ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300698; FRL 6022–1]

RIN 2070–AB78

Trichoderma Harzianum Strain T-39; Exemption from the Requirement of a Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a temporary tolerance for residues of the *Trichoderma harzianum* strain T-39 in/on strawberry, table grape and wine grape when applied/used as ground or foliar applications in accordance with the provisions of experimental use permit 11678–EUP–1. Makhteshim-Agan of North America, Inc. submitted an amended petition PP 6G4622 to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting an exemption from the requirement of a temporary tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Trichoderma harzianum* strain T-39.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300698], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300698], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300698]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 902W34, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308–8097; e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 24, 1998, (63 FR 34390) (FRL 5795–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by Makhteshim-Agan of North America Inc., 551 Fifth Ave., Suite 1100, New York, NY 10176. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a temporary tolerance for residues of the microbial antifungal agent *Trichoderma harzianum* strain T-39 in or on all food/feed commodities. The data which were evaluated for the Experimental Use Permit (EUP) granted in May of 1996 are sufficient to support the exemption from the requirement of a temporary tolerance in/on table grape, wine grape and strawberry. There were no comments received in response to the notice of filing. This exemption from the requirement of a tolerance will expire on November 30, 2000.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement of a temporary tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

A. Proposed Use

The rates, frequency and timing of the applications vary. The pesticide is to be applied by ground equipment as a foliar spray. Application rates are 2 to 4 pounds per acre per application from pre-bloom to harvest. 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. Strawberry may be treated with one to eight applications once per week throughout the growing season from pre-bloom to harvest.

B. Product Chemistry

The data submitted for product identity of the active ingredient, *Trichoderma harzianum* strain T-39, and end use product, Trichodex, are acceptable for the limited use proposed for this EUP. The active ingredient, *Trichoderma harzianum*, is a naturally-occurring fungus which can be found in the US and in the environment worldwide. The microbial pesticide

contains dried solids and solubles resulting from the fermentation of *Trichoderma harzianum* isolate T-39, containing T-39 fungus propagules as either conidia or mycelia. Published literature characterize *Trichoderma harzianum* strain T-39 by colony and structural morphology, and by intraspecific DNA primers. Additional data are likely to be required for more extensive use patterns.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the relevant available scientific data and other information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Results of the following studies support the lack of toxicity/pathogenicity of the Technical Grade Active Ingredient (TGAI), *Trichoderma harzianum*: acute oral, acute dermal, and the primary dermal irritation. The microbial pesticide was classified acute Toxicity Category III for these health effects.

The two acute eye irritation studies indicate a potential for the TGAI to cause severe eye irritation, placing the Technical Grade Active Ingredient in acute Toxicity Category I. However, another eye irritation study in which the test material was the End-use Product (EP), Trichodex, indicates the EP is mildly irritating or in the acute Toxicity Category III. This categorization is acceptable for labeling of the EP.

While the acute pulmonary study indicated that the TGAI *Trichoderma harzianum* did not replicate in the rat body, the reported data did not demonstrate a clear clearance pattern from the lungs. Based on this study and because the predominant inert ingredient is a known inhalation hazard, the microbial was classified as an acute Toxicity Category II pesticide for acute inhalation effects.

III. Aggregate Exposures and Risk

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures of consumers and major identifiable subgroups of consumers from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure and Risk

Dietary exposure to the microbial pesticide is likely to occur. The lack of acute oral toxicity/pathogenicity, and the ubiquitous nature of the microbial, support the establishment of an exemption from the requirement of a temporary tolerance for this active ingredient.

1. *Food*. The microbial pesticide can be easily removed from foods by washing, peeling, cooking and processing. For this EUP, strawberry, wine grape and table grape are to be treated in small areas in seven states AZ, CA. FL, NY, OH, OR, and WA. Consequently, dietary exposure to the microbial and the risk posed by ingestion of foods treated with the microbial pesticide, are likely to be minimal for adults, infants and children by the oral route.

2. *Drinking water exposure*. Oral exposure, at very low levels, may occur from ingestion of drinking water. However, the experimental permit allows use of this pesticide on a small area in one state on three crops, thus limiting potential exposure to drinking water. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity and the ubiquitous nature of the microbe.

