



Company Name: NSW DEPARTMENT OF PRIMARY
Product Name: INDUSTRIES RHDV K5
APVMA Approval No: 80188/100372

Label Name:	RHDV K5
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Signal Headings:	KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
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Constituent Statements:	ACTIVE CONSTITUENT: RABBIT HAEMORRHAGIC DISEASE VIRUS, 08Q712 STRAIN >30,000 ID50 UNITS
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Mode of Action:	
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Statement of Claims:	For the infection of wild European rabbits (<i>Oryctolagus cuniculus</i>) in accordance with directions of the appropriate State or Territory government authority.
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Net Contents:	At least 30,000 ID50 units of Lyophilised Rabbit Haemorrhagic Disease Virus (RHDV) 08Q712 strain
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Restraints:	<p>DO NOT administer by injection to any animal other than wild European rabbits.</p> <p>DO NOT administer by injection to rabbits visibly affected by myxomatosis. Rabbits affected by active myxoma virus infection may be less likely to die as a result of Rabbit haemorrhagic disease (RHD).</p> <p>DO NOT administer by injection to rabbits younger than 12 weeks. Younger rabbits may be infected with rabbit haemorrhagic disease virus (RHDV) but are less likely to die as a result of RHDV, particularly in the presence of maternal antibodies. RHDV may be administered to susceptible rabbits either by direct injection or by means of infected carrot or oat feed.</p>
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Directions for Use:	<p>Administration by intramuscular injection:</p> <p>Capture at least two wild rabbits from each warren. Using a sterile syringe, reconstitute the RHDV K5 lyophilised virus by adding 10 mL of sterile distilled water and swirl gently for a few minutes. Using a sterile syringe, remove a 0.5 mL dose of virus suspension from the vial. Inject each recipient rabbit at an intramuscular (IM) site in the hind leg with 0.5 mL of reconstituted virus suspension and release the rabbits back into the warren from which they were captured.</p>
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It is recommended that rabbits be captured and re-released into the same warren to maximise the likelihood of acceptance of the infected rabbit by its cohorts.

A minimum of two rabbits should be injected at each release site but preferably up to 20 rabbits should be treated.

Administration by medicated feed:

RHDV K5 can be administered to susceptible rabbits via the oral route on either oats or chopped carrots. Oats should be standard intact oats with husks attached. Carrots should be freshly diced.

RHDV K5 treated oats must be applied in trails but RHDV K5 treated chopped carrot may be applied by trails or broadcast. Free feed the area by broadcast or by trail with untreated oats or chopped carrots at a rate appropriate to the local rabbit density. Typically the rate will be in the range of 2-5 kg per km of trail for oats and 5-10 kg per km of trail for carrots. Free feeds should be given on at least two and, for oats, on preferably three occasions to train rabbits to accept the feed.

Prepare the RHDV K5 treated oats or carrots by first reconstituting lyophilised virus using 10 mL of distilled water and then diluting a reconstituted vial of virus to a final volume of 100 mL with distilled water (i.e. add the contents of one 10 mL vial to 90 mL of water). Add the diluted suspension to carrots or oats while tumbling in an enclosed mixing device (as per the minimum standard requirement of 1080 or pindone bait mixing), and continue to mix until the suspension is evenly distributed amongst the feed.

RATES OF APPLICATION OF RHDV TO FEED

The recommended dose rates of RHDV K5 to the feed are as follows:

One vial of reconstituted product (10 mL) diluted with an additional 90 mL of water (100 mL total volume) is sufficient to treat 5 kg of oats or 10 kg of chopped carrots.

Treated oats or carrots should be offered to rabbits in a number of warrens in the area in which it is desired to induce an outbreak of RHD by adequate deployment of trails or broadcast baiting.

The medicated feed should be used as soon as possible after preparation. It should be laid in the evening and bait not consumed by the following morning should be recovered and destroyed by deep burial.

Other Limitations:

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORIZED UNDER APPROPRIATE LEGISLATION.

