

The low toxicity of the subject active ingredient is demonstrated by the data summarized above. Based on this information, it can be concluded that aggregate exposure to *Bacillus sphaericus* over a lifetime will not pose appreciable risks to human health. There is reasonable certainty that no harm will result from aggregate exposure to residues of *Bacillus sphaericus* and, consequently, exempting *Bacillus sphaericus* from the requirement of a tolerance is considered safe.

2. *Infants and children.* It is the opinion of Abbott Laboratories that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus sphaericus*. A determination of safety for infants and children can be made due to the insignificant exposure expected beyond naturally occurring background levels and the low acute toxicity of this microbial insecticide. It can be concluded with reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus sphaericus* residues.

G. Existing Tolerances

Abbott Laboratories is not aware of any existing tolerances or tolerance exemption for *Bacillus sphaericus*. [FR Doc. 97-22374 Filed 8-21-97; 8:45 am] BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-756; FRL-5737-2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-756, must be received on or before September 22, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132,

CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus (PM) 90, Biopesticides and Pollution Prevention Division, (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5th floor, CS1, 2800 Crystal Drive, Arlington, VA. 22202, (703) 308-8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-756] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-756] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 17, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. BioWorks, Inc.

PP 6F4650

EPA has received a pesticide petition from Bioworks, Inc., 122 North Genesee Street, Geneva, New York 14456, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR Part 180 to establish an exemption from the requirement of a tolerance for *Trichoderma harzianum* Rifai strain KRL-AG2 in or on all raw agricultural commodities, except mushrooms.

A. Residue Chemistry

1. *Plant metabolism.* The active ingredient is *Trichoderma harzianum* Rifai strain KRL-AG2 (a.k.a. T-22), a strain of a naturally occurring soil microorganism. This organism controls plant diseases mechanically and is not absorbed or otherwise incorporated into the plant. It has no effect on plant metabolism. This organism controls plant disease by competing with plant pathogens for root and foliar surfaces for the establishment of fungal colonies. *Trichoderma harzianum* Rifai strain KRL-AG2 also controls plant pathogens by the mechanism of mycoparasitism.

2. *Analytical method.* BioWorks has not proposed an analytical method for assessing residues because this organism is naturally occurring, non-toxic and present in a wide variety of habitats, including water. Because there is a natural background population of this organism it would be impossible to distinguish between natural and introduced microbial populations and to establish and enforce any tolerance for this organism. *Trichoderma harzianum* (T-22) does not have adverse effects on the environment, animals or humans. This organism does not persist when applied to foliage or fruit. Ordinary environmental conditions cause rapidly declining population levels of the microbe soon after application to above-ground plant parts.

3. *Magnitude of residues.* The only residue expected at harvest is the background level of *Trichoderma harzianum* (T-22) currently present on agricultural commodities. Any *Trichoderma harzianum* (T-22), either naturally occurring or applied, remaining at harvest will be removed or rendered nonviable by the usual processing of the food or feed.

B. Toxicological profile

1. *Acute toxicity.* Strain T-22 was determined to be non-toxic during the initial Tier I toxicological tests. This pesticide is currently registered for seed treatments for which an exemption from tolerance exists for certain raw agricultural commodities (40 CFR 180.1102). In PR Notice 95-3, June 7, 1995 the Agency included this fungus in a list of low risk pesticides qualifying for reduced restricted entry intervals.

a. *Acute oral toxicity/pathogenicity.* Ingestion of this product produced no apparent signs of toxicity, pathogenicity, or infection following a 21-day test period in both female and male rats. The active ingredient is classified as toxicity category IV for oral toxicity.

b. *Acute pulmonary toxicity/pathogenicity.* A high concentration test

article given by intratracheal injection to male and female rats produced no apparent signs of toxicity or pathogenicity. The active ingredient is classified as toxicity category IV for pulmonary toxicity.

c. *Primary dermal and eye irritation.* EPA granted a waiver for the acute dermal toxicity studies in a letter dated June 28, 1990. The active ingredient is classified as toxicity category III for dermal exposure.

d. *Acute intravenous toxicity.* A high concentration test article was given by intravenous injection to male and female rats. Not apparent signs of toxicity or pathogenicity were observed.

e. *Hypersensitivity incidents reported.* No incidents of hypersensitivity in humans have been reported during the production and handling of this active ingredient.

f. *Immune response.* This organism is non-toxic and naturally occurring. There is no evidence of any negative impact on the immune systems of humans.

g. *Tissue culture.* All available literature indicates that the use of this organism as a pesticide is safe for humans.

