Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12, 3.3 Application

Application Number: 2022-0990
Application: Changes to Product Labels-New Site or Host, Application Number or Frequency
Product: PROBLAD
Registration Number: 31782
Active ingredient (a.i.): BLAD polypeptide
PMRA Document Number: 3498776

Purpose of Application

The purpose of this application was to add highbush blueberries to the registered label of PROBLAD, and to amend the maximum number of applications and the application interval for stone fruit and almonds.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

Since there are no changes to the registered formulations of PROBLAD, and the human health and safety database for this end-use product (EP) is considered complete, no additional toxicological information was required. The active ingredient, BLAD polypeptide, was considered to be of low acute toxicity via the oral, dermal, and inhalation routes of exposure. BLAD polypeptide was mildly irritating to the skin and eyes, but not a dermal sensitizer. For the uses of PROBLAD, the formulants are not expected to contribute to the toxicity of the formulations. For details see Proposed Registration Decision PRD2019-02 *BLAD Polypeptide Problad Technical Fungicide and Problad Plus Fungicide.*

The uses for foliar sprays (including rate, method, and timing of application) to highbush blueberries, stone fruits and almonds are consistent with existing uses on the label for other field food crops. The potential for dietary and occupational exposure from the uses of PROBLAD is not expected to increase, and therefore, no additional exposure information was required. The available information was sufficient to support the use of PROBLAD on highbush blueberries and the amended use directions for stone fruit and almonds.

When handled according to the label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, however, the risk is acceptable provided workers follow label directions and use personal protective equipment (PPE) as instructed. Dermal and ocular exposure can be minimized if workers wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks, shoes, and protective eyewear.

Overall, risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

Residential and non-occupational exposure to the EP is expected to be low when label directions are observed. Consequently, the risk to bystanders and individuals in residential areas and the general public is acceptable.

The PMRA has previously determined that specification of a maximum residue limit (MRL) under the *Pest Control Products Act* is not required for the active ingredient BLAD polypeptide.

Environmental Assessment

The use of PROBLAD on highbush blueberry in addition to the amended use directions for certain crops, do not represent an increased risk to the environment when this product is used according to label instructions.

Value Assessment

A rationale based on precedent lowbush blueberry claims was sufficient to demonstrate the value of adding highbush blueberry as a labeled crop. PROBLAD has a unique, multi-site mode of action, which may help manage resistance development in fungi.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information acceptable to add highbush blueberries to the registered label of PROBLAD, and to amend the maximum number of applications and the application interval for stone fruit and almonds.

References

PMRA Document Number	Reference
3347971	2015, Biodegradability in the CO2-evolution test according to OECD 301 B (July 1992), DACO: 7.1,7.4.1
3347972	2010, Assessment of the Ready Biodegradability with the Closed Bottle Test, DACO: 7.1,7.4.1
3347973	Monteiro, S., et al. "A nontoxic polypeptide oligomer with a fungicide potency under agricultural conditions which is equal or greater than that of their chemical counterparts." PLoS One 10.4 (2015): e0122095. DACO: 7.1,7.4.1
3327415	2022, Problad-DACO 10 Summary 21feb2022, DACO: 10.1,10.2.2,10.2.3,10.2.3.1,10.3.2