

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2015-4795
Application: Conversion to fulfill conditions of registration on a product with full registration
Product: Zequanox Biological Quagga and Zebra Mussel Control
Registration Number: 30486
Active ingredients (a.i.): *Pseudomonas fluorescens* strain CL145A
PMRA Document Number: 2695716

Background

Zequanox Biological Quagga and Zebra Mussel Control was granted full registration in 2012. There was outstanding data for product characterization and analysis identified, which has now been provided.

Purpose of Application

The purpose of this application was to provide the outstanding information identified in 2012.

Chemistry Assessment

Marrone Bio Innovations has provided information to fulfil the registration requirements for Zequanox Biological Quagga and Zebra Mussel Control. A new formulating site of this end-use product (EP) was also proposed.

Dry cell weight data were provided for batches of the EP produced using the technical grade active ingredient (TGAI) produced by the alternate site of manufacture and formulated at the new site of formulation.

Cell viability count, bioactivity and microbial contaminant analysis data were submitted for batches of EP formulated at the new site using TGAI produced at both sites of manufacture. The data indicated that although the active ingredient *Pseudomonas fluorescens* strain CL145A had been inactivated, the EP retained activity against quagga mussels. Levels of microbial contamination were within the limits imposed by the OECD issue paper on microbial contaminants in microbial pesticide products [ENV/JM/MONO(2011)43].

Storage stability data were provided for only one batch of EP. Significant seasonal variability was observed. The data were only sufficient to support a six month storage period at 4°C. The physical and chemical properties of EP formulated at the new site were provided and were consistent with what is currently registered. The data were sufficient to fulfill the registration requirements and to support the registration of the proposed formulating sites.

Health, Environmental and Value Assessments

Health, Environmental and Value Assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has reviewed the information provided and is able to continue to support the full registration for Zequanox Biological Quagga and Zebra Mussel Control, with no further outstanding data.

References

PMRA Document Number	Reference
2147788	2012, DACO: M2.9.1 Title: Product specifications, DACO: M2.12,M2.9.1 CBI
2563843	2015, 5-Batch Analysis of MBI-401 EP Produced at Marrone Michigan Manufacturing and CinChemPro, DACO: M2.9.2,M2.9.3 CBI
2605016	2016, MBI-401 SDP Storage Stability and Corrosion Characteristics Study, DACO: M2.11 CBI
2658465	2016, 2.9.2, 2.9.3, DACO: M2.9.2,M2.9.3 CBI
2658466	2016, MBI-401 SDP Batch Analysis Report - Wisconsin Bio (TGAI) /CinChemPro (SDP), DACO: M2.9.2,M2.9.3 CBI
2658472	2016, 2.9.2, 2.9.3, DACO: M2.9.2,M2.9.3 CBI

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