many types of bacteria have developed resistance following extensive use. About 10% of people report that they are allergic to penicillin; however, up to 90% of this group may not actually be allergic.Serious allergies only occur in about 0.03%. Those who are allergic to penicillin are most often given cephalosporin C (another beta-lactam antibiotic) because there is only 10% crossover in allergy between the penicillins and cephalosporins Penicillins, like other beta-lactam antibiotics, block not only the division of bacteria, including cyanobacteria, but also the division of cyanelles, the photosynthetic organelles of the glaucophytes, and the division of chloroplasts of bryophytes. In contrast, they have no effect on the plastids of the highly developed vascular plants.. Penicillin kills bacteria by inhibiting the completion of the synthesis of peptidoglycans, the structural component of bacterial cell wall. It specifically inhibits the activity of enzymes that are needed for the cross-linking of peptidoglycans during the final step in cell wall biosynthesis. It does this by binding to penicillin binding proteins with the beta-lactam ring, a structure found on penicillin molecules. This causes the cell wall to weaken due to fewer cross-links and means water uncontrollably flows into the cell because it cannot maintain the correct osmotic gradient. This results in cell lysis and death. Penicillin irreversibly binds to and inhibits the activity of the transpeptidase enzyme by forming a highly stable penicilloyl-enzyme intermediate. Because of the interaction between penicillin and transpeptidase, this enzyme is also known as penicillin-binding protein (PBP). PBPs are responsible for the final stages of bacterial cell wall assembly. These enzymes are targets of beta-lactam antibiotics. Two of the PBP activities include dd-transpeptidase and DD-carboxypeptidase activities, which carry out the cross-linking of the cell wall and trimming of the peptidoglycan, the major constituent of the cell wall, by an amino acid, respectively. The activity of the latter enzyme moderates the degree of cross-linking of the cell wall, which is carried out by the former. Both these enzymes go through an acyl-enzyme species in the course of their catalytic events. All bacteria possess at least one, most often several, monofunctional serine DD-peptidases. This enzyme is an excellent drug target because it is essential, is accessible from the periplasm, and has no equivalent in mammalian cells. DD-transpeptidase is the target protein of beta-lactam antibiotics (e.g. penicillin) This is because the structure of the beta-lactam closely resembles the D-ala-D-ala residue

Page 1 continued...

