Australian Government
Australian Pesticides and Veterinary Medicines Authority

PERMIT TO ALLOW SUPPLY AND MINOR USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT AS AN AID IN THE CONTROL OF VARIOUS DISEASES IN PIGS, POULTRY & RUMINANTS (CATTLE, SHEEP, GOAT)

PERMIT NUMBER – PER89454

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 17 APRIL 2020 TO 31 MAY 2028

Permit Holder:
ANIMAL CONSULTING ENTERPRISES PTY LTD
12 Gildea Lane
EAST BENDIGO VIC 3550

Supplier:
ANIMAL CONSULTING ENTERPRISES PTY LTD
12 Gildea Lane
EAST BENDIGO VIC 3550

Persons who can use the product under this permit:
Registered veterinary surgeons and persons acting under their direction.

CONDITIONS OF USE

Products to be used:

CUSTOM INACTIVATED *STREPTOCOCCUS SUIS* VACCINE FOR USE IN PIGS
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Streptococcus suis* killed whole cells as the only active constituent.

CUSTOM INACTIVATED *GLAESSERELLA PARASUIS* VACCINE FOR USE IN PIGS
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Glaesserella parasuis* killed whole cells as the only active constituent.

CUSTOM INACTIVATED *PASTEURELLA MULTOCIDA* VACCINE FOR USE IN PIGS AND POULTRY
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Pasteurella multocida* killed whole cells as the only active constituent.

CUSTOM INACTIVATED *ESCHERICHIA COLI* VACCINE FOR USE IN PIGS AND POULTRY
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Escherichia coli* killed whole cells as the only active constituent.

CUSTOM INACTIVATED *SALMONELLA SPP*. VACCINE FOR USE IN PIGS, POULTRY AND CATTLE
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Salmonella* spp. killed whole cells as the only active constituent.

CUSTOM INACTIVATED *ACTINOBACILLUS PLEUROPNEUMONIAE* VACCINE FOR USE IN PIGS
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Actinobacillus pleuropneumoniae* killed whole cells as the only active constituent.

CUSTOM INACTIVATED *PASTEURELLA MULTOCIDA* VACCINE FOR RUMINANTS (CATTLE, SHEEP, GOAT)
AN UNREGISTERED PRODUCT
Containing: 0.5-1.5x10^9 cfu/mL per serovar *Pasteurella multocida* killed whole cells as the only active constituent.

Directions for Use:

Animal	Disease	Rate
Pigs	As an aid in the control of disease caused by *Streptococcus suis*	Inactivated *Streptococcus suis* vaccine: 1 mL single dose via deep intramuscular injection to pigs or as directed by a veterinarian. As per label attachment 1.

Pigs	As an aid in the control of disease caused by *Glaesserella parasuis*	Inactivated *Glaesserella parasuis* vaccine: 1 mL dose via deep intramuscular injection to pigs. Vaccinate pigs twice allowing at least 3 weeks between doses. As per label attachment 2.
Pigs	As an aid in the control of disease caused by *Pasteurella multocida*	Inactivated *Pasteurella multocida* vaccine: 1 mL – 2 mL single dose via deep intramuscular injection to pigs or as directed by a veterinarian. As per label attachment 3.
Chickens	As an aid in the control of disease caused by *Pasteurella multocida*	Inactivated *Pasteurella multocida* vaccine: 0.5 mL single dose via subcutaneous injection to chickens, or as directed by a veterinarian. As per label attachment 3.
Turkeys	As an aid in the control of disease caused by *Pasteurella multocida*	Inactivated *Pasteurella multocida* vaccine: 1.0 mL single dose via subcutaneous injection to turkeys, or as directed by a veterinarian. As per label attachment 3.
Pigs	As an aid in the control of disease caused by *Escherichia coli*	Inactivated *Escherichia coli* vaccine: 0.5 mL – 1 mL dose via subcutaneous injection to piglets at 7 – 10 days. Then a booster of 1-2mL at 18 – 21 days, or as directed by a veterinarian. As per label attachment 4.
Poultry	To control disease caused by *Escherichia coli*	Inactivated *Escherichia coli* vaccine: 0.5 mL or 1.0 mL single dose via subcutaneous injection to poultry. As per label attachment 4.
Pigs	As an aid in the control of disease caused by *Salmonella spp*.	Inactivated *Salmonella spp*. vaccine: 1 mL single dose via deep intramuscular injection to pigs. As per label attachment 5.

