

NOTICE

clothianidin

in the products:

SUMITOMO SHIELD SYSTEMIC INSECTICIDE, SUMITOMO SAMURAI SYSTEMIC INSECTICIDE and SUMITOMO STEALTH SYSTEMIC INSECTICIDE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical (Australia) Pty Limited for the registration of three new products containing the active constituent clothianidin. The products are *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE*.

SUMITOMO SHIELD SYSTEMIC INSECTICIDE (containing 200 g/L clothianidin) is for the control of aphids and mirids in cotton and for the control of rust thrips and weevil borer in bananas.

SUMITOMO SAMURAI SYSTEMIC INSECTICIDE (containing 500 g/kg clothianidin) is for the control of woolly aphid in apples; mealybugs and codling moth in apples and pears and green peach aphid and oriental fruit moth in peaches and nectarines.

SUMITOMO STEALTH SYSTEMIC INSECTICIDE (containing 500 g/kg clothianidin) is for control of African black beetle larvae in turf.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Applications

Proposed Product Name:	SUMITOMO SHIELD SYSTEMIC INSECTICIDE
Applicant Company:	Sumitomo Chemical (Australia) Pty Limited
Active Constituent:	clothianidin
Poisons Scheduling:	Schedule 5
Statement of Claims:	For the control of aphids and mirids on cotton, rust thrips and weevil borer on bananas.
Pack sizes:	5 L, 20 L
Withholding Period:	Cotton: Harvest – Do not harvest for 5 days after application. Grazing/cotton trash – Do not graze treated cotton crops or cut for stockfood. Do not feed cotton trash to livestock. Bananas: Not required when used as directed.

Proposed Product Name:	SUMITOMO SAMURAI SYSTEMIC INSECTICIDE
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Applicant Company:	Sumitomo Chemical (Australia) Pty Limited
Active Constituent:	clothianidin
Poisons Scheduling:	Schedule 6
Statement of Claims:	For the control of mealybug, woolly aphid and codling moth in apples and pears, and green peach aphid and oriental fruit moth in peaches and nectarines.
Pack sizes:	2.5 kg, 5 kg
Withholding Period:	Apples, pears, peaches, nectarines: Do not harvest for 21 days after application. Do not graze treated area or cut treated area for stockfeed.
Proposed Product Name:	SUMITOMO STEALTH SYSTEMIC INSECTICIDE
Applicant Company:	Sumitomo Chemical (Australia) Pty Limited
Active Constituent:	clothianidin
Poisons Scheduling:	Schedule 6
Statement of Claims:	Control of African black beetle larvae in turf.
Pack sizes:	1 kg, 2.5 kg
Withholding Period:	Do not graze treated turf or lawn or feed turf or lawn clippings from any treated area to poultry or livestock.

Summary of the APVMA's evaluation of SUMITOMO SHIELD SYSTEMIC INSECTICIDE, SUMITOMO SAMURAI SYSTEMIC INSECTICIDE and SUMITOMO STEALTH SYSTEMIC INSECTICIDE in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* would not be an undue hazard to the safety of people exposed to them during their handling and use.

The Department of Health and Ageing, Office of Chemical Safety (OCS) Occupational Health and Safety (OHS) section, has conducted a risk assessment on *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* and concluded that they can be used safely.

Clothianidin displayed low acute oral, dermal and inhalational toxicity in rats. Acute oral toxicity was high in mice. Clothianidin was not a skin or eye irritant in rabbits and was not a skin sensitiser in guinea pigs.

The product *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* exhibits low oral and dermal toxicity and is not expected to be a skin irritant or a skin sensitiser. No inhalational data were supplied, however, given the low inhalational toxicity of the active constituent and the nature and concentration of the excipients, the product is expected to have low inhalational toxicity.

The product *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* exhibits moderate acute oral, but low dermal and inhalational toxicity. It is likely to be a slight eye irritant but is unlikely to be a skin irritant or a skin sensitiser.

The product *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* exhibits moderate acute oral, but low dermal and inhalational toxicity. It is likely to be a slight eye irritant but is unlikely to be a skin irritant or a skin sensitiser.

The APVMA has considered the findings of the OCS on this criterion and accepts its findings and recommendations.

- (ii) The APVMA is satisfied that the proposed use of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* will not be an undue hazard to the safety of people using anything containing their residues.

Residue data were assessed by the APVMA and Maximum Residue Limits (MRLs) are recommended for clothianidin in cotton seed, bananas, apples, nectarines, peaches and pears.

For *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, cotton has a harvest withholding period of 5 days. Treated cotton crops must not be grazed or cut for stockfood. No withholding period is required for the banana use pattern when used as directed (stem injection or trunk spraying).

For *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* apples, pears, peaches and nectarines have a harvest withholding period of 21 days after application. Treated areas must not be grazed or cut for stockfood.

Turf or lawns treated with *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* must not be grazed and turf and lawn clippings from treated areas cannot be fed to poultry or livestock.

The following MRLs recommended for clothianidin are apples (0.5 mg/kg), banana (*0.02 mg/kg), cotton seed (*0.02 mg/kg), edible offal (mammalian) (*0.02 mg/kg), eggs (*0.02 mg/kg), meat (mammalian) (*0.02 mg/kg), milks (*0.01 mg/kg), nectarines (2 mg/kg), peaches (2 mg/kg), pears (0.5 mg/kg), poultry meat (*0.02 mg/kg) and poultry, edible offal of (*0.02 mg/kg).

