Killed Fermentation Solids and Solubles of Myrothecium verrucaria (119204) Technical Document

Date Issued: August 1998

1. Description of the Chemical(s) (Biochemicals)

Generic Name of the Active Ingredient: killed fermentation solids and solubles of *Myrothecium verrucaria*

Trade and other name(s): ABG-9008 Nematicide

OPP Chemical Codes: 119204

Year of Initial Registration: 1996

Pesticide Type: Biological Nematicide

U.S. and Foreign Producers: Abbott Laboratories

2. Use Sites, Application Timing & Target Pests

- o **Target Pests**: *Meloidogyne spp.* (root knot nematode), *Heterodera/Globodera* (cyst nematode), *Pratylechus spp.* (lesion nematode), *Tylenchulus semipenetrans* (citrus nemadode), *Trichodorus spp.* (stubby-root nematode), *Xiphinema spp.* (dagger nematode), and other tylenchid nematodes parasitizing food, fiber and ornamental crops.
- o Registered Uses: For use on all food crop and ornamental commodities when applied pre-planting, pre-seeding or post-planting in accordance with good agricultural practices. Specifically, the use sites include: citrus, cucurbits (cucumber, melon, squash), field crops (such as cotton, peanuts, soybeans), ornamentals (including flowers, bedding plants, bulbs and, turf), fruiting vegetables (such as eggplant, pepper, and tomato), greenhouse/shade house and outdoor nursery crops, leafy vegetables and cole crops (such as lettuce, broccoli, cabbage, and cauliflower), pome fruits (such as apples and pears), root and tuber crops (such as beet, carrot, potato, and sugar beet), small fruit and berries (such as grape and strawberry), stone fruits (such as cherry, nectarine, peach, and plum), and special crops such as bananas, hops, kiwi fruits, pineapple, and tobacco.

3. Science Findings

A. Toxicology

The following toxicity studies were submitted and reviews were found acceptable.

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- 1. Acute Oral Toxicity in Rats, (End-Use) Guideline No.81-1: The mean oral LD $_{50}$ of ABG-9008 was greater than 5000 mg/kg rat body weight. Toxicity Category IV.
- Acute Oral Toxicity in Rats, (Technical) Guideline No 81-1: The acute oral LD₅₀ of ABG-9008 Technical in rats is greater than 5000 mg/kg. Toxicity Category IV.
- 3. Acute Dermal Toxicity in Rabbits, Guideline No 152-31: The dermal LD₅₀ of ABG-9008 in rabbits is greater than 2000 mg/kg. Toxicity Category III.
- 4. Acute Pulmonary Toxicity in Rats, Guideline No 152-32: The acute intratracheal LD_{50} of ABG-9008 is greater than 50 mg/kg rat body weight. Toxicity Cagegory IV.
- 5. Acute Inhalation Toxicity in Rats, Guideline Nos. 81-3: The LD_{50} of ABG-9008 Experimental Biological Nematicide was determined to be greater than an aerosolized dose of 5.99 mg/L.
- 6. Primary Eye Irritation in Rabbits, Guideline No 81-5: Rabbits displayed slight ocular irritation when given a single 0.1 ml dose. The irritation dissipated by day 3. Toxicity Category III.
- 7. Primary Dermal Irritation in Rabbits, Guideline No 152-35: Rabbits displayed mild dermal irritation over a 72 hour period following skin exposure of 0.5 g ABG-9008. The irritation disappeared by day 3. Toxicity Category IV.
- 8. Hypersensitivity Incidents, Guideline No. 152-37: No incidents of hypersensitivity have been reported for this organism.

B. Ecological Effects

The following ecological effects studies were submitted and most reviews are found acceptable:

1. Avian studies:

A. MRID No. 43337014, ABG-9008: An Avian Oral Toxicity Study with the Bobwhite. Guideline Reference No. 154-16. The results of the study indicate that ABG-9008 (Tech 1), a heat inactivated fermentation mixture of Myrothecium verrucaria, is practically nontoxic to bobwhite quail with the LD50 being greater than 2500 mg/kg/day for five days.

Adequacy of the Study: Satisfactory

B. MRID No. 43337013, ABG-9008: An Avian Oral Toxicity Study in the Mallard. Guideline Reference No. 154-16. The results of the study indicate that ABG-9008 (Tech 1), a heat inactivated fermentation mixture of Myrothecium verrucaria, is practically nontoxic to the mallard with the LD₅₀ being greater than 2500 mg/kg/day for five days. However, since histopathological examination and culturing

were not reported for areas showing anatomical abnormalities at necropsy, these observations remain unexplained. Adequacy of the Study: Satisfactory

