

LIST 2 INERT INGREDIENTS CURRENTLY
USED IN PESTICIDE PRODUCTS—
Continued

CAS Reg No.	Chemical Name
108-90-7	Monochlorobenzene
108-94-1	Cyclohexanone
111-42-2	Diethanolamine
111-76-2	2-Butoxy-1-ethanol
111-77-3	Diethylene glycol monomethyl ether
111-90-0	Diethylene glycol monoethyl ether
112-34-5	Diethylene glycol monobutyl ether
117-84-0	Dioctyl phthalate
107-98-2	1-Methoxy-2-propanol
124-16-3	1-Butoxyethoxy-2-propanol
131-11-3	Dimethyl phthalate
141-79-7	Mesityl oxide
149-30-4	Mercaptobenzothiazole
1330-20-7 ...	Xylene
5131-66-8 ...	1-Butoxy-2-propanol
25498-49-1 ...	Tripropylene glycol monomethyl ether
29385-43-1 ...	Tolyl triazole
29387-86-8 ...	Propylene glycol monobutyl ether
34590-94-8 ...	Dipropylene glycol monomethyl ether
No CAS Number.	Petroleum hydrocarbons
No CAS Number.	Xylene—range aromatic solvents

VI. Process for Future Removal of Inert Ingredients that are No Longer Used as Inert Ingredients

As a part of its ongoing inerts strategy, the Agency will perform future reviews of List 1, List 2, and List 3 inert ingredients to identify those inert ingredients which are no longer used. The Agency will issue future **Federal Register** notices removing those chemicals from its list of inert ingredients. Any associated exemptions from the requirement of a tolerance for such chemicals when used as inert ingredients will also be revoked. The Agency will not remove any List 4A or 4B inert ingredients from its list of inert ingredients since sufficient data have been presented to establish that the use of these chemicals as inert ingredients will not present a hazard to public health or the environment.

In an effort to identify inert ingredients which are no longer used, the Agency may contact registrants of pesticide products or manufacturers/suppliers of substances which are used as inert ingredients in pesticide formulations which contain specific inert ingredients the Agency believes may not actually be in use. This action may be necessary to verify the information currently contained in the Agency's database relative to product formulation information.

The Agency considers all alternate formulations valid for purposes of registration unless a registrant provides specific written notice to the Agency that a particular formulation will no longer be used. Therefore, the Agency wants to encourage registrants as part of their pesticide product stewardship program to provide the Agency with written notice identifying specific formulations that are no longer used as part of the pesticide product registration and amendment process. This action will assist the Agency in better identifying those inert ingredients that are no longer used in pesticide products as well as improving the overall accuracy of the Agency's product formulation information.

VII. Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket control number [OPP-36192] (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 Virginia 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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP-36192]. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 11, 1998.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98-16571 Filed 6-23-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-815; FRL-5795-9]

Pesticide Temporary Tolerance Exemption Petition; Notice of Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the filing of a pesticide petition proposing the extension of the exemption from the requirement of a temporary tolerance for residues of Trichodex (*Trichoderma harzianum* T-39) in and on all raw agricultural commodities as granted in Pesticide Petition 6G4622, concomitant with the extension of the Experimental Use Permit 11678-EUP-1. These extensions are requested to comply with the Food Quality Protection Act of 1997. The summary of the petition in this notice was prepared by the petitioner. **DATES:** Comments, identified by the docket control number PF-815, must be received on or before July 24, 1998. **ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch (7502C), 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. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow 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. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus (PM-90) Biopesticides and Pollution Prevention Division,

Office of Pesticide Programs,
Environmental Protection Agency, 401
M St., SW., Washington DC 20460.
Office location and telephone number:
5th floor, CS #1, 2800 Crystal Drive,
Arlington, VA 22202, Telephone
number 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-815] (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:
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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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF-815] 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: June 15, 1998.

Kathleen D. Knox,

*Acting 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.

Makhteshim-Agan of North America Inc.

PP 6G4622

EPA has received a request to extend the pesticide petition (PP 6G4622) 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. section 346a(d), to amend 40 CFR part 180 by extending the exemption from the requirement of a temporary tolerance for residues of the biofungicide Trichodex (*Trichoderma harzianum* T-39) in and on all raw agricultural commodities. According to the proposed extension request, 8,120 pounds (3,683 kg) of the microbial pesticide are to be applied to the sites previously described in the original Experimental Use Permit which has been in progress for 2 years.

EPA has determined that the petition contains 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.

As required by section 408 (d) of the FFDCA, as recently amended by the Food Quality Protection Act, Makhteshim-Agan of North America Inc. included in the petition a summary of the petition and authorization for the summary to be published in the **Federal Register** in a notice of the receipt of the petition. The summary represents the views of Makhteshim-Agan of North America Inc.; EPA as mentioned above is in the process of evaluating the petition. As required by section 408 (d)

(3) EPA is including the summary as part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

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*, 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* 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* resulting from Trichodex

applications do not pose a hazard to humans, plants and animals. *T. harzianum* 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 extension of the exemption from the requirement of a temporary 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 milligrams/kilograms (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. i. 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 in all RACs. Submitted studies indicate that residues of Trichodex do not pose a hazard to humans by route of ingestion.

ii. *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.

2. *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, and, (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.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-51908; FRL-5794-2]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical to notify EPA and comply with the statutory provisions pertaining to the manufacture or import of substances not on the TSCA Inventory. Section 5 of TSCA also requires EPA to publish receipt and status information in the **Federal Register** each month reporting premanufacture notices (PMN) and test marketing exemption (TME) application