

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 LD<sub>50</sub> greater than 500 milligrams/kilograms (mg/kg) body weight in rats, an acute dermal LD<sub>50</sub> 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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BILLING CODE 6560-50-F

## 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

requests received, both pending and expired. The information in this document contains notices received from May 1, 1998 to May 8, 1998.

**ADDRESSES:** Written comments, identified by the document control number "[OPPTS-51908]" and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG-099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: [oppt.ncic@epamail.epa.gov](mailto: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 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPPTS-51908]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under "SUPPLEMENTARY INFORMATION".

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this notice. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

**FOR FURTHER INFORMATION CONTACT:** Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-531, 401 M St., SW., Washington, DC, 20460, (202) 554-1404, TDD (202) 554-0551; e-mail: [TSCA-Hotline@epamail.epa.gov](mailto:TSCA-Hotline@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:** Under the provisions of TSCA, EPA is required to publish notice of receipt and status

reports of chemicals subject to section 5 reporting requirements. The notice requirements are provided in TSCA sections 5(d)(2) and 5(d)(3). Specifically, EPA is required to provide notice of receipt of PMNs and TME application requests received. EPA also is required to identify those chemical submissions for which data has been received, the uses or intended uses of such chemicals, and the nature of any test data which may have been developed. Lastly, EPA is required to provide periodic status reports of all chemical substances undergoing review and receipt of notices of commencement.

A record has been established for this notice under docket number "[OPPTS-51908]" (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 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center (NCIC), Rm. NEM-B607, 401 M St., SW., Washington, DC 20460.

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

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

In the past, EPA has published individual notices reflecting the status of section 5 filings received, pending or expired, as well as notices reflecting receipt of notices of commencement. In an effort to become more responsive to the regulated community, the users of this information and the general public, to comply with the requirements of TSCA, to conserve EPA resources, and to streamline the process and make it more timely, EPA is consolidating these separate notices into one comprehensive notice that will be issued at regular intervals.

In this notice, EPA shall provide a consolidated report in the **Federal Register** reflecting the dates PMN requests were received, the projected notice end date, the manufacturer or importer identity, to the extent that such information is not claimed as confidential and chemical identity, either specific or generic depending on whether chemical identity has been claimed confidential. Additionally, in this same report, EPA shall provide a listing of receipt of new notices of commencement.

EPA believes the new format of the notice will be easier to understand by the interested public, and provides the information that is of greatest interest to the public users. Certain information provided in the earlier notices will not be provided under the new format. The status reports of substances under review, potential production volume, and summaries of health and safety data will not be provided in the new notices.

EPA is not providing production volume information in the consolidated notice since such information is generally claimed as confidential. For this reason, there is no substantive loss to the public in not publishing the data. Health and safety data are not summarized in the notice since it is recognized as impossible, given the format of this notice, as well as the previous style of notices, to provide meaningful information on the subject. In those submissions where health and safety data were received by the Agency, a footnote is included by the Manufacturer/Importer identity to indicate its existence. As stated below, interested persons may contact EPA directly to secure information on such studies.

For persons who are interested in data not included in this notice, access can be secured at EPA Headquarters in the NCIC at the address provided above. Additionally, interested parties may telephone the Document Control Office at (202) 260-1532, TDD (202) 554-0551, for generic use information, health and safety data not claimed as confidential or status reports on section 5 filings.

Send all comments to the address listed above. All comments received will be reviewed and appropriate amendments will be made as deemed necessary.

This notice will identify: (I) PMNs received; and (II) Notices of Commencement to manufacture/import.

