

## Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

**Application Number:** 2018-1535  
**Application:** B.2.3: Change Identity of Formulants  
B.2.4: Change Proportion of Formulants  
**Product:** Bioprotec Plus  
**Registration Number:** 32425  
**Active ingredients (a.i.):** *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19  
**PMRA Document Number :** 2958486

### Purpose of Application

The purpose of this application was to amend the formulation of a registered end-use microbial product, Bioprotec Plus.

### Chemistry Assessment

Bioprotec PLUS is a registered end use product containing the microbial pest control agent (MPCA), *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19. A review of the submitted information/data indicated that the product produced using the new formulation of Bioprotec Plus is comparable in potency and physical and chemical characteristics to the registered product formulation.

### Health Assessments

Bioprotec Plus is a registered end use product containing the microbial pest control agent (MPCA), *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19. A review of the available information/data indicated that the end use product produced using the new formulation of Bioprotec Plus is not expected to pose any additional toxicological concerns for human health, and the existing toxicological database for Bioprotec Plus is sufficient to support the change in end use product formulation.

While the new formulant is classified as an eye irritant and a potential dermal sensitizer, and the proposed formulation change could result in workers handling minute amounts of the formulant which could lead to potential exposure by ocular and dermal routes, the formulant is only present in minute quantities in the end use product and the existing label precautions specify appropriate personal protective equipment to protect against these routes of exposure. The potential for bystander exposure as a result of the amendment to end use product formulation is unchanged from that of the registered end use product, since there are no modifications to the use pattern of Bioprotec Plus. Therefore, when applied according to the label instructions, the modification to the end sue product formulation of Bioprotec Plus is not expected to present any additional concerns for occupational or bystander exposure. The available information is sufficient to support the proposed change in formulation.

While the changes to the end use product formulation may result in consumers being exposed to slightly increased trace amounts of the new food-grade formulant due to consumption of crops treated with Bioprotec Plus, this amount is likely to be far less than what is already consumed by the general public since this ingredient is commonly used in a variety of food and beverages. Therefore, the existing database is sufficient to support the change in end use product formulation, and no additional dietary exposure information is required.

### **Environmental Assessment**

Bioprotec Plus is a registered end use product containing the microbial pest control agent (MPCA), *Bacillus thuringiensis* ssp. *kurstaki* strain EVB113-19. A review of the available information indicated that the new Bioprotec Plus formulation uses a minor formulant which is acceptable for both food and non-food uses and is not of environmental concern.

As well, the existing label precautions already mitigate environmental impact by instructing users not to contaminate aquatic habitats through equipment cleaning or waste disposal. Users are also requested not to allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Therefore, the changes to the Bioprotec Plus formulation are not expected to pose additional risk to the environment or non-target organisms when the product is applied according to the label instructions.

### **Value Assessment**

The new formulation was supported from a value perspective because it was not expected to have an impact on the efficacy of the product.

### **Conclusion**

The PMRA has reviewed the information provided in support of the updated formulation. Based on the results of this review, the amended formulation of Bioprotec Plus is acceptable for registration.

### **References**

None

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