



**PERMIT TO ALLOW EMERGENCY USE AND SUPPLY OF AN UNREGISTERED
AGVET CHEMICAL PRODUCT**

AS AN AID IN THE PREVENTION OF FACIAL ECZEMA IN CATTLE

PERMIT NUMBER – PER80579

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 24 DECEMBER 2014 TO 30 NOVEMBER 2015.

Permit Holder

DAIRY AUSTRALIA LIMITED
Level 5, IBM Centre
60 City Road
SOUTHBANK VIC 3006

Supplier:

DEBENHAM AUSTRALIA PTY LTD
18C McCartin Street Leongatha,
Vic, 3953, Australia

Persons who can use the product under this permit:

Stockfeed manufacturers, dairy farmers and veterinary surgeons acting on advice from the Permit Holder.

CONDITIONS OF USE

Product to be used:

UMICORE ZINC OXIDE PHARMACEUTICAL BP

Containing: 999 g/kg ZINC OXIDE as its only active constituent.

Directions for Use:

Animal	Purpose	Dose
Cattle (dairy heifers and lactating & non-lactating cows)	Facial eczema (Pithomycotoxicosis)	20mg zinc/kg bodyweight/day

Critical Use Comments:

- Use must be conducted in accordance with the recommendations contained within Dairy Australia's document "A review of facial Eczema" (Pithomycotoxicosis) Nov 2011 (updated 2013)
- **WARNING** The therapeutic dose recommended under this permit when used in conjunction with the method of administration may lead to zinc toxicity in treated animals. **DO NOT** exceed the dose rate of 20mg zinc/kg body weight/day and ensure that the "Facial Eczema HACCP plan Hazard Analysis – zinc toxicity and heavy metal contamination" instructions contained within Appendix D of the Dairy Australia document listed above are followed.

Jurisdiction:

VIC only.

Additional Conditions:

Zinc oxide used in this product **must** comply with a relevant Pharmaceutical standard.

Manufacturers **must** have GMP accreditation for the manufacture of premixes and supplements.

This Permit provides for the use of a product in a manner other than specified on the approved label of the product. Unless otherwise stated in this permit, the use of the product must be in accordance with instructions on its label (Attachments 1, 2 and 3).

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.

Supply:

The supplier must supply the product in a container that complies with the requirements of section 18(1) 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 labels in Attachments 1 2 and 3.

An example of a suitable label is in Attachments 1, 2 and 3. For another label to be deemed suitable for use with this permit it must be consistent with the labelling requirements as specified by the APVMA, Feedsafe QA and the DoHA Standard for Uniform Scheduling of Medicines and Poisons, including the dose rate of 20 mg/kg zinc per kg bodyweight/day as detailed in the Permit – Directions for use. The label must not contain any information that contradicts any details or conditions included in this permit.

The Supplier must retain all records of supply, possession and adverse experience reports relating to the Product under this permit, for 2 years after the permit has expired or has been surrendered, has been cancelled or has been suspended. These records must be made available to the APVMA upon request:

- a) immediately if the request is verbally from an APVMA Inspector who has attended the business premises of the Supplier; or
- b) in the time specified in written correspondence from APVMA containing the request.

Issued by Australian Pesticides and Veterinary Medicines Authority

ATTACHMENT 1 - Approved supplementary label for active chemical

THIS PRODUCT IS NOT REGISTERED
Supply and Use is currently authorized by APVMA Permit PER 15180

WARNING
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

Zinc Oxide Pharmaceutical BP

To be formulated into pelletised feed at below rates as an aid in the prevention of facial eczema in dairy cattle.

FEED RATE 10 – 16.25 g/cow/day

MINERAL/VITAMIN/ADDITIVE	% W/W
ZINC as umicore Zinc Oxide pharmaceutical BP	80 %

Cow Bodyweight	Dose Rate Cowday	Zinc Supplied
Kg	Gram	Gram/day
400	10.00	8
450	11.25	9
500	12.50	10
550	13.75	11
600	15.00	12
650	16.25	13