Withholding Periods:

Trade Advice:

General Instructions:

Rabbit haemorrhagic disease virus (RHDV) is a highly infectious and usually fatal pathogen that causes acute clinical symptoms resulting in death only to European rabbits (*Oryctolagus cuniculus*). All breeds of rabbits in Australia are derived from *Oryctolagus cuniculus* and are therefore potentially susceptible to infection with RHDV. A vaccine to protect pet and farmed rabbits from RHDV is available from your local veterinarian.

Once a rabbit is infected, the virus replicates rapidly within the liver. The rabbit usually dies within three days of infection but may survive longer and may recover. While young rabbits (less than 12 weeks old) often fail to succumb to RHDV, older rabbits are highly

susceptible. Rabbits that have become resistant to the Czech v351 RHDV strain, due to genetic immunity or exposure to the non-lethal rabbit calicivirus Australia 1 (RCV-A1) virus, may be more susceptible to infection by this strain of RHDV (08Q712).

To prevent resistance and ensure adequate rabbit control, administration to rabbits of any age should be avoided when there is a high proportion of rabbits younger than 12 weeks in the local population. Administration to rabbits of any age should also occur as part of an integrated approach to rabbit management with multiple options being used unless part of a research program or co-ordinated release. This may include the use of other products registered by the APVMA, warren ripping, removing harbour such as fallen logs, etc. The appropriate State or Territory government authority can provide advice on optimal RHDV release times and integrated approaches to rabbit control.

**Resistance
Warning:**

Precautions:

NOTE: RHDV has the potential to spread rapidly from individual infected rabbits to cohorts within the same warren and to new warrens in the same area or some distance (up to many kilometers) away from the initial site of infection. However, the rate of movement and proportion of warrens affected is highly variable. Since the factors which control the rate of spread are not fully understood, no guarantee can be given that the virus will spread from an infected rabbit to other rabbits.

Protections:

PROTECTION OF NATIVE ANIMALS:

Decline of rabbit numbers from any cause can result in increased predation on critical populations of vulnerable or endangered native animals, at least in the short term. If the existence of a critical population is suspected in the area of a deliberate release of RHDV K5, advice should be sought from State or Territory conservation agencies so that appropriate predator control measures can be implemented if necessary.

PROTECTION OF CROPS AND LIVESTOCK

DO NOT apply treated bait to crops or situations where livestock may have access to the bait.

**Storage and
Disposal:**

Freeze-dried virus is to be kept cool at all times during transport.

Freeze-dried virus can be stored at 4-8°C for up to 12 months. Do not re-freeze.

Use entire contents of freeze-dried virus vial within 24 hours of initial opening. Store open vial at 4-8°C.

Reconstituted virus may be stored at 4°C for no more than 24 hours before use.

Lay bait mixed with virus as soon as possible after preparation.

Any needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container. Open and used vials, and used needles and syringes, should not be left in the open environment, or in other places where unintended contact is possible. Used vials and syringes should be soaked in 0.5% sodium hypochlorite (e.g. a 1 in 20 dilution in water of household bleach solution containing 10% sodium hypochlorite) and buried in a local authority landfill. If a local authority landfill is not available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Unused baits should also be buried in this manner. Empty containers and products should not be burnt.

Equipment used to prepare the medicated feed should be decontaminated and cleaned at the end of each day by rinsing with 0.5% sodium hypochlorite. Following this treatment, wash thoroughly with excess water and allow equipment to dry.

Safety Directions:

RHDV affects only European rabbits *Oryctolagus cuniculus*. However, due to the presence of rabbit and viral proteins in the product, it is possible that accidental administration of the product to a user could be accompanied by an adverse allergic reaction.

When opening the container, reconstituting the virus, injecting live rabbits, preparing bait, using the prepared bait, collecting any untaken bait and disposing of bait, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), a face shield and chemical resistant gloves.

Wash hands after use. After each day's use wash or dispose of gloves, face shield and contaminated clothing.

First Aid Instructions:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.

