Australian Government
Australian Pesticides and Veterinary Medicines Authority

PERMIT TO ALLOW MINOR USE AND SUPPLY OF UNREGISTERED AGVET CHEMICAL PRODUCTS FOR THE TREATMENT OF THEILERIOSIS IN SPLENECTOMISED CALVES

PERMIT NUMBER – PER87537

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 DECEMBER 2020 TO 30 JUNE 2030

Permit Holder:
DEPARTMENT OF PRIMARY INDUSTRIES
Tick Fever Centre
280 Grindle Road
WACOL QLD 4076

Supplier:
DEPARTMENT OF PRIMARY INDUSTRIES
Tick Fever Centre
280 Grindle Road
WACOL QLD 4076

Persons who can use the product under this permit:
All Veterinary officers and Animal Attendants of the Tick Fever Centre who are operating under veterinary supervision.

CONDITIONS OF USE

Product to be used:
BUTALEX
AN UNREGISTERED PRODUCT
Containing: 50 mg/mL BUPARVAQUONE as the only active constituent.

PRIMAQUINE
AN UNREGISTERED PRODUCT
Containing: 50 mg/mL PRIMAQUINE PHOSPHATE as the only active constituent.

RESTRAINTS:
DO NOT use in calves intended for human consumption or export.

Directions for Use:

Animal	Disease	Dose
Calves confirmed to be infected with *Theileria orientalis*	Theileriosis caused by *Theileria orientalis*	2.5 mg/kg of buparvaquone administered intramuscularly in 2 doses at 48-hour intervals. 2 mg/kg primaquine phosphate administered subcutaneously up to 2 times as a knock down treatment. When administered in combination with buparvaquone, administer one dose of 2 mg/kg daily for 3 consecutive days, repeated 5 days after the end of the first series of treatments (a total of 6 doses over 10 days, not including knockdown doses).

Critical Use Comments:

- Calves are to be treated upon confirmation of *Theileria orientalis* in blood smears.
- Both drugs can be used concurrently.
- All treated calves are to be euthanised and disposed of without being supplied for human consumption or being supplied as pet food.
- Refer to the relevant product Safety Data Sheets for safety directions and first aid instructions.
- The Permit Holder is permitted to source Butalex only from MSD Animal Health, Germany for supply to and use by persons authorised by this permit to use The Product.
- The Permit Holder is permitted to supply Primaquine, on reconstitution, to persons authorised by this permit to use The Product.

Withholding Periods:
DO NOT use in calves intended for human consumption.

Jurisdiction:
QLD, specifically the Tick Fever Centre, 280 Grindle Road, Wacol QLD 4076.

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. Butalex product under this permit will carry an overseas label as per **Attachment 1**.

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 should be a label which is identical in content and format to the 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.

The Tick Fever Centre must provide to each employee who will use The Products, a copy of the permit and relevant Safety Data Sheets and explain to the employee the details and conditions contained within the permit.

Record keeping
Maintain records of all treatments performed under this permit. Details must include the date when the treatments occurred, the total amount of product used, and the names and addresses of the persons undertaking the use. These details must be maintained for a minimum period of two years from the date of expiry of this permit and must be made available to the APVMA upon request.

Maximum animals to be treated:
10 calves per year.

Issued by the Australian Pesticides and Veterinary Medicines Authority

Note: 12/06/2025- The name of the permit holder and supplier is updated to DEPARTMENT OF PRIMARY INDUSTRIES, added record keeping requirement, added product label examples, permit template updated to current standard. Permit expiry extended to 30/06/2030. Permit issued as Version 2.

Attachment 1

1. Label for Butalex:

2. Label for Primaquine

PRESCRIPTION ANIMAL REMEDY
FOR ANIMAL TREATMENT ONLY
PRIMAQUINE INJECTABLE

PRIMAQUINE PHOSPHATE SOLUTION (5%)
(For treatment of Theileriosis in cattle)

THIS PRODUCT IS NOT REGISTERED AND IS ONLY AVAILABLE UNDER APVMA PERMIT
PER87537 TO REGISTERED VETERINARIANS.

READ THE ATTACHED PERMIT AND LEAFLET BEFORE USING THIS PRODUCT.

Dose rate: 1 mL per 25 kg, for use with Butalex
Route of administration: Subcutaneous injection

*Apply red tag to animals after treatment

[Batch] [Expiry]