

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1804
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment
Product: HyCop Fungicide
Registration Number: 34645
Active ingredient (a.i.): Copper, present as copper hydroxide
PMRA Document Number: 3387690

Purpose of Application

The purpose of this application was to register a new commercial end-use product, HyCop Fungicide, for the control of labelled fungal diseases on various feed/food crops, based on a precedent product.

Chemistry Assessment

HyCop Fungicide is formulated as a wettable granule containing copper (present as copper hydroxide) at a concentration of 50%. This end-use product has a density of 0.34 g/mL and pH of 9.57. The required chemistry data for HyCop Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

HyCop Fungicide is of high acute oral toxicity, low acute dermal toxicity, and moderate acute inhalation toxicity. It is extremely irritating/corrosive to the eyes, not irritating to the skin, and is not a dermal sensitizer.

Occupational exposure to individuals handling HyCop Fungicide is not expected to result in health risks of concern when the product is used according to label directions. Precautionary and personal protective equipment statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any potential risk due to occupational exposure.

Bystander and residential exposure is not expected to result in health risks of concern when the product is used according to label directions.

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 a MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA has determined that the currently established MRL of 50 ppm for copper is considered adequate to cover residues of copper from copper (present as copper hydroxide) in/on the supported commodities. Residues of copper from copper (present as copper hydroxide) in terrestrial food crops at the established MRL will not pose an unacceptable risk.

Environmental Assessment

The uses on the HyCop Fungicide label are within the currently registered use pattern of the active ingredient copper. Therefore, no additional risk is expected when HyCop Fungicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

HyCop Fungicide is similar to the precedent products. Therefore, all claims for field uses included in the registration of the precedent products are acceptable for HyCop Fungicide.

The availability of HyCop Fungicide will provide Canadian growers with an additional product to manage common and economically important diseases on labelled crops grown in the field.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of HyCop Fungicide.

References

PMRA Document Number	References
3120181	2020, DACO 3 Extras - HyCop Fungicide (Parent), DACO: 3.1.1,3.1.2,3.1.3, 3.1.4,3.5.13,3.5.14,3.5.15,3.5.5
3120189	2016, Copper Hydroxide 50% WP - Determination of Explosive Properties, DACO: 3.5.12
3120191	2017, Copper Hydroxide 50% WP - Part III: Evaluation of Physiochemical Properties After Second Year of Storage, DACO: 3.5.1,3.5.10,3.5.2, 3.5.3, 3.5.5,3.5.6,3.5.7
3120192	2017, Copper Hydroxide 50% WP - Part II: Evaluation of Physiochemical Properties After First Year of Storage, DACO: 3.5.1,3.5.10,3.5.2,3.5.3,3.5.5, 3.5.6,3.5.7
3120193	2016, Copper Hydroxide 50% WP - Method Development and Validation for Determination of the Content of Active Substance in the Formulation, DACO: 3.4.1
3120196	2016, Copper Hydroxide 50% WP - Determination of Flammability, relative self-ignition temperature and oxidizing properties, DACO: 3.5.11,3.5.8
3120197	2020, Manufacturing Description - HyCop Fungicide, DACO: 3.2.1,3.2.2,3.2.3 CBI
3371764	2016, Copper Hydroxide 50% WP: Acute Oral Toxicity Study (Acute Toxic Class Method) in Wistar Rats, DACO: 4.6.1
3371765	2016, Copper Hydroxide 50% WP: Acute Dermal Toxicity Study in Wistar Rats, DACO: 4.6.2
3371767	2017, Copper Hydroxide 50% WP: Acute Eye Irritation/ Corrosion Study in New Zealand White Rabbits, DACO: 4.6.4
3371768	2017, Copper Hydroxide 50% WP: Acute Dermal Irritation/ Corrosion Study in New Zealand White Rabbits, DACO: 4.6.5
3371769	2017, Copper Hydroxide 50% WP: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs, DACO: 4.6.6
3373466	2019, Copper Hydroxide 50% WP: Acute Inhalation Toxicity Study in Wistar Rats, DACO: 4.6.3

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