Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: YATES NATURE'S WAY CITRUS AND ORNAMENTAL SPRAY

Applicant: DULUXGROUP (AUSTRALIA) PTY LTD

Product number: 69267

Application number: 60371

Purpose of Application and Description of Use: Registration of a 0.3 g/L Pyrethrins and 8 g/L Canola oil, emulsion product for the control of a range of insect pests on citrus, ornamentals and vegetables.

Active Constituent(s): CANOLA OIL
PYRETHRINS

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. 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

Dulux Group (Australia) Pty Ltd have submitted a data package seeking registration of the new home garden insecticide product Yates Nature's Way Citrus and Ornamental Spray containing pyrethrins at 0.3 g/L, and canola oil at 8 g/L in a ready to use emulsion. The product is intended for application directly to fruit trees, indoor and our door ornamental plants and vegetables for the control of citrus leaf miner, scale, aphids and white fly.

The ADI of 0.04 mg/kg bw/d for pyrethrum extract was established in 2003 in Australia, based on deliberations by the JMPR regarding a NOAEL of 4 mg/kg bw/d (100 ppm) from a chronic rat dietary study. There was an increased incidence of liver and thyroid tumours at the next highest dose of 1000 ppm. The ARfD for pyrethrins was established in 2003 at 0.2 mg/kg bw/d, based on effects seen in an acute neurotoxicity study in rats and using a 100-fold safety factor. Pyrethrins are in Schedule 5 of the SUSMP except in preparations containing 10% or less of permethrin. This product contains 0.03% pyrethrins. There is no established ADI for canola oil (oleic acid). No ARfD has been established for canola oil and no data were submitted to enable an ARFD to be set. Canola Oil is not listed in the SUSMP, Oleic acid is listed in Appendix B – for substances that do not require control by scheduling.

No toxicology data was provided with the application and the product acute toxicity profile was estimated from the available data on the product ingredients. The product is expected to have low acute oral, acute dermal and acute inhalational toxicity. It is not expected to cause eye irritation, skin irritation or skin sensitisation.

A qualitative exposure assessment was conducted, and in conjunction with the hazard profile, used to determine whether the proposed use of the product would be an undue health hazard to humans. The risk assessment concluded that risk mitigated was not required during product use. Based on the outcomes of the risk assessment, First Aid Instructions and a re-entry statement have been recommended for inclusion on the product label.

After consideration of the hazards associated with the proposed product, along with the exposure and risks expected with use of the proposed product, it was considered that the proposed use of "Yates Nature's Way Citrus and Ornamental Spray" will not be an undue health hazard to humans according to the criteria stipulated in Section 14 of the Ag/Vet Code Act of 1994.

External Efficacy Reviewer

Four trials for efficacy and one trial for crop safety were submitted in support of the claim to register Yates Nature's Way Citrus and Ornamental Spray product containing 0.3g/L pyrethrins and 8g/L canola oil for use against a range of insect pests and sooty mould.

These trials demonstrated efficacy of the subject product against the untreated control and bioequivalence with an extensive range of industry standards including Yates pyrethrum and spinetoram products and some other synthetic chemicals against thrips, whitefly, aphid and caterpillar pest species.

Trial data included a single trial for bioequivalence against cabbage white butterfly and green peach aphid in tomato; cabbage aphid in cabbage; silver leaf whitefly and melon thrips in watermelon; light brown apple moth in native daisy and rose aphid in roses. A range of vegetable seedlings and ornamental plants were tested for phytotoxicity against a single and double application of the product under greenhouse conditions. Precautionary statements have been included on the label in order to inform product users of sensitivity in delicate plants. In the submitted trial data, target pests were appropriately identified. Treatment application methodology, methods of assessment, data presentation and analysis were acceptable.

Trial data and supporting evidence demonstrated the claims for use of Yates Nature's Way Citrus and Ornamental Spray for a range of insect and mite pests as specified on the proposed label.

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.
83519	S	Greg Murdoch	Field evaluation of organic pyrethrin liquid formulations for insecticidal activity against a range of insects. One trial, Mangrove Mountain, NSW, Australia, 2012, Agrisearch Services Pty Ltd, Report number YATESAUS/11/15-2	April 2013	Efficacy and safety	Efficacy	Applicant	
83520	S	Paul Dafoe	Field evaluation of organic pyrethrin liquid formulations for insecticidal activity against a range of insects. One trial, Bundaberg, Qld, Australia, 2012, Report number YATESAUS/11/15-3	April 2013	Efficacy and safety	Efficacy	Applicant	
83521	S	Greg Murdoch	Field evaluation of organic pyrethrin liquid formulations for insecticidal activity against a range of insects. One trial, Berkeley Vale, NSW, Australia, 2012, Report number YATESAUS/11/15-4	May 2013	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
83518	S	Greg Murdoch	Field evaluation of organic pyrethrin liquid formulations for insecticidal activity against a range of insects. One trial, Taree, NSW, Australia, 2012, Report number YATESAUS/11/15-1	April 2013	Efficacy and safety	Efficacy	Applicant	
83524	S	Angela Thomas	Greenhouse evaulation of Yates Nature's Way Citrus & Ornamental Spray for Crop Safety	August 2013	Efficacy and safety	Phytotoxicity and crop safety	Applicant	

** S = Data submitted with the application*

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