

SAFETY DATA SHEET**Section 1: SUBSTANCE IDENTIFICATION AND SUPPLIER**

Product Name:	Juroclav Broad Spectrum Antibiotic Tablets
Product Codes:	503650 (50 mg x 100's); 503655 (250 mg x 250's); 503660 (500 mg x 100's)
Recommended Use:	For the treatment of bacterial infections sensitive to clavulanic acid and amoxicillin in dogs, cats and calves.
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.)(24 hours)

Section 2: HAZARD IDENTIFICATION

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

GHS Category	Hazard code	Hazard Statement
Skin Sensitization Category 1	H317	May cause an allergic skin reaction.
Single Target Organ Toxicity (STOT) – Repeated Exposure Category 2	H373	May cause damage to organs through prolonged or repeated exposure.
Aquatic toxicity (Acute) Category 1	H400	Very toxic to aquatic life.

GHS Label Elements:**Signal Word:****WARNING****Pictograms:**

Exclamation mark Health hazard Environment

Precautionary Statements:Prevention

- P102 Keep out of reach of children.
- P103 Read label before use.
- P261 Avoid breathing dust.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves.
- P273 Avoid release to the environment.

Response

- P101 If medical advice is needed, have product label or container on hand.
- P302 + P352 IF ON SKIN: Wash with plenty of water and soap.
- P314 Get medical advice / attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical advice / attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Disposal

P501 Dispose of contents/container in accordance with local/national regulations. Dispose of empty container by wrapping with paper and putting in garbage.

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: Accidental ingestion of the product may be damaging to the health of the individual. Penicillins can cause temporary diarrhoea, nausea, heartburn and itchiness of the anus. Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly life threatening.

Section 3: COMPOSITION INFORMATION

INGREDIENT	CAS No.	CONTENT
Amoxicillin (as amoxycillin trihydrate)	61336-70-7	27.8%
Clavulanic acid (as potassium clavulanate)	61177-45-5	7.7%
Ingredients not contributing to the hazards	-	< 70%

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 this SDS, product container or label at hand. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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 respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. 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. Keep subject warm and at rest. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. 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. For advice, contact a doctor or the National Poisons Centre on 13 1126 immediately.

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

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 toxic and corrosive fumes. Not 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: 2Z.

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 sweep up, avoiding generation of dust, 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.

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

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: Restricted Veterinary Medicine, for use only under the authority or prescription of a veterinarian. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin and eyes. Wash hands after use. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children Store at 25°C (air conditioning) in a dry place. Store away from foodstuffs.

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. An exposure limit for the mixture has not been established. No exposure standards for the ingredients are available. Do not handle until all safety precautions have been read and understood. Due to the small volumes involved, and the methods of administration, exposure under normal conditions of use would likely be limited to getting dust on to skin or in to eyes.

Engineering Controls: Not applicable for normal use. Handle bulk product in a well ventilated area.

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.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pink coloured, circular, flat-bevelled, uncoated tablets.	Upper / Lower Flammability Limits:	Not available.
Odour:	Not available.	Vapour Pressure:	Not applicable.
Odour Threshold:	Not available.	Vapour Density:	Not applicable.
pH:	Not applicable.	Relative Density / Specific Gravity:	Not applicable.
Melting Point / Freezing Point:	Not available.	Solubility:	Partly soluble in water – tablet disintegrates.
Boiling Point and Boiling Range:	Not available.	Partition Coefficient (n-octanol/water):	Not applicable
Flash Point:	Not flammable.	Auto-Ignition Temperature:	Not applicable.
Evaporation Rate:	Not available.	Decomposition Temperature:	Not applicable.
Flammability:	Not flammable.	Viscosity:	Not applicable.

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Elevated temperatures and/or direct sunlight.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Decomposes on heating and produces toxic fumes of 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 ingredients, the mixture is not considered to be an acute toxicant by the oral route. However, ingestion of amoxicillin may cause diarrhoea, nausea and vomiting.

Amoxicillin: LD₅₀ (oral): 15000 mg/kg (rat);
LD₅₀ (oral): 25000 mg/kg (mouse).

Potassium clavulanate: LD₅₀ (oral): 7936mg/kg (rat);
LD₅₀ (oral): 4526 mg/kg (mouse).

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. The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation. Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. REMARK: Amoxycillin 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.

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 not considered to be a skin irritant. However, may cause skin rashes in sensitised persons. REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant. Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). REMARK: Amoxicillin is a penicillin and the most important adverse reaction is hypersensitivity.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Sensitization Category 1**. Skin contact with the amoxicillin is more likely to cause a sensitisation reaction in some persons compared to the general population.

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. Not considered to affect reproduction, based on data for the ingredients.

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 classified as **Specific Target Organ Toxicity (Repeated exposure) Category 2**. 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). Allergic reactions, possibly serious in sensitised individuals. Potassium clavulanate has caused clinical, biochemical and haematological effects, reduced weight gain, gastrointestinal irritation and liver toxicity in chronic oral toxicity studies in animals.

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 classified as **Aquatic toxicity (Acute) Category 1**. Very ecotoxic in the aquatic environment due to the presence of amoxicillin which is toxic to algae.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Amoxicillin (as amoxicillin trihydrate)	HIGH	HIGH	LOW (LogKOW = 0.87)	LOW (KOC = 865.5)
Clavulanic acid (as potassium clavulanate)	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Dispose of empty container by wrapping with paper and placing 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. Environmentally Hazardous Substances meeting the descriptions of UN 3077 under the special provision AU01 are not subject to the ADG Code when transported by road or rail in a packaging that does not incorporate a receptacle exceeding 500 kg.

Section 15: REGULATORY INFORMATION

Poisons Schedule: S4

APVMA Registration Nos: 61669 (Juroclav 50); 61670 (Juroclav 250); 61671 (Juroclav 500).

ACIS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredients: Amoxicillin and Clavulanic acid are mentioned in SUSMP.

Section 16: OTHER INFORMATION**Legend:**

ADG	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7th Edition.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
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.
KOC	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
KOW	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
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 Plus

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

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: 10 May 2018 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 09 August 2017.

Revision History:

Date of Revision	Reason
09 August 2017	Updates to section 1, 2, 3, 4, 5, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.
10 May 2018	Reclassification of hazardous substances and minor updates to all sections.

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.

END OF SDS