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Registration Decision

Beauveria bassiana strain GHA

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Registration Decision for *Beauveria bassiana* strain GHA

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Beauveria bassiana* Technical, Botanigard ES and Botanigard 22 WP, containing the technical grade active ingredient *Beauveria bassiana* strain GHA, to control whitefly, aphids and thrips in greenhouse ornamentals and vegetables.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2009-03, *Beauveria bassiana* strain GHA. This Registration Decision² describes this stage of the PMRA's regulatory process for *Beauveria bassiana* strain GHA and summarizes the Agency's decision, the reasons for it and provides a summary of comments received during the consultation process as well as PMRA's response to these comments (see Appendix I). This decision is consistent with the proposed registration decision stated in PRD2009-03.

For more details on the information presented in this Registration Decision, please refer to the PRD2009-03 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Beauveria bassiana* strain GHA?

Beauveria bassiana strain GHA is a microbial pest control agent in the end-use products, Botanigard ES and Botanigard 22 WP. These end-use products provide control of whitefly, aphids, and thrips on greenhouse ornamentals and vegetables.

Beauveria bassiana is a fungus that grows naturally in soils throughout the world and acts as a parasite on various insect species. *Beauveria bassiana* is a “generalist entomopathogenic fungi”, which is a fungus which causes a disease in many types of insects. In the case of *Beauveria bassiana*, it causes a disease called “white muscardine disease” in most insects. While insects living in or near the soil have evolved natural defences against this fungus as it is common in their natural environment, it can be used as a biological insecticide against most other insects.

Health Considerations

Can Approved Uses of *Beauveria bassiana* strain GHA Affect Human Health?

***Beauveria bassiana* strain GHA is unlikely to affect human health when used according to the label directions**

People could be exposed to *Beauveria bassiana* strain GHA when handling and applying the products. The PMRA considers several key factors when assessing health risks: the microorganism's biological properties (for example, production of toxic byproducts), reports of any adverse incidents, its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies as well as the likely levels to which people may be exposed to this strain relative to exposures already encountered in nature to other strains of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in the hopes of identifying any potential pathogenicity, infectivity and toxicity concerns. *Beauveria bassiana* Technical was found to be a mild eye irritant. Therefore, the product labels will have the appropriate label statements.

No other significant toxicity or signs of disease were observed when *Beauveria bassiana* strain GHA was tested on laboratory animals.

Residues in Water and Food

Dietary risks from food and water are not of concern

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limits (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Strains of *Beauveria bassiana* are common in nature and the use of Botanigard ES and Botanigard 22 WP in greenhouses is not expected to significantly increase natural environmental background levels of this microorganism. Furthermore, no significant adverse effects were reported when *Beauveria bassiana* strain GHA was administered orally to rats. Therefore, the establishment of an MRL is not required for *Beauveria bassiana* strain GHA. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risks are minimal to non-existent.

Occupational Risks From Handling Botanigard ES and Botanigard 22 WP

Occupational risks are not of concern when Botanigard ES and Botanigard 22 WP are used according to label directions, which include protective measures.

Workers using Botanigard ES and Botanigard 22 WP can come into direct contact with *Beauveria bassiana* strain GHA on the skin, in the eyes, or by inhalation. For this reason, the label will specify that workers using Botanigard ES and Botanigard 22 WP must wear gloves, long-sleeved shirts, long pants, a NIOSH approved respirator (with any N, P, R or HE filter), and shoes plus socks. Eye goggles are also required when handling Botanigard 22WP. Early-entry workers will also be restricted from entering areas where Botanigard ES and Botanigard 22 WP have been applied for a period of 12 hours unless wearing the indicated personal protective equipment.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Beauveria bassiana* strain GHA is Introduced into the Environment?

Environmental risks are not of concern

Information on the environmental fate of *Beauveria bassiana* strain GHA suggests that, as a common soil microorganism, it is likely that *Beauveria bassiana* strain GHA could survive in outdoor soil under favourable environmental conditions (i.e., moisture, acidity levels) but that over time the populations of *Beauveria bassiana* strain GHA would return to natural background levels.

The effects of *Beauveria bassiana* strain GHA on birds, earthworms, fish, aquatic arthropods, terrestrial and aquatic plants, and beneficial and/or environmentally-important insects were examined. Although the risk to non-target organisms was found to be acceptable, in order to be protective of beneficial insects (including bees), the end-use product labels will instruct users to minimize overspray in the greenhouse. Labelling will also advise users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging. To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product for the first time and to minimize the accumulation of visible residues on plant surfaces, will also be required on the end-use product labels under the directions for use section.

Although avian pulmonary/inhalation/injection, wild mammal, and microorganism testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected.

Value Considerations

What Is the Value of Botanigard ES and Botanigard 22 WP?

Botanigard ES and Botanigard 22 WP are biopesticides that can be used to control whiteflies, aphids, and thrips on greenhouse vegetables and ornamentals.

These are biological control products which may be used on greenhouse ornamentals and vegetables in place of conventional chemical insecticides. The data reviewed demonstrated that Botanigard ES and Botanigard 22 WP will generally provide acceptable control of whiteflies, aphids, and thrips on greenhouse vegetables and ornamentals. However, depending on humidity and temperature, efficacy can be variable. Under unfavourable conditions, these products may not always provide good control. This is not unexpected given the mode of action of these products (a fungal biological control agent which causes a disease).

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the labels of Botanigard ES and Botanigard 22 WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Due to concerns with users developing allergic reactions through repeated high exposure to *Beauveria bassiana* strain GHA, anyone handling or applying Botanigard ES or Botanigard 22 WP must wear waterproof gloves, a long-sleeved shirt, long pants, and shoes plus socks. In addition, mixers/loaders and applicators must wear a dust/mist filtering mask. Furthermore, anyone handling or applying Botanigard 22 WP will be required to wear eye goggles as this formulation is a moderate eye irritant.

Environment

As a general precaution, the label prohibits the direct application of the products to aquatic habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, and wetlands), estuaries or marine habitats. The label also directs handlers to not contaminate surface water by disposal of equipment wash waters.

In order to be protective of beneficial insects (including bees) users will be instructed to minimize overspray in the greenhouse. Labelling will also advise the user that Botanigard ES and Botanigard 22 WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging.

