

## Evaluation Report for Category B, Subcategory 4.6 Application

**Application Number:** 2018-3884  
**Application:** B.4.6: Fulfill Conditions of Registration  
**Product:** Bioprotec Lawn Herbicide Concentrate  
**Registration Number:** 30881  
**Active ingredients (a.i.):** Citric Acid and Lactic Acid  
**PMRA Document Number:** 3127833

### Purpose of Application

The purpose of this application was to address the requirements of registration for Bioprotec Lawn Herbicide Concentrate. These conditions were microbial contamination and potency estimation data from 5 production-scale batches of the end use product as well as confirmatory storage stability data.

### Chemistry Assessment

Bioprotec Lawn Herbicide Concentrate contains the active ingredients lactic acid and citric acid at nominal concentrations of 4.24 and 4.75 g/L respectively. The registrant submitted waiver requests with rationales in lieu of potency, microbial contamination, and storage stability data for 5 production-scale batches of Bioprotec Lawn Herbicide Concentrate.

The information provided did not satisfy the requirements for potency estimation data for 5 production-scale batches of the end use product and storage stability data. Therefore, appropriate information must be provided to satisfy the requirements for potency and storage stability.

### Health, Environmental and Value Assessment

Health, environmental and value assessment

### Conclusion

The PMRA has reviewed the information provided to address the conditions of registration. Based on the review of this information, the following requirements of registration have not been satisfied:

1. potency estimation data for 5 production-scale batches of the end use product,
2. storage stability data.

Adequate information must be submitted to satisfy these requirements for registration.

## References

- 2911826 Waiver request for M2.9.2 Potency Estimation
- 2911827 Waiver request for M2.10.2 Analysis of Microbial Contaminants
- 2911828 Waiver request for M2.11 Storage Stability Testing

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