

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Ampiclox Dry Cow Intramammary Antibiotic Infusion
Product Code:	503285 (200 x 3.8 g syringes)
Recommended Use:	For treatment of bovine mastitis caused by organisms sensitive to Ampicillin and Cloxacillin, during the Dry Period.
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 IDENTIFICATION

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.

GHS Pictograms:

Health hazard



Exclamation mark

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

- P261 Avoid breathing vapours.
P264 Wash hands thoroughly after handling.
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+P341 IF INHALED: If breathing is difficult, 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.
P333+P313 If skin irritation or rash occurs: Get medical advice.

P337+P313	If eye irritation persists: Get medical advice.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P363	Wash contaminated clothing before reuse.
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
Cloxacillin benzathine	32222-55-2	16.8 %
Ampicillin	69-53-4	7.6%
Peanut oil		>60%
Other non-hazardous ingredients		<10%

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 product container or label at hand.
Inhalation:	Sensitive individuals may exhibit allergic reactions, possibly life-threatening. If suspected, 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 may exhibit allergic reactions, possibly life-threatening. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical advice, or contact the National Poisons Centre on 131126.
Skin:	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.
Eye:	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Remove contact lenses, if present and easy to do. If eye irritation persists, get medical advice.
Advice to Doctor:	Treat as an overdose of, or sensitivity to, penicillin antibiotics.

Section 5: FIRE FIGHTING MEASURES

Flash Point:	Not flammable. Combustible.
Hazardous Combustion Products:	If involved in a fire, may emit toxic and corrosive fumes.
Extinguishing Media:	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
Protective Equipment:	Gas-tight chemical resistant suit, protective gloves and boots and breathing apparatus
HAZCHEM Code:	None specified.
Special Hazards:	Avoid contamination with oxidising agents.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal:	Wipe up spill with absorbent material and place in sealed labelled containers. 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 / 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 Emergency Services.

Section 7: HANDLING AND STORAGE

Handling: This is a Schedule 4 (Prescription Animal Remedy) product, available only to or through 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 other personal protective equipment as required.

Storage: Keep out of reach of children. Store below 25°C, under secure conditions appropriate to local requirements for this class of drug. 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. 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:	Clear white viscous ointment.	Vapour Pressure:	Not available.
Odour:	Not available.	Vapour density:	Not available.
Odour threshold:	Not available.	Relative density:	Not available.
pH:	Not available.	Specific Gravity:	Not available.
Melting Point:	Not available.	Solubility in Water:	Immiscible.
Boiling Point:	Not available.	Partition coefficient:	Not available.
Flash Point:	Not available.	Auto-ignition temperature:	Not available.
Evaporation Rate:	Not available.	Decomposition temperature:	Not available.
Flammability:	Combustible.	Viscosity:	Not available.
Upper flammability limits:	Not available.		
Lower flammability limits:	Not available.		

Section 10: STABILITY AND REACTIVITY

Stability:	When stored appropriately this product should show no significant degradation within the Expiry period shown on the label.
Hazardous Polymerisation:	Not known to occur.
Materials to Avoid:	Avoid oxidising agents.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:	<p>Inhalation: The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Inhalation hazard is increased at higher temperatures. Not normally a hazard due to non-volatile nature of product. Inhalation of oil droplets or aerosols may cause discomfort and may produce chemical inflammation of the lungs. REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity.</p> <p>Ingestion: REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity. The product may cause gastrointestinal discomfort.</p> <p>Cloxacillin benzathine: LD₅₀ (oral): 5000 mg/kg (mouse and rat). Ampicillin: LD₅₀ (oral): 10000 mg/kg (rat); LD₅₀ (oral): 15200 mg/kg (mouse)</p>
Skin Irritation/ Corrosion:	<p>Based on available data for the ingredients, the mixture is classified as Skin Corrosion / Irritation Category 2 - Causes skin irritation. The material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity.</p>
Serious Eye Damage/ Irritation:	<p>Based on available data for the ingredients, the mixture is classified as Eye Irritation Category 2A - Causes serious eye irritation. Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn). REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity.</p>
Respiratory or Skin Sensitisation:	<p>Based on available data for the ingredients, the mixture is classified as Respiratory Sensitizer Category 1 and Skin Sensitizer Category 1 - May cause allergy or asthma symptoms or breathing difficulties if inhaled and May cause an allergic skin reaction. Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Respiratory sensitisation may result in allergic/asthma like responses; from coughing and minor breathing difficulties to bronchitis with wheezing, gasping. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population. REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity.</p>
Mutagenicity:	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic. However, there has been some concern that this material can cause mutations but there is not enough data to make an assessment.
Carcinogenicity:	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic. However, there has been some concern that this material can cause cancer but there is not enough data to make an assessment.
Reproductive Toxicity:	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have effects on reproduction.
STOT:	Prolonged use may cause skin rashes and contact dermatitis.

Aspiration hazard: REMARK: Cloxacillin and ampicillin are penicillins and the most important adverse reaction is hypersensitivity.

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 to the environment by GHS criteria. However, DO NOT discharge the mixture into sewer or waterways.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Cloxacillin benzathine	No data available	No data available	No data available	No data available
Ampicillin	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 Nos: 35842

ACIS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredients: Cloxacillin and Ampicillin are mentioned in 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.
AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
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.
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>, entries for Ampicillin (RN: 69-53-4) and Cloxacillin (RN: 61-72-3).

New Zealand Environmental Protection Authority, HSNO Chemical Classification and Information Database (CCID), entry for Ampicillin (Cas Number: 69-53-4).

THE VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>), entries for ampicillin and cloxacillin.

This version issued: 17 August 2017 and is valid for 5 years from this date.

Supercedes: This SDS supercedes the version issued on 03 October 2012.

Revision History:

Date of Revision	Reason
01 August 2017	Updates to section 1, 2, 3, 4, 5, 9, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.

END OF SDS