

Evaluation Report for Category B, Subcategory 1.1, 3.10 Application

Application Number: 2021-3331
Application: Changes to Product Chemistry – New Source (site) Same Registrant; Changes to Product Label – Tank Mixes
Product: Blossom Protect
Registration Number: 30552
Active ingredients (a.i.): *Aureobasidium pullulans* DSM 14940 and DSM 14941
PMRA Document Number: 3336583

Purpose of Application

The purpose of this application was to amend the end-use product, Blossom Protect, to change the formulating site, to change the name of the alternating site and to amend the mixing instructions on the label.

Product Characterization and Analysis

The results of the potency and microbial contamination analysis batch data submitted by the applicant support the new formulating site.

Health Assessments

A toxicological assessment was not required for this application.

The potential for dietary, occupational, and bystander exposure from the new mixing instructions of Blossom Protect is not expected to increase significantly. The new mixing instructions are not expected to pose an unacceptable risk to human health provided all label instructions are followed. The available information is sufficient to support the new mixing instructions for Blossom Protect from a health perspective.

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.

As no significant adverse effects were reported in previously reviewed Tier I acute oral toxicity/pathogenicity studies and no definitive data are available that would suggest the MPCA produces secondary metabolites of potential health concern, the specification of an MRL is not required for *Aureobasidium pullulans* DSM 14941 and *Aureobasidium pullulans* DSM 14940.

Environmental Assessment

The potential for non-target organism exposure from the new mixing instructions of Blossom Protect is not expected to increase significantly. The proposed use amendment is not expected to pose an unacceptable risk to the environment provided all label instructions are followed. The available information is sufficient to support the new mixing instructions for Blossom Protect from an environmental perspective.

Value Assessment

Revised instructions for mixing Blossom Protect with the buffer are more detailed and expected to result in useful spray mixtures.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the amendments to Blossom Protect to change the formulating site, to change the name of the alternating site and to revise the mixing instructions on the label.

References

PMRA Document Number	Reference
3275220	2021, Certificate of Analysis BLOSSOM PROTECT, DACO: M2.9.2 CBI
3275221	2021, Certificate of Analysis BLOSSOM PROTECT, DACO: M2.9.2 CBI
3275222	2021, Certificate of Analysis BLOSSOM PROTECT, DACO: M2.9.2 CBI
3275223	2021, Certificate of Analysis BLOSSOM PROTECT, DACO: M2.9.2 CBI
3275224	2021, Certificate of Analysis BLOSSOM PROTECT, DACO: M2.9.2 CBI

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