## I. 30 Premanufacture Notices Received From: 05/01/98 to 05/08/98

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P-98-0768 P-98-0769	05/04/98 05/01/98	08/02/98 07/30/98	CBI Ashland Chemical Company	(G) Petroleum product additive (G) A binder component for the production of sand foundry shapes	(G) Alkyl polyoxyalkylpropanamine (G) Modified isocyanic acid, polymethylenepolyphenylene ester
P-98-0770	05/01/98	07/30/98	Ashland Chemical Company	(G) A binder component for the production of sand foundry shapes	(G) Modified isocyanic acid, polymethylenepolyphenylene ester
P-98-0771	05/01/98	07/30/98	Ashland Chemical Company	(G) A binder component for the production of sand foundry shapes	(G) Modified isocyanic acid, polymethylenepolyphenylene ester
P-98-0772	05/01/98	07/30/98	Ashland Chemical Company	(G) A binder component for the production of sand foundry shapes	(G) Modified isocyanic acid, polymethylenepolyphenylene ester
P-98-0773	05/01/98	07/30/98	Ashland Chemical Company	(G) A binder component for the production of sand foundry shapes	(G) Modified isocyanic acid, polymethylenepolyphenylene ester
P-98-0774	05/01/98	07/30/98	Ciba Specialty Chemicals Corporation	(S) Chemical intermediate	(G) Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[(4,6-chloro-1,3,5-triazin-2-yl)amino]-disodium salt; substituted with dialkyl amines
P-98-0775	05/05/98	08/03/98	CBI	(S) Curing agent in epoxy powder coatings; curing agent in liquid epoxy adhesives	(G) Phenyl, alkyl, hydroxyalkyl substituted imidazole
P-98-0776	05/05/98	08/03/98	Applied power concepts, inc.	(S) Surfactant in hard surface cleaners or fabric softeners or for mixing oil and water products	(S) Ethanaminium, 2-(hexadecyloxy)- <i>n,n,n</i> ,-trimethyl-2-oxo,-chloride*
P-98-0777	05/05/98	08/03/98	Applied power concepts, inc.	(S) A detergent surfactant used for washing; application for unsecticide has also been applied for	(S) Mixture of: alpha-d-glucopyranoside, 1-6-bis-o-(1-oxooctyl)-b-d-fructofuranosyl and alpha-d-glucopyranoside, 6-o-(1-oxooctyl)-b-d-fructofuranosyl*
P-98-0778	05/04/98	08/02/98	CBI	(G) Chemical intermediate	(G) Arylether sulfide
P-98-0779	05/06/98	08/04/98	CBI	(G) Zinc plating additive	(G) Metal carboxylic acid complex
P-98-0780	05/07/98	08/05/98	Clariant corporation	(S) Corrosion inhibitor for metal removing	(S) Hexanoic acid, 6-[(1-oxoisooctyl)amino]-, compd. with 2,2' 2''-nitrilotris[ethanol](1:1)*
P-98-0781	05/05/98	08/03/98	CBI	(G) Surfactant in chemical specialties highly dispersive use	(G) Fluorinated amine oxide
P-98-0782	05/05/98	08/03/98	CBI	(G) Open, non dispersive (dyestuff)	(G) Triazine azo dyestuff
P-98-0783	05/04/98	08/02/98	CBI	(G) Chemical intermediate	(G) Amine hydrochloride
P-98-0784	05/04/98	08/02/98	CBI	(G) Chemical intermediate	(G) Arylether sulfide
P-98-0785	05/04/98	08/02/98	CBI	(G) Chemical intermediate	(G) Arylether sulfide
P-98-0786	05/07/98	08/05/98	CBI	(S) Epoxy curing agent	(G) Amine functional epoxy curing agent
P-98-0787	05/05/98	08/03/98	CBI	(G) Lubricant	(G) Sulfited fatty amine¶
P-98-0788	05/04/98	08/02/98	CBI	(S) Intermediate	(G) Acid functional ester
P-98-0789	05/04/98	08/02/98	CBI	(G) Open, non-dispersive use	(G) Polyester oligomer
P-98-0790	05/04/98	08/02/98	CBI	(G) Open, non-dispersive use	(G) Polyester oligomer
P-98-0791	05/04/98	08/02/98	CBI	(G) Open, non-dispersive use	(G) Polyester oligomer
P-98-0792	05/04/98	08/02/98	CBI	(G) Open, non-dispersive use	(G) Polyester oligomer
P-98-0793	05/08/98	08/06/98	Bedoukian research, inc.	(G) Chemical intermediate	(G) Aliphatic-oxy-substituted, saturated pyranil magnesium halide*
P-98-0794	05/08/98	08/06/98	Bedoukian research, inc.	(S) Chemical intermediate	(G) Mono-halo-substituted alkene¶
P-98-0795	05/08/98	08/06/98	CBI	(G) Coating components	(G) Modified petroleum distillate
P-98-0796	05/08/98	08/06/98	CBI	(S) Raw material/ reactant in the synthesis of an organic compound	(G) Methoxy substituted aliphatic amine
P-98-0797	05/08/98	08/06/98	CBI	(S) Intermediate in synthesis of another organic compound	(G) Dimethyl substituted heteromonocyclic amine

