

Evaluation Report for Category B, Subcategory 2.3 & 2.4 Application

Application Number: 2013-1666

Application: New / Changes EP Product Chemistry-Identity and Proportion of

Formulants

Product: Quadris Top

Registration Number: 30518

Active ingredients (a.i.): azoxystrobin and difenoconazole

PMRA Document Number: 2419706

Background

Quadris Top is a fungicide containing the active ingredients azoxystrobin and difenoconazole. It is registered for use as a foliar application on a variety of crops. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this application was to amend the registration of Quadris Top to include two alternate formulations of the product.

Chemistry Assessment

Quadris Top is a suspension containing the active ingredients azoxystrobin and difenoconazole at a nominal concentration of 200 g/L and 125 g/L, respectively. This product has a density between 1.102 and 1.117 g/mL and pH between 6.7 and 7.8. The chemistry requirements for Quadris Top have been fulfilled.

Health Assessments

The changes to Quadris Top resulted in alternate formulations that are toxicologically equivalent to the original formulation. Subsequently, no toxicological data were provided or are required.

Occupational and dietary exposure assessments were not required for this application.

Environmental Assessment

The changes in the formulation of Quadris Top are not expected to increase the environmental exposure relative to similar registered products. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment



The two alternate formulations were determined to be biologically equivalent to the original formulation based on 1) direct evidence from seven replicated field trials conducted in 2012 in which the performance of the first alternate formulation was shown to be similar to the original formulation and, 2) the similarity in composition of alternate formulation 2 to that of alternate formulation 1. There was no evidence of crop injury for either the original or the first alternate formulation. The value of registering alternate formulations, such as for Quadris Top, is that multiple formulations can be expected to help the pest control product manufacturer ensure continuity of supply in the marketplace as a result of changing price points and availability of formulants.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the submitted information is adequate to amend the registration of Quadris Top to include two new alternate formulations.

References

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