Based on the results of the Tier I tests there was no indication that subchronic or chronic studies were required.

2. *Metabolite toxicology.* Strain T-22 produces no known metabolites of any environmental or health concern. This organism controls plant disease by competing with plant pathogens for root and foliar surfaces for the establishment of fungal colonies and by mycoparasitism.

C. Aggregate Exposure

1. *Dietary exposure.* *Trichoderma harzianum* (T-22) is a non-toxic, naturally occurring fungi. There is no evidence that it presents any risk to animals or humans. It is present in many different types of environments worldwide. Because of its ubiquitous nature all humans and animals have some natural exposure to the organism. Proposed application methods, uses, and application rates will not result in a sustained increase in the population levels of this organism beyond the naturally occurring background levels of *Trichoderma harzianum* (T-22).

2. *Food.* Use of strain T-22 as a pesticide will result in little or no residue on food and feed and is highly unlikely to increase exposure of humans to *Trichoderma harzianum* (T-22) fungi by dietary means.

3. *Drinking water.* *Trichoderma harzianum* strains are commonly found in water worldwide. Their presence in drinking water does not present a risk

to animals or humans because the fungus is non-toxic and consumed in low concentrations. It is highly unlikely that use of strain T-22 as a pesticide will increase the concentration of this organism in the water supply beyond the already existing background levels of naturally occurring populations.

4. *Non-dietary exposure.* The only non-dietary exposure expected is to applicators. However, exposure to this organism resulting from its application according to label directions is not expected to present any risk of adverse health effects.

D. Cumulative Effects

Because this organism controls disease by mechanical, not chemical means, and the organism itself is non-toxic there will be no cumulative exposure created by other pesticides acting with the same mode of toxicity. In addition, no cumulative adverse health effects are expected from long-term exposure to this organism.

E. Safty Determination

1. *U.S. population.* Strain T-22 is a strain of naturally occurring non-toxic organism. Use of this organism as a pesticide product will result in little or no residues on food or feed. Since people are already exposed to this organism in nature, the incremental exposure from its use as a pesticide product is expected to be negligible.

2. *Infants and children.* Any differences in infants and children's dietary habits or exposure patterns to this organism do not correlate with an increased risk of harm to children. There is no information suggesting differential sensitivity of infants and children to this natural organism. Infants and children are currently exposed to this organism in the natural environment and no data suggest that the use of this organism as a pesticide will harm children.

F. Internal Tolerances

There are no international tolerances or tolerance exemptions for this biocontrol fungus.

2. Makhteshim-Agan of North America Inc.

PP 7F4812

EPA received a pesticide petition (PP 7F4812) from Makhteshim-Agan of North America Inc., 551 Fifth Avenue, Suite 1100, New York, NY 10176, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of the biofungicide Trichodex

(*Trichoderma harzianum* T-39) in or on all raw agricultural commodities.

A. Proposed Use Practices

Recommended application method and rate(s), frequency of application, and timing of application. Trichodex may be applied with conventional spray equipment for control of *Botrytis* (gray mold) on fruit and vegetable crops. The rate of application is two to four pounds of Trichodex per acre in sufficient gallonage to insure adequate coverage. The frequency and timing of application vary with the crop being treated. For example, one to four applications are made to wine grapes in a rotational program with conventional chemical fungicides, while four to six applications may be applied to wine grapes when the product is used alone. Table grapes are treated with one to three applications during pre-bloom to fruit set. Treatments on strawberry may include up to eight applications (once per week) throughout the growing season from pre-bloom to harvest.

B. Product Identity/ Chemistry

1. **Identity of the pesticide and corresponding residues.** The active ingredient is *Trichoderma harzianum* T-39, a fungus which occurs naturally in the environment worldwide, including in the U.S. The strain of *T. harzianum* used in Trichodex has been designated as "T-39." This strain has been characterized by colony and structural morphology, RFLP mapping and classified by intraspecific DNA primers. The strain is typical of *T. harzianum* and does not express characteristics of plant pathogenic strains. The organism does not persist in the environment and relies on repeated application to achieve plant protection. The organism degrades in the environment to natural organic constituents.

