Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2023-3635
Application: New End-Use Product (Product Chemistry) - Guarantee
Applicant: OCION Water Sciences Inc.
Product: Harvest Miracle
Registration Number: 35639
Active ingredient (a.i.): Copper (present as copper sulfate pentahydrate)
PMRA Document Number : 3750711

Purpose of Application

The purpose of this application was to register a new commercial fungicide end-use product, Harvest Miracle, for use against powdery mildew on certain field crops, including cannabis and industrial hemp.

Chemistry Assessment

Harvest Miracle is formulated as a solution containing copper (present as copper sulfate pentahydrate) at a concentration of 0.97%. This end-use product has a density of 1.020 – 1.050 g/mL and a pH of 1.0 – 1.5. The required chemistry data for Harvest Miracle have been provided, reviewed and found to be acceptable.

Health Assessment

Harvest Miracle is of slight acute toxicity by the oral route of exposure, low acute toxicity by the dermal and inhalation routes of exposure, corrosive to eyes and skin, and not a skin sensitizer. Due to its corrosivity, Harvest Miracle is considered irritating to the respiratory tract.

Occupational risk to individuals is acceptable when Harvest Miracle is used according to label directions. Precautionary and personal protective equipment statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander and residential exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no food or drinking water exposure concerns when the product is used according to label directions.

Foliar application of Harvest Miracle is permitted on outdoor cannabis and industrial hemp only during the vegetative stage.

Maximum Residue Limit (MRL)

Canada

As part of the assessment process prior to the registration of a pesticide, Health Canada's PMRA must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Health Canada has established a maximum residue level of 50 ppm for copper on fresh fruits and vegetables, and this applies to the uses of Harvest Miracle.

Environmental Assessment

The use of Harvest Miracle to control or suppress powdery mildew on various terrestrial food crops, cannabis, and industrial hemp is within the currently registered use pattern for copper. The risk is acceptable when Harvest Miracle is used in accordance with the label, which includes statements and spray buffer zones to mitigate risks to the environment.

Value Assessment

Use history information related to a comparable product previously registered in the United States by the same applicant was used to support the value of efficacy claims for Harvest Miracle against powdery mildew on certain field crops when applied according to the labelled use directions. The registration of Harvest Miracle will provide Canadian growers an alternative product with a low risk for pathogen resistance development that can be used as part of an integrated disease management program.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support registration of Harvest Miracle.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2209124	2012, 3.5.6 - 3.5.15 RWH, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.6,3.5.7, 3.5.8,3.5.9 CBI
2831383	2016, Product Chemistry, Accelerated Storage Stability, Corrosion Characteristics Testing of OCION PX10, DACO: 2.14.14,2.14.2,3.5.1, 3.5.10,3.5.14,3.5.2,3.5.5,5.13 CBI
2831385	2016, Physical and Chemical Properties Testing of OCION PX10, DACO: 2.14,2.14.15,2.14.6,3.5.11,3.5.9 CBI
2989849	2018, OCION BLUE_Chemistry_LabResults, DACO: 3.4,3.5.6,3.5.7,3.5.9 CBI
3513037	2023, Description Of The Formulation Process, DACO: 3.2.2

3513038	2023, Chemistry Requirements for the Registration of Manufacturing Concentrates (MA) and End-Use Products (EPs), DACO: 3.1.1,3.1.2,3.1.3, 3.1.4,3.2.1,3.2.2,3.3.1,3.4.1,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14, 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
3547171	2024, Harvest Miracle_December_2023, DACO: 3.0,3.4,3.4.1,3.5,3.5.1,3.5.10,3.5.11, 3.5.13,3.5.14,3.5.2,3.5.6,3.5.7,3.5.9
2831380	2016, Method Validation for the Assay Determination of Copper in OCION PX10 by ICP-OES, DACO: 2.0,2.13.1,2.13.2 CBI
3486084	2022, Evaluation of Harvest Miracle for Management of Powdery Mildew (Golovinomyces cichoracearum) on Cannabis (Cannabis sativa L.), DACO: 10.2.2, 10.2.3.1,10.2.3.2,10.3.1
3486085	2023, List of conventional and non-conventional registered pesticides for use on cannabis, DACO: 10.5.1
3547175	2024, Harvest Miracle_December 2023, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1, 10.2.3.2,10.2.3.3,10.2.3.4,10.3.1,10.3.2,10.4,10.5.5
3619123	2024, Value Summary and Efficacy, DACO: 10.1,10.2
3627713	2024, Harvest Miracle_August 2024, DACO: 10.2.4
3486088	2023, Acute Studies - End-Use Products, DACO: 4.6,4.6.1,4.6.3,4.6.4,4.6.5,4.6.6
3513039	2023, Toxicology Profile, DACO: 4.1,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6
3513047	2022, Evaluation of copper residue levels in cannabis (Cannabis sativa L.) plants treated with sprays of copper sulphate pentahydrate (Harvest Miracle), DACO: 10.2.3.3,7.8
3547172	2024, Harvest Miracle_December 2023, DACO: 5.1,5.2,5.3,5.4,5.5,5.6,5.6(A),5.6(B),5.7
3619115	2024, 7.8 Other Studies/Data/Reports, DACO: 7.8
3619117	2024, Use Description/Scenario (Application and Post Application), DACO: 5.2
3619120	2019, Acute eye irritation / Corrosion study of OCION PX10 in New Zealand White Rabbits., DACO: 4.6.4
3677824	2025, Harvest Miracle_January, 2025, DACO: 10.2
3708483	2025, Harvest Miracle_April, 2025, DACO: 5.2
3708484	Nadia Delavarpour, Cengiz Koparan, Yu Zhang, Dean D. Steele, Kelvin Betitame, Sreekala G. Bajwa, Xin Sun. 2023. A review of the current unmanned aerial vehicle sprayer applications in precision agriculture. Journal of the ASABE. 66:703-721, DACO: 5.2
3708973	Xuan Li, D Ken Giles, John T Andaloro, et. al. 2021 Comparison of UAV and fixed-wing aerial application for alfalfa insect pest control: evaluating efficacy, residues, and spray quality. Pest Manag Sci 2021, 77. DACO: 5.2

B. Additional Information Considered

i) Published Information

PMRA Document Number	Reference

3738334	European Union (EU), 2007, Chapter 4.1.2 - Human Health Effects, in European Union Voluntary Risk Assessment Report Copper, Copper II Sulphate Pentahydrate, Copper(I)Oxide, Copper(II)Oxide, Dicopper Chloride Trihydroxide, DACO: 4.6.3
3738336	European Chemicals Agency (ECHA), 1994, Skin sensitization study - study summary from ECHA registration dossier for copper sulphate pentahydrate, DACO: 4.6.6
3738337	Jones, C. and J. Nelson, 2018, Multi-Element Analysis of Cannabis Using ICP-MS. Agilent Technologies, USA, pp. 1–8, DACO: 7.4.1