First Aid Warnings:

Product Details

Product No: 80188
Product Name: RHDV K5
Applicant Name: NSW DEPARTMENT OF PRIMARY INDUSTRIES
Applicant Street Address: 161 KITE ST ORANGE NSW 2800
Category: A
Product Class: VVS - VERTEBRATE POISON-VIRUS
Formulation Type: WP - WETTABLE POWDER
Reg Status: R -REGISTERED
Reg Date: 21/04/2016
Expiry Date: 30/06/2016
Poison Schedule:
Shelf Life: 12
Pack Grouping: COMMERCIAL PACK SIZE
Info Status: 7
Last Edited By: Alice Coggan

Manufacturer Details

Company Code	Company Name	Street Address	License No	License Status
NDPI2	NSW DEPARTMENT OF PRIMARY INDUSTRIES	ELIZABETH MACARTHUR AGRICULTURAL INSTITUTE WOODBRIDGE ROAD MENANGLE NSW 2570		

Formulation Details

Constituent Name	Type	Seq	Amount	Unit
RABBIT HAEMORRHAGIC DISEASE VIRUS	A	0	0	LD50/mL
POTASSIUM GLUTAMATE	o	0	2	g/L
DIPOTASSIUM HYDROGEN ORTHOPHOSPHATE	o	0	0.3	g/L
ALBUMIN - BOVINE SERUM	o	0	10	g/L
PURIFIED STERILE WATER	o	0	0	qs L
SUCROSE	o	0	75	g/L

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POTASSIUM DIHYDROGEN PHOSPHATE	o	0	1	g/L
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Relation Product Details

Related Product No	Product Name	Relation Type	Comments
50675	RABBIT HAEMORRHAGIC DISEASE VIRUS (LYOPHILISED)	R	
82012	RABBIT HAEMORRHAGIC DISEASE VIRUS, 08Q712 STRAIN	T	

State Registration Details

State	Reg Status	Reg Date	First Reg Date	State Reference
ACT	R	31/12/9999	21/04/2016	
NSW	R	31/12/9999	21/04/2016	
NT	R	31/12/9999	21/04/2016	
QLD	R	31/12/9999	21/04/2016	
SA	R	31/12/9999	21/04/2016	
TAS	R	31/12/9999	21/04/2016	
VIC	R	31/12/9999	21/04/2016	
WA	R	31/12/9999	21/04/2016	

Label Registration Details

Approval No	Status	Approval Date	Comments
100372	A	21/04/2016	RLP

Pack Sizes

100mL

Product Comments

WHP: N/A

Condition Registration Details

Application No	Condition Type	Condition
100372	1	<p>This product can only be supplied in a container that must:</p> <ul style="list-style-type: none">(a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and(c) if it is intended to be opened more than once - be able to be securely and readily closed and reclosed; and(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:<ul style="list-style-type: none">(i) harm any person; or(ii) have an unintended effect that is harmful to the environment.
100372	2	<p>This product can only be supplied if the approved label contains an expiry date not greater than months after the date of manufacture of the product.</p>
100372	3	<p>The label affixed to containers must:</p> <ul style="list-style-type: none">(a) comply with the requirements of the Ag Labelling Code or Vet Labelling Code as relevant to the product and published in the APVMA Manual of Requirements and Guidelines (MORAG), or otherwise, any prescribed APVMA Labelling Standard, whichever is in effect at the time;(b) not contain any information inconsistent with the relevant particulars for label approval as defined by section 3 of the Agvet Code that have been determined by the APVMA.
100372	4	<p>The label affixed to containers must be supplied with an Expiry Date and Batch Number.</p> <ul style="list-style-type: none">(a) The Expiry Date and Batch Number must be either printed on the container or affixed by way of a sticker to either:<ul style="list-style-type: none">(i) the base of the main or ancillary panel of the approved label; or(ii) to the container. <p>The Expiry Date and Batch Number must comprise of numbers or letters, or a combination of numbers and letters and be in English.</p> <ul style="list-style-type: none">(b) Suitable prefixes may be used for the Expiry Date and Batch Number. These must be distinguishable from one another. For example, Expiry Date may include the prefix 'EXP' and Batch Number the prefix 'BN'. These details must be presented on the label or container (in accordance with (a) above) adjacent to one another and not in a position to be confused with any other numerical codes.

Application Details

Australian Pesticides and Veterinary Medicines Authority Product Information Report
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Application No	Date Received	Sub Category	Date Reg Decision	Application Brief
100372	04/09/2014	ITEM 2	21/04/2016	Registration of a Rabbit Haemorrhagic Disease Virus (Antigenic Variant) for use in Agricultural Chemical products.