Australian Government
Australian Pesticides and Veterinary Medicines Authority

PERMIT TO ALLOW SUPPLY AND MINOR USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT FOR TESTING FOR BOVINE TUBERCULOSIS IN CATTLE

PERMIT NUMBER – PER91171

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 for the purposes of supply and to supply the product to a person who can use the product under permit. This permit also allows a person, as stipulated below, to use the product 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 23 JULY 2021 TO 31 JULY 2024

Permit Holder and Supplier:
ASUREQUALITY AUSTRALIA PTY LTD
28 Mareno Road
TULLAMARINE VIC 3043

Persons who can use the product under this permit:
Registered veterinary surgeons.

CONDITIONS OF USE

Products to be used:
OBSERVE BOVINE TUBERCULIN PPD 30,000 IU/mL
AN UNREGISTERED PRODUCT
Containing: 30,000 IU/mL MYCOBACTERIUM BOVIS AN5 STRAIN as the only active constituent.

OBSERVE AVIAN TUBERCULIN 25,000 IU/mL
AN UNREGISTERED PRODUCT
Containing: 25,000 IU/mL MYCOBACTERIUM AVIUM D4ER STRAIN as the only active constituent.

Directions for Use:

Animal	Purpose	Rate
Cattle	Testing for bovine tuberculosis	Intradermal injection of 0.1 mL

Critical Use Comments:

- Use under permit is approved in cattle only.
- Unless otherwise stated, apply in accordance with directions listed at **Attachment 1**.
- The products must not be used past the container listed expiry date.

QUEENSLAND:

- For animals destined for export, all tests must be conducted by a registered veterinarian in AQIS approved facilities/feedlots.

ALL OTHER STATES/TERRITORIES

- Supply must be approved by the Chief Veterinary Officer or delegated state veterinary officer.

Withholding Period:
Not required when used as directed.

Jurisdiction:
All States and Territories.

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.

Disposal:
Dispose of container by wrapping with paper and putting in garbage.

Storage:
Store between 2 ℃ and 8 ℃ (refrigerate, do not freeze).

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**.

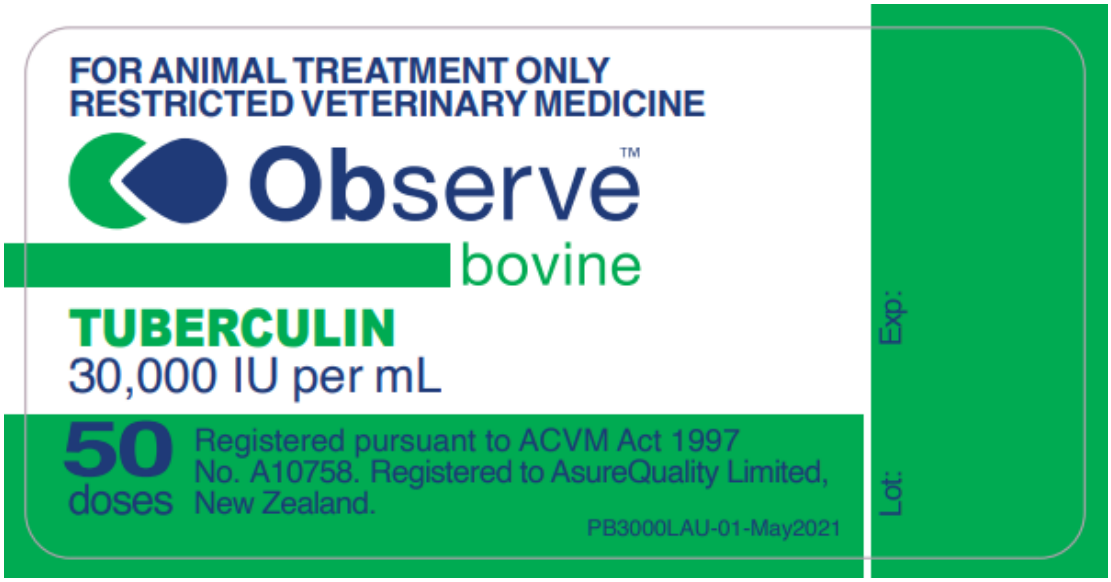
The holder of the permit must notify the APVMA of new information, including relevant information in accordance with section 161 of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994, in accordance with the obligation imposed by that section.

Supply
The supplier must supply the product in a container that complies with the requirements of section 18 of the Agricultural and Veterinary Chemicals Code Regulations. Attached to this container must be a label which is identical in content and format to the label at **Attachment 1**.

Issued by the Australian Pesticides and Veterinary Medicines Authority

Note: 29/07/2022 – Permit additional conditions updated. Permit expiry extended to 31/07/2024. Permit issued as Version 2.

Attachment 1



Attachment 1

FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE

Observe™
bovine

TUBERCULIN
30,000 IU per mL

Registered to: AsureQuality Limited,
Level 1, 7a Pacific Rise, Mt Wellington 1060,
New Zealand
Tel: + 64 9 573 8000
Fax: +64 9 573 8118
Registered pursuant to ACVM Act 1997
No. A10758.

