Australian Government
Australian Pesticides and Veterinary Medicines Authority

PERMIT TO ALLOW MINOR USE AND SUPPLY OF AN UNREGISTERED AGVET CHEMICAL PRODUCT

AS AN AID IN PROTECTION OF CAGED PIGEONS FROM PIGEON ROTAVIRUS

PERMIT NUMBER – PER93673

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 06 NOVEMBER 2024 TO 30 NOVEMBER 2026.

Permit Holder:
TREIDLIA BIOVET PTY LTD
Unit 76, Powers Business Park
45 Powers Road
SEVEN HILLS, NSW

Supplier:
TREIDLIA BIOVET PTY LTD
Unit 76, Powers Business Park
45 Powers Road
SEVEN HILLS, NSW

Persons who can use the Product under this permit:

- Registered veterinarians, and
- Persons generally who are involved in keeping or maintaining caged pigeons in Australia.

CONDITIONS OF USE

Products to be used:
TRÉIDLIA ROTAVAX VACCINE FOR PIGEONS
AN UNREGISTERED PRODUCT
Containing: A minimum 25 µg/mL of purified VP8 antigen as its only active constituent.

Directions for Use:

Animal/Host	Disease	Dosage and Administration
Pigeons	May aid in protection of caged pigeons from pigeon rotavirus	Use in accordance with the instructions set out in the label particulars at **Attachment 1**

IMPORTANT NOTE: This is not a registered vaccine. Efficacy has not been fully evaluated.

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 product supplied must be as described in the application data and any other information provided for assessment of this permit.
    b. The product must be prepared in a GMP category 1 (immunobiologicals) licensed facility.
    c. 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.
    d. The Permit Holder must ensure inactivation, residual formaldehyde and sterility is verified for every batch of vaccine prior to release. Any batch that fails sterility testing must be discarded. In-process control testing for sterility, completeness of inactivation and absence of detectable formaldehyde residues are carried out according to 9CFR, BP Vet /Eur Ph testing standards.
    e. The product must be formulated to the quantitatve and qualitatve particulars declared in the Permit application.
    f. Each batch of the Product must be monitored for safety in at least 10 birds of the target species 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 longer if 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 and/ relevant pigeon keepers.

3. On each occasion the Product(s) is supplied, the Permit Holder must retain records of the manufacturing details and supply records, including a list of names and addresses of veterinarians and/ relevant pigeon keepers supplied with the Product(s) and the amount of the Product(s) supplied to each person. 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 18 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. 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.

7. For each batch of the Product, the holder must make and keep a record containing the following particulars:
   a. To whom the Product was supplied
   b. Identity of the batch
   c. Batch records for each batch manufactured
   d. Quantity supplied
   e. Date of supply

f. Number of birds treated
g. Adverse events in vaccinated birds
h. Copies of the label

8. The Permit Holder must report any adverse event arising from the use of the Product in accordance with this permit to the APVMA's Coordinator, Adverse Experience Reporting Program, **Phone**: +61 2 6770 2300; **Email**: enquiries@apvma.gov.au

Issued by the Australian Pesticides and Veterinary Medicines Authority

FOR ANIMAL TREATMENT ONLY
TRÉIDLIA ROTAVAX VACCINE FOR PIGEONS
Containing minimum 25µg/mL pigeon rotavirus antigen

This Is Not A Registered Vaccine. Efficacy has not been fully evaluated.
Approved under APVMA permit 93673 as an aid in protection of caged pigeons from pigeon rotavirus.
Read The Permit Before Using This Product.

DIRECTIONS FOR USE: Mix well before use. Keep mixed during use.
DOSAGE & ADMINISTRATION: Inject 0.3 mL subcutaneously in the neck or inner thigh. Initially vaccinate twice one month apart then booster vaccinate every twelve months.
WITHHOLDING PERIOD: Zero (0) days.
USER SAFEY INFORMATION: 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.
FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131126

Tréidlia Biovet Pty Ltd; 76/45 Powers Rd, Seven Hills, NSW, 2147

Store at 2-8°C. Protect from light. Dispose of container by wrapping with paper and putting in garbage.

Batch: xxx/xx xx mL Exp: xx/xx