Penicillin can easily enter bacterial cell in case of Gram-positive species. This is because Gram-positive bacteria do not have an outer cell membrane and are simply enclosed in a thick cell wall.Penicillin molecules are small enough to pass through the spaces of glycoproteins in the cell wall. For this reason Gram-positive bacteria are very susceptible to penicillin
Penicillin, or any other molecule, enters Gram-negative bacteria in a different manner. The bacteria have thinner cell walls but the external surface is coated with an additional cell membrane, called the outer membrane. The outer membrane is a lipid layer (lipopolysaccharide chain) that blocks passage of water-soluble (hydrophilic) molecules like penicillin. It thus acts as the first line of defence against any toxic substance, which is the reason for relative resistance to antibiotics compared to Gram-positive species But penicillin can still enter Gram-negative species by diffusing through aqueous channels called porins (outer membrane proteins), which are dispersed among the fatty molecules and can transport nutrients and antibiotics into the bacteria. Porins are large enough to allow diffusion of most penicillins, but the rate of diffusion through them is determined by the specific size of the drug molecules. For instance, penicillin G is large and enters through porins slowly; while smaller ampicillin and amoxicillin diffuse much faster. In contrast, large vancomycin can not pass through porins and is thus ineffective for Gram-negative bacteria. The size and number of porins are different in different bacteria. As a result of the two factors - size of penicillin and porin-Gram-negative bacteria can be unsusceptible or have varying degree of susceptibility to specific penicillin.
The term "penam" is used to describe the common core skeleton of a member of the penicillins. This core has the molecular formula R-C9H11N2O4S, where R is the variable side chain that differentiates the penicillins from one another. The penam core has a molar mass of 243 g/mol, with larger penicillins having molar mass near 450 - for example, cloxacillin has a molar mass of 436 g/mol. 6-APA (C8H12N2O3S) forms the basic structure of penicillins. It is made up of an enclosed dipeptide formed by the condensation of L-cysteine and D-valine. This results in the formations of beta-lactam and thiazolidinic rings.
The key structural feature of the penicillins is the four-membered beta-lactam ring; this structural moiety is essential for penicillin's antibacterial activity. The beta-lactam ring is itself fused to a five-membered thiazolidine ring. The fusion of these two rings causes the beta-lactam ring to be more reactive than monocyclic beta-lactams because the two fused rings distort the beta-lactam amide bond and therefore remove the resonance stabilisation normally found in these chemical bonds. An acyl side side chain attached to the beta-lactam ring.
Hypersensitivity is the most important adverse effect of the penicillins. The major antigenic determinant of penicillin hypersensitivity is its metabolite, penicilloic acid, which reacts with proteins and serves as a hapten to cause an immune reaction. The penicillins are metabolized in the body and some of their metabolites are released to the environment. Among the metabolites are penicilloyl, penicilloic acid, and penilloic acid, in addition to the parent compound itself
Under physiologic conditions, 95% of penicillin spontaneously degrades to penicilloyl – also called the major antigenic determinant. The remaining portion of penicillin degrades mainly to penicilloate and penilloate, which, along with penicillin, are called the minor antigenic determinants. Penilloic acids are most common degradation products in penicillin derivatives
A variety of beta-lactam antibiotics have been produced following chemical modification from the 6-APA structure during synthesis, specifically by making chemical substitutions in the acyl side chain. For example, the first chemically altered penicillin, methicillin, had substitutions by methoxy groups at positions 2' and 6' of the 6-APA benzene ring from penicillin G. This difference makes methicillin resistant to the activity of beta-lactamase (also known as penicillinase), an enzyme by which many bacteria are naturally unsusceptible to penicillins.
Some bacteria produce enzymes that break down the beta-lactam ring, called beta-lactamases, which make the bacteria resistant to penicillin. Therefore, some penicillins are modified or given with other drugs for use against antibiotic-resistant bacteria or in immunocompromised patients. The use of clavulanic acid or tazobactam, beta-lactamase inhibitors, alongside penicillin gives penicillin activity against beta-lactamase-producing bacteria. beta-Lactamase inhibitors irreversibly bind to beta-lactamase preventing it from breaking down the beta-lactam rings on the antibiotic molecule. Alternatively, flucloxacillin is a modified penicillin that has activity against beta-lactamase-producing bacteria due to an acyl side chain that protects the beta-lactam ring from beta-lactamase
beta-Lactam antibiotics are indicated for the prevention and treatment of bacterial infections (bactericidal) caused by susceptible organisms. At first, beta-lactam antibiotics were mainly active only against Gram-positive bacteria, yet the recent development of broad-spectrum beta-lactam antibiotics active against various Gram-negative organisms has increased their usefulness.
beta-Lactams are classified according to their core ring structures. beta-Lactams fused to:
· saturated five-membered ring include the penams, carbapenams and clavams
· unsaturated five-membered ring include the penems and carbapenems