As some strains of *Beauveria bassiana* have been shown to be toxic to honeybees, users are directed to avoid applying the products to areas where honeybees are actively foraging.

To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product for the first time and to minimize the accumulation of visible residues on plant surfaces, are required on the label under the directions for use section.

One of the formulants in Botanigard ES contains heavy aromatic petroleum distillates which are toxic to aquatic organisms and will therefore be labelled as such on the end-use product label.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, <http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd>) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comments on precautionary statements proposed for the product label

A comment was received regarding the need for clarification of labels statements with respect to non-target organisms.

Response

PMRA is in agreement with the information provided in the comment.

The “Environmental Considerations” section of this document reflects the comment.

The comment also impacts the text of Section 4.2.1 and Section 7.3 of the Proposed Registration Decision PRD2009-03, *Beauveria bassiana* strain GHA.

The amended sections are presented below:

4.2.1 Effects on Terrestrial Organisms (Paragraph 16)

As the proposed uses of Botanigard ES and Botanigard 22 WP are limited to greenhouses there is no direct exposure to outdoor environments, and outside environments are only expected to be exposed to *Beauveria bassiana* strain GHA through operational activity (for example, removal and composting of spent crop growing media). Once outside, the dispersal of *Beauveria bassiana* strain GHA should be limited to mostly runoff and vectors. Based on these considerations, the amount of *Beauveria bassiana* strain GHA transferring to outdoor environments is expected to be low. Consequently, a significant increase in natural populations of *Beauveria bassiana* in outdoor terrestrial environments is not expected, and therefore hazards to non-target terrestrial organisms are expected to be minimal to non-existent. However, the greenhouse use of Botanigard ES and Botanigard 22 WP warrants particular attention with respect to the use of beneficial insects in integrated pest management programs, particularly since the MPCA has demonstrated commercial relevance against various insect orders or families, including Homoptera (for example, whitefly, *Bemisia* spp., *Trialeurodes vaporariorum*; aphid, *Myzuspersicae*, *Aphis gossypii*; leafhopper, *Erythroneura elegantula*), Thysanoptera (for example, thrips, *Frankliniella occidentalis*, *Thrips palmi*), Acrididae (for example, migratory grasshopper *Melanoplus sanguinipes*, North American grasshopper, African grasshopper, and locusts), and Lepidoptera (for example, Diamondback moth, *Plutella xylostella*, imported cabbage worm, *Pieris rapae*; cabbage looper, *Trichoplusia ni*). Non-target insect laboratory tests such as those submitted in the ecotoxicology package for *Beauveria bassiana* strain GHA reflect conservative measures of the potential for effects. Successful infection by *Beauveria bassiana* and spore germination requires suitable environmental conditions (for example, high moisture ca. 92–100%) which may or may not be reached in greenhouse settings. Other factors, such as behaviour of insects (for example, insect emergence, insect movement), seasonality, and habitat of insect species would further limit exposure, and thus mitigate risks to non-target insects. Nevertheless, based on the results from non-target insect testing and known

entomopathogenic nature of *Beauveria bassiana* strain GHA, it is reasonable to conclude that certain stages of particular insect species may be adversely affected in the event of direct exposure to Botanigard ES and Botanigard 22 WP under greenhouse conditions particularly when maximum application rates and repeat intervals are followed. Therefore, the labels will state that Botanigard ES and Botanigard 22 WP may be harmful to certain stages of particular beneficial insects. To reduce the risks to non-target insects, precautionary label statements will instruct users to minimize overspray in the greenhouse. Labelling will also advise users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and will instruct users to avoid applying the products to areas where honeybees are actively foraging.

7.3 Environmental Risk (Paragraph 4)

Although the non-target insect studies did not entirely meet guideline criteria, based on the low potential outdoor exposure of non-target terrestrial organisms, and on a weight of evidence from published and unpublished information, the use of Botanigard ES and Botanigard 22 WP is not expected to pose an unacceptable risk to non-target terrestrial organisms. Although the risk to the non-target insect species was found to be acceptable, in order to be protective of beneficial insects used commercially in greenhouses, the end-use product labels will state that Botanigard ES and Botanigard 22 WP may be harmful to certain stage of particular beneficial insects, and will instruct users to minimize overspray in the greenhouse. Labelling will also warn users that Botanigard ES and Botanigard 22WP may be harmful to bees exposed by direct contact, and instructs users to avoid applying the products to areas where honeybees are actively foraging. To reduce the potential for phytotoxic effects on crop plants, advisory statements notifying users to spot test plant surfaces before applying product and to minimize the accumulation of visible residues on plant surfaces, will also be required on the label under the directions for use section.

References

A. List of Studies/Information Submitted by Registrant

1.0 The Active Ingredient, its Properties and Uses & 2.0 Methods of Analysis

PMRA Document Number: 1147406

Reference: Laverlam International Corp. 2006. Bacterial And Fungal Identification In Botanigard ES Formulation, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1147407

Reference: Laverlam International Corp. 2006. Bacterial And Fungal Identification In Botanigard WP Formulation, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1147408

Reference: Laverlam International Corp. 2006 Response To Deficiency Notes, Data Numbering Code: M2.10.2

PMRA Document Number: 1147409

Reference: Laverlam International Corp. 2006. Spore Counts Botanigard ES Formulation, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1147410

Reference: Laverlam International Corp. 2006. Spore Counts Botanigard ES Formulation, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1147411

Reference: Laverlam International Corp. 2006. Results From 5-lot Analysis Of TGAI, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1147412

Reference: Mycotech Corp. 1991. Product Identity And Disclosure Of Ingredients, Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1147413

Reference: Castrillo, L. A. J. D. Vandenderg And S. P. Wraight. 2003. Strain-specific Detection Of Introduced Beauveria Bassiana In Agricultural Fields By Use Of Sequence-characterized Amplified Region Markers, Journal Of Invertebrate Pathology 82, Data Numbering Code: M2.7.1

PMRA Document Number: 1147414

Reference: De Hoog G. S. 1972. The Genera Beauveria Isaria Tritirachium And Acrodontium New-genus, Data Numbering Code: M2.7.1

