Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.11 Application

Application Number: 2023-0007
Application: Category B.3.11 (Addition of new pest)
Product: Avodigen
Registration Number: 33311
Active ingredients (a.i.): *Bacillus licheniformis* strain FMCH001, *Bacillus subtilis* strain FMCH002
PMRA Document Number: 3461479

Background

Avodigen is a seed-applied biological fungicide/nematicide that contains the active ingredients *Bacillus licheniformis* strain FMCH001 and *Bacillus subtilis* strain FMCH002. Both are common soil organisms that colonize the root surface during root growth and promote the growth of healthy root systems. The bacteria produce secondary metabolites that are believed to have antagonistic properties against fungal pathogens and deter pathogenic nematodes. Avodigen is registered to partially suppress seed rot and seedling blight on corn, soybean, canola, mustard, rapeseed and sunflower and root knot nematodes on corn and soybean. For specific details on registered uses, application rates, methods, precautions, and restrictions, refer to the product label.

Purpose of Application

The purpose of this application was to add a claim of partial suppression of seed rot and seedling blight caused by *Fusarium* spp. on corn and soybean to the label of Avodigen at the currently registered rates (i.e. 8.7 mL/seed unit-corn; 15.2 mL/seed unit-soybean). The applicant also proposed the addition of a claim to partially suppress root lesion nematode on corn at the registered rate of 8.7 mL/seed unit (80,000 seeds) to the Avodigen label.

Chemistry Assessment, Health Assessments and Environmental Assessment

A chemistry assessment was not required since there was no change to product chemistry. Health and environment assessments were not required since the use pattern remained unchanged.

Value Assessment

The results of two greenhouse and three field efficacy trials on corn and soybean were reviewed in support of the claims to partially suppress fusarium seed rot and seedling blight on corn and soybean. The greenhouse trials showed significant disease reduction and increased plant counts and biomass against three different species of *Fusarium* when applied to corn and soybean seed as proposed. Field trials against *Fusarium* spp. tested Avodigen tank mixed with other chemical fungicide seed treatments. The addition of Avodigen increased the level of efficacy and yield of the other fungicides on corn, demonstrating the value of this product when used combined with conventional fungicides. The results of the trials support a claim of partial suppression of seed rot and seedling blight caused by *Fusarium* spp. on corn and soybean when applied as proposed.

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Three additional greenhouse trials were reviewed to support the claim against root lesion nematode on corn. Avodigen significantly reduced root lesion nematode counts on corn roots. The results of the trials indicate that Avodigen partially suppresses root lesion nematode on corn.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the subject application and determined that the submitted information is adequate to support the addition of the claims of partial suppression of seed rot and seedling blight caused by *Fusarium* spp. on corn and soybean and partial suppression of root lesion nematode on corn to the Avodigen label.

References

PMRA#	Reference
3421692	2022, Value Summary for AVODIGEN (master copy Draco), containing, Bacillus licheniformis FMCH001 and Bacillus subtilis FMCH002 for Seed Treatment Application for the partial suppression of lesion nematode of corn and Fusarium seed rot and seedling blight of corn and soybean, DACO: M10.1, M10.3.1
3421693	1965, Appendix 1. Method for Root Lesion Nematode Extraction from Root of Corn, DACO: M10.1
3421694	2022, 10.4.2 PERFORMANCE BENEFITS, DACO: M10.4, M10.4.1, M10.4.2, M10.4.3, M10.4.4
3421696	2022, FMC GH Corn - Biocontrol of Fusarium spp., DACO: M10.2.2
3421697	2022, Pooled results for Fusarium inoculated trials on corn, DACO: M10.2.2
3421698	2022, Pooled results for Fusarium inoculated trials on soybean, DACO: M10.2.2
3421699	2022, FMC GH Soybean 1- Biocontrol of Fusarium spp. Report 1.doc, DACO: M10.2.2
3421700	2022, Impact of biological seed treatments on Fusarium of corn, DACO: M10.2.2
3421701	2022, Biological seed treatment impact on corn growth and yield (Fusarium), DACO: M10.2.2
3421702	2022, Impact of biological seed treatments on growth and yield of corn *Fusarium graminearum*, DACO: M10.2.2
3421703	2022, F4018/F4121 protection against Fusarium (Average of 3 trials WI 2014 to 2016), DACO: M10.2.2
3421704	2022, Nematode Protection by F4015 seed treatment in corn- Greenhouse Study, DACO: M10.2.2
3421705	2022, VHW30 Seed Treatment (F4015) for the protections against lesion nematode of corn, DACO: M10.2.2
3421706	2022, VHW30 (F4015) for the protections against lesion nematode of corn, DACO: M10.2.2
3421707	2022, VHW30 (F4015) seed treatment for the protections against lesion nematode of corn (Average of 3 trials), DACO: M10.2.2
3421708	2022, Biological IP Spectrum Testing CH200: Spot Plate Inhibition, DACO: M10.2.2
3421709	2022, Biological IP Spectrum Testing CH201, DACO M10.2.2

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