· unsaturated six-membered rings include cephems, carbacephems and oxacephems
beta-lactams not fused to any other ring are named monobactams.
beta-Lactam antibiotics are bactericidal, and act by inhibiting the synthesis of the peptidoglycan layer of bacterial cell walls. The peptidoglycan layer is important for cell wall structural integrity, especially in Gram-positive organisms, being the outermost and primary component of the wall. The final transpeptidation step in the synthesis of the peptidoglycan is facilitated by DD-transpeptidases, also known as penicillin binding proteins (PBPs). PBPs vary in their affinity for penicillin and other beta-lactam antibiotics. The number of PBPs varies between bacterial species.
beta-Lactam antibiotics are analogues of d-alanyl-d-alanine - the terminal amino acid residues on the precursor NAM/NAG-peptide subunits of the nascent peptidoglycan layer. The structural similarity between beta-lactam antibiotics and d-alanyl-d-alanine facilitates their binding to the active site of PBPs. The beta-lactam nucleus of the molecule irreversibly binds to (acylates) the Ser403 residue of the PBP active site. This irreversible inhibition of the PBPs prevents the final crosslinking (transpeptidation) of the nascent peptidoglycan layer, disrupting cell wall synthesis. beta-Lactam antibiotics block not only the division of bacteria, including cyanobacteria, but also the division of cyanelles, the photosynthetic organelles of the glaucophytes, and the division of chloroplasts of bryophytes. In contrast, they have no effect on the plastids of the highly developed vascular plants. This is supporting the endosymbiotic theory and indicates an evolution of plastid division in land plants.
Under normal circumstances, peptidoglycan precursors signal a reorganisation of the bacterial cell wall and, as a consequence, trigger the activation of autolytic cell wall hydrolases. Inhibition of cross-linkage by beta-lactams causes a build-up of peptidoglycan precursors, which triggers the digestion of existing peptidoglycan by autolytic hydrolases without the production of new peptidoglycan. As a result, the bactericidal action of beta-lactam antibiotics is further enhanced.
Another possibility that has been proposed to account for much of the cytotoxicity of beta lactams focuses on the oxidation of the guanine nucleotide in the bacterial nucleotide pool. The incorporation of oxidized guanine nucleotide into DNA could cause cytotoxicity. Bacterial cytotoxicity could arise from incomplete repair of closely spaced 8-oxo-2'-deoxyguanosine lesions in the DNA resulting in double-strand breaks. beta-Lactam antibiotics irreversibly binds to and inhibits the activity of the transpeptidase enzyme by forming a highly stable penicilloyl-enzyme intermediate. These enzymes are targets of beta-lactam antibiotics. DD-transpeptidase and DD-carboxypeptidase are responsible the cross-linking of the cell wall and trimming of the peptidoglycan, the major constituent of the cell wall, by an amino acid, respectively. The activity of the latter enzyme moderates the degree of cross-linking of the cell wall, which is carried out by the former. Both these enzymes go through an acyl-enzyme species in the course of their catalytic events. All bacteria possess at least one, most often several, monofunctional serine DD-peptidases. This enzyme is an excellent drug target because it is essential, is accessible from the periplasm, and has no equivalent in mammalian cells. DD-transpeptidase is the target protein of beta-lactam antibiotics. This is because the structure of the beta-lactam closely resembles the D-ala-D-ala residue
By definition, all beta-lactam antibiotics have a beta-lactam ring in their structure. The effectiveness of these antibiotics relies on their ability to reach the PBP intact and their ability to bind to the PBP. Hence, there are two main modes of bacterial resistance to beta-lactams:
· If the bacterium produces the enzyme beta-lactamase or the enzyme penicillinase, the enzyme will hydrolyse the beta-lactam ring of the antibiotic, rendering the antibiotic ineffective. The production of a beta-lactamase by a bacterium does not necessarily rule out all treatment options with beta-lactam antibiotics. In some instances, beta-lactam antibiotics may be co-administered with a beta-lactamase inhibitor (such as augmentin, clavulanic acid, boronic acids).
· As a response to the use of beta-lactams to control bacterial infections, some bacteria have evolved penicillin binding proteins with novel structures. beta-Lactam antibiotics cannot bind as effectively to these altered PBPs, and, as a result, the beta-lactams are less effective at disrupting cell wall synthesis. Notable examples of this mode of resistance include methicillin-resistant Staphylococcus aureus (MRSA) and penicillin-resistant Streptococcus pneumoniae. Altered PBPs do not necessarily rule out all treatment options with beta-lactam antibiotics.
Two structural features of beta-lactam antibiotics have been correlated with their antibiotic potency. The first is known as "Woodward's parameter", h, and is the height (in angstroms) of the pyramid formed by the nitrogen atom of the beta-lactam as the apex and the three adjacent carbon atoms as the base. The second is called "Cohen's parameter", c, and is the distance between the carbon atom of the carboxylate and the oxygen atom of the beta-lactam carbonyl. This distance is thought to correspond to the distance between the carboxylate-binding site and the oxyanion hole of the PBP enzyme. The best antibiotics are those with higher h values (more reactive to hydrolysis) and lower c values (better