Poultry	As an aid in the control of disease caused by *Salmonella spp*.	Inactivated *Salmonella spp*. vaccine: 0.5 mL single dose via subcutaneous injection to poultry. As per label attachment 5.
Cattle	As an aid in the control of disease caused by *Salmonella spp*.	Inactivated *Salmonella spp*. vaccine: 2 mL single dose via deep intramuscular injection to cattle. As per label attachment 5.
Pigs	As an aid in the control of disease caused by *Actinobacillus pleuropneumoniae*	Inactivated *Actinobacillus pleuropneumoniae* vaccine: 1 mL dose via deep intramuscular injection to pigs. Vaccinate pigs twice allowing at least 3 weeks between doses. As per label attachment 6.
Ruminants (cattle, sheep, goats)	As an aid in the control of disease caused by *Pasteurella multocida*	Inactivated *pasteurella multocida* vaccine: 1 mL - 2 mL single dose via deep intramuscular injection to cattle or as directed by a veterinarian As per label attachment 7.

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 1-7**.

Supply

1. The manufacturer, Animal Consulting Enterprises Pty Ltd, may supply the Products 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 Product(s) must be prepared in a GMP category 1 (immunobiologicals) licensed facility.
    c. Microorganisms used to prepare the Product(s) are identified to the level of species and serotype, subtype or genotype where appropriate.
    d. Where imported biological materials are used, evidence of the current Department of Agriculture, Fisheries and Forestry (DAFF) biological import permit must be provided on request.

e. 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.

f. Quality control tests for purity, microorganism/antigen content, completeness of inactivation and level of formalin, as appropriate are carried out according to British Pharmacopoea or 9CFR standards.

g. Tests for sterility must be carried out on each batch according to British Pharmacopoea or 9CFR standards.

h. The product must be formulated to the quantitative and qualitative particulars declared in the Permit application.

i. 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 where the microorganism(s) was/were isolated.

j. Each batch of the Product must be monitored for safety in at least following number of the target animals (cattle and pigs – 5 each; sheep, goat and poultry – 10 each) 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. Animal Consulting Enterprises Pty Ltd must supply the Products 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 **Attachment 1-7**.

3. Animal Consulting Enterprises Pty Ltd must provide a copy of the permit to the registered veterinarians on each occasion the vaccines are supplied.

4. On each occasion the Product(s) is supplied, Animal Consulting Enterprises Pty Ltd 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.

5. Animal Consulting Enterprises Pty Ltd must not supply the Product(s) for use where an APVMA - registered vaccine(s) is available without first receiving a written statement from the attending registered veterinarian indicating that the registered vaccine(s) has been administered and has proven to be inefficacious; and in situation where no cross protection has been observed by the serovars present in that product. These statements must be provided to the APVMA on renewal of this permit. The ineffectiveness of the registered product(s) should be reported to the APVMA via Adverse Experience Reporting Program (AERP).

6. Animal Consulting Enterprises Pty Ltd is authorised to supply the Product(s) with a shelf life not exceeding 24 months.

7. Animal Consulting Enterprises Pty Ltd 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

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

9. 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.

10. 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.

11. For each batch of the Product, Animal Consulting Enterprises Pty Ltd 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

01/05/2025 – Permit updated to current standards with condition related to registered vaccine, name of *Glaesserella parasuis* updated, mineral oil safety instructions and disposal statement updated, one label for *Pasteurella* for pigs removed and dosage of 1 mL - 2 mL has been incorporated in a consolidated label, a variant label for *Pasteurella* in poultry added without mineral oil safety instructions, expression of some actives updated as ‘per mL per serovar’. Permit expiry extended to 31/05/2028. Permit issued as Version 3.

Label Attachments

Attachment 1: Custom inactivated *STREPTOCOCCUS SUIS* vaccine for use in Pigs

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM INACTIVATED *STREPTOCOCCUS SUIS*
VACCINE FOR USE IN PIGS
Containing 0.5 – 1.5 x10^9 cfu/mL per serovar inactivated ***Streptococcus suis*** <*insert serovars*>

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in pigs on Farm xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 mL single dose via deep intramuscular injection to pigs or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 2: Custom inactivated *GLAESSERELLA PARASUIS* vaccine for use in Pigs

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM INACTIVATED *GLAESSERELLA PARASUIS*
VACCINE FOR PIGS

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated *Glaesserella parasuis <insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in pigs on Farm xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 mL dose via deep intramuscular injection to pigs.
Vaccinate pigs twice allowing at least 3 weeks between doses

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 3:
Custom inactivated *PASTEURELLA MULTOCIDA* vaccine for use in Pigs

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM INACTIVATED *PASTEURELLA MULTOCIDA*
VACCINE FOR USE IN PIGS

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Pasteurella multocida*** <*insert serovars*>

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in pigs on Farm xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 mL – 2 mL single dose via deep intramuscular injection to pigs or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Custom inactivated *PASTEURELLA MULTOCIDA* vaccine for use in Poultry

