

Evaluation Report for Category B, Subcategories 3.11, 3.12, 3.13 Application

Application Number: 2019-1375
Application: Changes to Product Labels-New Pests
Changes to Product Labels-New Host
Changes to Product Labels-Precautions
Product: Velondis Plus
Registration Number: 33256
Active ingredients (a.i.): *Bacillus subtilis* strain BU1814, *Bacillus amyloliquefaciens* strain MBI600
PMRA Document Number: 3079094

Purpose of Application

The purpose of this application was to add the pest *Fusarium* spp. to the label of Velondis Plus, to add crops within Crop Subgroup 6C with an increased application rate for lentils and to amend the storage stability statements on the product label from 6 months at 4°C to 24 months at 20°C.

Chemistry Assessment

Data were provided to support a storage interval for Velondis Plus for up to 24 months when the product is stored at 20°C. No further information is required to complete the product characterization and analysis database for Velondis Plus.

Health Assessment

No changes were made to the formulation of Velondis Plus and the toxicological database for Velondis Plus is complete; therefore, a toxicological assessment was not necessary. Velondis Plus is of low toxicity by the oral, inhalation, and dermal routes and minimally irritating to the skin and eyes and potentially sensitizing.

The label expansion for Velondis Plus as a commercial seed treatment on Crop Subgroup 6C with a rate increase is not expected to pose a health risk of concern based on the low toxicity profile for the microbial pest control agents and the end-use product. The risk mitigation measures, such as personal protective equipment, will minimize exposure and protect applicators, mixer/loaders, and handlers that are likely to be exposed.

The use expansion is not expected to significantly increase dietary exposure or exposure via drinking water. Consequently, dietary (food + drinking water) risk from the use of Velondis Plus is acceptable when used according to the label directions.

Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of MRLs, under the *Pest Control Products Act*, is not required for *Bacillus subtilis* strain BU1814 nor for *Bacillus amyloliquefaciens* strain MBI600.

Environmental Assessment

No changes were made to the formulation of Velondis Plus and the environmental toxicology database for Velondis Plus is complete.

Based on the use pattern as a seed treatment for soybean, there is reasonable certainty that no harm will be caused to terrestrial species (including avian animals, wild mammals, arthropods, non-arthropod invertebrates, and terrestrial plants) or to aquatic species (including freshwater fish, aquatic arthropods, and aquatic plants).

The use expansion for Velondis Plus as a commercial seed treatment on Crop Subgroup 6C with a rate increase is not expected to significantly increase environmental exposure. Consequently, environmental risks from the use expansion of Velondis Plus are not of concern.

Value Assessment

The applicant submitted the results of efficacy trials as well as scientific rationales to support the extrapolation of the previously registered uses of Velondis Plus to include Crop Subgroup 6C, and to support the claim of partial suppression of seed and seedling diseases caused by *Fusarium* spp. on soybean and Crop Subgroup 6C. Based on the value information provided, the extrapolation of claims to Crop Subgroup 6C, as well as the addition of the claim of partial suppression of seed rot, pre and post emergent damping-off, seedling blight, and root rot caused by *Fusarium* spp. to soybean and Crop Subgroup 6C is supported from a value perspective. Velondis Plus will offer an additional product to control seed and seedling diseases on soybean and crops in Crop Subgroup 6C.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to add the pest *Fusarium* spp. to the label of Velondis Plus, to add crops within Crop Subgroup 6C with an increased application rate for lentils, and to revise the storage interval to 24 months at 20°C.

References

PMRA Document Number	Reference
2977939	2019, Product Profile and Proposed Use Pattern BAS 154 U ST, DACO: M1.2
2977940	2018, Storage Stability on BAS 154 01 U, DACO: M2.11
2977979	2019, BAS 154 U ST and Velondis Plus - fungicide seed treatments for use in Crop Subgroup 6C, and soybean., DACO: 10.1, M10.3.1, M10.3.2.1, M10.3.2.2, M10.4.1,M10.4.2,M10.4.3,M10.4.4
2977980	2019, Field studies in support of the petition to register products containing <i>Bacillus subtilis</i> strain BU1814 and <i>Bacillus amyloliquefaciens</i> strain MBI 600 as seed treatments on soybean and Crop Subgroup 6C Crop Subgroup 6C Trial Reports, DACO: M10.2.2
2977981	2019, Field studies in support of the petition to register products containing <i>Bacillus subtilis</i> strain BU1814 and <i>Bacillus amyloliquefaciens</i> strain MBI 600 as seed treatments on soybean and Crop Subgroup 6C Soybean Trial Reports, DACO: M10.2.2

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