Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR VARIATION OF A REGISTERED CHEMICAL PRODUCT

Product name: TEMPRID 75 RESIDUAL INSECTICIDE

Applicant: BAYER CROPSCIENCE PTY LTD

Product number: 64371

Application number: 62534

Purpose of Application and Description of Use: Variation of label approval to include control of a range of insects in turf and ornamentals

Active Constituent(s): BETA-CYFLUTHRIN
IMIDACLOPRID

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Label Approval

1. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to the Conditions of Product Label Approval on the APVMA website.

ADVICE

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

Bayer CropScience Pty Ltd has submitted an application seeking the addition of a new use pattern in turf to the existing registered product, Temprid 75 Residual Insecticide containing imidacloprid at 50 g/L and betacyfluthrin at 25 g/L in a suspension concentrate formulation. The product is currently registered for domestic, commercial, industrial and public buildings for pest control and ornamental plants for Psyllids and scale control. The application is for the extension of use to turf, including public accessible golf courses, sport fields, bowling greens and commercial turf farms.

The OCS assessed toxicological studies on a formulation similar to Temprid 75 Residual Insecticide. The OCS estimated the acute toxicity profile of the product based on the individual toxicities of the active ingredients and excipients and their concentrations in the product. Together, this information was used to establish the acute toxicology profile for Temprid 75 Residual Insecticide. This profile has been used for the purpose of this human health risk assessment. The product is expected to be of low acute oral, acute dermal and acute inhalational toxicity. It is likely to be a slight skin and eye irritant, but not a skin sensitiser.

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. In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate exposure.

The risk assessment concluded that exposure to the product during mixing, loading and application by low pressure hand wand and ground boom equipment were determined to be at acceptable levels with the use of personal protective equipment (PPE). Thus, PPE is required during use (i.e. mixing, loading and application) of the product. Based on the outcomes of the risk assessment, First Aid Instructions and Safety Directions 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 for turf by hand wand and groundboom spray equipment, it was considered that the proposed use of Temprid 75 Residual 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	Inherited Application No.
39090	I	J Durando	Temprid SC (21% imidacloprid + 10.5% beta cyfluthrin SC): Acute dermal toxicity study in rats ? limit test	5 December 2007	Toxicology	Acute dermal studies, product	Bayer Cropscience Pty Ltd	48160
39080	I	D L Warren, M E Gastner	Acute dermal toxicity study with BAY FCR 4545 125 SC in rats	28 October 1996	Toxicology	Acute dermal studies, product	Bayer Cropscience Pty Ltd	48160
39082	I	J L Ivett	Primary eye irritation study in rabbits with BAY FCR 4545 125 SC	25 November 1996	Toxicology	Acute eye irritation studies, product	Bayer Cropscience Pty Ltd	48160
39088	I	J Durando	Temprid SC (21% imidacloprid + 10.5% beta cyfluthrin SC): Primary eye irritation study in rabbits	5 December 2007	Toxicology	Acute eye irritation studies, product	Bayer Cropscience Pty Ltd	48160
39085	I	J Durando	Temprid SC (21% imidacloprid + 10.5% beta cyfluthrin SC): Acute inhalation toxicity study in rats ? limit test	5 December 2007	Toxicology	Acute inhalation studies, product	Bayer Cropscience Pty Ltd	48160
39081	I	J Pauluhn	FCR 4545 125 SC 002: Study for acute inhalation toxicity to OECD guideline no. 403	12 Novemner 1986	Toxicology	Acute inhalation studies, product	Bayer Cropscience Pty Ltd	48160
39087	I	J Durando	Temprid SC (21% imidacloprid + 10.5% beta cyfluthrin SC): Acute oral toxicity up and down procedure in rats	20 November 2007	Toxicology	Acute oral studies, product	Bayer Cropscience Pty Ltd	48160
39079	I	D L Warren, A T Halliburton	Acute oral toxicity study with BAY FCR 4545 125 SC in rats	1 November 1996	Toxicology	Acute oral studies, product	Bayer Cropscience Pty Ltd	48160
39083	I	A Wakefield	Acute dermal irritation/corrosivity study in rabbits with BAY FCR 4545 125 SC	25 November 1996	Toxicology	Acute skin irritation studies, product	Bayer Cropscience Pty Ltd	48160