2. Aquatic studies:

- A. MRID No. 43337017, Acute Toxicity of ABG-9008 (Lot # 57-046-BD) to the Daphnid Daphnia magna. Guideline Reference No. 154-20. The results of the study indicate that ABG-9008 (tech 1), a heat inactivated fermentation mixture of Myrothecium verrucaria, is slightly toxic to Daphnia magna with the LC₅₀ being approximately 78 mg/L in a 48 hour static renewal study. However, these calculations were based on the nominal rather than the actual concentration of ABG-9008. Test material did not remain suspended or soluble during the course of the study and the analytical method could not measure actual concentration during the assay. Further, prior to taking samples the test vessels were stirred thus artificially increasing the amount of test material in suspension. The study is invalid since the concentration of ABG-9008 that the daphnids were exposed to is unknown. Adequacy of the Study: Invalid.
- B. MRID No. 43689601, Acute Toxicity of ABG-9008 (Lot #57-046-BD) to the Rainbow Trout, Oncorhynchus mykiss. Guideline Reference No. 154-19.: The results of the study indicate that ABG-9008 (Tech 1), a heat inactivated fermentation mixture of Myrothecium verrucaria, is highly toxic to rainbow trout with the LC₅₀ being approximately 0.825 mg/L in a 96 hour static renewal study. However, the actual material that was measured in the analytical method was not indicated since "measurement of ABG-9008 (Lot# 57-046-BD) concentrations in test media was attempted, but nominal concentrations were below the analytical detection limit and results were unacceptable." Due to the problems encountered with the analytical method and since "[i]nsoluble material was not noted in any test vessel during the test." It will be assumed that an amount nearly equal to the nominal concentration was in solution or suspension. However, we note that this is a weak assumption and allowed only because of the analytical method difficulties. Adequacy of the Study: Satisfactory.
- C.MRID No. 43337015, Acute Toxicity of ABG-9008-NP to the Rainbow Trout, Oncorhynchus mykiss. Guideline Reference No. 154-19.: The results of the study indicate that ABG-9008-NP, (Tech 2) a heat inactivated fermentation mixture of Myrothecium verrucaria, is moderately toxic to rainbow trout with the LC₅₀ being approximately 2.1 mg/L in a 96 hour static renewal study. However, the actual material that was measured in the analytical method was not indicated. The observation that "[i]nsoluble material was not noted in any test vessel during the test." supports the reported results that the measured concentrations were nearly equal to the nominal concentrations. Adequacy of the Study: Satisfactory
- D.MRID No. 43337016, Acute Toxicity of ABG-9008 to the Rainbow Trout, Oncorhynchus mykiss in Dilution Water Containing 10 mg/L Humic Acid. Guideline Reference No. 154-19. The results of the study indicate that ABG-9008 (Tech 1) in dilution water containing 10 mg/L humic acid was practically non-toxic to rainbow trout with the LC50 being greater than 100 mg/L in a 96 hour static renewal study.

However, these calculations were based on the nominal rather than the actual concentration of ABG-9008. Test material did not remain suspended or soluble during the course of the study and measured concentrations were not reported. The study is invalid since the concentration of ABG-9008 that the trout were exposed to is unknown. Adequacy of the Study: Invalid.

3. Non-target plant studies:

A. Abbott Laboratories' Justification for Waiver Request / Nontarget Plant Testing -ABG-9008-. Guideline Reference Nos. 154A-22: Phytotoxicity has not been observed in tests performed with ABG-9008 under laboratory, greenhouse, and field conditions. Doses employed were 5X higher than the recommended field rate of 20-40 lbs/A. In addition to nematode control, use of ABG-9008 provides increased plant growth responses. Plant growth responses included earliness in flowering, higher plant vigor, increased plant shoot and root weights, and significant enhancements in yield and quality of the fruits. Such responses have been observed in plants belonging to varied genera and families such as Tomatoes, Cucumbers, Potatoes, Squash, Eggplant, Strawberries, Sugarbeets, Lilies, Roses, Banana, Turf and Corn. The product has been applied as a pre-plant, at planting, post-planting, post-germination and during the plant growth cycle. Phytotoxic responses have not been observed. Application of the product does not result in reduction in germination for any of the crops tested; in fact, in certain instances significant improvement in plant stand has been observed. Since ABG-9008 is a soil-applied nematicide, this product has not been tested as a foliar treatment. Adequacy of Rationale: Based on the current application methods that limit foliar exposure, the lack of phytotoxicity observed, reported improved plant stand, and the killed microbial status of this material; this study is waived. However, it is noted that certain macrocyclic trichothecene mycotoxins and diketopiperazines are phytotoxic and Myrothecium verrucaria is a plant pathogen. This fungus is reported as a leaf and/or stem pathogen of many plants including tobacco, coffee, cotton, beans, rapeseed, and Zinnia; as well as a root pathogen of red clover and alfalfa. Therefore, the applicant should be reminded that suspected and confirmed incidences of phytotoxicity or possible disease must be reported to the Agency under FIFRA § 6(a)(2).

4. Non-target insect and honeybee studies:

A. Abbott Laboratories' Justification for Waiver Request / Nontarget Insects and Honey Bee Testing -ABG-9008-. Guideline Reference Nos. 154A-23, -24: ABG-9008 is used to control soil and plant nematodes and hence is applied to the soil and incorporated 3"-6" below the surface. The material will be applied by commercial applicators and will be raked, dressed, or cultivated into the soil. Such an application process minimizes contact with non-target insects and honey bees which are generally airborne. Little or no exposure to outside air, honey bees or non-target insects are anticipated in the application step. Since the product is not intended to be applied as a foliar pesticide, exposure to honey bees is not expected. Based on the testing done to date, this material contains no known mammalian toxin and shows a high degree of specificity

discriminating even free living nematodes from plant parasitic nematodes. ABG-9008 has not shown any insecticidal activity. According to the Standard Evaluation Procedures for Ecological Risk Assessment, nontarget insect and honey bee testing is required if the product's proposed use pattern will result in exposure to the above organisms. ABG-9008 is a soil-applied nematicide and will not result in exposure to these test organisms. In addition, the product shows a high degree of acute mammalian and environmental safety (see Attachments 1 and 2). Adequacy of the Rationale: Given the minimal exposure to above surface insects, including honey bees, due to soil application the studies may be waived. However, materials in the product, e.g. chitinases, may affect nontarget insects and honeybees if significant exposure to the product was to occur.

4. Summary of Data Gaps

Non-target aquatic toxicity has been mitigated with appropriate precautionary label statements which state: "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters."

5. Additional Contact Information

Ombudsman, Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460