## II. 12 Notices of Commencement Received From: 05/01/98 to 05/08/98

Case No.	Received Date	Commencement/Import Date	Chemical
P-92-0555	05/05/98	04/17/98	(G) Polyester/polyamide
P-95-0682	05/05/98	03/31/98	(G) Acrylic modified styrene/butadiene rubber
P-97-0685	05/05/98	04/05/98	(G) Sodium sulfonate polymer
P-97-0951	04/30/98	04/08/98	(G) Polyurethane
P-97-1023	05/01/98	04/18/98	(G) Phosphonomethylated polyamine

## II. 12 Notices of Commencement Received From: 05/01/98 to 05/08/98—Continued

Case No.	Received Date	Commence- ment/Import Date	Chemical
P-97-1077	04/30/98	04/16/98	(G) Benzenesulfonamide, 3-[(3-substituted-4,5-dihydro-5-oxo-1-phenyl-1h-pyrazol-4-yl)azo]- 4- <i>n-n</i> -bis[3-[[[3-(5,5-dimethyl-3-octadecyl-2-thiazolidinyl) hydroxyphenyl]sulfonyl]aminopropyl]-* (G) Azo red pigment
P-97-1092	05/05/98	04/20/98	(G) 2-naphthalenesulfonamide, <i>n,n</i> -bis(3-substituted propyl)-1-hydroxy-5-
P-98-0030	04/30/98	04/17/98	[(methylsulfonyl)amino]-, sulfate (1:1)(salt)* (G) Mixture of unsaturated polyesters, polyethers, and polyamide salts
P-98-0263	05/05/98	04/16/98	(G) Alkylol ammonium salt of a high-molecular weight carboxylic acid
P-98-0273	05/05/98	04/16/98	(G) Polyamine polyester
P-98-0288	05/01/98	04/24/98	(G) Polyurethane/acrylic grafted copolymer
P-98-0293	05/05/98	04/20/98	

**List of Subjects**

Environmental protection,  
Premanufacture notices.

Dated: June 16, 1998.

**Oscar Morales,**

*Acting Director, Information Management  
Division, Office of Pollution Prevention and  
Toxics.*

[FR Doc. 98-16771 Filed 6-23-98; 8:45 am]

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**ENVIRONMENTAL PROTECTION  
AGENCY**

[OPPTS-51907; FRL-5794-1]

**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 requests received, both pending and expired. The information in this document contains notices received from April 27, 1998 to April 30, 1998.

**ADDRESSES:** Written comments, identified by the document control number "[OPPTS-51907]" and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG-099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPPTS-51907]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under "SUPPLEMENTARY INFORMATION".

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**FOR FURTHER INFORMATION CONTACT:**

Susan B. Hazen, Director,  
Environmental Assistance Division  
(7408), Office of Pollution Prevention  
and Toxics, Environmental Protection  
Agency, Rm. E-531, 401 M St., SW.,  
Washington, DC, 20460, (202) 554-1404,  
TDD (202) 554-0551; e-mail: TSCA-  
Hotline@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Under the provisions of TSCA, EPA is required to publish notice of receipt and status reports of chemicals subject to section 5 reporting requirements. The notice requirements are provided in TSCA sections 5(d)(2) and 5(d)(3). Specifically, EPA is required to provide notice of receipt of PMNs and TME application requests received. EPA also is required to identify those chemical submissions for which data has been received, the uses or intended uses of such chemicals, and the nature of any test data which may have been developed. Lastly, EPA is required to provide periodic status reports of all chemical substances undergoing review and receipt of notices of commencement.

A record has been established for this notice under docket number "[OPPTS-51907]" (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 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center (NCIC), Rm. NEM-B607, 401 M St., SW., Washington, DC 20460.

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

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The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper