



**PERMIT FOR SUPPLYING A REGISTERED CHEMICAL PRODUCT WITH A
LABEL WHICH IS NOT IDENTICAL TO THE APPROVED LABEL**

PERMIT NUMBER 6868

Explanatory note

This permit is issued so that within certain defined conditions, a registered chemical product may lawfully be supplied with a label which is not identical to the label for containers for that product, which the Australian Pesticides and Veterinary Medicines Authority (APVMA) or the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has approved.

The conditions of this permit describe certain label variations of an administrative nature. Label approval holders do not need to make application to the APVMA to vary the approved label where the variations are within the conditions of this permit.

Any label variations which require technical assessment are outside the conditions of this permit, including changes pursuant to the *Standard for the Uniform Scheduling of Drugs and Poisons* or the *Handbook of First Aid Instructions and Safety Directions*. Label variations which require technical assessment may only be made if the APVMA has granted an application under section 27 of the Agvet Codes.

This permit is issued under section 114 of the Agvet Codes.

Subject to the conditions set out in Part B, permission is granted to any person to supply, or cause or permit to be supplied, a chemical product in a container where the label attached to the container is not identical (except for particulars relating to the batch number, date of manufacture or expiry date of the product) to a label approved by the APVMA or NRA for containers for that product in respect of matters set out in Part A.

This permit remains in force until it is cancelled.

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Martin Holmes
**Program Manager, Veterinary Medicines
Delegate**

DATED: 27 July 2007

PART A

Variation to company name or contact details (address, telephone number etc) on the product label

1. The company or person marketing a chemical product may be a distributor, the registrant, or the formulator.

Distributor

If the registrant or formulator appoint a distributor for the product, and only the distributor's name and contact details appear on the product label, and if those details change, no change is required to the registration record for the product.

Under this permit, the registrant can make the label variation without application to the APVMA, and without notifying the APVMA.

Registrant

If the registrant's name and contact details appear on the product label and the name or contact details change, under this permit the registrant can make the label variation without application to the APVMA.

Note however that the registrant must immediately notify the APVMA at the time of change to company name and contact details, so that the registration record can be amended. Notification is effected by submitting the form 'Change to Registration Records', available on the APVMA website at http://www.apvma.gov.au/forms/KP22_3F4.rtf

Formulator

If the formulator's name and contact details appear on the product label and the name or contact details change, under this permit the registrant can make the label variation without application to the APVMA.

Note however that the registrant must immediately inform the APVMA at the time of change to company name and contact details so that the registration record can be amended.

Note also that variation to the site of manufacture or formulation of the product is not within the scope of this permit. Variation to the site of manufacture or formulation of the product requires application under category 12 or 14. Information on procedures for making an application can be found at:

for veterinary products: *Vet* [MORAG](#)

for agricultural products: *Ag* [MORAG](#)

Variation to label instructions and standard statements

2. Addition of the expressions:

POISON, NOT TO BE TAKEN

or

NOT TO BE USED AS A FOOD CONTAINER

—to the APVMA-approved label, in order to comply with the provisions of the *Standard for the Uniform Scheduling of Drugs and Poisons* for containers of Schedule 5 poisons.

The expressions must be placed on the label in such a way that they do not interfere with other label information or instructions.

3. Addition and/or deletion of:

- dangerous goods and emergency transport advice
- country of origin statements
- weights and measures descriptors
- warranty, liability or conditions of sale statements

—in accordance with relevant controlling legislation and the latest edition of the [Agricultural Labelling Code](#) or [Veterinary Labelling Code](#) in MORAG Volume 5, as appropriate to the product.

