



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: NUFARM TALLY 800WG APHICIDE
Applicant: NUFARM AUSTRALIA LIMITED
Product number: 69374
Application number: 60630

Purpose of Application and Description of Use: Registration of an 800 g/kg pirimicarb, water dispersible granule product for the control of certain aphids on crops and pastures as per the directions for use.

Active Constituent(s): PIRIMICARB

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

Non-Standard Conditions of Registration/Approval

Nil.

ADVICE

Australian Government Department of Health and Ageing, Office of Chemical Safety

Nufarm Australia Limited has applied to register a new aphicide product, Nufarm Tally 800WG Aphicide, containing pirimicarb at 800 g/kg formulated as a water dispersible granule (WG). The proposed product is intended for the control of certain aphid species across a range of fruit crops, vegetables, ornamentals, broad acre crops and pastures.

The ADI for pirimicarb of 0.002 mg/kg bw/d was established in 1987, based on a NOEL of 2 mg/kg bw/d (5 ppm) from a 3-month dietary study in monkeys for inhibition of cholinesterase activity in plasma and red blood cells at the next highest dose of 25 mg/kg bw/d and using a 1000-fold safety factor. No ARfD has been set for pirimicarb, and no studies or data were submitted to allow an ARfD for pirimicarb to be established.

Pirimicarb is listed in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) except when included in Schedule 5. Pirimicarb is listed in Schedule 5 of the SUSMP when in preparations containing 0.5 per cent or less of pirimicarb. The product contains 80 per cent pirimicarb and is therefore a Schedule 6 poison.

The applicant did not provide any new toxicological data on the proposed product in the present submission. However, the applicant has submitted MSDS information on the excipients in the proposed product. The available toxicological database for pirimicarb held by the OCS, as well as the information submitted by the applicant, were relied on in considering whether the proposed use of the product would not be an undue health hazard to humans. The information made available to the OCS on the product excipients and previously evaluated data on the toxicology of the active constituent was relied on by the OCS to establish the acute hazard profile for the proposed product.

The product is expected to have moderate acute oral, acute dermal and acute inhalational toxicity. It is expected to be a moderate eye irritant, but is not expected to be a skin irritant or a skin sensitiser. The product is likely to be irritating to the gastric and respiratory tract mucous membranes based on an excipient present in the formulation.

The toxicology data and other information on the product provided and considered during this assessment justify the recommendations made and the Safety Directions established. The APVMA has considered the advice from the Office of Chemical Safety and is satisfied that the risk posed by the proposed product is similar to that already accepted for the registered reference products and has been previously considered the risk associated with the nominated reference products acceptable.

External Efficacy Reviewer

The data tendered in support of the application for registration of NUFARM TALLY 800WG APHICIDE included reports of three trials conducted to demonstrate the bioequivalence of Tally 800WG Aphicide with an acceptable and registered reference product. Both products contain the active ingredient, pirimicarb. The trials compared Tally 800WG and the reference product with two other registered industry standards, containing imidacloprid and pymetrozine. Trials were conducted against cabbage aphid, *Brevicoryne brassicae*, infesting cabbages and cauliflowers, and against black peach aphid, *Brachycaudus persicae*, infesting peaches.

The trials for which data were supplied were all of randomised complete block design, with three or four replicates. Aphid numbers in the Brassica trials were low to moderate, but populations in the untreated plots remained at levels enabling legitimate statistical comparison. The trials were conducted by personnel employed by well-established and reputable agricultural research companies, and the experimental design, product application and data analysis and its interpretation were appropriate.

In the cabbage trial, the reference product and Tally 800WG both applied at 250 g ai/ha, a dosage rate at the lower end of the recommended range appeared to give poor early control of the light infestation. Control of both adult and nymphal aphids was effective after two sprays eleven days apart. The low initial activity was attributed to the relatively cool temperatures experienced, the lower dosage applied, and low numbers of aphids present for data assessment on the datum plants. Increasing the size of the sample for the last assessment clarified the result.

Data from the cauliflower trial show only moderate reductions in cabbage aphid numbers were recorded for the reference product and Tally 800WG applied at 500g ai/ha, and the other products tested, 10 days after the first spray. However, seven days after the second treatment aphid control was recorded as 100% for all products, while the untreated population held up.

Mortality in the high population of black peach aphids infesting trees in the peach trial was achieved relatively quickly, with the reference product and Tally 800WG applied at 500g ai/ha and all of the other products reducing the population by around 90%, 7 days after treatment. Populations were reduced further by the second spray applied 10 days after the first.

In all three trials, Tally 800WG Aphicide achieved control of aphids equal to that of the reference product at equivalent application rates, and to the industry standards containing pymetrozine and imidacloprid. No phytotoxicity to the treated crops was noted.

Based on the data provided the APVMA is satisfied that Tally 800WG Aphicide should be as safe and efficacious as the reference product and industry standards tested.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
82084	S	Greg Murdoch	Evaluation of the efficacy of Tally 800WG and formulations of imidacloprid and pymetrozine for the control of cabbage aphid on cabbages, One trial, Mangrove Mountain, NSW Australia, 2012.	22 February 2013	Efficacy and safety	Efficacy	Applicant	
82085	S	Greg Murdoch	Evaluation of the efficacy of Product C and formulations of pirimicarb and pymetrozine for the control of black peach aphid in peaches, One trial, Mangrove Mountain, NSW Australia, 2012.	22 February 2013	Efficacy and safety	Efficacy	Nufarm Australia Ltd	
82083	S	Karina Bennett & David Kohler	Comparison of insecticides for the control of cabbage aphid (<i>Brevicoryne brassicae</i>) in cauliflower cv. Discovery, Forth, Tasmania, 2011.	30 April 2012	Efficacy and safety	Efficacy	Applicant	

* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application