

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2008-3619
Application: New source for the same registrant
Product: Bioprotec Technical
Registration Number: 26425
Active ingredients (a.i.): *Bacillus thuringiensis* Berliner spp. *kurstaki* strain HD-1
PMRA Document Number: 1736475

Purpose of Application

The purpose of this application is to register a new site of manufacture for the technical grade active ingredient Bioprotec Technical (Reg No. 26425), containing the microbial pest control agent *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 for Bioprotec Technical are identical to those employed at the currently registered site of manufacture. Potency data and microbial contaminant screening data from representative batches of Bioprotec Technical adequately support the procedures at the new site of manufacture. Therefore, the technical grade active ingredient produced at the new site of manufacture is considered equivalent to the technical grade active ingredient produced at the currently registered site of manufacture, and consequently, the *Product Characterization and Analysis* database adequately supports the new site of manufacture. The Agency can be reasonably assured that the 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

Since the technical grade active ingredient from the new site of manufacture is equivalent to that from the currently registered site of manufacture, a toxicological assessment was not required and no additional risks to human health and safety are anticipated. Existing precautionary and first aid statements on the labels are sufficient to cover any health risks associated with the technical grade active ingredient.

Environmental Assessment

Since the technical grade active ingredient from the new site of manufacture is equivalent to that from the currently registered site of manufacture, an environmental toxicology assessment was not required and no additional risks to the environment are anticipated. The existing precautionary statements on the labels are sufficient to cover any environmental risks associated with the technical grade active ingredient.

Value Assessment

This application is for a technical product, thus, a value assessment was not required.

Conclusion

The PMRA has completed an assessment of available information for Bioprotec Technical and has found the information sufficient to support the registration of a new manufacturing site.

References

- | | |
|--------------|---|
| PMRA 1640277 | 2008, Manufacturing process and quality assurance, DACO: M2.8 CBI |
| PMRA 1640278 | 1998, Manufacturing process and quality assurance, DACO: M2.8 CBI |
| PMRA 1640279 | 2008, Microbial contaminants 5 batches analysis, DACO: M2.8 CBI |
| PMRA 1640280 | 2008, Potency results 5 batches analysis, DACO: M2.8 CBI |
| PMRA 1640281 | 2008, Potency estimation and product guarantee, DACO: M2.9.2 CBI |
| PMRA 1640282 | 1998, Potency estimation and product guarantee, DACO: M2.9.2 CBI |
| PMRA 1640283 | 1998, Potency estimation and product guarantee, DACO: M2.9.2 CBI |
| PMRA 1640284 | 2008, Unintentional Ingredients, DACO: M2.9.3 CBI |
| PMRA 1640285 | 1998, Unintentional Ingredients, DACO: M2.9.3 CBI |
| PMRA 1640286 | 2008, Active ingredient or MPCA, DACO: M2.10.1 CBI |
| PMRA 1640288 | 1998, Active ingredient or MPCA, DACO: M2.10.1 CBI |
| PMRA 1640289 | 2008, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI |

PMRA 1640290 1998, Analysis for Microbial Contaminants, DACO: M2.10.2 CBI

PMRA 1640291 2008, 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 2009

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.