



Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2013-5087
Application: New/Changes Product Chemistry – Identity and Proportion of Formulants
Product: Met52 EC Bioinsecticide
Registration Number: 30829
Active ingredients (a.i.): *Metarhizium anisopliae* (strain F52)
PMRA Document Number : 2381885

Purpose of Application

The purpose of this application was to change the formulation of Met52 EC Bioinsecticide (Registration Number 30829, 2.0×10^9 *Metarhizium anisopliae* Strain F52 colony forming units/mL) to increase storage stability of the product. No changes in guarantee, sites, pests, doses/rates and/or label claims were requested.

Chemistry Assessment

The characterization data submitted to support the proposed new formulation was complete and was also found to support the revised storage claim. No further data are required for the product characterization and analysis assessment.

Health Assessments

In an acute dermal toxicity study, groups of 8 – 9 week old, Sprague-Dawley rats (five per sex) were dermally exposed to 5000 mg/kg body weight of Met52 EC Bioinsecticide for 24 hours to an area of approximately 10% of the total body surface area. Following exposure, the animals were observed for a period of 14 days. The dermal LD₅₀ is > 5000 mg/kg bw in male and female rats. Met52 EC Bioinsecticide is of low toxicity via the dermal route. There were no treatment related clinical signs other than dermal irritation. There were no treatment related necropsy findings or changes in body weight. This acute dermal toxicity study is classified as acceptable. This study satisfies the guideline requirement for an acute dermal toxicity study in the rat.

In a primary dermal irritation study, young adult New Zealand albino rabbits (three females) were dermally exposed to 0.5 mL of Met52 EC Bioinsecticide for four hours to a 6 cm² body surface area. Animals then were observed for three days. Irritation was scored by the method of Draize. Very slight erythema and very slight edema occurred in two animals. All animals were free of dermal irritation by the 72 hour interval. Met52 EC Bioinsecticide is slightly irritating to the skin based on the one hour maximum irritation score of 1.33 (maximum possible score of eight). This study is classified as acceptable. This study satisfies the guideline requirement for a primary dermal irritation study in the rabbit.

As a result of the assessment of the dermal toxicity and dermal irritation studies as well as an assessment of the formulation ingredients contained in Met52 EC Bioinsecticide, it was concluded that the occupational and bystander exposure and food exposure assessments did not need to be amended.

No further data are required to assess human health and safety testing, occupational, and bystander exposure, or food and feed residue exposure.

Environmental Assessment

As a result of the assessment of the formulation ingredients contained in Met52 EC Bioinsecticide, the environmental fate and toxicology assessments did not need to be amended. No further data are required to assess environmental fate or environmental toxicology.

Value Assessment

Four trials against whiteflies and thrips on greenhouse tomato, pepper, and strawberry demonstrated that the new Met52 EC Bioinsecticide formulation provided levels of control similar to the currently registered formulation with no observed phytotoxicity. Given the results of the four greenhouse crop trials and the broad spectrum of *Metarhizium anisopliae* Strain F52, it is expected that the proposed formulation would have similar levels of control of ticks and hairy chinch bugs and phytotoxicity to turf as the registered formulation.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product Met52 EC Bioinsecticide, and has found the information sufficient to support the new formulation.

References

PMRA Document Number	Reference
2347078	2013. Storage Stability Study for Met52 EC (2166) (PCP# 30829). DACO M2.11, M2.12. CBI
2347077	2012. Met52 EC/Tick-EX EC (2166) Product Chemistry. DACO M2.12.
2347089	2013. Met52 EC Manufacturing Process. DACO M2.8 CBI
2347076	2013. Summary of human health and safety testing. DACO M4.1.
2347075	2013. Met52 EC bioinsecticide: Acute Dermal Toxicity Study in Rats – Limit Test. DACO M4.4.
2347074	2013. Met52EC (2166): Primary Skin Irritation Study in Rabbits. DACO M4.5.2.
2347067	2012, Insecticide Efficacy and Selectivity of MET52 OD (NZBBA2110 and NZBBA2166) Against Whitefly (<i>Trialeurodes sp.</i>) on Protected Tomato (Greenhouse) in Spain in 2012, DACO: M10.2.2

2347068	2012, Insecticide Efficacy and Selectivity of MET52 OD (NZBBA2110, NZBBA2160 and NZBBA2166) on Thrips (<i>Thrips tabaci</i>) on Protected Pepper (Greenhouse) in Spain in 2012, DACO: M10.2.2
2347070	2012, Insecticide Efficacy and Selectivity of MET52 OD (NZBBA2110, NZBBA2160 and NZBBA2166) Against Whitefly (<i>Trialeurodes sp.</i>) on Protected Tomato (Greenhouse) in Spain in 2012, DACO: M10.2.2
2347072	2012, Study on the Efficacy of MET52 OD (NZBBA2110, NZBBA2160 and NZBBA2166) on Thrips (<i>Frankliniella occidentalis</i>) on Strawberry in Spain in 2012, DACO: M10.2.2

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