

# **Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.10, 3.11**Application

**Application Number:** 2021-3103

**Application:** New End-use Product (Product Chemistry) – Guarantee, Identity

of Formulants and Proportion of Formulants, and New Product

Label – Tank Mixes and New Pests

**Product:** Tivano PLUS

**Registration Number:** 34763

Active ingredients (a.i.): Citric acid and lactic acid

PMRA Document Number: 3427119

### **Purpose of Application**

The purpose of this application was to register a commercial end-use product, Tivano PLUS, used to suppress powdery mildew and angular leaf spot on field and greenhouse strawberry.

## **Chemistry Assessment**

Tivano PLUS is formulated as a solution containing citric acid at a concentration of 1.50% and lactic acid at a concentration of 2.57%. This end-use product has a density of 1.08-1.09 g/mL and pH of 3.2-3.6. The required chemistry data for Tivano PLUS have been provided, reviewed and found to be acceptable.

#### **Health Assessments**

A detailed review of the toxicological database was conducted for Tivano PLUS. Previously reviewed toxicological data for citric acid and lactic acid were considered acceptable to characterize the hazard profile of Tivano PLUS.

Citric acid and lactic acid are of low acute toxicity, however, both lactic and citric acid are slightly irritating to the skin, and eye irritation studies indicated that, at the concentrations found in Tivano PLUS, citric and lactic acid are capable of producing moderate to severe injury to the eye, particularly with repeated or prolonged exposure. Appropriate label statements and requirements for basic personal protective equipment will minimize exposure for individuals with repeated or prolonged exposure.

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, however, the risk is acceptable provided workers follow label directions and use personal protective equipment (PPE) as instructed.



Label warnings, directions for use, and risk mitigation measures are adequate to protect users of Tivano PLUS. Overall, risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

Residential and non-occupational exposure to Tivano PLUS is expected to be low when label directions are observed. Consequently, the risk to bystanders and individuals in residential areas and the general public is acceptable.

Residues of citric acid and lactic acid on treated food crops are possible at the time of harvest. Dietary risk to humans from the use of Tivano PLUS is acceptable due to the low toxicity profile of citric acid and lactic acid. In addition, the likelihood of residues contaminating drinking water supplies is minimal and not expected to contribute to increased dietary exposure. The levels of citric acid and lactic acid that would result on food crops from the use of Tivano PLUS are expected to be much lower than levels already consumed in the Canadian diet from other sources. Therefore, the specification of a maximum residue limit (MRL) under the *Pest Control Products Act* is not required for citric acid and lactic acid.

#### **Environmental Assessment**

The registration of Tivano PLUS for use as a bactericide and fungicide on field and greenhouse strawberries does not pose any additional risk to the environment when used according to label directions.

#### **Value Assessment**

Based on formulation similarities and a set of field bridging trials, it was concluded that Tivano Plus and a precedent product are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the value of claims for suppression of powdery mildew and angular leaf spot on field and greenhouse strawberry, which are registered on the precedent product, is determined to be acceptable for Tivano Plus.

The availability of Tivano Plus will provide Canadian growers, including those that rely on non-conventional products, with an additional option to manage common and economically important fungal and bacterial diseases of strawberry grown in the field and greenhouse.

#### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to register Tivano PLUS.

# References

PMRA Document Number	Reference
3248386	2021, DACOs 3.2.1 to 3.2.3, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
3248389	2021, DACO 3.4.1-3 Enforcement Analytical Method, DACO: 3.4,3.4.1 CBI
3248391	2021, DACO 3.4.2 Analysis of [CBI Removed], DACO: 3.4,3.4.2 CBI
3248392	2021, DACOs 3.5.1 to 3.5.15, DACO: 3.5,3.5.1,3.5.11,3.5.12,3.5.13,3.5.14, 3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3248394	2021, Storage stability report, DACO: 3.5,3.5.10 CBI
3248408	2021, Manufacturing process, DACO: 3.2.2 CBI
3261486	2021, Amended DACO 3.5.5, DACO: 3.5.5 CBI
3383479	2022, Storage stability, DACO: 3.5.10 CBI
3413724	2022, Formulation process, DACO: 3.2.2 CBI
3413723	2022, Description of starting material and formulation process, DACO: 3.2.1,3.2.2 CBI
3248405	2021, Use description, DACO: 5.2 CBI
3248406	2021, Data part 4 Toxicology - Human health, DACO: 4.1,4.2,4.2.1,4.2.2, 4.2.3,4.2.4,4.2.5,4.2.6
3248322	2021, Evaluation of the efficacy of Cyclone and Cyclone PLUS against powdery mildew in greenhouse cucumber, DACO: 10.2.3.3
3248327	2021, Efficacy trial summary Tomato, DACO: 10.2.3.3
3248329	2021, Evaluation de differentes formulations pour le controle du blanc dans le concombre en serre., DACO: 10.2.3.3
3248333	2021, Evaluer l'impact d'un bioproduit non fermente dans le controle du blanc dans le concombre en serre., DACO: 10.2.3.3
3248375	2021, DACO 10.1 Value Summaries, DACO: 10.1
3248379	2021, DACO 10.3.1 Non-Safety adverse effects, DACO: 10.3,10.3.1
3248413	2021, Evaluation of the efficacy of Tivano and Tivano PLUS on Angular Leaf Spot at different concentrations and application rates, DACO: 10.2.3.3
3248414	2021, Efficacite de biofongicides a base d'acide citrique et acide lactique pour le controle du blanc dans la fraise, DACO: 10.2.3.3
3248415	2021, Evaluation of the activity of organic acids based bioproduct on black rot ( <i>Guignardia bidwellii</i> ), DACO: 10.2.3.3
3248416	2021, Efficacy Summary Table of the submitted trials for Tivano and Tivano PLUS, DACO: 10.2.3.3
3354194	2022, Response to deficiencies Value Bioprotec Garden and Ornamentals RTU, DACO: 10.1,10.2.3.3
3354199	2022, Efficacy of Biofungicide as a foliar fungicide in the control of late season Powdery mildew in Chardonnay grapes, DACO: 10.2.3.3
3354200	2022, Evaluation of a biofungicide for <i>Erysiphe necator</i> ( <i>Uncinula necator</i> ) (Blanc, Oidium), Powdery Mildew Management in <i>Vitis vinifera</i> , DACO: 10.2.3.3

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