Australian Government
Australian Pesticides and Veterinary Medicines Authority

PERMIT TO ALLOW MINOR USE AND SUPPLY OF AN AGVET CHEMICAL PRODUCT FOR PREVENTION OF PNUEMONIC PASTEURELLOSIS INFECTION IN PIGS

PERMIT NUMBER – PER87382

This permit is issued to the Permit Holder in response to an application granted by the APVMA under section 112 of the Agvet Codes of the jurisdictions set out below. This permit allows a Supplier (as indicated) to possess the Product(s) for the purposes of supply and to supply the Product(s) to a person or persons who can use the Product under permit. This permit also allows a person or persons, as stipulated below, to use the Product(s) in the manner specified in this permit in the designated jurisdictions. This permit also allows the Permit Holder, the Supplier (if not one and the same) and any person stipulated below to claim that the Product can be used in the manner specified in this permit.

THIS PERMIT IS IN FORCE FROM 6 APRIL 2021 TO 31 MARCH 2027

Permit Holder:
DEPARTMENT OF JOBS, PRECINCTS AND REGIONS
Cnr Taylor Street and Midland Highway
EPSOM VIC 3551

Supplier:
DEPARTMENT OF JOBS, PRECINCTS AND REGIONS
Cnr Taylor Street and Midland Highway
EPSOM VIC 3551

Persons who can use the Product under this permit:
All registered veterinary surgeons and people under their direction.

CONDITIONS OF USE

Products to be used:
INACTIVATED PASTEURELLA MULTOCIDA VACCINE FOR PIGS
An unregistered product containing minimum 0.5-1.5 x10^9 cfu/dose inactivated *Pasteurella multocida* as the only active constituent.

Directions for Use:

Animal	Purpose	Dosage
Pigs	Prevention of Pneumonic Pasteurellosis infection	1mL intramuscular injection given at two weeks of age or as directed by the veterinarian. As per the label at **Attachment 1.**

Withholding Period:
Zero (0) days.

Jurisdiction:
All States and Territories.

Additional Conditions:
This permit allows for the use of a product in a manner specified on the permit. Persons who wish to prepare for use and/or use products for the purposes specified in this permit must read, or have read to them, the details and conditions of this permit. Unless otherwise stated, the use of the Product must be in accordance with the product label at **Attachment 1**.

Supply

1. The permit Holder may supply the Product to registered veterinarians if:

    a. The preparation of the Product(s) is/are restricted to cultures of microorganisms which have been inactivated and are non-toxic.
    b. The microorganism(s) used to prepare the Product(s) are isolated from animals and administered only to the animals in the same locality (farm, aquaculture site, holding or unit of origin).
    c. The Product(s) must be prepared in a GMP category 1 (immunobiologicals) licensed facility.
    d. Microorganisms used to prepare the Product(s) are identified to the level of species and serotype, subtype or genotype where appropriate.
    e. Where imported biological materials are used, evidence of a current Department of Agriculture, Fisheries and Forestry (DAFF) biological import permit must be provided on request.
    f. Each species of microorganism should be subjected to an inactivation kinetics study according to the British Pharmacopoeia before supply of the Product unless otherwise authorised by the APVMA.
    g. Isolates that are older than 24 months may only be used when the requesting veterinarian has provided justification for the continued use of the vaccines with regards to their efficacy and safety. The justification must be kept on file and made available to APVMA at the next renewal.

h. Quality control tests for purity, microorganism/antigen content, completeness of inactivation and level of formalin, as appropriate, are carried out according to British Pharmacopoeia or 9CFR standards.
i. Tests for sterility must be carried out on each batch according to British Pharmacopoeia or 9CFR standards.
j. The Product must be formulated to the quantitative and qualitative particulars declared in the permit application.
k. The Product may be administered at epidemiologically linked sites where the pathogenic microorganism(s) is/are present having an epidemiological link to the farm/unit were the microorganism(s) was/were isolated.
l. Each batch of the Product must be monitored for safety in at least 2 of the target animals in the most sensitive category, treated by the recommended route of administration.
The test animals must be observed for a minimum of 7 days(or as recommended by the attending veterinarian) for any adverse reactions before any further animals may be treated.

2. The permit Holder must supply the Product in a container that must:
   a. be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and
   b. have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and
   c. if it is intended to be opened more than once, be able to be securely and readily closed and reclosed; and
   d. have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and
   e. enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:
      (i) harm any person; or
      (ii) have an unintended effect that is harmful to the environment.
   f. Attached to this container must be a label, for which representative sample label(s) is/are included at **Attachment 1.**
   g. The permit Holder must provide a copy of the permit to the registered veterinarians.

3. On each occasion the Product(s) is supplied, permit Holder must retain records of the manufacturing details and supply records, including a list of names and addresses of veterinarians supplied with the Product(s) and the amount of the Product(s) supplied to each veterinarian. A copy of such records must be supplied to the APVMA on request and at the time of renewal of the permit.

