

10/16/92

NOTE TO DAVID BAYS

SUBJECT: Metarhizium anisopliae EEB Reviews for the Roach Control Chamber and Fly Control Chamber Products

Please concur and/or comment on my understanding of the applicability of the attached review.

1. The data requirements table applies to both products.
2. The Environmental Hazards Statement only applies to the fly product.

In addition to the two types of end-use products mentioned above, registration applications exist for technical products. Please concur and/or comment on my understanding of the applicability of the attached review to these products.

1. The data requirements table applies to these products.
2. The Environmental Hazards Statement for these products should read as follows.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

D. T. Rye
Concur

11/2/92
Date

Comments

Mike Mendelsohn

EEB REVIEW

Pesticide Name Bio-Path - Metarhizium anisopliae

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

EcoScience Corporation has requested a Section 3 Registration for Metarhizium anisopliae as the active ingredient for the control of roaches.

The active ingredient in Bio-Path is a naturally occurring soil bacterium which is pathogenic to certain insects. The fungus produces conidia that are naturally infectious (also serves as a survival structure in the soil) and if an insect comes into contact with these spores, the spore adhere, germinate and penetrate into the host insect. After proliferation in the hemolymph, the insect dies and the fungus produces new spores on the insect cadavers.

100.2.0 Formulation Information

Bio-Path™: Roach Control Chamber

ACTIVE INGREDIENT:

<u>Metarhizium anisopliae</u>	0.35%*
INERTS	99.65%

* Note: a minimum of 1×10^4 colony forming units per chamber

100.3.0 Application Methods, Directions, Rates

For best control clean area to eliminate alternative food sources, clutter and water sources.

Bio-Path™: Roach Control Chambers are a biological way to kill roaches, employing a living biological agent specific to certain insects without harming humans, domestic pets or the environment. It kills roaches without the use of conventional synthetic pesticides.

Caution: Do not shake chambers, this may dislodge some material. This will not affect the efficacy of the product. If material falls from the chamber, clean with a damp paper towel and put in trash. Avoid inhalation of dislodged material. Note: Do not remove or puncture label or chamber.

The chambers should be place anywhere that roaches occur. See the attached label for the specific Household, Residential, Commercial, Industrial and Institutional Use directions.

100.4.0 Target Organisms

Cockroaches

100.5.0 Precautionary Labeling

The label contains the following precautions:

CAUTION: KEEP OUT OF REACH OF CHILDREN

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

(Pesticide and container disposal directions are adequate)

101.0.0 Hazard Assessment

101.1.0 Discussion

The literature citations supplied with this submission indicate that Metarhizium anisopliae is naturally occurring and does not adversely effect birds, fish, aquatic invertebrates, plants, honey bee, and beneficial insect species. In addition, exposure of nontarget organisms to this pesticide will be limited due to its restricted use pattern. The product is contained in enclosed chambers and will only be placed in residential, commercial, industrial and institutional areas, such as homes, commercial establishments, industrial buildings and transportation vehicles. Therefore, the ecological effects data requirements will be waived for this product.

101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

Avian Studies

Reports in the literature indicate that Metarhizium anisopliae does not grow well at high temperatures, above 30C. Since the temperature found in the crop of birds is above 30C, the fungus would not be able to germinate and subsequently cause an infection in this environment. In addition, this fungus will generally only germinate in nature when it is in contact with a susceptible insect species. Also exposure to birds would be limited because of the restricted use pattern of the product.

Fish Studies

Literature reports indicate that *M. anisopliae* is an entomopathogen, having a host range restricted to insects and nematodes, and to our knowledge, no reports exist that show it would affect fish. Therefore, the registrant will be granted a waiver for fish testing.

Mammalian Wildlife

The data submitted to the toxicology branch indicate that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. In light of the above results risk to mammalian wildlife is expected to be minimal to nonexistent.

Aquatic Invertebrate Studies

Literature reports indicate that *M. anisopliae* is an entomopathogen, having a host range restricted to insects and nematodes, and to our knowledge, no reports exist that show it would affect aquatic invertebrates. However, one exception to these reports is that this fungus can potentially kill mosquitos but at only very high rates. The limited use of this fungus as proposed in this registration should not lead to a significant environmental exposure to mosquitos. Therefore, the registrant will be granted a waiver for aquatic invertebrate testing.

Nontarget Plant Studies

Literature reports indicate that *M. anisopliae* is an entomopathogen, having a host range restricted to insects and nematodes, and to our knowledge, no reports exist that show it would affect plants. Therefore, this product should not cause any adverse effects to nontarget plant species and the nontarget plant testing requirement will be waived.