- (iii) The APVMA is satisfied that the proposed use of the active constituent clothianidin in the products *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* is not likely to be harmful to human beings if used according to the product label directions.

The active constituent, clothianidin, has been evaluated and approved and the chemistry and manufacturing details of the products *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* have been found acceptable to the APVMA.

The active constituent, clothianidin had previously been included in Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) by the National Drugs and Poisons Scheduling Committee (NDPSC). Further, the NDPSC considered a

proposal to include clothianidin in Schedule 5 of the SUSDP when in preparations containing 20% or less of clothianidin. Therefore, the products *SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* are included in Schedule 6 of the SUSDP and *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* is included in Schedule 5 of the SUSDP. The appropriate Signal Headings appear on the labels. First Aid and Safety Directions for the products have been recommended by the OCS, and have been included on the product labels.

SUMITOMO SAMURAI SYSTEMIC INSECTICIDE and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* will be formulated overseas and imported into Australia. *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* will be formulated either in Australia or formulated overseas and imported into Australia. Based on the NOHSC hazard classification of active and non-active constituents and product toxicology information provided, *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* are determined to be a hazardous substances.

The APVMA has considered the findings of the OCS on this criterion and accepts its findings and recommendations.

- (iv) The APVMA is satisfied that the proposed use of the products *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE*, containing the active constituent clothianidin, when applied as described on the product labels, is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The Department of the Environment and Water Resources (DEW) has assessed the data submitted in support of registration of these products and has concluded the following.

Clothianidin degradation in soil is slow under terrestrial field conditions (broadcast sprayed to cultivated bare soil), with half-lives ranging from 1 to over 2 years, and in one case no dissipation being recorded. Binding to soil and sediment accounts for much of the dissipation of clothianidin in aquatic and soil metabolism studies under aerobic and anaerobic conditions.

Typical of the class of insecticide, clothianidin shows relatively low toxicity to birds, fish, daphnids, algae and aquatic plants, but is very highly toxic to mysid shrimps and chironomids. In mesocosm studies emerging insects were especially heavily affected and a No Observable Effect Concentration (NOEC) of 1 µg ac/L was determined. In the laboratory, clothianidin is very highly toxic to adult worker honeybees. A range of cage, tunnel and field studies showed that fresh residues of clothianidin significantly affected mortality of bees, but that aged residues had a decreased effect. Effects on beneficial insects may also be expected at the application rates proposed. Clothianidin is toxic to the soil invertebrates earthworms and collembola, with NOECs of 0.53 and 0.32 µg ac/kg soil dry weight respectively.

For foliar application to fruit trees, calculations indicate that for either a single foliar application per season at the maximum rate or two applications at two thirds the maximum rate to pome and stone fruit trees, clothianidin will not accumulate to levels that pose an unacceptable risk to soil invertebrates. Therefore, provided either a 40 m (for a single

spray at the maximum application rate) or a 50 m (for two sprays per season at two thirds the maximum application rate) downward buffers to waterbodies is applied, and the product is not applied within 48 h of predicted rainfall, registration of foliar application to pome and stone fruit of *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* is supported.

The proposed use of *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* as a soil drench is acceptable provided the product is not applied within 48 h of predicted rainfall.

The use of *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* on turf is supported provided a 10 m downwind buffer to waterbodies is applied.

The proposed use of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* in bananas will result in very little environmental exposure when used as a stem injection or trunk spray. Consequently, the registration of the use of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* on bananas is supported.

The ground application of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* on cotton is acceptable provided a 40 m downwind buffer to waterbodies is imposed. For aerial application the potential risk can be mitigated, provided a fine-medium spray quality for repeat applications and a 300 m downwind buffer to waterbodies is imposed. If a fine spray is to be used, only a single application is supported, also with a 300 m downwind buffer to waterbodies. Two applications with a fine spray may be used with an 800 m downwind buffer to waterbodies.

DEW has recommended that the APVMA be satisfied that subject to recommended label constraints, the proposed use of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* in accordance with good agricultural practice would not be likely to have an unintended effect that is harmful to animals plants or things, or to the environment.

The APVMA has considered the findings of DEW and accepts its findings and recommendations on this criterion.

- (v) The APVMA is satisfied that the proposed use of clothianidin in *SUMITOMO SHIELD SYSTEMIC INSECTICIDE* would not adversely affect trade between Australia and places outside Australia.

The APVMA has determined that use of *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* in accordance with the required instructions could potentially unduly prejudice trade and commerce between Australia and places outside Australia as per section 14(3)(e)(iv) of the Agvet Codes. The relevant commodities in the current application are exported and detectable residues are expected to occur above the standards of key export markets. Accordingly, a determination of undue prejudice to trade or commerce will be made following the completion of the public consultation process. Areas of concern and possible management strategies have been outlined in the Public Release Summary.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (i) The APVMA is satisfied the data from trials supporting the efficacy of *SUMITOMO SHIELD SYSTEMIC INSECTICIDE*, *SUMITOMO SAMURAI SYSTEMIC INSECTICIDE* and *SUMITOMO STEALTH SYSTEMIC INSECTICIDE* adequately demonstrate that under local conditions this product will be effective for the proposed uses.

Public Release Summary

A Public Release Summary of this evaluation is available from the APVMA website or by contacting (02) 6210 4748. Written submissions on the APVMA's proposal to grant the application for registration should be addressed in writing to:

Public Release Summary – clothianidin
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