

Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2023-0492
Application: Conversion - Fulfill requirements of registration
Product: Avodigen
Registration Number: 33311
Active ingredients (a.i.): *Bacillus subtilis* strain FMCH002 and *Bacillus licheniformis* strain FMCH001
PMRA Document Number: 3529931

Purpose of Application

The purpose of this application was to fulfill the Section 12 post-market requirement for outstanding guarantee data on commercial-scale batches of Avodigen from one of the registered formulating sites.

Product Characterization and Analysis

Product guarantee data for five batches of Avodigen were provided and found to be acceptable. Sufficient data were provided to address the identified information gap in the database for this end-use product.

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 the information acceptable to fulfill the post-market requirement for one of the formulating sites of Avodigen.

References

PMRA

Document

Number

3439029

Reference

2023, Batch data - MDPT, DACO: M2.10.1 CBI

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.