NZ registration statements

4. Addition and/or deletion of specified New Zealand classification or approval details and relevant New Zealand contact details. These statements should appear on an ancillary label panel and be prefixed by or include words such as ‘In NZ’. Alternatively, an identified NZ statement box may be used.

eg ‘Registered in NZ pursuant to the ACVM Act 1997, No. xxxx. See www.nzfsa.govt.nz/acvm for registration conditions’

NZ PAR statement

eg ‘Prescription Animal Remedy P.A.R. Class 1. For use only following a veterinary consultation’

NZ poisons information contact details

eg ‘New Zealand 0800 764 766 (0800 POISON)’

NZ registrant/distributor contact details

eg ‘Name, street address, website, phone’

5. Deletion of obsolete product names from compatibility statements.
6. Replacement of the statement 'environmentally friendly' with 'CFC free', where applicable and correct.
7. Amendment of disposal instructions to include either of the following:

For products that are used undiluted or are not applied via a spray tank

This container can be recycled if it is clean, dry, free of visible residues and has the **drumMUSTER** logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate or any undiluted chemical according to State legislative requirements. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any **drumMUSTER** collection or similar container management program site. The cap should not be replaced but may be taken separately.

or

For products that are applied via a spray tank

This container can be recycled if it is clean, dry, free of visible residues and has the **drumMUSTER** logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate by adding it to the spray tank. Do not dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any **drumMUSTER** collection or similar container management program site. The cap should not be replaced but may be taken separately.

For product containers that will not be recycled

The statement:

If not recycling, break, crush or puncture and bury empty packaging in a local authority landfill. If no landfill is available, bury the packaging below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and tree roots. Empty containers and product should not be burnt.

—may also be included with either of the above disposal instructions.

Label approval number (LAN)

8. Replacement of NRA with APVMA in the prefix to the LAN.
9. The inclusion of a pack size identifier in the LAN where a pack size identifier was not previously included in the LAN, provided that the pack size identifier is in accordance with the APVMA Label Approval Process, and provided there is no change to the product number or version control components of the number (refer to [‘The Label Approval Process’](#) in MORAG Volume 1).
10. Repositioning a LAN which the APVMA has stamped or otherwise placed on the label, so that the LAN follows the words ‘APVMA Approval No.’ or ‘APVMA’ as applicable.
11. Repositioning the block ‘APVMA Approval No: [LAN]’ to another position on the label.

Formatting changes

12. Addition and/or deletion of duplicate blocks of text or panels of the approved label on the same label part in accordance with the latest edition of the *Agricultural Labelling Code* or *Veterinary Labelling Code*, as appropriate to the product.
13. Addition or deletion of Australian-made expressions such as ‘Australian made’, ‘Made in Australia’, ‘Australian owned’, Australian based and owned’, or graphics that may imply that a product is Australian eg Australian flag, kangaroo, koala, where the expressions and/or graphics are applicable and accurate.

The expressions and/or graphics must be placed on the label in such a way that they do not interfere with other label information or instructions.
14. Variations to:
 - text weight, print size, type, case, font
 - column breaks and/or text wrapping that arise from variations permitted under this permit

—provided that the variations do not affect the product name and are in accordance with the latest edition of the *Agricultural Labelling Code* or *Veterinary Labelling Code*, as appropriate to the product.
15. Addition and/or deletion, or change in the placement of:
 - *drumMUSTER* logo
 - company logo
 - trademark or trademark symbol (® or ™)
 - patent numbers
 - barcode or printer’s number
16. Addition or deletion of stickers that indicate that a product or formulation is new. Stickers must only be used on a label for 6 months and then removed. Wording for stickers other than ‘New’, ‘New product’ and ‘New formulation’ must be approved by the APVMA.
17. Variations to background or print colours or graphics across a registrant’s range of registered products where the APVMA has granted approval for the variations for at least one product in the registrant’s range of registered products.
18. Mandatory changes to pesticide mode of action group letters or numerals and pesticide resistance management statements for resistance management strategies, that are in accordance with the *Agricultural Labelling Code*.

PART B

CONDITIONS OF THIS PERMIT

1. The label must be attached to containers for an agricultural or veterinary chemical product that is registered under Part 2 of the Agvet Code of the jurisdiction in which the supply takes place.
2. Any differences from the label approved by the APVMA or NRA for containers for the chemical product are with the consent of the registrant ie the person or company in whose name the product is registered with the APVMA and in whose name the approved label for that product is held.
3. Any conditions that apply to the approved label for the product must be complied with.
4. The registrant must provide an example of the marketed label and a version showing the differences from the approved label, at the request of the APVMA.