



ampicillin

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

Hazard Alert Code: MODERATE

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 1 of 17

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

ampicillin

OTHER NAMES

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)-", "for anhydrous form:", AB-PC, Acillin, Adobacillin, Alpen, Amblosin, Amcill, Amfipen, "Amipenix S", Amperil, Ampibol, 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, Pencline, Pentrex, Pentrexyl, "Pfizerpen A", Polycillin, Ponecil, Principen, Qidamp, Ro-Ampen, Semicillin, SK-Ampicillin, Synpenin, Tokiocillin, Tolomol, Totacillin, Totalciclina, Totapen, Ultrabion, Ultrabron, Vicillin, Vicillin, WY-5013, "for trihydrate:", "ampicillin A", Amcap, Ampichel, Ampinova, Amplin, Morepan, NCI-56086, "Pen A", Pensyn, Princillin, Trafarbiot, Ukopen, Vidopen, "for monohydrate:", Redicilin, antibiotic, Alphacin

PRODUCT USE

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. 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.

SUPPLIER

Company: Sigma- Aldrich Pty Ltd
Address:
12 Anella Avenue
Castle Hill
NSW, 2154
Australia
Telephone: +61 2 9841 0555
Telephone: 1800 800 097
Emergency Tel: **+44 8701906777**
Emergency Tel: **1800 448 456**
Fax: +61 2 9841 0500
Email: ausmail@sial.com
Website: www.sigma-aldrich.com

continued...

ampicillin

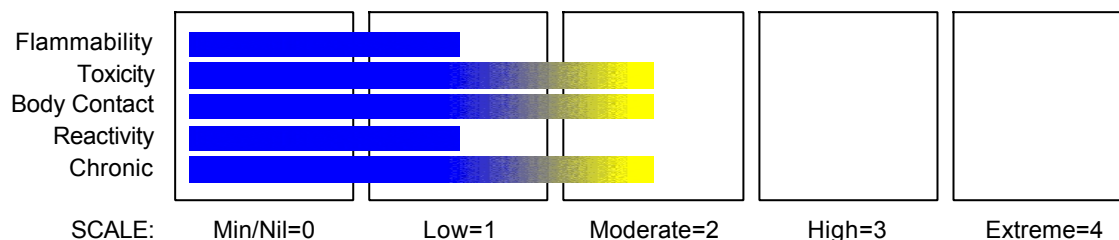
Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 2 of 17

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



GHS Classification

Eye Irritation Category 2A
Respiratory Sensitizer Category 1
Skin Corrosion/Irritation Category 2
Skin Sensitizer Category 1
STOT - SE Category 3



EMERGENCY OVERVIEW

HAZARD DANGER

Determined by Chemwatch using GHS criteria

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

PRECAUTIONARY STATEMENTS

Prevention

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash ... thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response

P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P304+P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 3 of 17
Section 2 - HAZARDS IDENTIFICATION

P304+P341	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P363	Wash contaminated clothing before reuse.
Storage	
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
Disposal	
P501	Dispose of contents/container to ...

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
ampicillin	69-53-4	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

- 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

- 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.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 4 of 17

Section 4 - FIRST AID MEASURES

- 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.

NOTES TO PHYSICIAN

- Treat symptomatically.

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.

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:

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

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

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,

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 5 of 17

Section 5 - FIRE FIGHTING MEASURES

such materials may cause fires and / or dust 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)
 - 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 (CO₂), nitrogen oxides (NO_x), sulfur oxides (SO_x), other pyrolysis products typical of burning organic material.
- May emit poisonous fumes.
- May emit corrosive fumes.

FIRE INCOMPATIBILITY

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

Personal Protective Equipment

Gas tight chemical resistant suit.

Limit exposure duration to 1 BA set 30 mins.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 6 of 17

Section 6 - ACCIDENTAL RELEASE MEASURES

- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- 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 MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR 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 storing and handling recommendations.
 - Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
- 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.