B. Other Non-Occupational Exposure

The experimental use sites for *Trichoderma harzianum* strain T-39 are strawberry, wine grape and table grape for control of Botrytis by displacement. Therefore, exposure and risk to adults, infants and children via treated lawns or recreational areas are not likely if the pesticide is used as labeled.

1. *Dermal exposure*. The experimental use permit allows limited use of the pesticide in small areas in seven states. Workers are most likely to be dermally exposed during treatment of strawberry, wine grape and table grape. Because the pesticide is placed in Acute Toxicity Category III for dermal effects and the experimental use of the pesticide is limited, the exposure and risk to workers is likely to be minimal. Appropriate Personal Protective Equipment have been recommended by the Agency to mitigate against potential dermal exposure to pesticide handlers.

2. *Inhalation exposure*. The pesticide is considered an Acute Toxicity Category II microbial pesticide on the basis of inhalation studies. Adequate Personal Protective Equipment, including a dust-mist filtering respirator with NIOSH/MSHA prefix TC–21C, or equivalent, such as N–95, R–95 or P–95 respirator, and a Restricted-Entry Interval of 12 hours are required to mitigate against potential exposure and risk posed by the use of the pesticide during the experimental field trials.

IV. Cumulative Exposure to Substances with Common Mechanisms of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' There are other species and strains of *Trichoderma* registered. As discussed under Product Chemistry, the Agency has received information to distinguish strain T-39 from other registered strains. It is not clear to the Agency whether the registered strains share a common mechanism of toxicity, or any mechanism of toxicity with strain T-39.

V. Safety Factors

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre-and-post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when *Trichoderma harzianum* strain T-39 is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply.

VI. Infants and Children

The pesticide is to be applied to strawberry, wine grape and table grape to small areas in seven states as previously described. Because of this limited use pattern, and its low toxicity/pathogenicity, there is minimal potential for exposure and risk to infants and children.

VII. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to *Trichoderma harzianum* strain T-39 from the limited use pattern of this experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

VIII. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

The Agency is requiring standard microbial assays and analytical methods to identify the active ingredient and potential contaminants.

C. Environmental Effects

This final rule also extends the Experimental Use Permit associated with the exemption from the requirement of a temporary tolerance. Data and information have been provided to support the extension of the EUP. The application of this pesticide to the experimental fields is not likely to have adverse effects on avian species, fish and honey bee. These data include two 14–day acute oral avian studies in the mallard duck and bobwhite quail, a 96–hour study for freshwater fish, and a honeybee study. While the studies were not adequate for a section 3(c) 2(b) registration, they are adequate for the limited EUP. Additional data are required for more extensive use patterns.

IX. Conclusions

The Agency has concluded that the experimental use of this pesticide will not pose any adverse health effects to the U.S. population, infants and children, nor to the environment because of the low toxicological profile and the limited use patterns discussed above for this EUP. As a result, EPA establishes an exemption from temporary tolerance requirements pursuant to FFDCA section 408(j)(3) for *Trichoderma harzianum* strain T-39 in/on strawberry, table grape and wine grape. This exemption from the requirement of a temporary tolerance expires November 30, 2000. This rule also concurrently extends the Experimental Use Permit to November 30, 2000.

X. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by November 16, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

XI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, as described above, will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained 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 objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket contol number (OPP–300698). No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

XII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the requirement of a temporary tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require and prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from

Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In additions, since tolerance exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

XIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 26, 1998.

Kathleen D. Knox,

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

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1201, is added to subpart D to read as follows:

§180.1201 Trichoderma harzianum strain T-39; exemption from the requirement of a temporary tolerance.

Trichoderma harzianum strain T-39 is exempted from the requirement of a temporary tolerance in/on table grapes, wine grapes and strawberries treated in accordance with the Experimental Use Permit 11678–EUP–1. This exemption from the requirement of a tolerance will expire on November 30, 2000.

[FR Doc. 98–24839 Filed 9–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300707; FRL–6026–4]

RIN 2070-AB78

Desmedipham; Extension of Tolerances for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends time-limited tolerances for residues of the herbicide desmedipham in or on red beet roots at 0.2 part per million (ppm) and red beet tops at 15 ppm for an additional 1-year period, to August 31, 1999. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on red beets. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective September 16, 1998. Objections and requests for hearings must be