

Oral Nutritional Compounds (Animal Feeds)

Does my ONC product have to be registered?

To be exempt from registration, an ONC trade name product must **not**:

- be medicated, ie contain any substances that are generally accepted to be therapeutic or pharmacological, except in a nutritional context (unless it contains a registered product and meets the conditions of registration for that product)
- contain any feed additive* that is not listed in the ACVM GRAS list
- make any therapeutic or pharmacological claims other than general health claims attributable to a nutritional benefit
- contain any substance of uncertain status as either a nutrient or feed additive
- use any slow release mechanism containing high/concentrated levels of substances.

See the ACVM Amendment Regulations 2005 for more details.

* Any feed additive included must be listed on the ACVM Generally Recognised As Safe (GRAS) list, which can be viewed on the NZFSA website (<http://www.nzfsa.govt.nz/acvm/registers-lists/gras/onc.htm>).

Products must be 'fit for purpose'

ONC products are only fit for purpose if they do not:

- produce residues in primary produce
- result in toxic reactions, malnutrition, physical harm or contain micro-organisms at levels that could cause pain or distress in the animal.

There have been incidents of feeds containing levels of aflatoxins sufficient to produce residues in primary produce and of pet food in America being contaminated with melamine at levels toxic to cats and dogs. These incidents highlight the importance of products being fit for purpose. The registrant, promoter, or seller must ensure (and be able to prove) the product is fit for purpose.

Inclusion of registered products in oral nutritional compounds

Registered therapeutic or pharmacological substance products may be included in ONCs if:

- the agricultural compounds are registered under the Act, and
- the incorporation of the agricultural compounds is consistent with any conditions of their registration.

In other words, ONCs that contain a registered product must comply with the conditions of registration of that product.

Example: including a registered over-the-counter product in an ONC

To meet the conditions of registration for the product, the following must be considered and included on the ONC label if necessary.

1. Any warnings on the registered product label that should be included on the label of the feed (eg, for ionophores the warnings about feeding to dogs and horses and not using other ionophores at the same time should be included).
2. The inclusion rate of the active ingredient should be included so the concentration of the active ingredient in the finished feed is known.
3. The recommended feeding rate (grams of feed to be fed per kilogram of live weight) to achieve the required dose rate as stated on the registered products label should be included.
4. Only claims that are approved on the registered product label can be included on the label of the feed. The correct dose of active ingredient must be given for the particular claims made (eg some ionophores will have a higher inclusion rate for prevention of coccidiosis than for other claims. Claims can be made only if the correct feeding rate to achieve the recommended dose for that claim is provided.)

See example label on next page.

EXAMPLE ONLY

FOR ANIMAL TREATMENT ONLY*

Super Calf

Contains 45mg/kg coccistat
(as 300mg/kg Coccidiostat AXXX)
Calf starter feed with coccidiostat

Directions:

For control of coccidiosis and improved liveweight gain.*

Feed 1kg Super Calf per 50kg calf to provide 45mg/kg liveweight coccistat per day.

Caution: Do not allow dogs, horses or other equids access to feeds containing Coccidiostat as ingestion by these species may be fatal.*

Withholding periods: Cattle meat nil, milk nil.*

Contraindications: Care must be exercised when feeding concurrently with other antimicrobials. Do not feed with other ionophores, eg monensin capsules, liquid or premix. Do not exceed recommended dose rates. Not to be used for single dose treatment.*

Net Contents: 20kg
Ingredients: xx
Manufactured by: xx
Batch: xx
Expiry: xx

Coccidiostat is registered pursuant to the ACVM Act 1997 No Axxxx. See www.nzfsa.govt.nz/acvm for registration conditions.*

What information should be on my product label?

Specific requirements for product labels are:

- trade name
- name and address of producer (if applicable)
- name and address of manufacturer (if applicable)
- ingredients
- directions for use, including the species, type and intended class of animal
- details of any precautions to be taken
- batch number, manufacturing date and best before date (if applicable).

**For further information:
Approvals and ACVM Group
New Zealand Food Safety Authority
PO Box 2835, Wellington 6041
Tel: 04 894 2550
Email: acvm@nzfsa.govt.nz**

This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.



What you need to know about:

Oral Nutritional Compounds (Animal Feeds)

**Agricultural Compounds and
Veterinary Medicines Act 1997
Compliance**