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	binding to PBPs) The extended-spectrum penicillins are a group of antibiotics that have the widest antibacterial spectrum of all penicillins. Some sources identify them with anti-pseudomonal penicillins, others consider these types to be distinct. This group includes the carboxypenicillins and the ureidopenicillins. Aminopenicillins, in contrast, do not have activity against Pseudomonas species, as their positively charged amino group does not hinder degradation by bacterially produced beta-lactamases. Ureidopenicillins incorporates a polar side chain that enhances penetration into Gram-negative bacteria and reduces susceptibility to cleavage by Gram-negative beta lactamase enzymes. These properties confer activity against the important hospital pathogen Pseudomonas aeruginosa.

Details of the manufacturer or supplier of the safety data sheet

Registered company name	**Steriscience Specialties Pvt Ltd**
Address	Opp IIMB, Bilekahalli, Dorasani Palya, Begur Hobli,Bannerghata Road,BENGALURU Karnataka 560076 India
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Emergency telephone number

Association / Organisation	**Steriscience Specialties Pvt Ltd**	**CHEMWATCH EMERGENCY RESPONSE**
Emergency telephone numbers	+91 80 69093100	+918000403230
Other emergency telephone numbers	Not Available	+61 3 9573 3188

Once connected and if the message is not in your preferred language then please dial 01

SECTION 2 Hazards identification

Classification of the substance or mixture

NFPA 704 diamond

Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Acute Toxicity (Oral) Category 5, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Skin) Category 1, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3

Label elements

Hazard pictogram(s)	
Signal word	**Danger**

Hazard statement(s)

H303	May be harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

Precautionary statement(s) Prevention

P261	Avoid breathing dust/fumes.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances

CAS No	%[weight]	Name
69-53-4	>98	Ampicillin for Injection, USP

Mixtures

See section above for composition of Substances

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Wash out immediately with fresh running water. ▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▸ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: ▸ Immediately remove all contaminated clothing, including footwear. ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Inhalation	▸ If fumes or combustion products are inhaled remove from contaminated area. ▸ Lay patient down. Keep warm and rested. ▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▸ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▸ Transport to hospital, or doctor, without delay.
Ingestion	▸ If swallowed do **NOT** induce vomiting. ▸ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▸ Observe the patient carefully. ▸ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▸ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▸ Seek medical advice.

Indication of any immediate medical attention and special treatment needed

Ampicillin is widely distributed in body fluids and tissues. It appears in pleural, pericardial, peritoneal and synovial fluids and diffuses across the placenta into foetal circulation. Little passes into normal cerebrospinal fluid. Plasma half-life is about 1 to 2 hours with about 20% bound to plasma proteins. 30% appears in the urine within 6 hours. Significant concentrations are achieved in the bile. Treatment regime proposed is identical to that for penicillin G exposure:
Penicillins are widely distributed in body fluids and tissues. They appear in pleural, pericardial, peritoneal and synovial fluids and diffuse across the placenta into foetal circulation. Only small amounts pass into normal cerebrospinal fluid. Plasma half-life is about 30 minutes with about 55-80% bound to plasma proteins. 20-35% appears in the urine within an hour. Only small concentrations appear in the bile.
When cutaneous reactions occur, they may subside spontaneously within a few hours or days following withdrawal of the antibiotic. Administration of antihistamines, or in the absence of a response, corticosteroids, may control reactions. At the first sign of an immediate reaction to penicillin treatment, 0.3 to 1 ml of adrenalin injection should be given intramuscularly (or in severe cases, 0.2 ml well diluted intravenously) followed by a further dose should no improvement occur. This may be followed by an antihistamine such as diphenhydramine or chlorpheniramine, given parenterally and a corticosteroid given intravenously. Should bronchospasm be severe, aminophylline (250 mg in 10 ml) may be given intravenously. Assisted respiration is necessary if there is upper airways obstruction and plasma or suitable electrolyte solutions should be given intravenously if circulatory failure occurs. Severe urticaria and/or joint pains may be treated with oral corticosteroids.
MARTINDALE; The Extra Pharmacopoeia, 29th Edition.
Treatment of penicillin overdose may include the following:
· Perform gastric decontamination in cases of severe ingestion.
· Administer activated charcoal as a slurry.
· Manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine.
· For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital.
For hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation.
· Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
· Treat dysrhythmias with standard antiarrhythmic drugs, if necessary.
· Monitor fluid and electrolyte status and patients with severe vomiting and/or diarrhea.
· Monitor for renal and hematologic abnormalities.
· For coagulopathies,administer vitamin K.
· For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis.

