

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.10, 3.11, 3.12 Application

Application Number: 2021-3102

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

of Formulants and Proportion of Formulants, and New Product

Label – Tank Mixes, New Pests and New Site or Host

Product: Cyclone PLUS

Registration Number: 34762

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

PMRA Document Number: 3425524

Purpose of Application

The purpose of this application was to register a commercial end-use product, Cyclone PLUS, for use against certain fungal or bacterial diseases on a range of fruit or vegetable crops grown in the greenhouse and/or field, outdoor/greenhouse ornamentals as well as indoor/field-grown cannabis and field-grown hemp.

Chemistry Assessment

Cyclone PLUS is formulated as a solution containing citric acid at a concentration of 1.41% and lactic acid at a concentration of 2.54%. This end-use product has a density of 1.07-1.08 g/cm³ and pH of 3.2-3.6. The required chemistry data for Cyclone PLUS have been provided, reviewed and found to be acceptable.

Health Assessments

A detailed review of the toxicological database was conducted for Cyclone PLUS. Previously reviewed toxicological data for citric acid and lactic acid were considered acceptable to characterize the hazard profile of Cyclone 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 Cyclone 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 Cyclone 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 Cyclone 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 Cyclone 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 Cyclone 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 Cyclone PLUS for use as a bactericide and fungicide on terrestrial food crops, greenhouse food and non-food crops, terrestrial non-food and non-feed seed and fibre crops, and outdoor ornamentals, does not pose any additional risk to the environment when used according to label directions.

Value Assessment

The efficacy and crop safety of Cyclone PLUS was compared to that of the precedent products in field and greenhouse bridging trials. Based on this comparison, as well as additional apple and grape field efficacy trials, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the value of all claims registered on the precedent products as well as claims to suppress fireblight on apple and powdery mildew on grape is determined to be acceptable for Cyclone PLUS.

The availability of Cyclone 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 on certain fruit, vegetable, ornamentals, cannabis and hemp crops grown in the field, greenhouse and/or indoors.

Conclusion

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

References

PMRA Document	Reference
Number 3248291	2021, Description of Starting Materials, DACOs 3.2.1 to 3.2.3, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
3248294	2021, Enforcement Analytical Method, DACO 3.4.1 and 3.4.2, DACO: 3.4,3.4.1,3.4.2 CBI
3248295	2021, DACO 3.4.2 Analysis of [CBI Removed], DACO: 3.4,3.4.2 CBI
3248298	2021, Storage stability report, DACO: 3.5,3.5.10 CBI
3248343	2021, Cyclone Plus Manufacturing process, DACO: 3.2.2 CBI
3248345	2021, Enforcement analytical methodology, protocole de dosage d'acide lactique et d'acide citrique par spectrophotométrie, DACO: 3.4,3.4.1 CBI
3260696	2021, Amended DACO 3.5.5, DACO: 3.5.5 CBI
3329248	2022, Additional part 3 chemistry data, DACO: 3.0 CBI
3374973	2022, Storage stability, DACO: 3.5.10 CBI
3413663	2022, Description of starting materials and formulation process, DACO: 3.2.1,3.2.2 CBI
3413664	2022, Formulation process, DACO: 3.2.2 CBI
3248341	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
3264569	2021, Amended DACO 5.2, DACO: 5.2
3264570	2021, DACO 7.4.1 Supervised residue trial study, DACO: 7.4.1
3264571	2021, DACO 7.8.1 Other study/Pyrolysis Study, DACO: 7.8
3248280	2021, DACO 10.1 Value Summaries, DACO: 10.1
3248284	2021, DACO 10.3.1 Non-Safety adverse effects, DACO: 10.3,10.3.1
3248322	2021, Evaluation of the efficacy of Cyclone and Cyclone PLUS against powdery mildew in greenhouse cucumber, DACO: 10.2.3.3
3248324	2021, Evaluation de biofongicides pour lutter contre le mildiou dans le concombre de champ en regie biologique, DACO: 10.2.3.3
3248325	2021, Evaluation of Cyclone PLUS for efficacy against Powdery Mildew on grapevines; Phelps, NY 2017, DACO: 10.2.3.3
3248326	2020, Evaluating fungicides for control anthracnose fruit rot in blueberries, 2020., DACO: 10.2.3.3
3248327	2021, Efficacy trial summary Tomato, DACO: 10.2.3.3
3248328	2021, Summary efficacy trials excel table, 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
3248330	2021, Evaluation de concentration reduite de Cyclone PLUS pour le controle du blanc dans la culture du concombre de serre, DACO: 10.2.3.3
3248331	2021, Evaluation de bioproduits non fermente pour le controle du blanc dans le concombre en serre., DACO: 10.2.3.3

3248332	2021, Evaluer l'impact d'un bioproduit non fermente dans 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
3248334	2018, Evaluation of bactericide programs for the management of fire blight on 'Gala' apples in NY, 2018., DACO: 10.2.3.3
3248335	2021, Evaluation of Different Products for Fire Blight Management, DACO: 10.2.3.3
3248336	2021, Evaluation of Cyclone PLUS for Fire Blight Management in PNW, DACO: 10.2.3.3
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
3354186	2022, Response to deficiencies Value Cyclone PLUS, DACO: 10.1,10.2.3.3
3354187	2022, Efficacy of Biofungicide as a foliar fungicide in the control of late season Powdery mildew in Chardonnay grapes, DACO: 10.2.3.3
3354188	2022, Evaluation of a biofungicide for Erysiphe necator (<i>Uncinula necator</i>) (Blanc, Oidium), Powdery Mildew Management in <i>Vitis vinifera</i> , DACO: 10.2.3.3
3354189	2022, Excel summary efficacy data, DACO: 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
3378749	2022, DACO 10, DACO: 10.1

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.