
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Moxylan Ready-To-Use Injection Broad Spectrum Antibiotic
Product Identifier:	150 mg/mL Amoxicillin as the trihydrate
Product Code:	501625 (100 mL)
Recommended Use:	For the treatment of bacterial infections sensitive to amoxicillin in dogs, cats, cattle and pigs.
Restrictions on Use:	For animal treatment only
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Customer Centre:	1800 023 312 (9am – 5pm, Monday to Friday)
Email:	customerservice@jurox.com.au
National Poisons Information Centre:	131126 (Australia-wide) (24 hours)
Emergency Telephone Number:	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Skin Corrosion/Irritation Category 2	H315	Causes skin irritation.
Eye Irritation Category 2A	H319	Causes serious eye irritation.
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction.
Respiratory Sensitizer Category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS Label Elements:

Signal Word: **DANGER**

Pictograms:



Exclamation mark



Health hazard

Precautionary Statements:Prevention

P261 Avoid breathing vapours.
P264 Wash hands thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of work place.
P280 Wear protective gloves/eye protection.
P284 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 victim 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.
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 CENTRE or doctor/physician.
P362+P364 Take off contaminated clothing and wash before reuse.

Disposal

P501 Dispose of unused product in accordance with local regulations.
Dispose of empty container by wrapping with paper and placing in garbage.
Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

N.B.: The above statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Other hazards: Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly life threatening.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Amoxicillin trihydrate	61336-70-7	17.8%
Phenol	108-95-2	< 1%
Ingredients not contributing to the hazards	-	< 80%

Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 131126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Symptoms and Effects of Exposure: May cause allergic reactions, possibly serious in sensitised individuals.

Inhalation: Is not expected to cause problems by inhalation except in individuals sensitive to amoxicillin. If problems do occur, remove patient to fresh air. Lay patient down and keep warm and rested. Encourage patient to blow nose to ensure clear passage for breathing. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen. Seek medical assistance immediately.

Ingestion: Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly life threatening. If swallowed, DO NOT induce vomiting. Rinse mouth with water. If vomiting occurs, maintain clear and open airway. For advice, contact the National Poisons Centre on 131126. Seek medical assistance immediately. Show this SDS to a medical practitioner.

Skin: Mild irritant. May cause skin rashes in sensitised persons. If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention. Remove and wash / dispose of contaminated clothing promptly. Can lead to allergic reactions and breathing difficulty in hypersensitive individuals.

Eye: Mild to moderate irritant. If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.

Injection: Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately. Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly life threatening.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat as an overdose of penicillin antibiotics.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable.

Hazardous Combustion Products: If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and breathing apparatus.

Hazchem Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Due to the nature of the packaging, large spills are unlikely to occur. In the event of a large spill, wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill or refer to the relevant Land Waste Management Authority.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling: Care required to avoid accidental self-injection. Do not handle this product if you are sensitised or if you have been advised not to work with such preparations. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin and eyes. Wash hands after use. Use other personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store below 30°C (room temperature). Contents of broached vials may be stored if necessary at 25°C (air conditioning) for up to 28 days provided contamination is avoided. Protect from light. Store away from foodstuffs.

Other Information: Always read the label before use.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: Not applicable for normal use. No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood. Known exposure limits for ingredients are as follows:

Occupational Exposure Limits (OEL)

Australian Exposure Standards

INGREDIENT	TWA	STEL
Phenol	4 mg/m ³ / 1 ppm	Not available

Engineering Controls: Use only in a well ventilated area. Ensure that the work environment remains clean.

Personal Protective Equipment (PPE):

Eye Protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

Skin Protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory Protection: Not required for the normal use of this product.

