

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.2.6, B.3.1, B.3.11, B.3.12 Application

Application Number: 2009-3274
Application: Changes EP Product Chemistry-Guarantee, Identity, Proportion of Formulants, New combination of TGAIs
Changes to Product Labels – Application Rate Increase, New Pests, New Site
Product: Kocide 3000
Registration Number: 30343
Active ingredients (a.i.): copper as elemental (present as copper sulphate and copper hydroxide)
PMRA Document Number: 2306556

Purpose of Application

The purpose of this application was to register a new end-use product Kocide 3000, using Kocide 2000 (PCP 27348) as a partial precedent as a fungicide for terrestrial food crops.

Chemistry Assessment

Kocide 3000 is a granular solid containing the active copper, present as copper hydroxide at a concentration of 30% nominal. This product has a density of 0.54-0.70 g/cm³ and a pH of 7.5-9.5. The chemistry requirements for Kocide 3000 have been completed.

Health Assessments

In rats, Kocide 3000 is slightly toxic by the acute oral route (LD₅₀ = 1847 mg/kg bw), but of low toxicity by dermal and inhalation routes. It is mildly irritating to rabbit eyes and non-irritating to rabbit skin. Kocide 3000 is not a potential skin sensitizer in guinea pigs.

The application rates for each crop are less than those that are registered on the Kocide 2000 Fungicide label. All other aspects of the use pattern are the same between the two products. As such, the disposition, translocation and magnitude of the copper residues is not expected to increase and the dietary exposure to residues resulting from the new formulation will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Use of the new end-use product, Kocide 3000, should not result in unacceptable exposure when compared to the currently registered use pattern for the active ingredient, copper. No risks of concern are expected provided workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

Three end use products, Kocide 2000 (Reg No. 27348), Kocide 101 (Registration Number 14417) and Kocide DF (Registration Number 24538) with copper hydroxide as technical active are currently registered for use on beans, peppers (greenhouse and field), potatoes and tomatoes (greenhouse and field) by ground applications. The proposed application rates for the new formulation, Kocide 3000 Fungicide, are lower than those of the registered products and also the method of application and the crops are the same. The use of new formulation product, Kocide 3000, is therefore, not expected to pose any additional environmental concerns.

Value Assessment

Three field trials tested the efficacy of Kocide 3000 against bacterial spot on bell peppers, bacterial spot on tomatoes and septoria leaf spot on tomatoes. The tested rates were close to or below the lower proposed rate for the corresponding disease claim. Kocide 3000 did significantly reduce disease severity in each trial, with levels of protection ranging between 38% and 66%, which corresponds at best to a suppressive effect. The Kocide 3000 reduced rates were not compared with the Kocide 2000 registered rates in the data package, and Kocide 3000 did not perform up to the expected efficacy standards required to support a control claim.

Considering that lower rates of Kocide 3000 still showed a suppressive effect on three major pest/crop combinations, and had a consistent and positive impact on yield and defoliation, the registration of Kocide 3000 for suppression of the labelled diseases can be supported on a conditional basis. Additional data are required to fully support Kocide 3000 for suppression of the labelled pathogens. Label claims may be upgraded to control if supportive evidence is provided by the applicant.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of Kocide 3000 and has found the information sufficient to support conditional registration of the new end-use product.

References

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