PMRA Document Number: 1147415

Reference: Mycotech Corp. 1993. Sop 03-05: Characterization Of Beauveria Bassiana, Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1147416

Reference: Mycotech Corp. And Biogenetics Services Inc. 1993. B. Bassiana Strain GHA Cdna Library Construction And Rflp Analysis. Lab Study No. 93-003, Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1147417

Reference: Laverlam International Corp. 2006. Response To Deficiency Notes. The Genera Beauvaria Isaria Tritirachium And Acrodontium New-genus, Data Numbering Code: M2.7.1

PMRA Document Number: 1147418

Reference: Laverlam International Corp. 2006. Rationales And Response To Deficiency Notes, Data Numbering Code: M2.7.2

PMRA Document Number: 1147419

Reference: Cagan, L. And M. Svercel. 2001. The Influence Of Ultraviolet Light On Pathogenicity Of Entomopathogenic Fungus Beauveria Bassiana. Journal Of Central European Agriculture, Data Numbering Code: M2.7.2

PMRA Document Number: 1147420

Reference: Hallsworth, J. & Magan N, Culture Age, Temperature, And Ph Affect The Polyol And Trehalose Contents Of Fungal Propagules, Applied And Environmental Microbiology 62, Data Numbering Code: M2.7.2

PMRA Document Number: 1147421

Reference: Miscellaneous. 2006. Various Documents Cited In Rationale. Data Numbering Code: M2.7.2

PMRA Document Number: 1147422

Reference: O'callaghan, M. E. M. Gerard And V. W. Johnson. 2001. Effect Of Soil Moisture And Temperature On Survival Of Microbial Control Agents. New Zealand Plant Protection Society, Data Numbering Code: M2.7.2

PMRA Document Number: 1147423

Reference: Vey, A. And J. Fargues. 1977. Histological And Ultrastructural Studies Of Beauveria Bassiana Infection In Leptinotarsa Decemlineata Larvae During Ecdysis, Journal Of Invertebrate Pathology, Data Numbering Code: M2.7.2

PMRA Document Number: 1147424

Reference: Laverlam International Corp. 2006. Response To Deficiency Notes, Data Numbering Code: M2.8

PMRA Document Number: 1147426

Reference: Mycotech Corp. Sop 03-12 Quality Assurance For Production Run, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1147427

Reference: Mycotech Corp. 1998. Minor Modifications To Manufacturing Process, N/a, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1147428

Reference: Laverlam International Corp. 2006. Culture Maintenance Statement, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1147429

Reference: Laverlam International Corp. 1998. Sop 03-02 Fungal Spore Counts, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1147430

Reference: Laverlam International Corp. 1998. Sop 03-03 Fungal Spore Viability Test, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1147431

Reference: Laverlam International Corp. 1998. Sop 03-06 Enumeration Of Microbial Contaminants In Whole Culture, TGAI, And Formulated Product, Data Numbering Code: M2.10.2, M2.8 Confidential Business Information

PMRA Document Number: 1147432

Reference: Laverlam International Corp. 2006. Response To Deficiency Notes, Data Numbering Code: M2.10.3

PMRA Document Number: 1147433

Reference: Mycotech Corp. 1995. Analysis Of Mycotrol GH TGAI (beauveria Bassiana Strain GHA Conidial Powder) For The Metabolites Beauvericin And Bassianolide, 94-009, Data Numbering Code: M2.10.3 Confidential Business Information

PMRA Document Number: 1147434

Reference: Mycotech Corp. 1999. Analysis Of Mycotrol GH TGAI (beauveria Bassiana Strain GHA Conidial Powder) For The Metabolites Beauvericin And Bassianolide, 94-009, Data Numbering Code: M2.10.3 Confidential Business Information

PMRA Document Number: 1147435

Reference: Mycotech Corp. 1993. Discussion Of Formation Of Unintentional Ingredients, Data Numbering Code: M2.10.3 Confidential Business Information

PMRA Document Number: 1147436

Reference: Mycotech Corp. 1993. Analysis Of Mycotrol GH TGAI (beauveria Bassiana Strain GHA Conidial Powder) For The Metabolite Oosporein, 93-032, Data Numbering Code: M2.10.3 Confidential Business Information

PMRA Document Number: 1147437

Reference: Strasser, H. A. Vey Anf T. M. Butt. 2000. Are There Any Risks In Using Entomopathogenic Fungi For Pest Control, With Particular Reference To The Bioactive Metabolites Of Metarhizium, Tolypocladium And Beauveria Species? Biocontrol Science & Technology, Data Numbering Code: M2.10.3

PMRA Document Number: 1147438

Reference: Laverlam International Corp. 2006. Stability Data (response To Deficiency Notes), Data Numbering Code: M2.11

PMRA Document Number: 1221536

Reference: Marchisio, V. F. A. Fusconi And S. Rigo. 1994. Keratinolysis And Its Morphological Expression In Hair Digestion By Airborne Fungi. Mycopathologia 127, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1221537

Reference: Marchisio, V. F. 2000. Keratinophilic Fungi: Their Role In Nature And Degradation Of Keratinic Substrates, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1221541

Reference: Fromtling, R. A, S. D. Kosanke, J. M. Jensen, And G. S. Bulmer. Fatal Beauveria Bassiana Infection In A Captive American Alligator. Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1261794

Reference: Laverlam International Corp. 2004. Beauveria Bassiana Product Characterization And Analysis, Data Numbering Code: M2.1,M2.2,M2.3,M2.4,M2.5 Confidential Business Information

PMRA Document Number: 1261795

Reference: Laverlam International Corp. 2004. Summary Document Product Identity. Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1261796

Reference: Laverlam International Corp. 2004. Summary Document Biological Properties Of The Microorganism Beauveria Bassiana Strain GHA. Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1261797

Reference: Laverlam International Corp. 2004. Biological Properties, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1261798

Reference: Mycotech Corp. 1991. Manufacturing Process, Jpdoc009, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1261799

Reference: Mycotech Corp. 1997. Minor Modifications To Manufacturing Process For Mycotrol TGAI And Manufacturing Process For Mycotrol ES End Product Formulation. Document No. 2, Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 1261800

Reference: Mycotech Corp. 1997, Five-lot Analysis Of Beauveria Bassiana Strain GHA Technical Grade Active Ingredient (TGAI). 97-01, Data Numbering Code: M2.9.2 Confidential Business Information

