



# SAFETY DATA SHEET

Title: AMPICLOX DRY COW INTRAMAMMARY		Document: SDS-AU005	
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Status: Current	Issue Date 05-Jun-2020	Effective Date: 05-Jun-2020	Review Date: 05-Jun-2025

## Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

<b>Product Name:</b>	<b>Ampiclox Dry Cow Intramammary Antibiotic Infusion</b>
<b>Product Identifier:</b>	A stable suspension containing ampicillin and cloxacillin in a long acting base.
<b>Product Code:</b>	503285 (200 x 3.8 g syringes)
<b>Recommended Use:</b>	For treatment of bovine mastitis caused by organisms sensitive to ampicillin and cloxacillin, during the dry period.
<b>Restrictions on Use:</b>	For animal treatment only.
<b>Company Identification:</b>	Avet Health Pty Ltd
<b>Address:</b>	Unit F24, 16 Mars Road, Lane Cove NSW 2066 Australia
<b>Email:</b>	info@avet.health
<b>Customer Centre:</b>	1300 28 38 28
<b>National Poisons Information Centre:</b>	13 11 26 (24 hours)
<b>Emergency Telephone Number:</b>	1300 28 38 28 (9am – 5pm, Monday to Friday)

## Section 2: HAZARDS IDENTIFICATION

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

GHS Category	Hazard code	Hazard Statement
Skin 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.

**Signal word:** **DANGER**

**GHS Pictograms:**





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**Health hazard                      Exclamation mark**  
**Precautionary statements:**

General

- P101                      If medical advice is needed, have product container or label at hand.  
P102                      Keep out of reach of children.  
P103                      Read carefully and follow all instructions

Prevention

- P264                      Wash hands thoroughly after handling.  
P280                      Wear protective gloves and eye protection/face protection.  
P261                      Avoid breathing vapours.  
P284                      In case of inadequate ventilation wear respiratory protection.  
P272                      Contaminated work clothing should not be allowed out of the workplace.  
P271                      Use only outdoors or in well-ventilated areas.

Response

- P302+P352              IF ON SKIN: Wash with plenty of water and soap.  
P332+P313              If skin irritation occurs: Get medical advice or attention.  
P362+P364              Take off contaminated clothing and wash it before reuse.  
P305+P351+P338      IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.  
P337+P313              If eye irritation persists: Get medical advice or attention.  
P304+P340              IF INHALED: remove person to fresh air and keep comfortable for breathing.  
P342+P311              If experiencing respiratory symptoms: Call a POISON CENTER or doctor.  
P312                      Call a POISON CENTER or doctor if you feel unwell.

Storage

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

Disposal

- P501                      Dispose of empty syringe by wrapping in 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:** None known.



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## Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Ampicillin Sodium	69-53-4	< 10%
Cloxacillin Sodium	7081-44-9	< 20%
Butylated hydroxyanisole	25013-16-5	< 1%
Peanut oil	8002-03-7	> 60%
Ingredients not contributing to the hazards	-	< 10%

## Section 4: FIRST AID MEASURES

**General Information:** Consult the National Poisons Centre on 13 11 26 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 reaction in persons suffering from a penicillin or peanut allergy. Persons with known hypersensitivity to these ingredients should avoid using the product or administer it with extreme caution.

**Inhalation:** If fumes or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary. 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 and seek medical assistance immediately.

**Ingestion:** If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. 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.

**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.

**Eye:** If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye. Continue flushing for at least 20 minutes. If eye irritation persists, get medical advice/attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

**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, or sensitivity to, penicillin antibiotics and/or peanuts.



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## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** Not flammable.

**Hazardous Combustion Products:** If involved in a fire, may emit poisonous 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:** Protective gloves and boots and breathing apparatus.

**HAZCHEM Code:** Not specified.

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Wear gloves and appropriate protective clothing. Avoid breathing vapours and contact with skin and eyes. Clean up all spills immediately. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or water courses and call emergency services.

**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:** Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin and eyes and avoid inhalation of vapours. Use in a well-ventilated area. Do not allow clothing wet with material to stay in contact with skin. Use personal protective equipment as required. Do not eat, drink or smoke while handling product. Wash hands thoroughly after use.

**Storage:** Keep out of reach of children. Store below 30°C (room temperature). Protect from light. Store in original container, tightly closed in a cool, dry, well-ventilated place. DO NOT re-use the container. Store locked up.

**Other Information:** Avoid contact with incompatible substances as listed in Section 10. 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.



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**Exposure Limits:** No exposure limits have been assigned for this product. Known exposure limits for ingredients are as follows:

INGREDIENT	TEEL-1	TEEL-2	TEEL-3
Ampicillin Sodium	Not Available	Not Available	Not Available
Cloxacillin Sodium	Not Available	Not Available	Not Available
Butylated hydroxyanisole	Not Available	Not Available	Not Available
Peanut oil	Not Available	Not Available	Not Available

**Engineering Controls:** Handle in a well-ventilated area. Ensure that the work environment remains clean.

**Personal Protective Equipment (PPE):**

Eye protection: Safety glasses with side shields or chemical goggles are recommended when handling bulk quantities of this product.

Skin protection: When handling bulk quantities, prevent skin contact by wearing chemical protective gloves e.g. PVC. Wear safety gumboots, e.g. rubber.