Environment

The purpose of the application is to extend the use of Temprid 75 Residual Insecticide (SC formulation containing 25 g/L beta-cyfluthrin and 50 g/L imidacloprid) to include turf and ornamental uses. For turf use, three applications are proposed at 5L/ha in 7-day intervals using ground boom application equipment. For ornamental use, three applications were proposed at 80mL/100L in 14-day intervals using ground boom application equipment. It was assumed the spray volume was 500L/ha for the purpose of risk assessment.

Both turf and ornamental use patterns (rate & frequency) are proposed in a tank mix with MERIT Turf and Ornamental Insecticide (200g/L imidacloprid, APVMA product no. 59696) at 1.25L/ha and 30mL/100L, respectively, thereby increasing the imidacloprid fraction of the application.

For the proposed use patterns, the environmental risks of imidacloprid and beta-cyfluthrin individually are individually covered by the nominated references products 59696 (Merit Turf and Ornamental Insecticide) and 54134 (Tempo Residual Insecticide), respectively. This assessment considered whether the combination of the two actives posed an additional risk and if so whether that risk was acceptable.

One or both active constituents have no activity against birds, aquatic plants, algae, earthworms, soil micro-organisms, and terrestrial plants and, as a result, additive toxicity of beta-cyfluthin and imidacloprid was not expected. Therefore, risks of the product were considered to be no greater than the nominated reference products.

Fish, aquatic invertebrates and bees have known sensitivity to both active constituents. Information was submitted on toxicity of an SC formulation (12.5 g/L beta-cyfluthrin; 100 g/L imidacloprid) to these organisms. When comparing the measured toxicity values to estimated values assuming additive toxicity of the active constituents, it was determined that the effects of the two active constituents were not additive. Therefore, the risks of the product to fish, aquatic invertebrates and bees were considered to be no greater than the nominated reference products.

Mammals and predatory & parasitic (beneficial) arthropods also have known sensitivity to both active constituents. However, no formulation toxicity information was submitted; therefore, risks of combination toxicity of beta-cyfluthrin and imidacloprid were assessed assuming additive toxicity.

For mammals, a realistic worst case scenario assumed a small (25g) herbivorous mammal fed on 100% grass directly treated with the product. Under this scenario, risks of combined toxicity to mammals were determined to be acceptable for ornamental uses. For turf uses, it was determined that risks to herbivores were of greatest concern with minimal risks to omnivores and insectivores. Risks to herbivores were considered to be acceptable when considering expected mean residue concentrations, and assuming residues did not accumulate between applications (due to rain events, mowing, etc.), and assuming the herbivore obtained no more than 10% of its diet directly from the treated area.

A hazard statement has been included on the label for beneficial arthropods, within the treatment area. For ornamental uses, risk of spray drift was determined to be acceptable at ≥10 metres from the treatment area. For turf uses, unacceptable risks due to spray drift within 200m from the treatment area could not be ruled out and therefore an advisory statement to minimise spray drift was recommended for the label.

Overall, risks to non-target species were determined to be acceptable with a hazard statement recommended for beneficial arthropods and an advisory statement to minimise risk to beneficial arthropods in habitats adjacent to the treatment area.

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.
88764	S	Dorgerloh, M.; Bayer CropScience AG, Monheim, Germany	Acute toxicity of imidacloprid & beta-cyfluthrin SC 100 & 12.5 to water fleas (Daphnia magna). DOM 22086; MO-03-002731. Bayer Document ID M-082815-01-1	26 February 2003	Environment toxicology	Aquatic organisms acute	Applicant	
88761	S	Dorgerloh, M.; Bayer CropScience AG, Monheim, Germany	Acute toxicity of FCR 4545 12.5 SC & NTN 33893 100 to fish (Lepomis macrochirus). DOM 22069; MO-03-001962. Bayer Document ID M-079083-01-1	30 January 2003	Environment toxicology	Aquatic organisms acute	Applicant	
88778	S	Nikolakis, A.; Maus, C.; Bayer CropScience AG, Monheim, Germany	Assessment of potential synergistic effects between nitro-substituted neonicotinoids and pyrethroids with regard to honeybee toxicity. Bayer Document ID M-418535-01-1	5 August 2011	Environment toxicology	Non-target invertebrates (terrestrial) bees	Applicant	