PMRA Document Number: 1261801

Reference: Mycotech Corp. 1993, Certification Of Ingredient Limits. Document No. 7, Data Numbering Code: M2.9.2 Confidential Business Information

PMRA Document Number: 1261802

Reference: Mycotech Corp. 1993, Discussion Of Formation Of Unintentional Ingredients. Document No. 5, Data Numbering Code: M2.10.2,M2.10.3,M2.9.3 Confidential Business Information

PMRA Document Number: 1261803

Reference: Mycotech Corp. 1997. Five-lot Analysis Of Beauveria Bassiana Strain GHA Technical Grade Active Ingredient (TGAI). 97-01, Data Numbering Code: M2.10.1 Confidential Business Information

PMRA Document Number: 1261804

Reference: Mycotech Corp. 1993. Certification Of Ingredient Limits. Document No. 7, Data Numbering Code: M2.10.1 Confidential Business Information

PMRA Document Number: 1261806

Reference: University Of Florida Citrus Research And Education Centre. 1993, Allozyme Characterization Of Beauveria Bassiana Strain GHA. 93-004, Data Numbering Code: M2.7.1 Confidential Business Information

PMRA Document Number: 1261807

Reference: Laverlam International Corp. 2004. Storage Stability Testing. Data Numbering Code: M2.11 Confidential Business Information

PMRA Document Number: 1261808

Reference: Laverlam Internatinoal Corp. 2004. Summary Of Physical And Chemical Properties. Data Numbering Code: M2.12 Confidential Business Information

PMRA Document Number: 1425502

Reference: Laverlam Internatinoal Corp. 2006, Brand Name Products With Contain Orchex, Data Numbering Code: M2.9.1 Confidential Business Information

PMRA Document Number: 1425503

Reference: Humber, R And K. Hansen. 2005. Beauveria And Allied Fungi, Data Numbering Code: M2.7.1

PMRA Document Number: 1425504

Reference: Loisey, B. And C. Wizda. 2002. Nonylphenols And Their Ethoxylates, Data Numbering Code: M2.9.1 Confidential Business Information

PMRA Document Number: 1425505

Reference: Laverlam Internatinoal Corp. 2007. Laverlam Response To Request For Clarification On Botanigard Submission, Data Numbering Code: M2.7.1,M2.9.1 Confidential Business Information

PMRA Document Number: 1425506

Reference: United States Environmental Protection Agency. 2003. Ambient Aquatic Life Water Quality Criteria For Nonylphenol - Draft, Data Numbering Code: M2.9.1

PMRA Document Number: 1459098

Reference: Zimmermann, G. 2007, Review On Safety Of The Entomopathogenic Fungi *Beauveria Bassiana* And *Beauveria Brongniartii*. Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536474

Reference: Begley, C. G. And P. Waggoner. 1992. Soft Contact Lend Contamination By *Beauveria Bassiana*. *Iclc*, Vol. 19, pp 247-252, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536476

Reference: Cabo, J. F. G. , J. E. Serrano And M. C. B. Asensio. 1995. Mycotic Pulmonary Disease By *Beauveria Bassiana* In A Captive Tortoise, *Mycoses*, Vol 38, pp 167-169, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536477

Reference: Dehoog et. al. 2000. *Beauveria Bassiana*, Atlas Of Clinical Fungi, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536478

Reference: Domsch et. al. 1993. *Beauveria*, Companion of Soil Fungi, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536479

Reference: Drouhet, E. And B. Dupont. 1980. Chronic Mucocutaneous Candidosis And Other Sperficial And Systemic Mycoses Successfully Treated With Ketocazole, *Reviews Of Infectious Diseases*, Vol 2, pp 606-620, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536480

Reference: Eriksson, O. E. 2005. Outline Of Ascomycota, *Myconet*, Vol 11, pp 1-45, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536481

Reference: European Parliament And Of The Council. 2000. Directive 2000/54/EC, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536482

Reference: Freour, P. M. Lahourcade, And P. Chomy. 1966. Les Champignons Beauveria En Pathologie Humaine. La Presse Medicale, Vol 45, pp 2317-2321, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536483

Reference: Freour, P. M. Lahourcade And P. Chomy. 1966. Sur Une Mycose Pulmonaire Nouvelle Due A Beauveria, Journal De Medecine De Bordeaux, No 6, pp 823-836, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536484

Reference: Freour, P. M. Lahourcade And P. Chomy. 1966. Une Mycose Nouvelle: Etude Clinique Et Mycologie Dune Localisation Pulmonaire De Beauveria, Societe Medicale Des Hopitaux De Paris, Vol 117, pp 197-206, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536485

Reference: Fromtling, R. A. J. M. Jensen, B. E. Robinson And G. S. Bulmer. 1979. Fatal Mycotic Pulmonary Disease Of Captive American Alligators, Veterinary Pathology, Vol 16, pp 428-431, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536486

Reference: Georg, L. K. W. M. Williamson, E. B. Tilden, And R. E. Getty. [year] Mycotic Pulmonary Disease Of Captive Giant Tortoise Due To Beauveria Bassiana And Paecilomyces Fumoso-roseus. Communcable Disease Center, pp 80-89, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536487

Reference: Guarro, J. And Cano, J. Phylogeny Of Onygenalean Fungi Of Medical Interest, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536488

Reference: Henke, M. O. G. S. De Hog, U. Gross, G. Zimmermann, D. Kraemer, And M. Weig. 2002. Human Deep Tissue Infection With An Entomopathogenic Beauveria Species, Journal Of Clinical Microbiology, Vol 40, pp 2698-2702, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536489

Reference: Index Fungorum Partnership. 2006. Species Fungorum, Species Synonymy, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536490

Reference: Ishibashi, Y. H. E. Kaufman, M. Ichinoe, And S. Kagawa. 1986. The Pathogenicity Of Beauveria Bassiana In The Rabbit Cornea, Mykosen, Vol 30, pp 115-126, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536491

Reference: Kislak, T. A., A. Cu-unjeng, L. Sigler, And J. Sugar. 1999. Medical Management Of Beauveria Bassiana Keratitis, Cornea, Vol 19, pp 405-406, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536492

