
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Moxylan Tablets
Product Code:	501620 (50mg), 501655 (200mg)
Recommended Use:	For the treatment of amoxicillin susceptible bacterial infections in dogs and cats.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	131126 (Australia-wide)
Emergency Telephone Number:	1800 023 312 (Monday – Friday, 9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION¹

Hazard Classifications: Considered a Hazardous Substance according to the criteria of GHS.
Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

GHS Hazard Classification:*

GHS Category	Hazard code	Hazard Statement
Skin Corrosion/Irritation Category 2	H315	Causes skin irritation.
Eye Irritation Category 2A	H319	Causes serious eye irritation.
Respiratory Sensitizer Category 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction.
Specific target organ toxicity - single exposure Category 3	H335	May cause respiratory irritation.

GHS Pictograms:

Exclamation mark



Health hazard

Signal Word: ***DANGER****Precautionary Statements: *****Prevention**

- P261 Avoid breathing dust and vapours from reconstituted product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves e.g. PVC or vinyl, protective clothing, face protection and protective eyewear e.g. Safety glasses with eye side shields or chemical goggles.
P285 In case of inadequate ventilation wear respiratory protection.
P272 Contaminated work clothing should not be allowed out of the workplace.

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 IF IN EYES: Rinse cautiously with water for several minutes.
 +P338 Remove contact lenses, if present and easy to do. Continue rinsing.
 P312 Call a POISON CENTRE or doctor if you feel unwell.
 P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
 P362 Take off contaminated clothing and wash before reuse.

Storage

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

Disposal

P501 Dispose of contents/container in accordance with local/national regulations.

*N.B.: These 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.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Cellulose	9004-34-6	>60%
Amoxicillin trihydrate	26787-78-0	30 - 60 %
Other non-hazardous ingredients	-	10 - <30%

Section 4: FIRST AID MEASURES

General information: Consult the National Poisons Centre on 13 1126 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 product container or label at hand.

Inhalation: If fumes, aerosols or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. 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.

Ingestion: Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly life threatening. If swallowed, immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin: Mild irritant. May cause skin rashes in sensitised persons. If skin contact occurs, immediately remove all contaminated clothing, including footwear. Wash affected area thoroughly with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention.

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

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 boots and breathing apparatus.

Special hazards: Fire Incompatibility: Avoid contamination with oxidising agents.

Hazchem Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up / 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.

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

Environmental Precautions: If contamination of drains and waterways occurs, advise Emergency Services.

Section 7: HANDLING AND STORAGE

Handling: Avoid contact with skin and eyes. Use personal protective equipment as required.

Storage: Store in original container, away from foodstuffs. Store below 25°C. (air conditioning) in a dry place.

Other Information: Always read the label before use. See label for further information on handling and storage.

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: No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.

Protective Equipment: Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.

Engineering Controls: Handle in a well ventilated area.

Hygiene Precautions: Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: A speckled, off-white circular tablet.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

Melting Point: Not available.

Boiling Point: Not available.

Flash Point: Not flammable.

Evaporation Rate: Not available.

Flammability: Not applicable.

Upper flammability limits: Not applicable.

Lower flammability limits: Not applicable.

Vapour Pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Specific Gravity: Not available.

Solubility in Water: Insoluble - disintegrates.

Partition coefficient: Not available.

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not applicable.

Section 10: STABILITY AND REACTIVITY

Stability:	When stored appropriately this product should show no significant degradation within the expiry period shown on the labelling.
Hazardous Polymerisation:	Not known to occur.
Materials to Avoid:	None known.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:	<p>Inhalation: Not normally a hazard due to physical form of product.</p> <p>Ingestion: Large doses of cellulose may be administered orally as non-nutritive bulk, with doses of up to 30 g/day tolerated as bulk laxative while extremely large oral doses may produce disturbances to the gut. Polysaccharides are not easily absorbed from the digestive tract, but may produce a laxative effect. Larger doses may produce intestinal or stomach blockage. Penicillins can cause temporary diarrhoea, nausea, heartburn and itchiness of the anus. They are fairly safe in the non-allergic. Not classified as acutely toxic.</p> <p>Amoxicillin: LD₅₀ (oral): 15000 mg / kg (rat); LD₅₀ (oral): 25000 mg / kg (mouse). The ADI for Amoxicillin: 0.2 mg/kg/day; NOEL: 200 mg/kg/day.</p> <p>Microcrystalline Cellulose: LD₅₀ (oral): >5000 mg/kg (rat).</p>
Skin Irritation/Corrosion:	Based on available data for the ingredients, the mixture is classified as Skin Corrosion/Irritation Category 2- causes skin irritation. Skin contact is not thought to have harmful health effects (as classified under EC Directives), however the mixture may still produce health damage following entry through wounds, lesions or abrasions. REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.
Serious Eye Damage/Irritation:	Based on available data for the ingredients, the mixture is classified as Eye Irritation Category 2A – Eye irritant.
Respiratory or Skin sensitisation:	Based on available data for the ingredients, the mixture is classified as Respiratory Sensitizer Category 1 & Skin Sensitizer Category 1- May cause allergy or asthma symptoms or breathing difficulties if inhaled & May cause an allergic skin reaction. REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.
Chronic Effects:	May cause allergic reactions, possibly serious in sensitised individuals. Repeated ingestion of penicillins can cause nausea and/or vomiting, stomach upset, diarrhoea, sore or dry throat, and a sore or black hairy tongue.
Mutagenicity:	Not known to be a mutagen.
Carcinogenicity:	Not known to be carcinogenic.
Reproductive Toxicity:	Not known to cause reproductive toxicity.
STOT:	Based on available data for the ingredients, the mixture is classified as Specific target organ toxicity - single exposure Category 3 – May cause respiratory tract irritation.
Aspiration hazard:	No available data.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity:	<p>DO NOT discharge into sewer or waterways, However under GHS criteria, the mixture is not considered to be toxic to the environment.</p> <p>Amoxicillin: Fish: LC50 (96 h): 1633.114mg/L; Algae or other aquatic plants: EC50 (96 h): 392.461mg/L.</p>
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Microcrystalline Cellulose: Fish: LC50 (96 h): 7.45058mg/L;
 Algae or other aquatic plants: EC50 (96 h): 17857.93905mg/L.

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

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to APVMA approved label or by approved waste collection.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration No: 50605 (50 mg) and 50606 (200 mg)

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

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

ADG	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7 th Edition.
ADI	Acceptable Daily Intake.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
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.
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.
PPE	Personal Protective Equipment.
PVC	Polyvinyl Chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.

References:

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Amoxicillin anhydrous (RN: 26787-78-0).

New Zealand Environmental Protection Authority, HSNO Chemical Classification and Information Database (CCID), entry for Amoxicillin trihydrate (Cas Number: 61336-70-7).

THE VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>, entry for Amoxicillin.



This version issued: 18 July 2017 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 28 August 2012.

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.

END OF SDS