See **www.foodsafety.govt.nz** for
registration conditions

AsureQuality
Kaitiaki Kai

STORE AT 2 TO 8 DEGREES CELSIUS
DO NOT FREEZE
PROTECT FROM LIGHT
KEEP OUT OF REACH OF CHILDREN

W4599

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Attachment 1

FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE

Observe™
bovine

TUBERCULIN
30,000 IU per mL

Active Ingredients: Purified Protein Derivative of *Mycobacterium bovis*, strain AN5, 30,000 IU/mL.

Indications: For use as an aid in the diagnosis of mycobacterial infection in cattle.

Directions for Use: For use under the authority or prescription of a veterinary surgeon or by persons approved under the Australian Biosecurity Act 2015 and Australian Export Control Act 1982 when applying cattle tuberculin tests.

Test Application

The following instructions are guidelines only:
Injections of 0.1 mL must be made intradermally. It is recommended syringes are calibrated to 0.1 mL and the needle of the syringe is 22-26 gauge and 3-4 mm long. Syringes should be kept clean and sterilised. Contamination of the syringe with disinfectants or alcohol may interfere with testing. When filling syringes, care must be taken to prevent contamination of vials.

Preferred site of injection:

Cattle: caudal fold for the single intradermal test and the cervical site for the comparative cervical test (CCT).

When using the cervical sites, care is required to evenly clip hair close to the skin surface (2mm or less mean length) prior to injecting. The recommended size of the clipped area is 10 x 10 cm for each injection site.
When applying a CCT use Observe™ Bovine Tuberculin 30,000 IU per mL in conjunction with Observe™ Avian Tuberculin 25,000 IU per mL.

Test Interpretation:

It is recommended the test be read 72 hours after injection.

Skin test reactions are to be classified in accordance with the requirements of OSPRI, the TBfree New Zealand programme and the National Operational Plan pursuant to the Biosecurity Act 1993 and the Biosecurity (National Bovine Tuberculosis Pest Management Plan) Order 1998 (the Order).

Retesting: To avoid desensitisation, a retest using bovine and/or avian PPD tuberculin should not be applied until 60 days after any previous tuberculin test.

Product Information

Withholding period: Nil

Storage: Refrigerate (2°C to 8°C). Do not freeze. Protect from light - keep vials in closed box.

Transportation: May be transported at 2°C to 37°C for a period not longer than 14 days. Do not freeze.

Use: Do not use after the expiry date. Use immediately after opening. Discard unused contents.

Method of Disposal: Unused, part-used and empty vials should be destroyed according to local regulations.

Safety Precautions: In the case of accidental self-injection, an area of intense local irritation may develop for up to 96 hours later.
If irritation occurs, you are advised to consult your medical practitioner.
Store out of the reach of children.

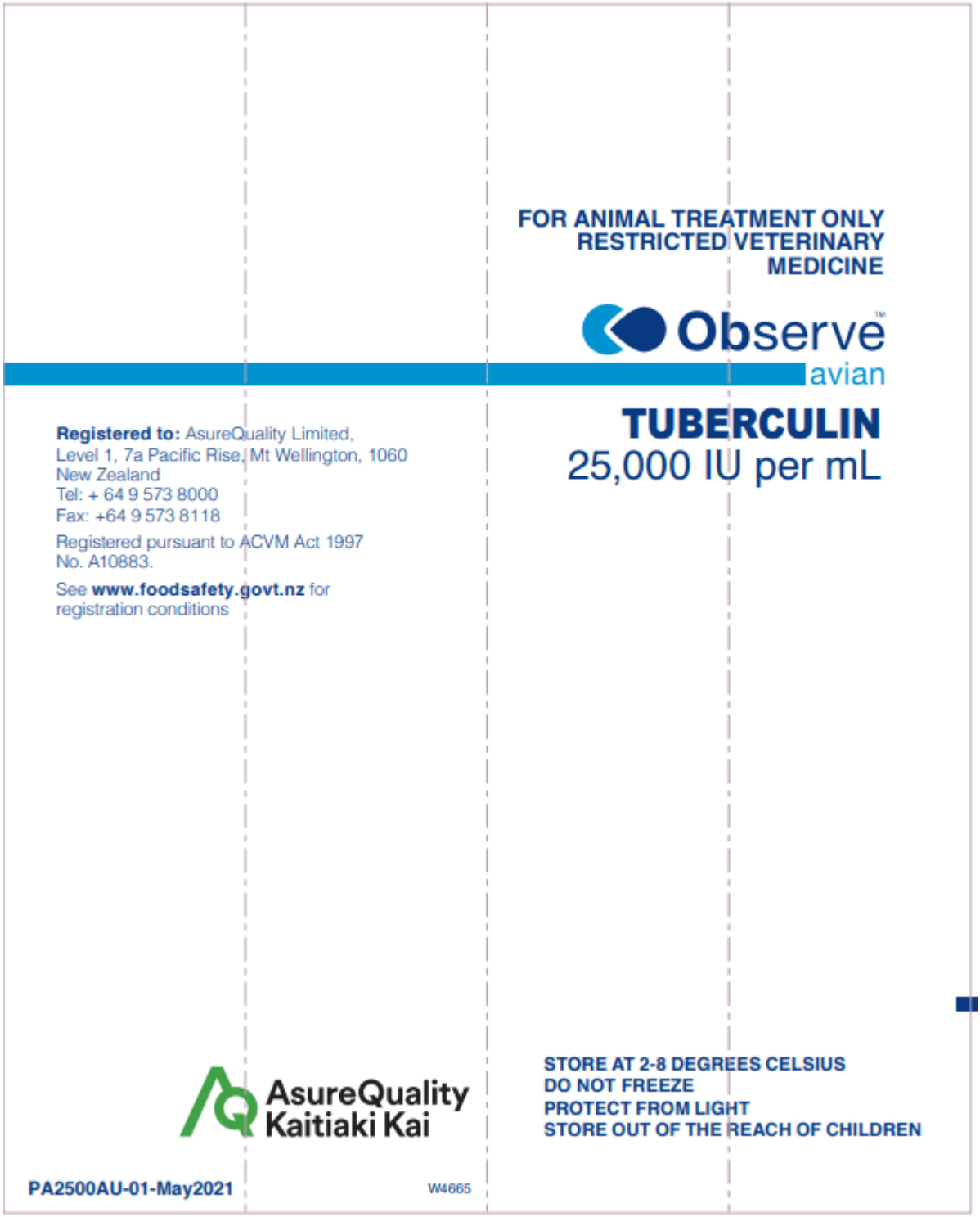
Manufactured by: Prionics Lelystad B.V.,
Platinastraat 33, 8211 AR Lelystad,
The Netherlands

Registered to: AsureQuality Limited,
Level 1, 7a Pacific Rise, Mt Wellington 1060,
New Zealand
Tel: + 64 9 573 8000
Fax: +64 9 573 8118

Registered pursuant to ACVM Act 1997
No. A10758. See **www.foodsafety.govt.nz** for registration conditions.

PB3000PAU-01-MAY2021

Attachment 1



Attachment 1

FOR ANIMAL TREATMENT ONLY
RESTRICTED VETERINARY MEDICINE

Observe™
avian

TUBERCULIN
25,000 IU per mL

Active Ingredients: Purified Protein Derivative of Mycobacterium avium, strain D4ER, 25,000 IU/mL.

Indications: For use as an aid in the diagnosis of mycobacterial infection in cattle.

Directions for use: For use under the authority or prescription of a veterinary surgeon by persons approved under the Australian Biosecurity Act 2015 and Australian Export Control Act 1982 when applying cattle tuberculin tests. Shake well before use.

Test Application

The following instructions are guidelines only:

Dose: 0.1mL intra-dermally. It is recommended syringes are calibrated to 0.1 mL and the needle of the syringe is 22-26 gauge and 3-4 mm long. Syringes should be kept clean and sterilized. Contamination of the syringe with disinfectants or alcohol may interfere with testing. When filling syringes, care must be taken to prevent contamination of vials.

Preferred site of injection:

Cattle: the mid cervical site as a comparative cervical test (CCT);

When using the cervical sites, care is required to evenly clip hair close to the skin surface (2mm or less mean length) prior to injecting. The recommended size of the clipped area is 10 x 10 cm for each injection site.

When applying a CCT use Observe™ Bovine Tuberculin 30,000 IU per mL in conjunction with Observe™ Avian Tuberculin 25,000 IU per mL.

Test Interpretation:

It is recommended the test be read 72 hours after injection.

Skin test reactions are to be classified in accordance with the requirements of OSPRI, the TBfree New Zealand programme and the National Operational Plan pursuant to the Biosecurity Act 1993 and the Biosecurity (National Bovine Tuberculosis Pest Management Plan) Order 1998 (the Order).

Retesting: To avoid desensitization, a retest using bovine and/or avian PPD tuberculin should not be applied until 60 days after any previous tuberculin test.

Product Information

Withholding period: Nil

Storage: Refrigerate (2°C – 8°C). Do not freeze.

Keep the vials in the closed box in order to protect from light.

Transportation: May be transported at 2°C – 37°C for a period not longer than 14 days. Do not freeze.

Use: Do not use after the expiry date. Use immediately after opening. Discard unused contents. Do not mix with other vaccines or immunological products.

Method of Disposal: Unused, part-used and empty vials should be destroyed according to local regulations.

Safety Precautions: In the case of accidental self-injection, an area of intense local irritation may develop for up to 96 hours later. If irritation occurs, you are advised to consult your medical practitioner.

Store out of reach of children.

Manufactured by: Prionics Lelystad B.V., Platinastraat 33, 8211 AR Lelystad, The Netherlands

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