Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: OPTIGARD ANT BAIT GEL
Applicant: SYNGENTA CROP PROTECTION PTY LIMITED
Product number: 63523
Application number: 45864

Purpose of Application and Description of Use: Registration of a 0.1 g/kg Thiamethoxam bait product for indoor and outdoor control of sugar feeding ants in and around buildings.

Active Constituent(s): THIAMETHOXAM

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 http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml.

ADVICE

Australian Government Department Of Health And Ageing, Office Of Chemical Safety

Thiamethoxam is a nitromethylene-derived compound with a broad spectrum of activity against various insects. It has contact stomach and systemic activity, and interacts with nicotinic acetylcholine receptors in the nerve fibre membrane. It is currently classified in Schedule 6 of the SUSDP except in preparations containing 60% or less of thiamethoxam which are in Schedule 5. The current ADI for thiamethoxam is 0.02 mg/kg bw/day, based on a NOEL of 2 mg/kg bw/day in a reproduction study in rats. No ARfD has been established for thiamethoxam.
The data package provided comprised five acute toxicology studies on the product and an acute inhalation study on a substantially similar material. The acute toxicology studies have been conducted in accordance with contemporary test guidelines. The data provided in the acute studies were relied on by the OCS in considering whether the proposed use of the product would not be an undue health hazard to humans.
Based on the findings of the acute toxicity studies evaluated, the product has low acute oral toxicity (LD_{50} >5000 mg/kg bw), low dermal toxicity (LD_{50} >5500 mg/kg bw) and low inhalational toxicity (LC_{50} >2610 mg/m^3). It is not a skin or eye irritant in rabbits and is not a skin sensitiser in guinea pigs.
The toxicological data and other information on the product considered in this assessment justify the Safety Directions “Wash hands after use” and the warning statement “Do not place in exposed areas accessible to children, pets and other animals”.

The proposed use of “OPTIGARD® Ant Bait Gel” 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.
24348	S	Kuhn JO	Thiamethoxam RB (0.01) (A12536A) Acute dermal toxicity study in ratsStillmeadow, Inc. Sugarland TX 77478 USA	24/04/06	Toxicology	Acute Dermal Studies, Product	Applicant	
24351	S	Kuhn JO	Thiamethoxam RB (0.01) (A12536A) Acute Eye Irritation Study in RabbitsStillmeadow, Inc. Sugarland TX 77478 USA	02/12/05	Toxicology	Acute Eye Irritation Studies, Product	Applicant	
24349	S	Noakes JP	Thiamethoxam RB (0.11 G/L) (A13934D) 4-hour acute inhalation toxicity study in ratsCentral Toxicity Laboratory, Alderley park MacClesfield, Cheshire UK	04/03/04	Toxicology	Acute Inhalation Studies, Product	Applicant	
24347	S	Kuhn JO	Thiamethoxam RB (0.01) (A12536A) Acute oral toxicity study in ratsStillmeadow, Inc. Sugarland TX 77478 USA	08/08/06	Toxicology	Acute Oral Studies, Product	Applicant	
24350	S	Kuhn JO	Thiamethoxam RB (0.01) (A12536A) Acute Dermal Irritation Study in Rabbits.Stillmeadow,	08/12/05	Toxicology	Acute Skin Irritation Studies, Product	Applicant	

			Inc. Sugarland TX 77478 USA					
24352	S	Kuhn JO	Thiamethoxam RB (0.01) (A12536A) Skin sensitisation study in guinea pigsStillmeadow, Inc. Sugarland TX 77478 USA	24/05/06	Toxicology	Acute Skin Sensitisation Studies, Product	Applicant	

Australian Government Department Of Environment And Heritage

Existing information on fate and ecotoxicity was used in this assessment. The active constituent is of low to moderate persistence in the field, but it is not expected to accumulate in the soil or bioaccumulate, mainly due to its water solubility. Thiamethoxam is of low toxicity to birds but it is highly toxic to bees, other non-target insects and aquatic invertebrates. Given the ready water solubility and moderate persistence of the chemical the potential risk to aquatic organisms was considered. The environmental risk was assessed based on two factors, which are the amount of the product, and the specific domestic use, targeted to ants inside and near buildings where ants are active. Given the very low treatment rate which when used outdoors will be placed in protected cracks and crevices, or in bait stations, exposure to sensitive organisms will be low and the risk arising from use is expected to be acceptable.