SUITABLE CONTAINER

- Glass container is suitable for laboratory quantities.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 7 of 17
Section 7 - HANDLING AND STORAGE

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



- +: May be stored together
O: May be stored together with specific preventions
X: Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC	Notes
Australia Exposure Standards	ampicillin (Manganese, fume (as Mn))		1		3				
Australia Exposure Standards	ampicillin (Manganese, dust & compounds (as Mn))		1						

EMERGENCY EXPOSURE LIMITS

Material	Revised IDLH Value (mg/m ³)	Revised IDLH Value (ppm)
ampicillin 58347-1	500	
ampicillin 58347-1	10	

MATERIAL DATA

AMPICILLIN:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace. At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 8 of 17

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

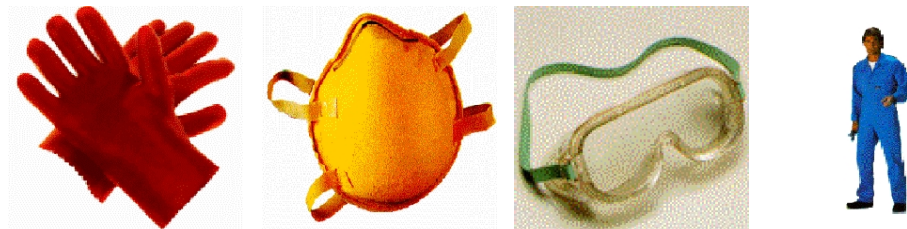
OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

OEL STEL (Russia): 0.1 mg/m³ Allergen

PERSONAL PROTECTION



EYE

■ 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 lens 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 national equivalent].

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 9 of 17

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

HANDS/FEET

■ 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. 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.
- Contaminated gloves should be replaced.

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). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC 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
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- 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.

RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)
- 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 -

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 10 of 17

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- 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 . 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.
 - Use approved positive flow mask if significant quantities of dust becomes airborne.
 - Try to avoid creating dust conditions.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

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.

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:
solvent, vapours, etc. evaporating from tank
(in still air)
aerosols, fumes from pouring operations,
intermittent container filling, low speed
conveyer transfers (released at low velocity
into zone of active generation)

Air Speed:
0.25- 0.5 m/s (50- 100 f/min.)
0.5- 1 m/s (100- 200 f/min.)

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 11 of 17

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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

1: Room air currents minimal or favourable to capture

2: Contaminants of low toxicity or of nuisance value only.

3: Intermittent, low production.

4: Large hood or large air mass in motion

Upper end of the range

1: Disturbing room air currents

2: Contaminants of high toxicity

3: High production, heavy use

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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

White odourless, hygroscopic crystalline powder; does not mix well with water (1:150).

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 12 of 17

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

State	Divided Solid	Molecular Weight	403.4 (.3H ₂ O)
Melting Range (°C)	199- 202 (decomp)	Viscosity	Not Applicable
Boiling Range (°C)	Not available	Solubility in water (g/L)	Partly Miscible
Flash Point (°C)	Not Available	pH (1% solution)	3.5- 5.5 (0.25%)
Decomposition Temp (°C)	199	pH (as supplied)	Not Applicable
Autoignition Temp (°C)	Not Available	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- Penicillins can cause temporary diarrhoea, nausea, heartburn and itchiness of the anus. They are fairly safe in the non-allergic. Hypersensitive patients can present with acute inflammation of the kidneys and anaphylactic shock, which can cause death within minutes. A generalised sensitivity reaction can occur in 1 to 3 weeks. This includes hives, swellings (especially of the face, lips and tissues around the mouth), redness of the skin, skin shedding, purple discolouration, extreme weakness, abdominal cramps, fever, joint pain, constriction of airways, severe asthma, chest pains, low blood pressure, cyanosis, collapse of circulation and lung swelling. Serum sickness type syndromes include enlarged spleen, joint pain and inflammation, muscle pain, general unwellness, lymph disorders and mental changes. There may be cross-sensitivity between penicillins and other members of their family, as well as cephalosporins and cephamycins.

