

Evaluation Report for Category B, Subcategory 3.1, 3.11, 3.12 Application

Application Number: 2018-1920
Application: Changes to product label; reduction to application rate, new pests and new site
Product: Tivano
Registration Number: 30468
Active ingredients (a.i.): Citric acid and lactic acid (present as fermentation products of *Lactobacillus casei* strain LPT-111)
PMRA Document Number: 2913283

Purpose of Application

The purpose of this application was to reduce the rate of Tivano when applied to strawberries, and to expand the product's label to include use on greenhouse strawberries for the suppression of powdery mildew (*Sphaerotheca macularis f. sp. fragariae*) and angular leaf spot (*Xanthomonas fragariae*).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Since no changes in the formulation of Tivano were made and the human health and safety database is considered complete, no additional toxicological information was required. The changes, including rate and site of application, are consistent with registered uses of Tivano.

The potential for dietary and occupational exposure from the changes is not expected to increase, and therefore, no additional exposure information is required.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The microbial pest control agent (MPCA) is a strain of bacterium commonly used in the food industry to produce dairy products such as cheese and yogurt, and citric acid and lactic acid are naturally found in fruit, as well as used as additives in beverages such as soft drinks. The levels of the MPCA and these organic acids that would result on food crops from the use of Tivano are expected to be much lower than levels already consumed in the Canadian diet from other sources. Therefore the establishment of an MRL is not required for *Lactobacillus casei* strain LPT-111, citric acid, or lactic acid.

Environmental Assessment

Since no changes to the formulation of Tivano were made and the environmental toxicological database is considered complete, no additional environmental toxicological information was required. Previously submitted information indicates that the use of Tivano for terrestrial and greenhouse food crops does not pose an environmental risk of concern to non-target organisms if the directions on the label are followed. The changes, including rate and site of application, are consistent with registered uses of Tivano. The available information is sufficient to support the changes for Tivano.

Value Assessment

Results of five efficacy trials conducted in Canada and scientific rationales were provided to support the use of Tivano on field and greenhouse strawberry for the suppression of powdery mildew and angular leaf spot. Tivano is already registered for these uses, and the provided information demonstrated that the product suppresses powdery mildew at the reduced rate. Further, since the product is known to be effective against the pathogens on field strawberry, it is expected that the level of management will be maintained when applied on greenhouse strawberry. Based on these considerations, the uses on field and greenhouse strawberry are supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to approve the reduced rate of Tivano when applied to strawberries, and to expand the product's label to include use on greenhouse strawberries.

References

PMRA

Document

Number	Reference
2773711	2017, Response to data deficiencies, DACO: 10.2.3.3
2773712	2015, Evaluation of a new biopesticide against angular leaf spot in a commercial operation system, DACO: 10.2.3.3
2773713	2015, Evaluation of the efficacy of Tivano on angular leaf spot at different concentrations and application rates, DACO: 10.2.3.3
2881611	2018, Value summary, DACO: M10.1
2881615	2018, Efficacit du biofongicide Tivano pour le controle du blanc de la fraise en champ, DACO: M10.2.2
2881616	2018, Efficacit de Tivano en pour le controle du blanc dans la fraise, DACO: M10.2.2
2881618	2018, Evaluation of products for management of angular leaf spot in annual strawberry, 2017-2018, DACO: M10.2.2

ISSN: 1911-8082

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