

## Evaluation Report for Category B, Subcategory 1.1, 4.6 Application

**Application Number:** 2021-1624  
**Application:** Changes to Product Chemistry – New Source (site);  
Fulfill Conditions of Registration  
**Product:** Avodigen  
**Registration Number:** 33311  
**Active ingredients (a.i.):** *Bacillus licheniformis* strain FMCH001 and *Bacillus subtilis* strain FMCH002  
**PMRA Document Number:** 3294705

### Purpose of Application

The purpose of this application was to fulfill the outstanding post market data requirement identified during the initial registration of the end-use product, Avodigen, of providing guarantee data on commercial-scale batches of Avodigen from each of the formulating sites. In addition, a new formulation site and repackaging site was added to the end-use product.

### Chemistry Assessment

Product guarantee data were provided for commercial-scale batches of Avodigen formulated at one of the original formulation sites and a new formulating site. The guarantee data were adequate to address the identified post-market data requirement for this EP and to register the additional formulating site.

Acceptable information was also provided to support the addition of a site for repackaging Avodigen.

### Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to fulfill the outstanding post market data requirement of providing guarantee data at one of the formulating sites and to register a new formulating and repackaging site for Avodigen.

### **Additional Information Being Requested**

Since guarantee data were provided only for pilot-scale batches of Avodigen, guarantee data on five commercial-scale batches of Avodigen from the registered formulation site will be required as post-market data.

## References

### PMRA

#### Document

#### Number

#### Reference

3220858	2020, Batch data - <CBI Removed>, DACO: M2.10.1 CBI
3220859	2020, Batch data - <CBI Removed>, DACO: M2.10.1 CBI
3279211	2021, M2.8 - Avodigen PCP 33311, DACO: M2.8 CBI

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