

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2021-3119
Application: New End-Use Product (Product Chemistry) – Guarantee, Identity of Formulants and Proportion of Formulants
Product: Cyclone Cannabis
Registration Number: 34767
Active ingredients (a.i.): Citric acid and lactic acid
PMRA Document Number: 3426241

Purpose of Application

The purpose of this application was to register a domestic end-use product, Cyclone Cannabis, for use against powdery mildew on indoor/field-grown cannabis and hemp.

Chemistry Assessment

Cyclone Cannabis 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/mL and pH of 3.2-3.6. The required chemistry data for Cyclone Cannabis have been provided, reviewed and found to be acceptable.

Health Assessments

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

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 Cannabis, 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 Cannabis. Overall, risks to domestic users are acceptable when the precautionary statements on the labels are followed which include PPE.

Residential and non-occupational exposure to Cyclone Cannabis 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 Cannabis 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 Cannabis 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 Cannabis for use as a fungicide on terrestrial food crops and greenhouse food crops 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 Cyclone Cannabis and a precedent product are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the value of the claim to suppress powdery mildew on indoor and field-grown cannabis and hemp, which is registered on the precedent product, is determined to be acceptable for Cyclone Cannabis.

The availability of Cyclone Cannabis will provide Canadian domestic cannabis and hemp growers with a product to manage a common and important fungal disease of cannabis and hemp crops grown in the field and indoors.

Conclusion

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

References

PMRA Document Number	Reference
3248601	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
3248604	2021, Enforcement Analytical Method, DACO 3.4.1 and 3.4.2, DACO: 3.4,3.4.1,3.4.2 CBI
3248605	2021, DACO 3.4.2 Analysis of [CBI Removed], DACO: 3.4,3.4.2 CBI
3248606	2021, Chemical and Physical Properties of the technical grade active ingredient, 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
3248608	2021, Storage stability report, DACO: 3.5,3.5.10 CBI
3248625	2021, Manufacturing process, DACO: 3.2.2 CBI
3248627	2021, Protocole de dosage d'acide lactique et d'acide citrique par spectrophotometrie, DACO: 3.4,3.4.1 CBI
3266361	2021, Amended DACO 3.5.5, DACO: 3.5.5 CBI
3375036	2022, Storage stability, DACO: 3.5.10 CBI
3413671	2022, Formulation process, DACO: 3.2.2 CBI
3413670	2022, Description of starting material and formulation process, DACO: 3.2.1,3.2.2 CBI
3248623	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
3264575	2021, Amended DACO 5.2, DACO: 5.2
3264577	2021, DACO 7.4.1 Supervised residue trial study, DACO: 7.4.1
3264579	2021, DACO 7.8.1 Other study/Pyrolysis Study, DACO: 7.8
3248280	2021, DACO 10.1 Value Summaries, DACO: 10.1
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
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
3248333	2021, Evaluer l'impact d'un bioproduct non fermente dans le controle du blanc dans le concombre en serre., 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
3248590	2021, DACO 10.1 Value Summaries, DACO: 10.1
3248594	2021, DACO 10.3.1 Non-Safety adverse effects, DACO: 10.3,10.3.1

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