State/External Efficacy Reviewer

The purpose of this application is to vary the Temprid 75 Residual Insecticide label to add insect control in turf and ornamentals (non-food uses). The two active ingredients in Temprid 75 are already approved for use in Australia for insect control in turf and ornamentals. Tempo Residual Insecticide (25 g/L beta-cyfluthrin,) and Merit Turf and Ornamental Insecticide (200 g/L imidacloprid) are approved for use in turf and ornamentals.

The bioefficacy of Temprid 75 was evaluated in nine bioefficacy trials covering a range of representative insect pests in turf. In most cases the bioefficacy trials included the reference product Tempo Residual Insecticide. Other products also registered for the same pest and some experimental treatments were included in some studies. All the studies were conducted using outdoor small plots, with foliar application by handheld pressurised boom-spray or quad bike-mounted compressed air boom sprayer. In most cases efficacy was evaluated by monitoring populations of surviving insects over the following weeks using a drench technique, while in one case the numbers of dead insects on the ground surface were monitored for 3 days following application.

The outcome of the bioefficacy trials supports the label claims for similar efficacy to the reference product Tempo Residual Insecticide for the following turf pest situations: adult Argentine stem weevil, adult billbug, adult African black beetle, and mole crickets. For lawn armyworm, the rate tested was higher than the maximum proposed label rate for that pest of 4 L/ha and the study would only be useful to support the rate tested, that is, 5 L/ha.

For lawn armyworm and for other turf pest situations where Temprid 75 Residual Insecticide is used alone, argument was made for efficacy based on equivalence with the reference product Tempo Residual Insecticide for the rate of the β-cyfluthrin active constituent at the rates proposed for each pest. Similarly, equivalence with the reference product Merit Turf and Ornamental Insecticide can be argued for turf pest situations requiring tank mixing with it to arrive at the same rate of imidacloprid,

For pest situations with ornamentals, equivalence can again be argued with the Tempo Residual Insecticide label for pests where Temprid 75 Residual Insecticide is used alone, and the Merit Turf and Ornamental Insecticide label for pest situations where tank mixing to achieve the necessary rate of imidacloprid is needed.

The proposed label is drawn from the existing labels for Tempo Residual Insecticide and Merit Turf and Ornamental Insecticide for the corresponding pest situations and is generally satisfactory. For Lepidopterous pests a range of rates is indicated, and it is noted that it would be appropriate to include comment qualifying when the higher rate should be used.

The crop safety of Temprid 75 Residual Insecticide in turf was evaluated as part of the bioefficacy trials. Rates of 4.8-5 L/ha were shown in these trials to be safe to use on established couch, kikuyu and creeping bent grass. Studies were conducted with a wider range of cool season and warm season turf varieties and a range of ornamental plant species, using Temprid 75 Residual Insecticide alone or in combination with Merit Turf and Ornamental Insecticide and including elevated rates. These studies confirmed crop safety to common turf species and to the 8 ornamental species tested. Consistent with the Tempo 25 SC label, the draft label for Temprid 75 SC carries a precaution to protect the much wider range of ornamental plants that may be treated compared to those assessed.