Reference: Liu, Z. Z. Liang, A. Liu, Y. Yao, K. D. Hyde, And Z. Yu. 2002. Molecular Evidence For Teleomorph-anamorph Connections In Cordyceps Based In Its-5.8s Rdna Sequences, Mycology Research, Vol 106, pp 1100-1108, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536493

Reference: Low, C.d.t. P. R. Badenoch, And D. J. Coster. 1997. Beauveria Bassiana Keratitis Cured By Deep Lamellar Dissection. Cornea, Vol 16, pp 698-699, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536494

Reference: Marchisio, V. F. 2000, Keratinophilic Fungi: Their Role In Nature And Degradation Of Keratinic Substances, pp 86-92, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536495

Reference: Marchisio, V.F. , A. Fusconi, And S. Rigo. 1994, Keratinolysis And Its Morphological Expression In Hair Digestion By Airborne Fungi, Mycopathologia, Vol 127, pp 103-115, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536496

Reference: McDonnell, P.J. T. P. Werblin, L. Sugler And W. R. Green. 1984. Mycotic Keratitis Due To Beauveria Alba, Cornea, Vol 3, pp 213-216, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536497

Reference: Quesada-moraga, E. And A. Vey. 2004. Bassiacridin, A Protein Toxic For Locusts Secreted By The Entomopathogenic Fungus Beauveria Bassiana, Mycology Research, Vol 108, pp 441-452, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536498

Reference: Rehner, S.A. And E. Buckley. 2004. A Beauveria Phylogeny Inferred From Nuclear Its And Efl-alpha Sequences: Evidence For Cryptic Diversification And Links To Cordyceps Teleomorphs, Mycologia, Vol 97, pp 84-98, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536499

Reference: Sachs, S.W. J. Baum, And C. Mies. 1985. Beauveria Bassiana Keratitis, British Journal Of Ophthalmology, Vol 69, pp 548-550, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536500

Reference: European Commission, Health And Consumer Protection Directorate-general. 2005. Guideline Developed With The Standing Committee On The Food Chain And Animal Health On The Taxonomic Level Of Micro-organisms To Be Included In Annex 1 To Directive 91/414/EEC, Data Numbering Code: M2.7.2.

PMRA Document Number: 1536501

Reference: Tucker, D.L. C. H. Beresford, L. Sigler, And K. Rogers. 2004. Disseminated Beauveria Bassiana Infection In A Patient With Acute Lymphoblastic Leukemia, Journal Of Clinical Microbiology, Vol 42, pp 5412-5414, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536502

Reference: Westwood, G.S. S. W. Huang And N. O. Keyhani. 2005. Allergens Of The Entomopathogenic Fungus Beauveria Bassiana, Clinical And Molecular Allergy, Vol 3, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1536503

Reference: Beaumont, F. H. F. Kauffman, J. R. De Monchy, H. J. Sluiter, And K. De Cries. 1985. Volumetric Aerobiological Survey Of Conidial Fungi In The North-east Netherlands, Allergy, Vol. 40, pp 181-186, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 806681

Reference: Laverlam International Corp. 2004. Registrant S Name And Address. Data Numbering Code: M2.1,M2.2,M2.3,M2.4,M2.5,M2.6 Confidential Business Information

PMRA Document Number: 806684

Reference: Laverlam International Corp. 2004. Manufacturing Process For Mycotrol ES End Product Formulation. . Document No. 2. Data Numbering Code: M2.8 Confidential Business Information

PMRA Document Number: 806691

Reference: Mycotech Corp. 1996. Physical And Chemical Properties Of Mycotrol ES (emulsifiable Suspension) (beauveria Bassiana Strain GHA): Color, Odor, Physical State, Viscosity, Specific Gravity, And Miscibility. 96-04, Data Numbering Code: M2.0 Confidential Business Information

PMRA Document Number: 1147187

Reference: Laverlam International Corp. 2006. Product Release Standards, Data Numbering Code: M2.8

PMRA Document Number: 1147188

Reference: Laverlam International Corp. 2006. Msds For Formulants. Response. Data Numbering Code: M2.9.1

PMRA Document Number: 1147189

Reference: Laverlam International Corp. 2006. 5 Batch Analysis Of Botanigard ES. Response. Data Numbering Code: M2.9.2 Confidential Business Information

PMRA Document Number: 1147191

Reference: Laverlam International Corp. 2006. Response To Deficiency Letter, Data Numbering Code: M2.10.2

PMRA Document Number: 1147192

Reference: Mycotech Corp. 2006. Effect Of Temperature On Shelf-life, Data Numbering Code: M2.11 Confidential Business Information

PMRA Document Number: 1147193

Reference: Mycotech Corp. 1998. Storage Stability Of Mycotrol Botanigard Es, 96-14, Data Numbering Code: M2.11

PMRA Document Number: 1147431

Reference: Laverlam Internatioanl Corp. 1998. SOP 03-06 Enumeration Of Microbial Contaminants In Whole Culture, TGAI, And Formulated Product, Data Numbering Code: M2.10.2 Confidential Business Information

PMRA Document Number: 1602256

Reference: Idaho Food Quality Assurance Laboratory. 2008. Analysis Of Fungal Spores For Beauvericin. Twin Falls, ID. May 28, 2008.

3.0 Impact On Human And Animal Health

PMRA Document Number: 806617

Reference: Summary. Data Numbering Code: M4.1 Confidential Business Information

PMRA Document Number: 806618

Reference: Summaries. Data Numbering Code: M4.2.1

PMRA Document Number: 806619

Reference: IIT Research Institute. Toxicity/pathogenicity Testing Of Beauveria Bassiana Strain GHA Following Acute Oral Challenge In Rats. L08433, Study 6, Data Numbering Code: M4.2.2 Confidential Business Information

PMRA Document Number: 806620

Reference: IIT Research Institute. 1993, Acute Dermal Toxicity Study Of Beauveria Bassiana GHA In Rabbits. L08433, Study 3, Data Numbering Code: M4.4

PMRA Document Number: 806621

Reference: Summary. Data Numbering Code: M4.5.1

PMRA Document Number: 806622

Reference: IIT Research Institute. 1998. Dermal Irritation Study. L084608 SN30, Data Numbering Code: M4.5.2