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· Hemodialysis may aid in the removal of penicillins from the blood.
[Meditext 2007 and PDR 2007]
Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

Special hazards arising from the substrate or mixture

Fire Incompatibility	‣ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Advice for firefighters

Fire Fighting	‣ Alert Fire Brigade and tell them location and nature of hazard. ‣ Wear breathing apparatus plus protective gloves. ‣ Prevent, by any means available, spillage from entering drains or water courses. ‣ Use water delivered as a fine spray to control fire and cool adjacent area. ‣ **DO NOT** approach containers suspected to be hot. ‣ Cool fire exposed containers with water spray from a protected location. ‣ If safe to do so, remove containers from path of fire. ‣ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	‣ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ‣ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ‣ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. ‣ In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC). ‣ When processed with flammable liquids/vapors/mists,ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts. ‣ A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people. ‣ Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type. ‣ Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport. ‣ Build-up of electrostatic charge may be prevented by bonding and grounding. ‣ Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting. ‣ All movable parts coming in contact with this material should have a speed of less than 1-meter/sec. ‣ A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source. ‣ One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapours). ‣ Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases. Combustion products include: carbon monoxide (CO) carbon dioxide (CO_2) nitrogen oxides (NOx) sulfur oxides (SOx) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	‣ Clean up waste regularly and abnormal spills immediately. ‣ Avoid breathing dust and contact with skin and eyes. ‣ Wear protective clothing, gloves, safety glasses and dust respirator. ‣ Use dry clean up procedures and avoid generating dust.

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	▸ Vacuum up or sweep up. **NOTE:** Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). ▸ Dampen with water to prevent dusting before sweeping. ▸ Place in suitable containers for disposal.
Major Spills	Moderate hazard. ▸ **CAUTION**: Advise personnel in area. ▸ Alert Emergency Services and tell them location and nature of hazard. ▸ Control personal contact by wearing protective clothing. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Recover product wherever possible. ▸ **IF DRY:** Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. **IF WET:** Vacuum/shovel up and place in labelled containers for disposal. ▸ **ALWAYS:** Wash area down with large amounts of water and prevent runoff into drains. ▸ If contamination of drains or waterways occurs, advise Emergency Services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	▸ Avoid all personal contact, including inhalation. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Prevent concentration in hollows and sumps. ▸ **DO NOT** enter confined spaces until atmosphere has been checked. ▸ **DO NOT** allow material to contact humans, exposed food or food utensils. ▸ Avoid contact with incompatible materials. ▸ When handling, **DO NOT** eat, drink or smoke. ▸ Keep containers securely sealed when not in use. ▸ Avoid physical damage to containers. ▸ Always wash hands with soap and water after handling. ▸ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▸ Use good occupational work practice. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS. ▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. ▸ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ▸ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▸ Establish good housekeeping practices. ▸ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds. ▸ Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area. ▸ Do not use air hoses for cleaning. ▸ Minimise dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used. ▸ Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition. ▸ Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance. ▸ Do not empty directly into flammable solvents or in the presence of flammable vapors. ▸ The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges. Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source. ▸ Do NOT cut, drill, grind or weld such containers. ▸ In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.
Other information	▸ Store in original containers. ▸ Keep containers securely sealed. ▸ Store in a cool, dry area protected from environmental extremes. ▸ Store away from incompatible materials and foodstuff containers. ▸ Protect containers against physical damage and check regularly for leaks. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS. For major quantities: ▸ Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams}. ▸ Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.

Conditions for safe storage, including any incompatibilities

Suitable container	▸ Glass container is suitable for laboratory quantities ▸ Polyethylene or polypropylene container. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	▸ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

Continued...

