

Evaluation Report for Category B, Subcategory B.3.12 Application

Application Number: 2016-1261
Application: Application type description
Product: Votivo 240 FS Nematicide
Registration Number: 31996
Active ingredients (a.i.): *Bacillus firmus* strain I-1582
PMRA Document Number: 2643084

Background and Purpose of Application

Votivo 240 FS Nematicide, which contains *Bacillus firmus* strain I-1582 as its active ingredient, is a seed-applied biopesticide registered for the partial suppression of nematode pests in corn and soybean. It was first registered in 2015.

The purpose of this application was to register a use of Votivo 240 FS Nematicide on sorghum for partial suppression of nematodes and a new labeled tank mix partner.

Chemistry Assessment

A chemistry assessment was not required for this application

Health Assessments

No new toxicology data were submitted in support of this submission. Based on previously reviewed information and data, *B. firmus* strain I-1582 is not pathogenic or infective in rats via the acute oral, pulmonary and intravenous infectivity routes. Furthermore, Votivo 240 FS Nematicide is of low toxicity via the oral, pulmonary, and dermal routes. It is not irritating to the skin of rabbits and minimally irritating to the eyes of rabbits. The toxicology database for this product is considered complete.

The new use of Votivo 240 FS Nematicide is consistent with current uses registered for this product. The treatment of sorghum is not expected to significantly increase exposure to workers and bystanders if the directions for use on the label are followed. The recommended protective equipment, precautions, and decontamination procedures to follow in the event of product exposure and/or spills are the same as those currently found on the registered label. No increased occupational or bystander risks are anticipated with the addition of sorghum.

The dietary risk associated with *B. firmus* strain I-1582 is not expected to be significantly altered by the addition of sorghum to the product's use pattern. As noted above in the context of the toxicological assessment, the microbial pest control agent is not infective or pathogenic to rats via the oral, pulmonary, or intravenous routes. Furthermore, Votivo 240 FS

Nematicide is of low toxicity via the oral, pulmonary, and dermal routes. Based on all the available data, negligible to no risk is expected for the general population, including infants and children, or animals.

No additional studies are required to support these amendments to the registration of Votivo 240 FS Nematicide.

Environmental Assessment

No new environmental studies were submitted or requested to support the new use on sorghum. The environmental fate studies, non-target organism studies, scientific rationales and supporting published scientific literature previously submitted in support of the initial registration of *B. firmus* strain I-1582 were determined to be sufficient (PRD2011-24). The use of Votivo 240 FS Nematicide as a seed treatment on sorghum is not expected to pose an unacceptable risk to birds, mammals, arthropods, fish or plants.

Value Assessment

A scientific rationale was reviewed in support of the new claims. The activity of Votivo 240 FS Nematicide against the subject nematodes on sorghum has been established based on the registered uses for corn and soybean. The nematodes in question have a wide host range, similarly infecting different crops and other plant species.

A tank-mixture with Allegiance FL is currently registered on the Votivo 240 FS Nematicide label for use on corn and soybean. Tank-mixtures with recommended conventional seed treatments, including Allegiance FL, have been shown not to alter the nematicidal function of the active ingredient *B. firmus* strain I-1582. Moreover, Allegiance FL is registered in Canada for use on sorghum against *Pythium* and downy mildew.

The registration of this new use will provide Canadian growers with a microbial nematicide seed treatment to partially suppress important plant-parasitic nematodes on sorghum.

Conclusion

The PMRA has assessed the information provided in support of the new use on sorghum and tank mix recommendation for Votivo 240 FS Nematicide and determined it to be sufficient to register these label changes.

References

PMRA Document Number	Reference
2500197	2015, Votivo 240 FS Nematicide - Data to Support a Formulation Change. DACO: M10.1, M10.2, M10.2.1, M10.2.2, M10.3, M10.3.1, M10.3.2, M10.3.2.1, M10.3.2.2, M10.4, M10.4.1, M10.4.2, M10.4.3, M10.4.4
2613169	2015, Value Assessment of Votivo 240 FS Nematicide (Bacillus firmus) - Label expansion to include sorghum. DACO: M10.1, M10.2, M10.2.2, M10.3, M10.3.1, M10.3.2, M10.3.2.1, M10.3.2.2, M10.4, M10.4.1, M10.4.2, M10.4.3, M10.4.4

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