PMRA Document Number: 806623
Reference: IIT Research Institute. 1998. Dermal Sensitization Study Of Beauveria Bassiana Strain GHA In Guinea Pigs Using The Buehler Method. L08608 SN30, Data Numbering Code: M4.6

PMRA Document Number: 806624
Reference: IIT Research Institute. 1998. Primary Eye Irritation Study Of TGAI (lot 95-19a) In Rabbits. 80203952, Data Numbering Code: M4.9 Confidential Business Information

PMRA Document Number: 806626
Reference: IIT Research Institute. 1993, Pulmonary Toxicity/pathogenicity Testing Of Beauveria Bassiana Strain GHA Following Acute Intratracheal Challenge In Rats. L08433, Study 4, Data Numbering Code: M4.2.3

PMRA Document Number: 806627
Reference: Laverlam International Corp. 2004. Summary. Data Numbering Code: M4.3.1

PMRA Document Number: 806628
Reference: IIT Research Institute. 1993. Toxicity/pathogenicity Testing Of Beauveria Bassiana Strain GHA Following Acute Intraperitoneal Challenge In Rats. L08433, Study 5, Data Numbering Code: M4.3.3

PMRA Document Number: 1147439
Reference: Cytotest Cell Research GMBH. 2006. Salmonella Typhimurium And Escherichia Coli Reverse Mutation Assay With Beauveria Bassiana Strain GHA Conida Spores, 923900, Data Numbering Code: M4.8

PMRA Document Number: 1147440
Reference: Mycotech Corp. 2000. Summary Of Work-related Injuries And Illnesses: Forms 2000-2004, Data Numbering Code: M4.9

4.0 Impact On The Environment

PMRA Document Number: 806625
Reference: Summaries. Data Numbering Code: M9.1

PMRA Document Number: 806629
Reference: Emerald Bioagriculture Corporation. 2004. Avian Oral Toxicity. Data Numbering Code: M9.2.1,M9.2.2

PMRA Document Number: 806630
Reference: Emerald Bioagriculture Corporation. 2004. Freshwater Fish. Data Numbering Code: M9.4.1

PMRA Document Number: 806631
Reference: Emerald Bioagriculture Corporation. 2004. Terrestrial Arthropods (non-target Insect Testing) Honeybee Testing. Data Numbering Code: M9.5.1

-
- PMRA Document Number: 806632
Reference: Emerald Bioagriculture Corporation. 2004. Aquatic Arthropods (freshwater Aquatic Invertebrate Testing). Data Numbering Code: M9.5.2
- PMRA Document Number: 806633
Reference: Emerald Bioagriculture Corporation. 2004. Non-arthropod Invertebrates. Data Numbering Code: M9.6
- PMRA Document Number: 806634
Reference: Emerald Bioagriculture Corporation. 2004. Microorganisms. Data Numbering Code: M9.7
- PMRA Document Number: 806635
Reference: Emerald Bioagriculture Corporation. 2004. Terrestrial Plants. Data Numbering Code: M9.8.1
Confidential Business Information
- PMRA Document Number: 847910
Reference: Mycotech Corporation. 1997. Effect Of Beauveria Bassiana (mycotech Strain GHA) On Invertebrates In Rangeland And Alfalfa Agrosystems. Data Numbering Code: M9.5.1
- PMRA Document Number: 847911
Reference: Springborn Laboratories Inc. 1993. Beauveria Bassiana (BD GHA 1991) 21-day Toxicity To Daphnids (daphnia Magna) Under Static Renewal Conditions. 93-7-4883, Data Numbering Code: M9.5.2
- PMRA Document Number: 847912
Reference: Wildlife International Ltd. 1998. Beauveria Bassiana Strain GHA A 96 -hour Toxicity Test With The Fresh Water Algae (selenastrum Capricornutum. Data Numbering Code: M9.8.2
- PMRA Document Number: 847913
Reference: Mycotech Corporation. 1993. Risk Assessment. Data Numbering Code: M9.9
- PMRA Document Number: 847914
Reference: Mycotech Corporation. 1993. Response Of Young American Kestrels (Falco parvarius) To Beauveria Bassiana Strain GHA. Data Numbering Code: M9.2.1
- PMRA Document Number: 847915
Reference: Hartmann, G. C. And S. S. Wasti. 1980. Avian Safety Of Three Species Of Entomogenous Fungi. Comp. Physiol. Ecol.5(4): 242-245. Data Numbering Code: M9.2.1
- PMRA Document Number: 847916
Reference: Springborn Laboratories Inc. 1993. Beauveria Bassiana (bb GHA 1991) Evaluation Of Potential Embryo-larval Toxicity And Pathogenicity To Fathead Minnow (Pimephales promelas) Under Static Renewal Conditions. Laboratory Report No. 93-8-4910. Data Numbering Code: M9.4.1
-

PMRA Document Number: 847917

Reference: University Of Montana, Division Of Biological Sciences. 1996. Multiple Endpoint, Holistic Assessment Of The Effects Of Mycotrol WP (*Beauveria bassiana* Strain GHA) On Outdoor *Apis Mellifera* L. Colonies. Data Numbering Code: M9.5.1

PMRA Document Number: 847918

Reference: South Dakota Agricultural Experiment Station. 1993. Acute Toxicity/pathogenicity Of *Beauveria Bassiana* Strain GHA To *Tenibrio Molitor* (coleoptera: Tenebrionidae). Laboratory Project ID 93-015. October 19, 1993. Data Numbering Code: M9.5.1

PMRA Document Number: 847919

Reference: Montana State University, Department Of Entomology And Mycotech Corporation. 1993. Acute Toxicity/pathogenicity Of *Beauveria Bassiana* Strain GHA To Predators/parasites: *Xylocoris Flavipes* (hemiptera: Anthocoridae). Laboratory Project ID 93-019. Data Numbering Code: M9.5.1

PMRA Document Number: 847921

Reference: Jones, W. A. And T. J. Poprawski. 1996. *Bemisia Argentifolii* Parasitized By *Eretmocerus* Sp. Is Immune To Infection By *Beauveria Bassiana*. Mycotech Project ID 96-07. Data Numbering Code: M9.5.1