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *PASTEURELLA MULTOCIDA*
INACTIVATED VACCINE FOR POULTRY

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Pasteurella multocida*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in poultry on Farm XXXX

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: Chickens - 0.5 ml single dose via subcutaneous injection to poultry. Turkeys – 1.0 mL single dose via subcutaneous injection to poultry or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Custom inactivated *PASTEURELLA MULTOCIDA* vaccine for use in Poultry (variant label to be used for vaccine formulation with Aluminium hydroxide as the only adjuvant)

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *PASTEURELLA MULTOCIDA*
INACTIVATED VACCINE FOR POULTRY

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Pasteurella multocida*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in poultry on Farm XXXX

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: Chickens - 0.5 ml single dose via subcutaneous injection to poultry. Turkeys – 1.0 mL single dose via subcutaneous injection to poultry or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY INFORMATION: Take care to avoid self-injection. In the event of self-administration, seek medical attention if you are concerned. Show the package leaflet or label to the medical practitioner.

FIRST AID: If poisoning occurs contact a doctor or Poisons Information Centre. Phone Australia 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 4: Custom inactivated *ESCHERICHIA COLI* vaccine for use in Pigs and poultry

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN
CUSTOM INACTIVATED *ESCHERICHIA COLI VACCINE* FOR POULTRY

Containing 0.5 – 1.5 x 10^9 cfu/mL per Serovar inactivated ***Escherichia coli*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in poultry on Farm: xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 0.5 mL or 1.0 mL single dose via subcutaneous injection to poultry

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM INACTIVATED *ESCHERICHIA COLI* VACCINE FOR PIGS
Piglets/Weaners

Containing 0.5 – 1.5 x 10^9 cfu/mL per Serovar inactivated ***Escherichia coli*** <*insert serovars*>

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in pigs on Farm xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: Piglets: 7 – 10 days: 0.5 – 1 mL dose via subcutaneous injection to pigs. Then a booster of 1 - 2 mL at 18 – 21 days or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 5:

Custom inactivated *SALMONELLA SPP* vaccine for use in Pigs, Poultry and Cattle

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *SALMONELLA SPP* INACTIVATED VACCINE FOR POULTRY

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Salmonella spp*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in poultry on Farm xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 0.5 mL single dose via subcutaneous injection to poultry

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *SALMONELLA SPP* INACTIVATED VACCINE FOR PIGS

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Salmonella spp*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in Pigs on Farm xxxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 mL single dose via deep intramuscular injection to Pigs

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *SALMONELLA SPP* INACTIVATED VACCINE FOR CATTLE

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Salmonella spp*** *<insert serovars>*

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in Cattle on Farm: xxxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 2 mL single dose via deep intramuscular injection to Cattle

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 6: Custom inactivated *ACTINOBACILLUS PLEUROPNEUMONIAE* vaccine for use in PIGS

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *ACTINOBACILLUS PLEUROPNEUMONIAE*
INACTIVATED VACCINE *FOR PIGS*

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Actinobacillus pleuropneumoniae***
<insert serovars>

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit PER89454 for use in pigs on Farm:xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 mL dose via deep intramuscular injection to pig.
Vaccinate pigs twice allowing at least 3 weeks between doses.

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date:

Attachment 7: Custom inactivated PASTEURELLA MULTOCIDA vaccine for ruminants (cattle, sheep, and goat)

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF REACH OF CHILDREN

CUSTOM *PASTEURELLA MULTOCIDA* INACTIVATED VACCINE FOR RUMINANTS (cattle, sheep, goat)

Containing 0.5 – 1.5 x 10^9 cfu/mL per serovar inactivated ***Pasteurella multocida*** <*insert serovars*>

This is not a registered vaccine and must be administered under veterinary supervision.
Approved under APVMA Permit 89454 for use in ruminants (cattle, sheep, and goat) on Farm**:** xxxx

Read the permit before using this product
NET Contents: at least 250 mL

DIRECTIONS FOR USE: Shake well before use, keep mixed during use.
CAUTION: Discard if previously frozen

DOSAGE & ADMINISTRATION: 1 – 2 mL single dose via deep intramuscular injection to cattle or as directed by a veterinarian

WITHHOLDING PERIOD: Zero (0) days

USER SAFETY 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 mineral oil 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 131 126. Additional information is listed on the material safety data sheet.

Animal Consulting Enterprises; Gildea Lane Bendigo East, Victoria Phone: (03) 5443 9665
Store at 2 to 8°C (Refrigerate, **do not freeze**). Dispose of container by wrapping with paper and putting in garbage.

Batch No.: Date of Manufacture: Expiry Date: