

Evaluation Report for Category B, Subcategory 3.10 and 3.12 Application

Application Number: 2016-1989
Application: B.3.10 - Tank Mixes
B. 3.12 - New Site or Host
Product: Integral
Registration Number: 29453
Active ingredients (a.i.): *Bacillus subtilis* (Strain MBI600)
PMRA Document Number: 2698053

Purpose of Application

The purpose of the application was to amend the label of Integral Liquid Biological Fungicide (PMRA Reg. No. 29453) to include use on corn including field, pop, and sweet (including seed production) for the partial suppression of seedling diseases caused by *Rhizoctonia* spp. and *Fusarium* spp. when applied alone and for the control of these diseases in combination with the registered chemical seed treatment Maxim Quattro.

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

No new data were submitted in support of this application. Based on previously reviewed information and data, *Bacillus subtilis* strain MBI600 is not pathogenic or infective in rats via the oral, pulmonary and intravenous infectivity routes; furthermore, *B. subtilis* strain MBI600 was of low toxicity via the oral and dermal routes.

The use of Integral is consistent with existing registered uses for this product. The treatment of corn 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 for this product. No additional occupational or bystander risks are anticipated with the addition of corn on the product label.

The addition of corn to the product's use pattern is not expected to significantly alter the dietary risk to *B. subtilis* strain MBI600. As previously noted, the microbial pest control agent (MPCA) is not infective or pathogenic to rats via the oral, pulmonary, and intravenous routes; and is of low toxicity via the oral 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.

Environmental Assessment

No new environmental studies were submitted and none are required to support the use on corn. The environmental fate studies, non-target studies, scientific rationales and supporting published scientific literature previously submitted in support of initial regulation of *B. subtilis* strain MBI600 were determined to be sufficiently complete. The use of Integral as a seed treatment on corn is not expected to pose an unacceptable risk to birds, mammals, arthropods, fish and plants.

Value Assessment

Efficacy data were provided in support of the use claims. Overall, Integral demonstrated an acceptable level of disease suppression against pre- and post-emergence damping-off caused by *Rhizoctonia solani* and *Fusarium* spp. on corn when applied alone. Data also demonstrated that both tank-mixing of Integral with Maxim Quattro and Maxim Quattro alone significantly increased stand establishment in the fields where *Rhizoctonia* or *Fusarium* inoculum was applied, though the differences between two treatments were not significant at any assessment date. It should be noted that similar diseases caused by these soil-borne fungi are presently registered on the Integral label for use on canola and soybean. Those soil-borne pathogens are non-host-specific and have the ability to infect a broad range of crops in similar manner.

The registration of these uses will provide Canadian growers with an end use product to manage these important diseases on corn (field, pop and sweet corn) and contribute to the resistance management. Based on the efficacy data provided and the current registration of Integral, the use claims are supported.

Conclusion

The PMRA has reviewed the information provided in support of Integral Liquid Biological Fungicide (PMRA Reg. No. 29453) for use on corn including field, pop, and sweet (including seed production) for the partial suppression of seedling diseases caused by *Rhizoctonia* spp. and *Fusarium* spp. when applied alone and for the control of the same diseases in combination with the registered chemical seed treatment Maxim Quattro. Based on the results of this review, the requested amendment is acceptable for full registration.

References

- 2631315 2016, Petition to Register INTEGRAL for Seed Treatment Application in Corn - VALUE SUMMARY, DACO: M10.1, M10.3.1, M10.3.2.1, M10.4.1, M10.4.2, M10.4.3
- 2631316 2016, Petition to Register INTEGRAL for Seed Treatment Application in Corn - FIELD STUDIES - REPORTS, DACO: M10.2.2

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