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.
88723	S	Harvey, S. Westgate Research	Evaluate the efficacy of several insecticides for control of Armyworm (Spodoptera mauritia) in a turfgrass situation. Campbell Park, West Pennant Hills, NSW. 2125. WR-AW-2010-BAY00012	26 February 2010	Efficacy and safety	Efficacy	Applicant	
88724	S	Harvey, S. Westgate	Evaluate the efficacy of several insecticides for control of African Black Beetle (Heteronychus	26 February 2010	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source *	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
		Research	arator), Mole Cricket (Gryllotalpa spp.) and Armyworm (Spodoptera mauritia) in a turfgrass situation. Thomas Thompson Oval, Cherrybrook, NSW. 2126. WR-AW-2010-BAY00013					
88725	S	Harvey, S. Westgate Research	Evaluate the efficacy of several insecticides for control of Billbug (Sphenophorus brunnipennis) and Mole Cricket (Gryllotalpa spp.) in a turfgrass situation. Muirfield Golf Club, North Rocks, NSW. 2151. WR-AW-2010-BAY00014	10 March 2010	Efficacy and safety	Efficacy	Applicant	
88726	S	Sumner, M. Peracto WA	Comparison of Tempo 25SC and Temprid SC75 with Deltamethrin SC250 and Maxguard SC80 for control of adult African Black Beetle (Heteronychus arator) in couch grass (Cynodon dactylon) turf. Wanneroo, Western Australia, 2009. BES 010-09	8 December 2009	Efficacy and safety	Efficacy	Applicant	
88727	S	Sumner, M. Peracto WA	Comparison of TEMPO 25SC, TEMPRID 75SC and Deltamethrin 250SC with Maxguard 80SC for control of adult billbug (Sphenophorus brunnipennis) in kikuyu turf grass (Pennisetum clandestinum). Gosnells, Western Australia 2010. BES 011-10	8 December 2009	Efficacy and safety	Efficacy	Applicant	
88728	S	Harvey, S., Looby, P. Westgate Research	Evaluate the efficacy of several BES insecticides for control of African Black Beetle (Heteronychus arator). WR-ABB-2011-BAY0062.	29 October 2011	Efficacy and safety	Efficacy	Applicant	
88730	S	Harvey, S., Looby, P. Westgate Research	Evaluation of insecticides for Argentine Stem Weevil (Listronotus bonariensis) control in turf. Avondale Golf Club, NSW. 2012, 2013. WR-ASW-2012-2013-BAY00112	8 February 2013	Efficacy and safety	Efficacy	Applicant	
88731	S	Harvey, S., Looby, P. Westgate Research	Evaluation of insecticides for Argentine Stem Weevil (Listronotus bonariensis) control in turf. Avondale Golf Club, NSW. 2011, 2012. WR-ASW-2011-2012-BAY0077	19 April 2012.	Efficacy and safety	Efficacy	Applicant	
88732	S	Harvey, S., Looby, P. Westgate Research	Evaluation of insecticides for Argentine Stem Weevil (Listronotus bonariensis) control in turf.	18 May 2012	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source *	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
			Avondale Golf Club, NSW. 2011, 2012. WR-ASW-2011-2012-BAY0084.					
88735	S	Kaapro, J., Bayer CropScience Pty Ltd	Evaluation of turf phytotoxicity with combinations of the insecticides Temprid and Merit. IE14AUST01JK01.	2 April 2014	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88736	S	Kaapro, J., Bayer CropScience Pty Ltd	Evaluation of ornamental phytotoxicity with combinations of the insecticides Temprid and Merit. IE14AUST02JK02.	11 April 2014	Efficacy and safety	Phytotoxicity and Crop Safety	Applicant	
88734	S	Kaapro, J., Bayer CropScience Pty Ltd	Evaluation of ornamental phytotoxicity with Temprid Insecticide, Cobbitty, NSW. 2012. IE12AUSY02JK02. (Corrected report).	11 September 2012	Efficacy and safety	Phytotoxicity and Crop Safety	BAYER CROPSCIENCE PTY LTD	
88733	S	Kaapro, J., Bayer CropScience Pty Ltd	Evaluation of turf phytotoxicity with Temprid Insecticide, Cobbitty, NSW. 2012. IE12AUSY02JK02. (Corrected report)	11 September 2012	Efficacy and safety	Phytotoxicity and Crop Safety	BAYER CROPSCIENCE PTY LTD	

** S = Data submitted with the application*

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