EYE

- This material can cause eye irritation and damage in some persons.

SKIN

- This material can cause inflammation of the skin oncontact 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

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 13 of 17

Section 11 - TOXICOLOGICAL INFORMATION

is suitably protected.

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.

CHRONIC HEALTH EFFECTS

- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic 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). 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. Prime symptom is breathlessness; lung shadows show on X-ray.

TOXICITY AND IRRITATION

AMPICILLIN:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY

Oral (rat) LD50: 10000 mg/kg
Oral (mouse) LD50: 15200 mg/kg
Intraperitoneal (rat) LD50: 4500 mg/kg
Intravenous (rat) LD50: 6200 mg/kg
Oral (mouse) LD50: >5000 mg/kg
Intraperitoneal (mouse) LD50: 3250 mg/kg
Intravenous (mouse) LD50: 4600 mg/kg
Intracerebral (mouse) LD50: 380 mg/kg

IRRITATION

Nil Reported
Nil Reported

- Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 14 of 17

Section 11 - TOXICOLOGICAL INFORMATION

the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, 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.

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.

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.

for trihydrate:

[RTECS No.: XH 8425000]

Foetotoxicity recorded.

for anhydrous form

[RTECS No.: XH 8350000]

Hallucinations, excitement, agranulocytosis, thrombocytopenia, blood changes, changes in teeth and supporting structures recorded.

CARCINOGEN

Ampicillin	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	3
Nickel, metallic and alloys	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	2B

Section 12 - ECOLOGICAL INFORMATION

AMPICILLIN:

- DO NOT discharge into sewer or waterways.

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 15 of 17
Section 12 - ECOLOGICAL INFORMATION

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
ampicillin	HIGH	No Data Available	LOW	MED

GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles

Name / Cas No / RTECS No	EHS	TRN	A1a	A1b	A1	A2	B1	B2	C1	C2	C3	D1	D2	D3	E1	E2	E3
Propyl benzene / CAS:69- 53- 4 /	119	268	NI		NI	NI	3	NI	NI	NI	NI	NI	NI		(T)	FE	NI

Legend:

EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg), C2=Acutemammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation& corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities,
For column A2: R=Readily biodegradable, NR=Not readily biodegradable.
For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic, I=Immunotoxic.
For column E1: NT=Not tainting (tested), T=Tainting test positive.
For column E2: Fp=Persistent floater, F=Floater, S=Sinking substances.
The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard.
(GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

Section 13 - DISPOSAL CONSIDERATIONS

- 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 MSDS 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

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)

Issue Date: 7-Nov-2009

NC618TCP

CHEMWATCH 58347-1

Version No:5

CD 2011/2 Page 16 of 17

Section 13 - DISPOSAL CONSIDERATIONS

that properties of a material may change in use, and recycling or reuse may not always be appropriate.

- 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.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

GESAMP hazard profiles for this material can be found in section 12 of the MSDS.

Section 15 - REGULATORY INFORMATION

REGULATIONS

ampicillin (CAS: 69-53-4,7177-48-2) is found on the following regulatory lists;

"Australia Inventory of Chemical Substances (AICS)", "Australia New Zealand Food Standards Code - Maximum Residue Limits (Australia only) - Schedule 1", "International Agency for Research on Cancer (IARC) - Agents

Reviewed by the IARC Monographs"

Section 16 - OTHER INFORMATION

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
ampicillin	69- 53- 4	R43
ampicillin	7177- 48- 2	R43

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
ampicillin	69-53-4, 7177-48-2

- Classification of the preparation and its individual components has drawn on official and authoritative

continued...

ampicillin

Hazard Alert Code: MODERATE

ampicillin (REVIEW)
Issue Date: 7-Nov-2009
NC618TCP

CHEMWATCH 58347-1
Version No:5
CD 2011/2 Page 17 of 17
Section 16 - OTHER INFORMATION

sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)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.

This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH. TEL (+61 3) 9572 4700.

Issue Date: 7-Nov-2009
Print Date: 3-Sep-2011