PMRA Document Number: 1147441

Reference: Mycotech Corporation. 2006. Response To Deficiency Notes. Data Numbering Code: M9.4.1,M9.5.1,M9.6

PMRA Document Number: 1147442

Reference: Mycotech Corporation. 2006. Response Data. Statement From Cefas Regarding *B. Bassiana*, Data Numbering Code: M9.4.1

PMRA Document Number: 1147443

Reference: Heinrich, B. 1979. Thermoregulation Of African And European Honeybees During Foraging, Attack, And Hive Exits And Returns. *Journal of Experimental Biology* 80: 217-229. Data Numbering Code: M9.5.1

PMRA Document Number: 1147444

Reference: Shipp, L. J. P. Kapongo, P. Kevan, B. Broadbent. 2006. Bumble Bee Vectored *Beauveria Bassiana* For Control Of Greenhouse Pests, Entomological Society Of America, Data Numbering Code: M9.5.1

PMRA Document Number: 1147445

Reference: Wildlife International Ltd. 1998. An Acute Toxicity Study With The Earthworm In An Artificial Soil Substrate. Project No. 488-101a. Data Numbering Code: M9.6

PMRA Document Number: 1474516

Reference: Mycotech Corporation. 1993. Acute Toxicity/pathogenicity Of *Beauveria Bassiana* Strain GHA For The Beneficial Insect Herbivore: *Aphona Flava* Guill (coleoptera: Chrysomelidae). Laboratory Project No. 93-021. Data Numbering Code: M9.5.1

5.0 Value

PMRA Document Number: 806711

Reference: Summaries of Lab Growth Studies. DACO: M10.1

PMRA Document Number: 806712

Reference: 2000, BotaniGard : an Extended Laboratory Test to determine Effects of Two Formulations of *Beauveria bassiana* on the Parasitic Wasp *Aphidius rhopalosiphi* (DeStefani-Perez). MT002ARE, DACO: M10.2.1

Reference: PMRA Document Number: 806713

Shipp, J.L. et al. Influence of Humidity and Greenhouse Microclimate on the Efficacy of *Beauveria bassiana* (Balsamo) for Control of Greenhouse Arthropod Pests. Agriculture and Agri-Food Canada Greenhouse and Processing Crops Research Centre, DACO: M10.2

PMRA Document Number: 806714

Reference: 2000, BotaniGard : an Extended Laboratory Test to Determine Effects of Two Formulations of *Beauveria Bassiana* on the Minute Pirate Bug *Orius laevigatus*. MT0030LE, DACO: M10.2.1

PMRA Document Number: 806715

Reference: 2000, BotaniGard : an Extended Laboratory Test to Determine Effects of Two Formulations of *Beauveria bassiana* on the Predatory Mite *Typhlodromus pyri* (DeStefani-Perez). MT001TPE, DACO: M10.2.1

PMRA Document Number: 806716

Reference: 1999, BotaniGard : an Extended Laboratory Test to Determine Effects of Two Formulations of *Beauveria bassiana* on the Parasitic Wasp *Aphidius rhopalosiphi* (DeStefani-Perez). MT002ARE, DACO: M10.2.1

PMRA Document Number: 806717

Reference: 1999, BotaniGard : an Extended Laboratory Test to Determine Effects of Two Formulations of *Beauveria bassiana* on the Predatory Mite *Typhlodromus pyri* (DeStefani-Perez). MT001TPE, DACO: M10.2.1

PMRA Document Number: 806718

Reference: 1999, BotaniGard : An Extended Laboratory Test to Determine Effects of Two Formulations of *Beauveria bassiana* on the Minute Pirate Bug *Orius leavigatus*. MT0030LE, DACO: M10.2.1

PMRA Document Number: 806719

Reference: BotaniGard : A Microbial Insecticide, Based on the Entomopathogenic Fungus *Beauveria bassiana*, for Control of Greenhouse Whitefly, *Trialeurodes vaporariorum*, in *Gerbera*, *Gerbera jamesonii*, and for Control of Silverleaf Whitefly, *Bemisia argentifolii*, in *Poinsettia*, *Euphorbia pulcherrima*. Proefstation voor Bloemisterij en Glasgroente.. Data Numbering Code: M10.2.2.

PMRA Document Number: 806724
Reference: Nature and Economics of Pest/Disease Problem in Canada. DACO: M10.4.2

PMRA Document Number: 806725
Reference: Current Crop Protection Tools. DACO: M10.4.3

PMRA Document Number: 806726
Reference: Contribution to IPM Strategies/Practices. DACO: M10.4.4

PMRA Document Number: 1147194
Reference: Efficacy Overview Mycotrol mycoinsecticide, DACO: M10.2.1

PMRA Document Number: 1147195
Reference: Miscellaneous efficacy studies, DACO: M10.2.1

B. Additional Information Considered

i) Published Information

1.0 Methods of Analysis

PMRA Document Number: 1443979
Reference: Bidochka, M.J. J. E. Kasperski, and G. A. M. Wild. 1998. Occurrence of the entomopathogenic fungi *Metarhizium anisopliae* and *Beauveria bassiana* in soils from temperate and near-northern habitats. *Canadian Journal of Botany*. Vol. 76: p. 1198-1204

2.0 Impact On Human And Animal Health

PMRA Document Number: 1430526
Reference: Ali-shtayeh, M. S. And Jamous, R, M.F. 2000. Keratinophilic Fungi And Related Dermatophytes In Polluted Soil And Water Habitats, Department Of Biological Sciences, An-Najah National University, Nablus, Palestinian Authority:p. 51-59. Data Numbering Code: 12.5, M2.0, M4.0.

PMRA Document Number: 1443979
Reference: Bidochka, M.J. J. E. Kasperski, And G. A. M. Wild. 1998. Occurrence Of The Entomopathogenic Fungi *Metarhizium Anisopliae* And *Beauveria Bassiana* In Soils From Temperate And Near-northern Habitats. *Canadian Journal of Botany* (1998), Vol. 76: P. 1198-1204. Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1536234
Reference: Goettel, M. S. And S. T. Jaronski. 1997. Safety And Registration Of Microbial Agents For Control Of Grasshoppers And Locusts. In: *Memoirs Of The Entomological Society Of Canada*. No. 171. Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1459098

Reference: Zimmerman, G. 2007. Review On Safety Of The Entomopathogenic Fungi *Beauveria bassiana* And *Beauveria brongniartii*. *Biocontrol Science And Technology*. 17(5-6): 553-596.

