

Evaluation Report for Category B, Subcategory 3.10, 3.12 Application

Application Number: 2007-0267
Application: B.3.10: Add Tankmix
B.3.12: Add New Site or Host
Product: Actara 240SC Insecticide
Registration Number: 28407
Active ingredients (a.i.): Thiamethoxam
PMRA Document Number: 1577320

Purpose of Application

The purpose of this application is to amend the label of the currently registered end-use product, Actara 240SC Insecticide (Reg. No. 28407), to include use as a potato seed piece treatment alone and in a tankmix with Maxim Liquid PSP Fungicide.

The evaluation of the application to register Maxim Liquid PSP Fungicide (2007-0268) is not complete at this time. Therefore, the tankmix with Maxim Liquid PSP Fungicide is not acceptable to appear on the Actara 240SC Insecticide label.

Chemistry Assessment

As Actara 240SC Insecticide is currently registered, a chemistry assessment for this application is not required.

Health Assessments

As Actara 240SC Insecticide is currently registered, a toxicology assessment for this submission is not required.

Residue data for thiamethoxam in potatoes were submitted to support the use expansion of Actara 240SC Insecticide for use as a potato seed piece treatment alone and in a tankmix with Maxim Liquid PSP (a.i. fludioxonil). Previously reviewed residue data from field trials conducted on potatoes treated with an in-furrow and/or foliar applications of Actara 240SC Insecticide were reassessed in the framework of this petition. In addition, a potato processing study was also reassessed to determine the potential for concentration of thiamethoxam residues into processed commodities.

Maximum Residue Limit(s)

Based on the maximum residues observed in potatoes treated according to the Actara 240SC Insecticide label directions, maximum residue limits (MRLs) to cover residues of thiamethoxam

and metabolite CGA 322704 in/on potatoes and processed commodities will be established as shown in Table 1. Residues of thiamethoxam and metabolite CGA 322704 in processed commodities not listed in Table 1 are covered under the MRL for the raw agricultural commodity (RAC), potato.

| TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs) | | | | | | | | |
|--|---|-----------------------|---------------------------|------------|---------------------------------------|------------------------|---|------------------------|
| Commodity | Application Method/ Total Application Rate (g a.i./ha) | PHI (days) | Residues (ppm) | | Experimental Processing Factor | Established MRL | MRLs Previously Proposed in PMRL 2007-11 | Recommended MRL |
| | | | Min | Max | | | | |
| Potatoes | Potato seed piece treatment | 92-118 | <0.02 | 0.056 | -- | 0.02* | 0.03 | 0.05 |
| Potato chips | 4.6 g a.i./100 kg seed pieces | -- | -- | -- | 1.9 | 0.02* | 0.04 | 0.08 |

* reflects MRL currently established in Table II, Division 15, FDR for “All food crops”

The residue data provided tested the application of Actara 240SC Insecticide to potato seed pieces at 80% of the maximum application rate. In order to confirm the recommended MRLs will cover the residues of thiamethoxam and metabolite CGA 322704 when Actara 240 SC Insecticide is applied at the maximum application rate, confirmatory field trials are required.

Following the review of all available data, MRLs of 0.05 ppm for potatoes and of 0.08 ppm for potato chips are recommended to cover residues of thiamethoxam and metabolite CGA 322704. Furthermore, the magnitude of the thiamethoxam residues in potatoes was not affected when tank mixed with fludioxonil (Maxim Liquid PSP). Residues of thiamethoxam and metabolite CGA 322704 in these commodities at the recommended MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Exposure to Actara 240SC Insecticide for mixer/loader/applicators and post applications workers has been assessed. The Actara 240SC Insecticide label has been amended to include appropriate Precautionary and Personal Protective Equipment statements.

Environmental Assessment

The use of Actara 240SC Insecticide as a potato seed piece treatment would be an alternative application to the currently registered use of Actara 240SC Insecticide as an in-furrow spray in potatoes. The active ingredient in Maxim Liquid PSP, fludioxonil, is currently registered as a potato seed piece treatment in the end-use product Maxim MZ PSP (Reg. No. 27965).

Based on the above, no increase in environmental exposure is expected with the use of Actara 240SC Insecticide alone or in a tank mix with Maxim Liquid PSP as a potato seed piece treatment.

Value Assessment

Five trials were submitted in support of the use of Actara 240SC Insecticide as a potato seed piece treatment for control of Colorado potato beetle, aphids (including green peach, potato, buckthorn, and foxglove aphid), and potato leafhopper. These trials were conducted in Canada (Ontario, PEI, Quebec) and the USA (Idaho, Wisconsin) in 2006. These studies were designed to monitor Colorado potato beetle control, however, when populations of potato leafhoppers and aphids were present these species were also assessed. Two formulations of thiamethoxam, Actara 240SC Insecticide (called Platinum 2 SC in trials conducted in the USA) and Cruiser 5 FS were tested. Imidacloprid (Admire 240SC, or Admire Pro 4.6 SC) was used as a commercial standard. In most trials, Actara 240SC Insecticide was applied in-furrow at the same rate (g a.i./ha) as the Actara 240SC Insecticide as a potato seed piece treatment. The Actara 240SC Insecticide potato seed piece treatments were tankmixed with Maxim Liquid PSP Fungicide at a rate of 5.2 mL product per 100 kg potato seed pieces. A fungicide-only check treatment was also included in all trials.

The data demonstrated acceptable efficacy for Colorado potato beetle. While pest pressure was generally low for the other proposed pests, application of Actara 240SC Insecticide as a potato seed piece treatment, had an effect on these pest species. Acceptable crop tolerance was observed for potato plants when Actara 240SC Insecticide was applied as a potato seed piece treatment alone and in a tankmix with Maxim Liquid PSP Fungicide at a rate of 5.2 mL product per 100 kg potato seed pieces.

Based on the facts that (1) the data provided indicates the application of Actara 240SC Insecticide as a potato seed piece treatment alone and in a tankmix with Maxim Liquid PSP Fungicide provides acceptable efficacy for Colorado potato beetle and had an effect on aphids and leafhoppers, and (2) Actara 240SC Insecticide is registered for all the proposed pests as an in-furrow treatment, the PMRA expects acceptable control of Colorado potato beetle, aphids (including green peach, potato, buckthorn, and foxglove aphid), and potato leafhopper in potato crops when Actara 240SC Insecticide is applied as a potato seed piece treatment alone and in a tankmix with Maxim Liquid PSP Fungicide.

Conclusion

The PMRA has completed an evaluation of the subject application and has granted a conditional registration of the use of Actara 240SC alone as a potato seed piece treatment. This conditional registration is based on the submission and evaluation of confirmatory residue data.

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| 1366473 | 2006, Processed Feed/Food - Note to Reviewer, DACO: 7.4.5 |
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2.0 Value Assessment

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