Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: VERTIMEC PRO INSECTICIDE / MITICIDE

Applicant: SYNGENTA AUSTRALIA PTY LTD

Product number: 69685

Application number: 61442

Purpose of Application and Description of Use: Registration of 18 g/L Abamectin, suspension concentrate product for control of insects and mites on apples, capsicums, citrus, hops, ornamentals, pears, tomatoes and strawberries.

Active Constituent(s): ABAMECTIN

ABAMECTIN MANUFACTURING CONCENTRATE

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 and Ageing, Office of Chemical Safety

Abamectin has an ADI (Acceptable Daily Intake) of 0.0005 mg/kg bw/d, established in 1999 based on a NOEL (No Observed Effect Limit) of 0.5 mg/kg bw/d in a 3-week rabbit developmental study with the observation of teratogenicity at the next highest dose of 1 mg/kg bw/d. A safety factor of 1000 was applied for intra-species variability and inter-species differences as the produced foetal abnormalities may represent an acute toxic effect. The acute reference dose (ARfD) for abamectin is 0.005 mg/kg bw/d, and was established in 2003 based on a NOEL of 0.5 mg/kg bw/d in a rabbit development study for foetal abnormalities (clubbed forefeet) at the next highest dose of 1 mg/kg bw/d, using a 100-fold safety factor.

Abamectin is listed in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), except when included in Schedule 5 or 6. Abamectin is in Schedule 6: (a) in preparations for pesticidal use containing 4 per cent or less of abamectin except when included in Schedule 5; or (b) in slow-release plastic matrix ear tags for livestock use containing 1 g or less of abamectin. Abamectin is in Schedule 5 in preparations for internal use for the treatment of animals containing 1 per cent or less of abamectin. The proposed product contains 1.8 per cent abamectin, and its toxicological profile is consistent with inclusion in Schedule 6.

The data package provided in the present submission comprised six acute toxicology studies on the product. The acute toxicology studies were considered adequate for the assessment of the toxicology profile of the product. The proposed product had moderate acute oral toxicity and low acute dermal and acute inhalational toxicity. It was shown to be a slight skin and eye irritant but was not a skin sensitiser. The acute toxicology data evaluated in this assessment was relied on by the OCS to establish a hazard profile for the proposed product.

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 when conducting open mixing and loading and ground-boom applications in open cabs and when applying *via* hand-held application devices is acceptable with the use of appropriate personal protective equipment (PPE). 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, it was considered that the proposed use of “Vertimec Pro Insecticide/Miticide” for certain applications 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.
85359	S	Durando, J.	Abamectin SC (A13796I) - Acute Dermal Toxicity in Rats	2008	Toxicology	Acute dermal studies, product	Applicant	
85360	S	Durando, J.	Abamectin SC (A13796I) - Primary Eye Irritation in Rabbits	2008	Toxicology	Acute eye irritation studies, product	Applicant	
85361	S	Durando, J.	Abamectin SC (A13796I) - Acute Inhalation Toxicity in Rats	2008	Toxicology	Acute inhalation studies, product	Applicant	
85362	S	Durando, J.	Abamectin SC (A13796I) - Acute Oral Toxicity Up-and-Down Procedure in Rats	2008	Toxicology	Acute oral studies, product	Applicant	
85363	S	Durando, J.	Abamectin SC (A13796I) - Primary Skin Irritation in Rabbits	2008	Toxicology	Acute skin irritation studies, product	Applicant	
85364	S	Durando, J.	Abamectin SC (A13796I) - Dermal Sensitization Test - Buehler Method	2008	Toxicology	Acute skin sensitisation studies, product	Applicant	

State/External Efficacy Reviewer

Ten trials (conducted in Australia and overseas) were presented to demonstrate efficacy and bioequivalence of the proposed product to a registered industry standard.

Seven trials were field trials and were conducted on commercial farms or field research stations and three trials were greenhouse trials. Five trials were conducted on apples, 2 trials on tomatoes and 3 trials in strawberry crops. The trials assessed efficacy against two species of mite, Two-spotted mite *(Tetranychus urticae)* and European red mite (*Panonychus ulmi).* Pest pressure in most of the trials was high. The overseas trials were conducted in similar geographic regions to those in Australia on crops representative of the crops on the proposed label.

The field trials were randomised complete block design with 3-4 replicates and untreated controls. They assessed numbers of mites (pest and predatory mites), % leaves infested, leaf discolouration, crop damage and phytotoxicity. Site details, details of experimental conditions and raw data were also included for all trials.

Results showed that the proposed product and the industry standard were bioequivalent at the same rate of active ingredient; that the proposed product was effective in reducing mite numbers and that it was safe to use on apples, tomatoes and strawberries at rates up to 1500mL/ha (27gai/ha).

Trials on the other crops and pests on the label were not included in the submission. However, as the trial results demonstrated bioequivalence of the candidate with an industry standard and as these other crops and pests are included on the industry standard label at the same rates as proposed for the candidate label, their inclusion on the proposed label is supported.

The APVMA is satisfied that the proposed product, when used according to the proposed label instructions should be efficacious and safe to the target crops.

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.
85347	S	Tancred, S.	Comparison of A-13796-I 018SC with Vertimec 018 EC for the control of two-spotted mite (Tetranychus urticae) in apples cv Royal Gala. Stanthorpe, Queensland, Australia, 2009-10	2010	Efficacy and safety	Efficacy	Applicant	
85348	S	Enjuanes, I.	Abamectin SC018 registration: Panonychus on Pome fruits	2009	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
85349	S	Molinero, C.	Abamectin SC018 registration: Panonychus on Pome fruit	2009	Efficacy and safety	Efficacy	Applicant	
85350	S	Tosi, L.	Abamectin SC018 registration in EAME: mites on fruits	2009	Efficacy and safety	Efficacy	Applicant	
85351	S	Panato, D.	Abamectin SC018 registration in EAME: mites on fruits	2009	Efficacy and safety	Efficacy	Applicant	
85352	S	Monsour, C.	Efficacy and safey of A-13796-I 018SC compared with Vertimec 018 EC, Acramite 480 ScC and Pegasus 500 SC for the control of two-spotted mite (Tetranychus urticae) in tomatoes cv Pinnacle. Bowen, Queensland, 2011	2011	Efficacy and safety	Efficacy	Applicant	
85353	S	Japon, Fu P.	Abamectin SC018 registration in EAME: tetranychus veges	2009	Efficacy and safety	Efficacy	Applicant	
85354	S	Kolditz, M.	Abamect SC018 (A13796I) registration in EU: strawberry	2012	Efficacy and safety	Efficacy	Applicant	
85355	S	Aversa, A.	Abamectin SC018 registration in EAME: Tetranychus veges	2009	Efficacy and safety	Efficacy	Applicant	
85356	S	Rodrigues, S.	Abamectin SC018 registration in EAME: Tetranychus veges	2009	Efficacy and safety	Efficacy	Applicant	
85357	S	Khajehali J, Van Nieuwenhuyse P, Demaeght P, Tirry L and Van Leeuwen T	Acaricide resistance and resistance mechanisms in Tetranychus urticae populations from rose greenhouses in the Netherlands	2011	Efficacy and safety	Efficacy	Public	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
85358	S	Sato, M.E., Da Silva, M.Z., Raga, A., and de Souza Filho, M.F.	Abamectin resistance in Tetranychus urticae Koch (Acari: Tetranychidae): Selection, Cross-resistance and Stability of Resistance	2005	Efficacy and safety	Efficacy	Public	

** S = Data submitted with the application*

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