State/External Efficacy Reviewer

Trial reports provided as support for the efficacy of Optigard Ant Bait Gel covered Australian (5), US (14) and Malaysian (1) trials, undertaken both in the field and in the laboratory. Six reports involved field trials (four in Australia and two in the US), with the remainder being laboratory trials (one in Australia, one in Malaysia and fourteen in the US). The Australian trials were undertaken on two appropriate pest ant species; black ants (*Ochtellus* spp) (3 field trials) and Argentine ant (*Linepithema humile*) (one laboratory trial and one fieldtrial). The Malaysian trial was undertaken on a species not present in Australia (*Tapinoma indicum*) but was considered relevant as other ants of this genus are present in as pests Australia. The US trials involved argentine ants (two field and four lab), carpenter ants (*Camponotus* spp; four lab) and odours house ants (*Tapinoma s*essile; four lab).

Laboratory trials involved no-choice and choice tests (ie bait or sucrose solution ± dead insects or other diet), for either a group of worker ants or a 'mini colony', including workers (150-1000) zero to a few queens and brood (eggs, larvae and pupae). Ants were generally field caught and kept for no longer than a few months before using. Trials were replicated (3-5) and treatments applied randomly. The amount of bait applied varied from less than a gram to a few grams per container. Trial set-up involved either ants and bait (and food) in the same container or bait and food separated from the nest area via metal coils (ie 'slinkies') or clear poly tubes to better simulate ants travelling to food sources. Efficacy was assessed via mortality, activity (eg ants on bait or passes per time period) and bait consumption.

The Australian field trials were generally well conducted, with a suitable number of treatment sites and application was generally as per label instructions and comparison was made to an industry standard as a positive control. Australian field trials assessed activity of the target species on or around baits or monitoring stations. Measuring abundance by a rank scoring method is a relatively insensitive method of measurement, however it was found to likely under-estimate actual efficacy when analysed. US field trials were considered suitable as supporting information.

Australian field trials on black ants achieved 45-55% reduction in worker ant activity at 5 weeks and 71-82% at seven weeks. In the same trial a similar 0.01% thiamethoxam liquid version produced 61% at 5 weeks and 86% at 7 weeks. In a separate trial the same liquid formulation achieved 83.6% activity reduction at 5 weeks, however this trial used 100 mL/nest ($20m^2$). The industry standard (positive control) was inferior in both trials used (24% & 32% at 5 weeks and 40% at 7 weeks).

The US field trial on Argentine ants showed that ant activity near the structure, as measured by sucrose consumption, fluctuated throughout (60% @ 7 days, 19% @ 14 days and 46% @ day 30). Away from the structure efficacy was slightly worse. A similar amount of the proposed bait was consumed compared to a lower concentration 0.003% thiamethoxam gel and the US industry standard. US laboratory trials had markedly different results where all three experiments had near 100% and 100% mortality at only 24 or 48 hours respectively. A trial with queens had near 100% queen death at 72 hours. Australian trials on Argentine ants used a liquid 0.01% formulation. The laboratory trial achieved 87% and 98% worker mortality in 24 and 48 hours respectively and 96% queen death at 24 hours. The Australian field trial started well with 75% less activity at 24 hours but then activity fluctuated with 30%, 45% and 24% less activity than pre-baiting levels at 14, 21 and 35 days after baits were applied. A US field trial using a similar 0.003% gel produced 78-86% control up to 14 days after treatment but then declined to 57% at 35 days.

For carpenter ants the three US laboratory trials produced variable results: trial 1 achieving 49% and 53% mortality at 7 and 13 days after treatment; trial 2 had approximately 90% and 100% mortality at 7 days and 14 days; and trial 3 had near 100% mortality by 2 days and 100% at 3 days after treatment respectively.