Other: For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	An oily, off white, smooth and uniform suspension.	Upper / Lower Flammability Limits:	Not available.
Odour:	Not available.	Vapour Pressure:	Not available.
Odour Threshold:	Not available.	Vapour Density: Relative Density /	Not available.
pH:	Not available.	Specific Gravity:	0.92 – 0.96.
Melting Point / Freezing Point:	Not available.	Solubility:	Insoluble.
Boiling Point and Boiling Range:	Not available.	Partition Coefficient (n-octanol/water):	Not available.
Flash Point:	Not flammable.	Auto-Ignition Temperature:	Not available.
Evaporation Rate:	Not available.	Decomposition Temperature:	Not available.
Flammability:	Not flammable.	Viscosity:	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity: May react with oxidizing agents.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label. Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include carbon dioxide, nitrogen oxides, sulfur oxides and other pyrolysis products typical of burning organic material.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. However, there is a limited evidence that mixture may produce nausea and vomiting.

Amoxicillin:

LD₅₀ (oral): 15000 mg/kg (rat)

LD₅₀ (oral): 25000 mg/kg (mouse)

NOEL: 200 mg/kg/day.

ADI: 0.2 mg/kg/day

Phenol:

LD₅₀ (oral): 317 mg/kg (rat)

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route. Nevertheless, good hygiene practice requires that exposure be kept to a minimum.

REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Injection: Effects will vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling), to acute allergic reaction.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard. However, may cause hypersensitivity.

Respiratory Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory irritant. However, inhaling amoxicillin is more likely to cause a sensitisation reaction in some persons compared to the general population. Long-term exposure of amoxicillin to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems.

REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Corrosion/Irritation Category 2**. May cause skin reaction described as non-allergic contact dermatitis.

REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Phenol

Skin (rabbit): 500 mg open - SEVERE

Skin (rabbit): 500 mg/24hr - SEVERE

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Eye Irritation Category 2A**. Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). Phenol may produce severe irritation to the eye causing pronounced inflammation.

REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Phenol

Eye (rabbit): 100 mg rinse - mild

Eye (rabbit): 5 mg - SEVERE

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Respiratory Sensitizer Category 1 & Skin Sensitizer Category 1**. 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.

REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant.

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure. However, repeated ingestion of penicillins can cause nausea and/or vomiting, stomach upset, diarrhoea, sore or dry throat, sore or black hairy tongue and may affect the respiratory system. 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.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as ecotoxic by GHS criteria. However, DO NOT discharge into sewer or waterways.

Amoxicillin: LC50 (96 hr) (fish): 1633.114 mg/L
EC50 (96 hr) (algae / aquatic plants): 392.461 mg/L

Phenol: LC50 (96 hr) (fish): 0.00175 mg/L
EC50 (96 hr) (algae / aquatic plants): 0.0611 mg/L
EC50 (48 hr) (crustacea): 3.1 mg/L

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Amoxicillin	High	High	Low	Low
Phenol	Low	Low	Low	Low

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classed as a Dangerous Good for land, sea and air transport.

Hazchem Code: None specified.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA Registration No: 50608

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Amoxicillin, is mentioned in the SUSMP.

Section 16: OTHER INFORMATION**Legend:**

ADI	Acceptable Daily Intake.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
EC	European Commission.
EC₅₀	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms.
EPA	Environmental Protection Authority.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
LC₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEL	No Observable Effect Level.
OEL	Occupational Exposure Limits.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
STEL	Short term exposure limit.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
TWA	Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours.

References:

ChemID Plus

<https://chem.nlm.nih.gov/chemidplus/>

HCIS (Hazardous Chemical Information System)

<http://hcis.safeworkaustralia.gov.au/HazardousChemical>

EPA New Zealand Chemical Classification and Information Database (CCID)

<https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid>

HSDB (Hazardous Substances Data Bank)

<https://toxnet.nlm.nih.gov>**This version issued:** 15 May 2018 and is valid for 5 years from this date.**Supersedes:** This SDS supersedes the version issued on 18 July 2017.**Revision History:**

Date of Revision	Reason
18 July 2017	Updates to section 1, 2, 3, 10, 11, 12 & 15; Updates to Legend, and addition of Revision History in Section 16.
15 May 2018	Updates to section 1, 2, 3, 4, 6, 7, 8, 10, 11 and Revision History in Section 16.

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END OF SDS