Nontarget Insect Studies

There is only one report in the literature to our knowledge that demonstrates an adverse effect to nontarget insects from this fungus. The exception is *Ophyra aenescens*, a muscid fly, whose larval stage is predaceous on house fly larvae in poultry houses. There is some disagreement over the utility of using or relying on this fly species as a biocontrol measure, however it is used by some farmers. This concern may be alleviated by the proper placement of the roach chambers. *Ophyra* adults tend to fly low and are usually found close to the

manure surface in high rise poultry houses. Placing the chambers high up, away from the manure surface, should minimize harmful effects on these flies. Therefore, this product should not cause adverse effects to nontarget insect species if properly used and the nontarget insect testing requirement will be waived.

Honey Bee Studies

No literature reports to our knowledge are known to exist that demonstrate adverse effects to honey bees even though the fungus is found abundantly in nature. Exposure to honey bees should be limited due to the restricted use of the product. Therefore, this product should not cause adverse effects to honey bee and the nontarget honey bee data requirement will be waived.

101.3.0 Endangered Species Considerations

EEB feels that there will not be a "may effect" situation for endangered mammals, birds, plants and aquatic species from the proposed uses of this product.

101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M. The wavier requests and studies submitted by the registrant are adequate to address the data requirements for the registration of a microbial pesticide and can be used to make a risk assessment.

Generic Data Requirements For Bio-Path™

Data Requirement	Test ¹ Substance	Use ² Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?
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§158.740 Microbial Pesticide Nontarget Organism - Tier I

Avian Testing

154-16 Avian Acute Oral

- upland gamebird	TGAI	I	No	--	No ³
- waterfowl	TGAI	I	No	--	No ³

Aquatic Organism Testing

154-19 Freshwater Fish LC50

- rainbow trout	TGAI	I	No	--	No ³
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154-20	Freshwater Invertebrate Testing					
	- <u>Daphnia magna</u>	TGAI	I	No	--	No ³
154-22	Nontarget plant studies					
	- terrestrial	TGAI	I	No	--	No ³
	- aquatic	TGAI	I	No	--	No ³
154-23	Nontarget insect testing					
	- parasitic wasps	TGAI	I	No	--	No ³
	- green lacewing	TGAI	I	No	--	No ³
	- ladybird beetle	TGAI	I	No	--	No ³
154-24	Honey bee testing					
	- Dietary	TGAI	I	No	--	No ³

¹ TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.

² The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, Outdoor; I = Indoor.

³ These data requirements will be waived based on a lack of exposure due to the products restricted use pattern (confined to a chamber and used in structures), occurrence in nature with a lack of documented adverse effects to nontarget organisms, and literature reports that demonstrates that this fungus is an entomopathogen (having a host range limited to insects and nematodes).

101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) needs to have the following additions/modifications:

ENVIRONMENTAL HAZARD STATEMENT:

This product is pathogenic to muscid flies (Ophyra aenescens), a biocontrol agent for house fly larvae in poultry houses. In Poultry Houses: The chambers should be placed high up, away from the manure surface to minimize harmful effects on these flies.

102.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Bio-Path™ by EcoScience Corporation for the control of cockroaches in Residential, Commercial, Industrial and Industrial areas. The registrant has adequately addressed all of the ecological effects testing requirements.

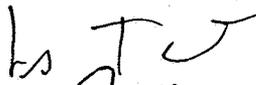
All of the testing requirements have been waived for this product due to a lack of exposure to nontarget organisms because of this product's restricted use pattern. The Metarhizarium anisopliae fungus is contained in a chamber (box) and is placed in structures which are generally indoors. The only way for the fungus to be moved outdoors is by being carried by the target roaches but this would amount to a very small environmental exposure. Also the fungus is naturally occurring and the small amount of the fungus that could be released in this way would not significantly add to the background level of fungus in the environment. In addition, to our knowledge no reports of adverse effects to nontarget organisms have been reported in the literature. The one exception is the muscid fly, which can be used as a biocontrol agent for house flies in poultry houses. This beneficial insect is susceptible to M. anisopliae. The registrant will need to add a precautionary statement to the label (See section 101.4) to alleviate this concern.

Therefore, EEB concludes that the proposed uses of Bio-Path™ will lead to a minimal risk to nontarget organisms or endangered species.

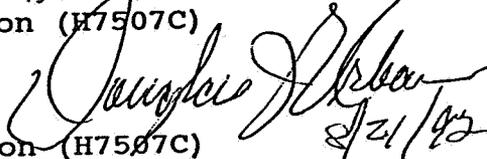
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