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

Other: When handling bulk quantities of this product, overalls, PVC apron, barrier cream, skin cleansing cream and eye wash unit may be required.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White ointment.	<b>Lower flammability limits:</b>	Not available.
<b>Odour:</b>	Not available.	<b>Vapour Pressure:</b>	Not available.
<b>Odour threshold:</b>	Not available.	<b>Vapour density:</b>	Not available.
<b>pH:</b>	Not available.	<b>Relative density:</b>	Not available.
<b>Melting Point:</b>	Not available.	<b>Specific Gravity:</b>	Not available.
<b>Boiling Point:</b>	Not available.	<b>Solubility in Water:</b>	Immiscible.
<b>Flash Point:</b>	Not available.	<b>Partition coefficient:</b>	Not available.
<b>Evaporation Rate:</b>	Not available.	<b>Auto-ignition temperature:</b>	Not available.
<b>Flammability:</b>	Not flammable.	<b>Decomposition temperature:</b>	Not available.
<b>Upper flammability limits:</b>	Not applicable.		



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**Viscosity:** Not available.

## Section 10: STABILITY AND REACTIVITY

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

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

**Conditions to Avoid:** Extreme temperatures.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** Combustion products include carbon dioxide, nitrogen oxides, silicon dioxide 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.

Ampicillin Sodium:	Oral (mouse) LD <sub>50</sub> : 5000 mg/kg;
Cloxacillin Sodium:	Oral (mouse) LD <sub>50</sub> : 5000 mg/kg;
Butylated hydroxyanisole:	Oral (mouse) LD <sub>50</sub> : 1100 mg/kg.

**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 and that suitable control measures be used in an occupational setting.

**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. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Entry into the bloodstream, 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.

Butylated hydroxyanisole:	Dermal (rat) LD <sub>50</sub> : >2000 mg/kg.
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**Skin Corrosion / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Skin Irritant Category 2**.

**Serious Eye Damage / Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as **Eye Irritant Category 2A**.

**Respiratory and Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is classified as both a **Respiratory Sensitiser Category 1** and a **Skin Sensitiser Category 1**. Exposure to ampicillin, cloxacillin or peanut oil may induce hypersensitivity reactions in some



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individuals. Anaphylactic shock and skin rash may occur. Persons with known hypersensitivity to any of these ingredients should avoid using the product or administer it with extreme caution.

**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.

**STOT: Single exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is considered to be a **Specific Target Organ Toxicant After Single Exposure Category 3**. Prolonged exposure to ampicillin, cloxacillin or peanut oil may have respiratory effects.

**STOT: Repeat exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to be a Specific Target Organ Toxicant after repeat exposure.

**Aspiration Hazard:** No data available.

**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 an aquatic toxicant.

### Fish

Ampicillin Sodium:	LC <sub>50</sub> (96h): 797.502 mg/L
Cloxacillin Sodium:	No Data
Butylated hydroxyanisole:	LC <sub>50</sub> (96h): 1.56 mg/L
Peanut oil:	No Data

### Crustacea

Ampicillin Sodium:	No Data
Cloxacillin Sodium:	No Data
Butylated hydroxyanisole:	EC <sub>50</sub> (48h): 2.3 mg/L
Peanut oil:	No Data

### Algae and other aquatic plants

Ampicillin Sodium:	EC <sub>50</sub> (96h): 232.291mg/L
Cloxacillin Sodium:	No Data
Butylated hydroxyanisole:	EC <sub>50</sub> (72h): 1.9 mg/L
Peanut oil:	No Data



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Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Ampicillin Sodium	HIGH	HIGH	LOW (LogKOW = 1.35)	LOW (KOC = 534.4)
Cloxacillin Sodium	No Data	No Data	No Data	No Data
Butylated hydroxyanisole	HIGH	HIGH	LOW (BCF = 21)	LOW (KOC = 1390)
Peanut oil	No Data	No Data	No Data	No Data

## Section 13: DISPOSAL INFORMATION

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

**Container Disposal:** Dispose of container by wrapping with paper and placing in garbage.

## Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Not classified as a Dangerous Good for land, sea or air transport.

## Section 15: REGULATORY INFORMATION

**Poison Schedule (SUSMP):** S4

**APVMA No.:** 35842

**AICS:** 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 Avet Health Pty Ltd 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 Avet Health Pty Ltd 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:

<b>AICS</b>	Australian Inventory of Chemical Substances.
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority.
<b>BCF</b>	Bioconcentration factor.
<b>CAS No.</b>	Chemical Abstracts Service Registry Number.





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<b>EC<sub>50</sub></b>	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.
<b>GHS</b>	Globally Harmonized System of Classification and Labelling of Chemicals.
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
<b>KOC</b>	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
<b>KOW</b>	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.
<b>LC<sub>50</sub></b>	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
<b>LD<sub>50</sub></b>	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme.
<b>PPE</b>	Personal Protective Equipment.
<b>PVC</b>	Polyvinyl chloride.
<b>SDS</b>	Safety Data Sheet.
<b>STOT</b>	Specific Target Organ Toxicity.
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons.
<b>TEEL-1</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.
<b>TEEL-2</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.
<b>TEEL-3</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death.

## References:

ChemID Plus

Chemwatch

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

## Revision History:

Date of Revision	Reason
01 AUG 2017	Updates to Sections 1, 2, 3, 4, 5, 9, 11, 12, 13 & 15; Updates to the legend and the addition of Revision History in Section 16.
05 JUN 2020	Revision of SDS after review of classification. Minor updates to all sections.

**END OF SDS**