2. **Magnitude of residue anticipated at the time of harvest and method used to determine the residue.** Makhteshim-Agan of North America has requested waivers for these data requirements. The waiver requests were based on the known low toxicity of Trichodex, the natural occurrence of *T. harzianum* T-39 in the environment, the non-toxic mode of action, the submitted data and information available in the open literature.

3. **Statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.** Makhteshim-Agan of North America has not proposed an analytical method, because residues of *T. harzianum* T-39 resulting from Trichodex applications do not pose a

hazard to humans, plants and animals. *T. harzianum* T-39 from naturally occurring strains is commonly found in the environment and can be reasonably expected to exist whether or not Trichodex has been applied to the growing crop.

C. Mammalian Toxicological Profile

Provide the following or rationale for waiver request.

1. **Acute toxicity.** The health effects data submitted in the Makhteshim-Agan of North America Inc. petition and all other relevant material have been fully evaluated by the EPA in their approval of an Experimental Use Permit for large scale field evaluation of Trichodex. The mammalian toxicological data considered in support of the exemption from the requirement of a tolerance for Trichodex include: an acute oral toxicity study in rats, a primary eye irritation study in rabbits and an acute inhalation study in rats. All three studies were assigned Toxicity Category III. The submitted acute dermal toxicity study in rabbits, primary dermal irritation study in rabbits, and a dermal sensitization study in guinea pigs were assigned Toxicity Category IV.

The results of these studies indicated that Trichodex has an acute oral LD₅₀ greater than 500 mg/kg body weight in rats, an acute dermal LD₅₀ greater than 1,150-1,570 mg/kg body weight in rabbits. Trichodex caused reversible eye irritation with complete clearance after 7 days. No dermal irritation in rabbits was observed, however, the product was found to be a delayed contact dermal sensitizer in guinea pigs (based on the modified Beuhler Assay). The acute pulmonary toxicity/ pathogenicity study in the rat showed no evidence of pathogenicity or Trichodex reproduction in the tissues examined. Although the study was of insufficient duration to achieve complete clearance in the lung, the study demonstrated clearance in brain, blood, lymph nodes, kidney, liver, spleen, and caecum. Toxicity Category III was assigned to pulmonary exposure mitigated by label instructions indicating personal protective equipment for applicators.

2. **Genotoxicity, reproductive and developmental toxicity, subchronic toxicity, and chronic toxicity.** The T-39 strain of *T. harzianum*, the active ingredient in Trichodex, does not produce fungal metabolites as its primary mode of action against target plant pathogens. Submitted studies using the Ames Test and Mouse Micronucleus test show no indication of genotoxic or reproductive effects.

D. Aggregate Exposure

1. **Dietary exposure— a. Food.** Trichodex is based on a naturally occurring organism normally found in the environment. For the purposes of assessing the potential dietary exposure under this exemption, it should be considered that *T. harzianum* may be present on all RACs. Submitted studies indicate that residues of Trichodex do not pose a hazard to humans by route of ingestion.

b. **Drinking water.** Based on the available studies presented for use in the assessment of environmental risk, it is not anticipated that drinking water will provide a route of exposure to residues of Trichodex. The anticipated use pattern for Trichodex does not include use in or on waterways. Even though Trichodex can be washed off treated plants by rain and during processing of crops by water, it degrades in an aqueous environment into organic constituents by normal biological, physical, and chemical processes.

c. **Non-dietary exposure.** Based on label directions for use as a foliar applied biofungicide. The only non-dietary exposure is to applicators of the product. However, exposure to Trichodex resulting from its proper application according to label directions for the use of personal protective equipment is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

Other than a possible allergic reaction to spores present in the product following repeated exposure, no cumulative adverse health effects are expected from long-term exposure to Trichodex. Risk of dermal sensitization is addressed on the label which specifies proper personal protective equipment to minimize exposure.

Exposure through other pesticides and substances with a common mode of toxicity with this pesticide.

Consideration of a common mechanism of toxicity is not appropriate for several reasons:

(1) Trichodex has a non-toxic mode of action.

(2) Only a small number of pesticidal products containing *T. harzianum* as an active ingredient are currently registered.

(3) The species is ubiquitous in nature.

(4) The active ingredient has been demonstrated to be non-toxic in submitted acute studies.