Data Numbering Code: M.2.7.2.

PMRA Document Number: 1593933

Reference: Cook, R. J. W. L. Bruckhart, J. R. Coulson, M. S. Gottle, R. A. Humber, R. D. Lumscen, J. V. Maddox, M. L. McManus, L. Moore, S. F. Meyer, P. C. Quimby, Jr. J. P. Stack, And J. L. Vaughn. 1996. Commentary: Safety Of Microorganisms Intended For Pest And Plant Disease Control: A Framework For Scientific Evaluation. *Biological Control* 7 (0102): pp.333-351. Data Numbering Code: M2.0, M4.0.

PMRA Document Number: 1591639

Reference: Gürcan, S. H. M. Tugrul, Y. Yörük, B. Özer, M. Tatman-otkun, And M. Otkun. 2006. First Report Of *Empyema* Caused By *Beauveria Bassiana*. *Mycoses* 49: 246-248. Data Numbering Code: M.2.7, M.4.0.

PMRA Document Number: 1591644

Reference: Lorigo, A. A. Moretti, G. Castella, M. Kostecki, P. Golinski, A. Ritieni, And J. Chelkowski. 1998. Beauvericin Production In *Fusarium* Species. *Applied Environmental Microbiology* 64(8): 3084-3088. Data Numbering Code: M2.7, M4.0.

PMRA Document Number: 1593938

Reference: Mel'nikova, E. A. And V. I. Murza 1980. Investigation Of The Safety Of Industrial Strains Of Microorganisms And Microbial Insecticides. *Journal of Hygiene, Epidemiology, and Microbiological Immunity* 24(4): 425-431. Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1593936

Reference: Strasser, H. And M. Kirchmair 2006. Potential Health Problems Due To Exposure In Handling And Using Biological Control Agents. J. Eilenberg And H, M.T. Hokkanen (eds.) *An Ecological And Societal Approach To Biological Control*. (2006); pp.275-293. Data Numbering Code: M2.0, M4.0.

PMRA Document Number: 1591641

Reference: Simpanya, M. F. 2000. Chapter 1: Dermatophytes: Their Taxonomy, Ecology, And Pathogenicity. In: *Biology Of Dermatophytes And Other Keratinophilic Fungi*. R. K. S. Kushwaha And J. Guarro. (eds.). *Revista Iberoamericana De Micrologia*. Bilboa, Spain. pp. 1-12. Data Numbering Code: M2.7, M4.0.

3.0 Impact On The Environment

PMRA Document Number: 1443979

Reference: Bidochka, M.J. J. E. Kasperski, and G. A. M. Wild. 1998. Occurrence of the entomopathogenic fungi *Metarhizium anisopliae* and *Beauveria bassiana* in soils from temperate and near-northern habitats. *Canadian Journal of Botany* 76:1198-1204 Data Numbering Code: M2.7.2.

PMRA Document Number: 1593936

Reference: Strasser, H. and M. Kirchmair 2006. Potential Health Problems Due to Exposure in Handling and Using Biological Control Agents. J. Eilenberg and H, M.T. Hokkanen (eds.) An Ecological and Societal Approach to Biological Control. (2006); p.275-293. Data Numbering Code: M2.0, M4.0, M9.0.

PMRA Document Number: 1536234

Reference: Goettel, M. S. and S. T.Jaronski. 1997. Safety and Registration of Microbial Agents For Control of Grasshoppers and Locusts. In: Memoirs of the entomological society of Canada. No. 171. Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1536280

Reference: Mel'nikova, E. A. and V. I. Murza. 1980. Investigation of the Safety of Industrial Strains of Microorganisms and Microbial Insecticides. Journal of Hygiene, Epidemiology and Microbiological Immunity. 24(4): 425-431 Data Numbering Code: M2.0, M4.0, M9.0

PMRA Document Number: 1593954

Reference: Jacobsen, A, M. G. K. Mortensen, and H. C. B. Hansen. 2004. Organic Compounds in the Environment. Degradation and Mobility of Linear Alkylbenzene Sulfonate and Nonylphenol in Sludge-Amended Soil. January-February 2004. Journal of Environmental Quality. 33:232-240, Data Numbering Code: M8.0, M9.0

PMRA Document Number: 1593955

Reference: Chang, B.V. B. W. Chiang, and S. Y. Yuan. 2006. ScienceDirect - Biodegradation of nonylphenol in soil. Chemosphere 66: 1857-1862. Data Numbering Code: M8.0, M9.0

PMRA Document Number: 1593956

Reference: McSweeney, B. and J. Currie. 2002. Institute for Health and Consumer Protection, European Chemicals Bureau, Existing Substances. European Union Risk Assessment Report - 4-nonylphenol (branched) and nonylphenol - Risk Assessment, European Chemicals Bureau. Data Numbering Code: M9.0

PMRA Document Number: 1593960

Reference: Topp, E. and A. Starratt. 1999. Rapid mineralization of the endocrine-disrupting chemical 4-nonylphenol in soil. Environmental Toxicology and Chemistry. 19 (2): 313-318. Data Numbering Code: M8.0, M9.0

PMRA Document Number: 1593961

Reference: Health Canada and Environment Canada. 2001. Canadian Environmental Protection Act, 1999 - Priority Substance List Assessment Report- Nonylphenol and its Ethoxylates. Environment and Health Canada. Data Numbering Code: M8.0, M9.0

PMRA Document Number: 1572774

Reference: Middaugh, D.P. Genthner, F.J. 2004, Infectivity and teratogenicity of Beauveria bassiana in Menidia beryllina embryos - Abstract. Vol. 27, No. 1, Data Numbering Code: 9.4

PMRA Document Number: 1572775

Reference: Genthner, F.J. Middaugh, D.P. 1992, Effects of *Beauveria bassiana* on embryos of the inland silverside fish (*Menidia beryllina*). *Applied Environmental Microbiology*. 1992; 58(9) Abstract, Data Numbering Code: 9.4