4. The permit Holder is authorised to supply the Product(s) with a shelf life not exceeding 24 months.

5. The permit Holder must retain samples of each batch of vaccine prepared, stored at the recommended storage temperature for at least 12 months past the nominal expiry date. In the event of unexpected adverse reactions arising from the use of a particular batch of vaccine, such retention samples can be tested to determine the cause.

Use

6. An inactivation kinetics report to be provided to the APVMA following the manufacture of the first batch of custom *Pasteurella multocida* vaccine

7. Registered veterinarians and people under their direction are permitted to use inactivated Autogenous Vaccines only on properties where the microorganism(s) is/are isolated.

8. The prescribing veterinarian must monitor the vaccinated herd and must report (verbally or in writing) immediately to the Permit Holder and to the office of the State Chief Veterinary Officer any evidence of morbidity or mortality in the vaccinated animals during the monitoring period. Verbal reports should be followed up in writing.

9. The Holder of the permit must notify the APVMA of new information, including relevant information in accordance with section 161 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, in accordance with the obligation imposed by that section.
   The Holder in consultation with the prescribing veterinarian and the appropriate State Veterinary Officer, must fully investigate all reported cases of adverse reactions (including lack of efficacy) and report to the APVMA.

10. For each batch of The Product, permit Holder must make and keep a record containing the following particulars:

    a. details of manufacture of the Product and results of tests conducted
    b. origin, identification and passage history of the isolates
    c. storage condition of the master seed of the isolate
    d. the quantity of the Product prepared
    e. the vaccine formulation (qualitative & quantitative details)
    f. the disease(s) identified and treated
    g. the amount of the Product supplied per species of animals including prescribing veterinarian and farm details
    h. the species of animals treated
    i. the frequency of adverse drug reactions including injection site reactions
    j. copies of labels
    k. reports about the efficacy of The Product

Issued by the Australian Pesticides and Veterinary Medicines Authority

Note: 13/03/2024 – Permit updated to current standard, added inactivation kinetics study. Quality control test, permit label updated, updated disposal statement and first aid instructions. Permit expiry extended to 31/03/2027. Permit issued as Version 2.

Attachment 1

Front label

FOR ANIMAL TREATMENT ONLY

CUSTOM *Pasteurella multocida*
INACTIVATED VACCINE FOR PIGS

ACTIVE CONSTITUENTS:
Inactivated *Pasteurella multocida*
Concentration: 0.5 – 1.5 x 10^9 CFU/mL

THIS IS NOT A REGISTERED VACCINE
AND MUST BE ADMINISTERED UNDER VETERINARY SUPERVISION

Approved under APVMA Permit PER87382 as an aid in the control of *Pasteurella multocida* infection in pigs on Farm: [FARM NAME, LOCATION]

READ THE PERMIT BEFORE USING THIS PRODUCT
Read Safety directions before use.
NET Contents: at least [250ml or 500mL]

Back Label

DIRECTIONS FOR USE:
Shake well before use and keep mixed during use.
Dose: 1mL intramuscular injection given at two weeks of age or as directed by the veterinarian.

WITHHOLDING PERIOD: Zero (0) days.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre.
Phone Australia 131126

USER SAFETY INFORMATION: Take care to avoid accidental self-injection. This product contains mineral oil and is an irritant. In the event of self-administration, it can cause significant pain and swelling at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required. Contact a doctor immediately, even if only a very small amount is injected, and take this package leaflet/carton with you. Allow the wound to bleed freely and DO NOT squeeze or interfere with the injection site.

Ancillary advice to the medical practitioner

This product contains mineral oil. Even small amounts of self-administered [adjuvant type] can cause intense swelling and a persistent granulomatous inflammatory reaction. If injected into a finger joint or tendon sheath, the product may track along the tendon, perhaps also involving the draining lymph nodes. The swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit.

Following appropriate immediate local cleansing, corticosteroids may be considered to decrease the severity of any local reaction. Ascertain the patient's tetanus immunisation status, and provide booster or primary series, as appropriate.

In some cases of self-injection, PROMPT surgical attention may be required. The wound should be incised and irrigated to remove the vaccine, especially where there is involvement of finger pulp or tendon. Complete curettage or total excision of the lesion may be required for chronic granulomatous reactions. Meticulous technique is required to stop inadvertent spread of the product.

DISPOSAL: Dispose of containers by wrapping with paper and putting in garbage. Discarded needles should be immediately placed in a designated and appropriately labelled sharps container.

Pig Services Centre – THE STATE OF VIC DEPT OF JOBS, PRECINCTS AND REGIONS
Cnr Midland Highway & Taylor Street, Epsom, Victoria 3551.
Phone: 0427 331 533

Store at 2 to 8°C (Refrigerate, **DO NOT FREEZE**)
Batch No: XXXXXXXXX Expiry Date: MMMYYYY