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
AMPICILLIN FOR INJECTION, USP	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Ampicillin for Injection, USP	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
Ampicillin for Injection, USP	E	≤ 0.01 mg/m³
Notes:	*Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.*	

Exposure controls

Appropriate engineering controls

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.
When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.
Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.
Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.
Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved.
Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.
The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.
The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:
10; high efficiency particulate (HEPA) filters or cartridges
10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.
25-50; a full face-piece negative pressure respirator with HEPA filters
50-100; tight-fitting, full face-piece HEPA PAPR
100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Personal protection

Eye and face protection

When handling very small quantities of the material eye protection may not be required.
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles.
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or

Continued...

	national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	**NOTE:** ▸ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▸ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: · frequency and duration of contact, · chemical resistance of glove material, · glove thickness and · dexterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. · Contaminated gloves should be replaced. As defined in ASTM F-739-96 in any application, gloves are rated as: · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended. It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times. Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example: · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. ▸ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▸ Double gloving should be considered. ▸ PVC gloves. ▸ Change gloves frequently and when contaminated, punctured or torn. ▸ Wash hands immediately after removing gloves. ▸ Protective shoe covers. [AS/NZS 2210] ▸ Head covering. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. ▸ polychloroprene. ▸ nitrile rubber. ▸ butyl rubber. ▸ fluorocaoutchouc. ▸ polyvinyl chloride. Gloves should be examined for wear and/ or degradation constantly.
Body protection	See Other protection below
Other protection	▸ For quantities up to 500 grams a laboratory coat may be suitable. ▸ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. ▸ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. ▸ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. ▸ Eye wash unit. ▸ Ensure there is ready access to an emergency shower. ▸ For Emergencies: Vinyl suit

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G =

Continued...

Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

· Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
· The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
· Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
· Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
· Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
· Use approved positive flow mask if significant quantities of dust becomes airborne.
· Try to avoid creating dust conditions.
Class P2 particulate filters are used for protection against mechanically and thermally generated particulates or both.
P2 is a respiratory filter rating under various international standards, Filters at least 94% of airborne particles
Suitable for:
· Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.
· Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.
· Biologically active airborne particles under specified infection control applications e.g. viruses, bacteria, COVID-19, SARS

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White to off white crystalline powder

Physical state	Divided Solid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	Not Applicable	**Decomposition temperature (°C)**	199
Melting point / freezing point (°C)	199-202 (decomp)	**Viscosity (cSt)**	Not Applicable
Initial boiling point and boiling range (°C)	Not Applicable	**Molecular weight (g/mol)**	403.4 (.3H2O)
Flash point (°C)	Not Available	**Taste**	Not Available
Evaporation rate	Not Applicable	**Explosive properties**	Not Available
Flammability	Not Available	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Available	**Surface Tension (dyn/cm or mN/m)**	Not Applicable
Lower Explosive Limit (%)	Not Available	**Volatile Component (%vol)**	Negligible
Vapour pressure (kPa)	Negligible	**Gas group**	Not Available
Solubility in water	Partly miscible	**pH as a solution (Not Available%)**	3.5-5.5 (0.25%)
Vapour density (Air = 1)	Not Applicable	**VOC g/L**	Not Applicable

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Beta-lactam antibiotics often cause allergies, including rash, itching wheals, blood changes and shock occasionally. Digestive symptoms include diarrhoea, nausea and vomiting. Penicillins can cause temporary diarrhoea, nausea, heartburn and itchiness of the anus. They are fairly safe in the non-allergic.

Continued...

Skin Contact	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	This material can cause eye irritation and damage in some persons.
Chronic	Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population. There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Allergic contact dermatitis is relatively common amongst those handling the penicillins or following repeated topical application of penicillin containing ointments. Repeated ingestion of penicillins can cause nausea and/or vomiting, stomach upset, diarrhoea, sore or dry throat, and a sore or black hairy tongue. Resistance may develop for some bacteria, and there may be overgrowth of non-susceptible organisms (superinfection). Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.

Ampicillin for Injection, USP	**TOXICITY**	**IRRITATION**
	Oral (Mouse) LD50; >5000 mg/kg[2]	Not Available
Legend:	*1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*	

