Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2017-2974
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: NU-COP 30HB
Registration Number: 33329
Active ingredient (a.i.): Copper, present as copper hydroxide
PMRA Document Number : 2933359

Purpose of Application

The purpose of this application was to register NU-COP 30HB, containing Copper, present as copper hydroxide for use on field crops and greenhouse food crops, based on a registered precedent.

Chemistry Assessment

NU-COP 30HB is formulated as a dry flowable containing copper, present as copper hydroxide at a concentration of 30%. This end-use product has a density of 0.7-0.8 g/mL and pH of 7.83. The required chemistry data for NU-COP 30HB have been provided, reviewed and found to be acceptable.

Health Assessments

Potential exposure to copper hydroxide may occur by applying the end use product, entering treated sites, or consuming food and water. PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Registration is only supported for uses that are determined as having no health risks of concern.

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed.

NU-COP 30HB is highly acutely toxic by the oral route, of low acute toxicity by the dermal route, is severely irritating to the eyes, minimally irritating to the skin, but not a dermal sensitizer.

Occupational exposure to individuals handling NU-COP 30HB 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 exposure is not expected to result in health risks of concern when the product is used according to label directions.

Residential and non-occupational exposure is not expected to result in health risks of concern when the product is used according to label directions.

Maximum Residue Limit

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 specified MRL of 50 ppm for copper is considered adequate to cover residues of copper from copper, present as copper hydroxide, in/on these commodities, as a result of the use of NU-COP 30HB. 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

Use of NU-COP 30HB for control of fungal diseases on labelled field and greenhouse crops is not expected to pose additional environmental concerns over those of the registered precedent product.

Value Assessment

Efficacy data were provided from two bridging trials on dry beans where the performance against halo blight was assessed for both NU-COP 30HB and the precedent product. Assessments of phytotoxicity were also conducted in both trials.

Based on the results from the confirmatory efficacy trials, the registration of NU-COP 30HB Fungicide is supported from a value perspective. This product will provide growers with an additional copper product to manage bacterial and fungal diseases on certain vegetable and potato crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of NU-COP 30HB.

References

2773750	2017, Additional Product Chemistry for NU-COP 30HB CBI, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5 CBI
2773751	2017, Additional Product Chemistry for NU-COP 30HB Parent, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5
2773760	2014, Summary of OPPTS 830.1000 Series Product Properties Test Guidelines, DACO: 3.5.11,3.5.12,3.5.13,3.5.15,3.5.9,3.6
2773761	2014, Copper Hydroxide 30% DF: Enforcement Analytical Method for the Determination of Copper Hydroxide by Titration, DACO: 3.4.1
2773762	2014, Copper Hydroxide 30% DF: Physical and Chemical Characteristics: Color, Physical State, Odour, Oxidation/Reduction, pH, and Density/Bulk Density, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8
2773763	2014, Copper Hydroxide 30% DF: Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
2773764	2014, Product Identity and Composition, DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3, 3.4,3.4.1 CBI
2926193	2014, Copper Hydroxide 30% DF Acute Oral Toxicity - Up-And-Down Procedure in Rats, Data Numbering Code: 4.6.1
2926194	2014, Copper Hydroxide 30% DF Acute Dermal Toxicity in Rats, Data Numbering Code: 4.6.2
2926195	2014, Copper Hydroxide 30% DF Acute Inhalation Toxicity in Rats, Data Numbering Code: 4.6.3
2926196	2014, Copper Hydroxide 30% DF Primary Skin Irritation in Rabbits, Data Numbering Code: 4.6.5
2926197	2014, Copper Hydroxide 30% DF Dermal Sensitization Test in Guinea Pigs - Buehler Method, Data Numbering Code: 4.6.6
2926198	2014, Copper Hydroxide 30% DF Primary Eye Irritation Study in Rabbits, Data Numbering Code: 4.6.4
2828647	2017, Phytotoxicity and Yield for Albaugh Generic Copper Fungicide on Beans , DACO: 10.2.3.3
2828648	2017, Phytotoxicity and Yield for Albaugh Generic Copper Fungicide on Beans , DACO: 10.2.3.3

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