Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: FURY 120 SC GENERAL HOUSEHOLD INSECTICIDE

Applicant: FMC AUSTRALASIA PTY LTD

Product number: 69934

Application number: 62090

Purpose of Application and Description of Use: Registration of a 80 g/L Bifenthrin and 40 g/L Alpha-cypermethrin, suspension concentrate for knockdown and residual control of a wide range of internal pests including ants, clothes, moths, cockroaches, flies, fleas sliverfish and bedbugs and external pests including ants (including funnel ants), biting midges, fleas, flies, mosquitoes, papernest wasps, spiders and ticks.

Active Constituent(s): ALPHA-CYPERMETHRIN

BIFENTHRIN

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.

ADVICE

Australian Government Department of Health, Office of Chemical Safety

Information and scientific argument were submitted by FMC Australasia Pty Ltd for registration of a new insecticide product Fury 120 SC General Household Insecticide, containing bifenthrin at 80 g/L and alpha-cypermethrin at 40 g/L in a suspension concentrate. Fury 120 SC is intended for knockdown and residual control of a wide range of internal pests including ants, clothes moths, cockroaches, flies, fleas, silverfish and bed bugs and external pests including ants, biting midges, fleas, flies, mosquitoes, paper nest wasps and spiders.

The ADI for bifenthrin is 0.01 mg/kg bw/d and was established in 1992 based on a NOEL of 1 mg/kg bw/d from a rat developmental study for maternal tremors at the next highest dose of 2 mg/kg bw/d and incorporating a 100 fold safety factor. An Acute Reference Dose (ARfD) has not been established in Australia for bifenthrin, and no data were submitted to enable an ARfD to be set. Bifenthrin is listed in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with a cut off to Schedule 6 for preparations containing 25 percent or less of Bifenthrin. Preparations containing 0.5 % or less of bifenthrin are not considered to require control by scheduling.

The ADI for alpha-cypermethrin is 0.05 mg/kg bw/d and was established in 1994 based on a NOEL of 4.7 mg/kg bw/d (90 ppm) from a 13-week dog study for ataxia, body tremors, agitation and abnormal gait at the next highest dose of 14.1 mg/kg bw/d (270 ppm) and incorporating a 100 fold safety factor. An ARfD has not been established for alpha- cypermethrin, and no data were submitted to enable an ARfD to be set. Alpha-cypermethrin is in Schedule 7 of the SUSMP, except when in Schedules 5 or 6. Alpha-cypermethrin is in Schedule 6 in aqueous preparations containing 25% or less of alpha-cypermethrin or in other preparations containing 10% or less of alpha-cypermethrin, expect when included in Schedule 5. Alpha-cypermethrin is in Schedule 5 in aqueous preparations containing 3% or less of alpha-cypermethrin or in other preparations containing 1.5% or less of alpha-cypermethrin.

The proposed product contains 8 percent bifenthrin and 4 percent alpha-cypermethrin in an aqueous preparation and is therefore designated as Schedule 6 poison.

Based on the findings of the toxicological studies evaluated, the proposed product has moderate acute oral toxicity and low acute dermal and inhalational toxicity. The product is not irritating to eyes or skin and does not cause skin sensitisation.

An 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. Based on the outcomes of the risk assessment, appropriate First Aid Instructions, Precautionary Statements and Safety Directions were derived for inclusion on the product label.

The APVMA is satisfied that the proposed use of Fury 120 SC General Household Insecticide 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.

Data relied on to provide the advice

Data No		Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inheri Applica No.
86800		S	C. Gelis	In-vitro percutaneous absorption of bifenthrin	20 February 2007	OH and S	Other information	FMC Australasia Pty Ltd	
86802		S	Derek Gammon & Liu Zhiwei	Biflex Duo 200: Dermal absorption and Occupational risk assessments for termite uses	July 2011	OH and S	Other information	FMC Australasia Pty Ltd	
86801		S	M.F. Hughes & B.C. Edwards	In vitro dermal absorption of pyrethroid pesticides in human and rat skin.	2010	OH and S	Worker exposure	Prev Sub, Not Protected	

State/External Efficacy Reviewer

Data from efficacy trial and crop safety field (semi-shade) trial, conducted in NSW in 2013 were provided to demonstrate that Fury 120 SC General Household Insecticide—containing 80 g/L bifenthrin and 40 g/L alpha-cypermethrin—is bioequivalent to a registered reference standard for the control of ants, spiders and cockroaches and is safe to apply over the top of five different potted house plants.

The efficacy trial compared the performance of the product and the reference standard for the knockdown and residual control of black house spider, meat ant and American cockroach on glazed tile and pine plywood surfaces. For crop safety the products were applied at up to 2x the label rate on young seedlings of Begonia, African violet, maidenhair fern, petunia and cucumber. The species that were selected for testing, some of which are particularly sensitive to chemical application, are accepted as covering the range of plant foliage types usually present in domestic and commercial situations. All trials used suitable methodology, data analysis and scientific rigour. They were conducted in situations equivalent to the commercial and domestic claims on the label. The trials used Randomised Complete Block design, with 3-4 replicates and, treated and untreated controls. Data analysis was performed by analysis of variance with means separated using least significant difference techniques.

Results from the trials showed that both products demonstrated 90-100% control of these pests on both surface types for up to 12 weeks. There was no significant difference in the efficacy of the product and that of the reference standard. Similarly, the crop safety trial showed comparable results between the product and the reference standard.

The APVMA is satisfied that the proposed product, if used as proposed and approved, would be effective according to criteria determined by the APVMA, and would not be likely to have an unintended effect that is harmful to the crop.

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.
86797	S	P. Farmilo	A Comparison of The Knockdown and Residual Control Given By Fury 120 SC Against Black House Spiders, Meat Ants and American Cockroaches.	6 September 2013	Efficacy and safety	Efficacy	Applicant	
86799	S	K. Webb	Phytotoxicity to Ornamental and other plants following application of Fury 120EW or Fury 120SC.	30 November 2013	Efficacy and safety	Phytotoxicity and crop safety	Applicant	

** S = Data submitted with the application*