AMPICILLIN FOR INJECTION, USP	for trihydrate: [RTECS No,: XH 8425000] Foetotoxicity recorded. for anhydrous form [RTECS No.: XH 8350000] Hallucinations, excitement, agranulocytosis, tyhrombocytopenia, blood changes, changes in teeth and supporting structures recorded. Ampicillin is comparatively less toxic than other antibiotics, and side effects are more likely in those who are sensitive to penicillins and those with a history of asthma or allergies. In very rare cases, it causes severe side effects such as angioedema, anaphylaxis, and C. difficile infection (that can range from mild diarrhea to serious pseudomembranous colitis). Some develop black "furry" tongue. Serious adverse effects also include seizures and serum sickness. The most common side effects, experienced by about 10% of users are diarrhea and rash. Less common side effects can be nausea, vomiting, itching, and blood dyscrasias. The gastrointestinal effects, such as hairy tongue, nausea, vomiting, diarrhea, and colitis, are more common with the oral form of penicillin. Other conditions may develop up several weeks after treatment. Ampicillin overdose can cause behavioral changes, confusion, blackouts, and convulsions, as well as neuromuscular hypersensitivity, electrolyte imbalance, and kidney failure Ampicillin is one of the most used drugs in pregnancy and has been found to be generally harmless both by the Food and Drug Administration in the U.S. (which classified it as category B) and the Therapeutic Goods Administration in Australia (which classified it as category A) It is the drug of choice for treating Listeria monocytogenes in pregnant women, either alone or combined with an aminoglycoside. Pregnancy increases the clearance of ampicillin by up to 50%, and a higher dose is thus needed to reach therapeutic levels. Ampicillin crosses the placenta and remains in the amniotic fluid at 50–100% of the concentration in maternal plasma; this can lead to high concentrations of ampicillin in the newborn. While lactating mothers secrete some ampicillin into their breast milk, the amount is minimal In newborns, ampicillin has a longer half-life and lower plasma protein binding The clearance by the kidneys is lower, as kidney function has not fully developed The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested. Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production. Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins. Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. The substance is classified by IARC as Group 3: **NOT** classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.

Acute Toxicity	✔	**Carcinogenicity**	✘
Skin Irritation/Corrosion	✔	**Reproductivity**	✘
Serious Eye Damage/Irritation	✔	**STOT - Single Exposure**	✔
Respiratory or Skin sensitisation	✔	**STOT - Repeated Exposure**	✘
Mutagenicity	✘	**Aspiration Hazard**	✘

Legend: ✘ *– Data either not available or does not fill the criteria for classification*
✔ *– Data available to make classification*

Toxicity

Continued...

Ampicillin for Injection, USP	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	EC20(ECx)	96h	Algae or other aquatic plants	80.32mg/l	4
	EC50	48h	Crustacea	>1000mg/l	4
	LC50	96h	Fish	>1000mg/l	4
Legend:	*Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*				

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Ampicillin for Injection, USP	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
Ampicillin for Injection, USP	LOW (LogKOW = 1.35)

Mobility in soil

Ingredient	Mobility
Ampicillin for Injection, USP	LOW (KOC = 534.4)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	▸ Containers may still present a chemical hazard/ danger when empty. ▸ Return to supplier for reuse/ recycling if possible. Otherwise: ▸ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: ▸ Reduction ▸ Reuse ▸ Recycling ▸ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted. ▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains. ▸ It may be necessary to collect all wash water for treatment before disposal. ▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▸ Where in doubt contact the responsible authority.

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO

Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
Ampicillin for Injection, USP	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
Ampicillin for Injection, USP	Not Available

SECTION 15 Regulatory information

Safety, health and environmental regulations / legislation specific for the substance or mixture

Continued...

Ampicillin for Injection, USP is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (Ampicillin for Injection, USP)
China - IECSC	No (Ampicillin for Injection, USP)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (Ampicillin for Injection, USP)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	No (Ampicillin for Injection, USP)
Legend:	*Yes = All CAS declared ingredients are on the inventory* *No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.*

SECTION 16 Other information

Revision Date	19/04/2022
Initial Date	12/05/2005

SDS Version Summary

Version	Date of Update	Sections Updated
6.1	18/04/2022	Acute Health (swallowed), CAS Number, Chronic Health, Classification, Disposal, Exposure Standard, Personal Protection (Respirator), Physical Properties, Storage (storage requirement), Synonyms, Toxicity and Irritation (Other), Use
7.1	19/04/2022	Use

Other information

Ingredients with multiple cas numbers

Name	CAS No
Ampicillin for Injection, USP	69-53-4, 7177-48-2, 33604-21-6, 37234-64-3, 47355-94-2, 50584-05-9, 800-79-3, 8056-87-9, 96707-69-6, 98520-55-9, 19379-33-0

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average PC—
STEL: Permissible Concentration-Short Term Exposure LimitIARC:
International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory

Continued...

NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

end of SDS