



Evaluation Report for Category B, Subcategory 3.1, 3.11, 3.12, 3.4 Application

Application Number: 2020-0815
Application: Changes to Product Labels-Application Rate Increase or Decrease,
New Pests, New Site or Host and Application Method
Product: SERIFEL
Registration Number: 30054
Active ingredient (a.i.): *Bacillus amyloliquefaciens* strain MBI600
PMRA Document Number: 3158382

Purpose of Application

The purpose of this application was to amend the product label of SERIFEL to add crop/pest combinations, add an application method (in-furrow application on potatoes) and increase the rate of application on proposed crops (lettuce and tomato). Additionally, to extend the QA/QC method / storage stability from 16-months to up to 3 years (36-months).

Product Characterization Assessment

The amended storage statement for the end-use product (EP) SERIFEL is considered acceptable. The EP is stable at room temperature for up to 3 years from the date of manufacture. No additional information is required to support the amended storage statement.

Health Assessments

The human health and safety database for this end-use product (EP) is considered complete, no additional toxicological information is required for the EP and the technical grade of the active ingredient (TGAI), *Bacillus amyloliquefaciens* strain MBI600 Technical.

The expected risk to human health posed from the foliar application to carrot, potato, sugar beet, lettuce (field and greenhouse), pepper (field and greenhouse), field cucumber, field cucurbits, caneberries, bushberries, and field and greenhouse low growing berries at a rate of 0.25 – 0.5 kg/ha. As well as the foliar application to field and greenhouse tomato at a rate of 0.25 – 1.0 kg/ha and in-furrow application to potato at a rate of 0.25 – 0.5 kg/ha is acceptable. The potential for dietary and occupational exposure from the use of Serifel is not expected to increase significantly, and therefore, no additional exposure information is required. The available information is sufficient to support the new uses of SERIFEL.

Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether 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 a maximum residue limit (MRL) under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

PMRA has not specified a maximum residue level (MRL) for *Bacillus amyloliquefaciens* strain MBI600. The available information is sufficient to support the proposed new uses of Serifel.

The available information is sufficient to support the use of SERIFEL for foliar application to carrot, potato, sugar beet, lettuce (field and greenhouse), pepper (field and greenhouse), field cucumber, field curcurbits, caneberries, bushberries, and field and greenhouse low growing berries at a rate of 0.25 – 0.5 kg/ha. As well as the foliar application to field and greenhouse tomato at a rate of 0.25 – 1.0 kg/ha and in-furrow application to potato at a rate of 0.25 – 0.5 kg/ha.

Environmental Assessment

The environmental toxicological database for this end-use product (EP) is considered complete, no additional environmental toxicological information is required for the EP or the technical grade of the active ingredient, *Bacillus amyloliquefaciens* strain MBI600 Technical.

Uses include foliar application to carrot, potato, sugar beet, lettuce (field and greenhouse), pepper (field and greenhouse), field cucumber, field curcurbits, caneberries, bushberries, and field and greenhouse low growing berries at a rate of 0.25 – 0.5 kg/ha. As well as the foliar application to field and greenhouse tomato at a rate of 0.25 – 1.0 kg/ha and in-furrow application to potato at a rate of 0.25 – 0.5 kg/ha. The expected risk to non-target organisms posed by the increased application rate and from the new uses are acceptable provided all label instructions are followed.

The available information is sufficient to support the new uses of SERIFEL.

A toxicology assessment was not required for this application.

Value Assessment

A review of 134 efficacy trials and use history information provided evidence that SERIFEL can be expected to suppress or partially suppress certain diseases on carrot, potato, sugar beet, lettuce, peppers, tomato, cucurbits, caneberries, bushberries and low growing berries. The addition of these uses to the label of SERIFEL will provide growers with an alternative, non-conventional product for use in an integrated pest management program to manage the listed diseases and will potentially mitigate resistance development to conventional fungicides. The addition of these uses will also provide organic growers with a new product to manage the listed diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the amendment to the SERIFEL product label.

References

PMRA Document Number	References
3097027	2020, Product Characterization Table Serifel, DACO: M2.1, M2.2, M2.3, M2.4, M2.5, M2.6
3097028	2019, Shelf life of BAS 9747 1 F –Serifel – under normal conditions, DACO: M2.10.1, M2.11, CBI
3097029	2020, Petition to register SERIFEL for foliar use in field and greenhouse grown crops and for in-furrow treatment for potato, DACO: M10.1,M10.4.1,M10.4.2,M10.4.3,M10.4.4
3097030	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown crops and for in-furrow treatment for potato, DACO: M10.2.2,M10.3.1
3097039	2020, Field studies in support of the petition to register SERIFEL for foliar use in field grown bushberries and caneberries, DACO: M10.2.2
3097040	2020, Field studies in support of the petition to register SERIFEL for foliar use in field grown carrot, DACO: M10.2.2
3097041	2020, Field studies in support of the petition to register SERIFEL for foliar use in field grown potato, DACO: M10.2.2
3097042	2020, Field studies in support of the petition to register SERIFEL for foliar use in field grown sugar beet, DACO: M10.2.2
3097043	2020, Field studies in support of the petition to register SERIFEL for in-furrow use in field grown potato, DACO: M10.2.2
3097044	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown cucurbits, DACO: M10.2.2
3097045	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown low growing berries, DACO: M10.2.2
3097046	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown lettuce, DACO: M10.2.2
3097047	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown pepper, DACO: M10.2.2
3097048	2020, Field and greenhouse studies in support of the petition to register SERIFEL for foliar use in field and greenhouse grown tomato, DACO: M10.2.2
3097050	2020, SERIFEL for Use on Sugar Beet, DACO: M10.4.3
3097051	2020, SERIFEL for Use on Bushberries and Caneberries, DACO: M10.4.3
3097052	2020, SERIFEL for Use on Lettuce, DACO: M10.4.3
3131758	2020, Field and greenhouse studies in support of the petition to register SERIFEL - Berries and Small Fruits Trial Reports, DACO: M10.2.2
3131759	2020, Field and greenhouse studies in support of the petition to register SERIFEL - Carrots Trial Reports, DACO: M10.2.2
3131760	2020, Field and greenhouse studies in support of the petition to register SERIFEL Cucurbits Trial Reports, DACO: M10.2.2
3131761	2020, Field and greenhouse studies in support of the petition to register SERIFEL Lettuce Trial Reports, DACO: M10.2.2

- 3131762 2020, Field and greenhouse studies in support of the petition to register SERIFEL Peppers Trial Reports, DACO: M10.2.2
- 3131763 2020, Field and greenhouse studies in support of the petition to register SERIFEL Potato Trial Reports, DACO: M10.2.2
- 3131764 2020, Field and greenhouse studies in support of the petition to register SERIFEL Sugar beet Trial Reports, DACO: M10.2.2
- 3131766 2020, Field and greenhouse studies in support of the petition to register SERIFEL Tomato Trial Reports, DACO: M10.2.2
- 3131767 2020, Field studies in support of the petition to register SERIFEL for foliar use in field grown potato, DACO: M10.2.2

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