F. Safety Determination

1. **U.S. population in general.** Trichodex is based on a naturally

occurring organism normally found in the environment and on crop plants. The low toxicity of the subject active ingredients is demonstrated by the data summarized above. Based on this information, it has been determined that aggregate exposure to Trichodex over a lifetime will not pose appreciable risks to human health and there is a reasonable certainty that no harm will result from Trichodex residues. Since people are exposed to *T. harzianum* from natural sources, the incremental exposure from its use in pesticide products is expected to be negligible.

2. *Infants and children.* It has been determined that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of Trichodex. It is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to Trichodex residues.

G. Existing Tolerances

1. *Existing tolerances or tolerance exemptions.* A temporary tolerance exemption in conjunction with an Experimental Use Permit for Trichodex is currently in effect. EPA has also promulgated permanent exemptions from the requirement for a tolerance for strains of *T. harzianum* other than T-39.

2. *International tolerances or tolerance exemptions.* No maximum residue level has been established for Trichodex by the Codex Alimentarius Commission. Exemptions from the requirement of a tolerance have been granted for Trichodex in all international registrations.

[FR Doc. 97-22375 Filed 8-21-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-00215; FRL-5724-5]

Printed Wiring Board Cleaner Technologies Substitutes Assessment, Making Holes Conductive; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability for Comment.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the draft document entitled "Printed Wiring Board Cleaner Technologies Substitutes Assessment: Making Holes Conductive." This document details the findings of EPA's Design for the Environment (DfE)

Printed Wiring Board (PWB) Project regarding alternative technologies for performing the "making holes conductive" function during the manufacture of PWBs.

DATES: Comments are due no later than October 6, 1997.

ADDRESSES: Comments should be mailed in triplicate to: TSCA Public Docket, Rm. NEG 99, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC, 20460. Comments and data may also be submitted electronically by following the instructions under Unit II. No CBI should be submitted through e-mail. Comments are available for public inspection and copying in the TSCA Nonconfidential Information Center, Rm. NEB 607, 401 M St., SW., Washington, DC. Free copies of the complete 2-volume report (EPA 744-R-97-002 a and b) can be obtained by contacting the EPA's Pollution Prevention Information Clearinghouse (PPIC), at 401 M St., SW., (7407), Washington DC, 20460; 202-260-1023; fax 202-260-4659, or the report can be reviewed on the DfE home page at <http://www.epa.gov/dfc>.

FOR FURTHER INFORMATION CONTACT: Dipti Singh, Design for the Environment Program, Office of Pollution Prevention and Toxics (7406), U.S. EPA, 401 M St., SW., Washington, DC, 20460; 202-260-1678, e-mail: oppt.dfc@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Project Background

EPA's Design for the Environment (DfE) Program began working with the printed wiring board (PWB) industry in 1994, to identify and evaluate environmentally beneficial and cost effective alternatives to PWB manufacturing technologies. The DfE PWB Project is a voluntary, cooperative partnership between EPA, the PWB industry, public-interest groups, and other stakeholders. The goal of this Project is to provide information that will assist the PWB industry in making informed decisions when evaluating and implementing beneficial alternatives to PWB manufacturing technologies.

For purposes of this study, the project evaluated seven alternative technologies for performing the "making holes conductive" (MHC) function during the manufacture of PWBs. The non-conveyorized electroless copper process was considered the baseline process against which alternative technologies and equipment configurations were compared. With this notice, EPA is announcing the availability of the draft document entitled "Printed Wiring

Board Cleaner Technologies Substitutes Assessment: Making Holes Conductive." This document marks the culmination of over 2-years of research by the DfE PWB Project and the University of Tennessee Center for Clean Products and Clean Technologies. The data gathered on the comparative risk, performance, cost, and natural resource requirements of the alternatives and baseline technologies are presented in this document.

II. Public Record

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPPTS-00215], and will include any comments and data submitted electronically. A public version of this record, including printed/paper versions of electronic comments, which does not include any information claimed as confidential business information CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding Federal legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: oppt.ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPPTS-00215]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

Dated: August 12, 1997.

Mary Ellen Weber,

Director, Economics, Exposure, and Technology Division, Office of Pollution Prevention and Toxics.

[FR Doc. 97-22376 Filed 8-21-97; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2217]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

August 19, 1997.

Petitions for reconsideration have been filed in the Commission's rulemaking proceeding listed in this