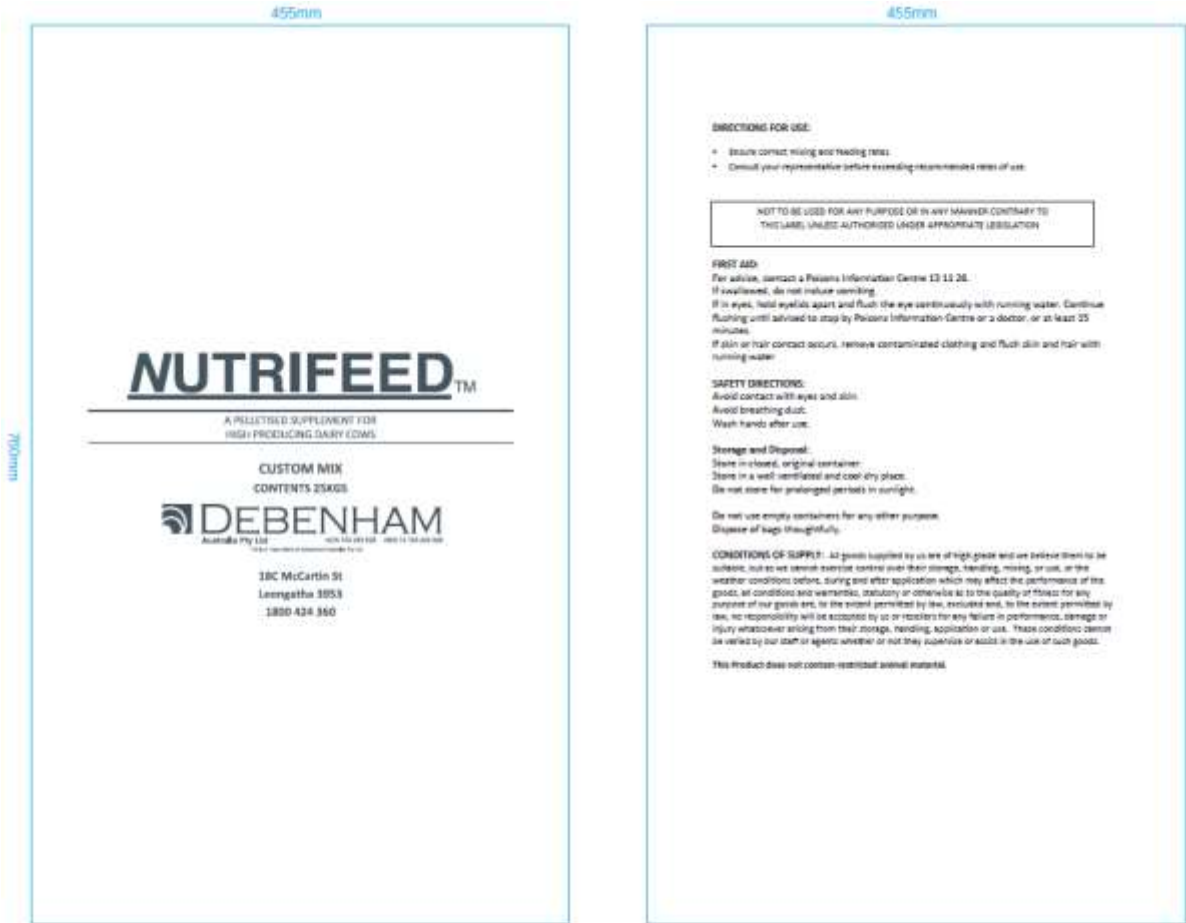
WARNING-Not to be fed:

- Longer than 100 days in a season as continued exposure to high levels of zinc may cause animal health problems. Consult a vet if required to feed longer than 100 days.
- In excess of the recommended dose rate which is based on cow bodyweight.
- For feeding to heifers and calves consult your nutritionist or a company representative.

Withholding Period: Meat: NIL, Milk: NIL.

ATTACHMENT 2 - Approved label (Part A) for a finished pelletised feed additive/supplement

**THIS PRODUCT IS NOT REGISTERED
Supply and Use is currently authorized by APVMA Permit PER 15180**



ATTACHMENT 3 - Approved label (Part B) for a finished pelleted feed additive/supplement

**THIS PRODUCT IS NOT REGISTERED
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FOR ANIMAL TREATMENT ONLY**

NUTRIFEED FE Zn 22% DEBW045

An aid in the prevention of facial eczema in dairy cattle.

FEED RATE 35 – 60 g/cow/day

MINERAL/VITAMIN/ADDITIVE	% W/W
ZINC as umicore Zinc Oxide pharmaceutical BP	22 %

Cow Bodyweight	Dose Rate Cowday	Zinc Supplied
Kg	Gram	Gram/day
400	35	7.7
450	40	8.8
500	45	9.9
550	50	11.0
600	55	12.1
650	60	13.2

WARNING-Not to be fed:

- Longer than 100 days in a season as continued exposure to high levels of zinc may cause animal health problems. Consult a vet if required to feed longer than 100 days.
- In excess of the recommended dose rate which is based on cow bodyweight.
- For feeding to heifers and calves consult your nutritionist or a company representative.

Withholding Period: Meat: NIL, Milk: NIL.

This Product does not contain restricted animal material.

DOM December 14

Expiry date of product 12 months after date of manufacture