



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2009-2245
Application: B.1.1: New / Changes TGAI or ISP Prod Chemistry-New Source (site) same registrant
Product: Bioprotec Technical
Registration Number: 26425
Active ingredients (a.i.): *Bacillus thuringiensis* Berliner spp. *kurstaki* strain HD-1 [BTB]
PMRA Document Number: 1812455

Purpose

AEF Global has submitted an application to register a new site of manufacture for the technical grade active ingredient (TGAI) Bioprotec Technical (Registration No. 26425), containing the microbial pest control agent (MPCA) *Bacillus thuringiensis* Berliner spp. *kurstaki* strain HD-1.

Chemistry Assessment

The manufacturing methods and quality control procedures, and analytical methods for potency, microbial contamination screening at the new site of manufacture of Bioprotec Technical, are identical to those employed at first site of registration. Potency data and microbial contaminant screening data from representative batches of Bioprotec Technical adequately support the procedures at the new site of production. Therefore, the TGAI produced at the new site of manufacture are considered identical to those previously registered, and consequently, the *Product Characterization and Analysis* database adequately supports the new site of manufacture. The PMRA can be reasonably assured that manufacturing of Bioprotec Technical at the new site of manufacture will not pose an unacceptable risk to human health, or to the environment.

Health Assessments

No health assessment was required for this submission.

Environmental Assessment

No environmental assessment was required for this submission.

Value Assessment

No value assessment was required for this submission.

Conclusion

Following the assessment of all available data, the PMRA is able to support the proposed amendment to add a new manufacturing site for Bioprotec Technical.

References

PMRA No.	Title
1775275	2009, Manufacturing process and quality assurance, DACO: M2.8 CBI
1775278	1998, Manufacturing process and quality assurance, DACO: M2.8 CBI
1775279	2009, Microbial contaminants 5 batches analysis, DACO: M2.8 CBI
1775280	2009, Potency results 5 batches analysis, DACO: M2.8 CBI
1775281	2009, Mouse toxicity results of 5 batches, DACO: M2.8 CBI
1775282	2009, Potency estimation and product guarantee, DACO: M2.9.2 CBI
1775283	1998, Potency estimation and product guarantee, DACO: M2.9.2 CBI
1775284	1998, Potency estimation and product guarantee, DACO: M2.9.2 CBI
1775288	2009, Unintentional Ingredients, DACO: M2.9.3 CBI
1775289	1998, Unintentional Ingredients, DACO: M2.9.3 CBI
1775290	2009, Active ingredient or MPCA, DACO: M2.10.1 CBI
1775291	1998, Active ingredient or MPCA, DACO: M2.10.1 CBI
1775292	2009, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
1775293	1998, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI
1775294	2009, Analysis for the other unintentional ingredients, DACO: M2.10.3 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2010

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.