The four laboratory trials with *Tapinoma* spp also produced variable results but were generally slower than the other species tested. Trial four did achieve 100% mortality by 3 days, however the greatest mortality in other trials were 72% at 60 days (trial 1), 92% after 31 days (trial 2) and 71% after 7 days. Brood declined at similar rates, while queens proved difficult to kill in the US but easy to kill in the Malaysian trial.

An additional three US laboratory trials using Argentine ant, carpenter ants and odorous house ants were consistent in demonstrating that bait aged for up to 14 days prior to challenge in ants was still effective although at 14 days the level of efficacy began to decline in comparison in some species.

The data and information presented has demonstrated that:

- Optigard Ant Bait Gel is able to kill ants that feed on it as well as those ants (including queens and brood) which feed on bait transferred from other ants;
- Different sugar feeding species, including Australian pest species can be affected by the product.
- Differences in biology and behaviours between species can have considerable influence on bait effectiveness;
- Field results are not always predictable based on laboratory results other than the same level of control if possible does take considerable longer to achieve;
- Large reductions in ant activity may take many weeks and possibly months and colony elimination may not be possible in all situations;
- The more bait available to ants and the greater number of ants feeding is likely to provide quicker and a greater level of control; and
- Aged bait is likely to remain effective for 14 days or more but for best effects should be replaced if ants are active and feeding.

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.
24355	S	Anon	Field study to Compare the Efficacy of Two Syngenta Ant Baits and Ant Rid against Black Ants. Insect Research Laboratory, Faculty of Science. University of Technology, Sydney	11/06/07	Efficacy and Safety	Efficacy	Applicant	
24356	S	Widmer MP, Davis T, Smith	Assessment of Optigard AB Liquid Ant Bait Against Laboratory Colonies of Argentine Ants, Linepithema humile (MAYR). Social Insect Research Section, Department of Agriculture, Government of Western Australia	03/05	Efficacy and Safety	Efficacy	Applicant	
24353	S	Anon	Field study to Compare the Efficacy of Syngenta Optigard AB and Combat Ant-Rid Liquid Ant Baits against Black Ants Insect Research Laboratory, Faculty of Science. University of Technology, Sydney	19/04/05	Efficacy and Safety	Efficacy	Applicant	
24354	S	Anon	Field study to Compare the Efficacy of Three Syngenta Ant Baits against Black Ants. Insect Research Laboratory, Faculty of Science. University of Technology, Sydney	19/06/06	Efficacy and Safety	Efficacy	Applicant	
24357	S	Anon	Field study to Compare the Efficacy of Syngenta Optigard AB and Combat Ant-Rid Liquid Ant Baits against Argentine Ants. Insect Research Laboratory, Faculty of Science. University of Technology, Sydney	07/04/05	Efficacy and Safety	Efficacy	Applicant	
24361	S	Lee C-Y	Laboratory evaluation of gel baits against the ghost ant, Tapinoma indicum. Urban Entomology Laboratory, Vector Control Research Unit, School of Biological Sciences, Universiti Sains Malaysia, 11800 Penang, Malaysia.	29/01/07	Efficacy and Safety	Efficacy	Applicant	
24359	S	Cox D, Zajac M	Performance of Optigard Gel Baits to Control Argentine Ants. Department of Entomology, UC, Riverside, CA, USA	08/11/06	Efficacy and Safety	Efficacy	Applicant	
24360	S	Cox D, Zajac M	Efficacy data supporting A15236A and A15277A.Syngenta Crop Protection Inc., Greensboro, NC, USA	06/11/06	Efficacy and Safety	Efficacy	Applicant	
24363	S	Silverman, J,	The Argentine Ant: Challenges in Managing an	17/09/0	Efficacy and Safety	Other Information	Public	

		Brightwell, RJ	Invasive Unicolonial Pest.	7				
24364	S	Roux, A	A study of characteristics enabling successful invasion and difficulty in control of the argentine ant. New College Florida.	18/05/04	Efficacy and Safety	Other Information	Public	
24362	S	Cooper ML, Daane, KM	Argentine ant management: Liquid bait program for vineyards. University of California. Integrated viticulture management online.	2007	Efficacy and Safety	Other Information	Public	

** S = Data submitted with the application*
I = Data inherited (that is, referenced) from another application