

September 8, 1999, (64 FR 48900) entitled "Trademark Law Treaty Implementation Act Changes." This document amends 37 CFR 2.76(b)(1), 2.88(b)(1), 2.89(a)(3), and 2.89(b)(3) to correct a cross-reference. Specifically, these sections are amended to refer to "§ 2.33(a)" rather than "§ 2.33(a)(2)."

In rule FR Doc. 99-22957, published on September 8, 1999, (64 FR 48900), make the following corrections:

#### § 2.76 [Corrected]

1. On page 48922, in the third column, in § 2.76, in paragraph (b)(1) introductory text, in line 5, correct "§ 2.33(a)(2)" to read "§ 2.33(a)".

#### § 2.88 [Corrected]

2. On page 48923, in the second column, in § 2.88, in paragraph (b)(1) introductory text, in line 3 from the top of the column, correct "§ 2.33(a)(2)" to read "§ 2.33(a)".

#### § 2.89 [Corrected]

3. On page 48923, in the third column, in § 2.89, in paragraph (a)(3), in line 2 from the top of the column, correct "§ 2.33(a)(2)" to read "§ 2.33(a)".

4. On page 48923, in the third column, in § 2.89, in paragraph (b)(3), in line 5, correct "§ 2.33(a)(2)" to read "§ 2.33(a)".

Dated: September 17, 1999.

**Albin F. Drost,**

*Acting Solicitor.*

[FR Doc. 99-24676 Filed 9-21-99; 8:45 am]

BILLING CODE 3510-16-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-300918; FRL-6381-7]

RIN 2070-AB78

### 2,6-Diisopropylnaphthalene; Temporary Exemption From the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide 2,6-diisopropylnaphthalene (2,6-DIPN) when applied/used to inhibit sprouting in potatoes held in storage. Platte Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting the temporary tolerance

exemption. This regulation eliminates the need to establish a maximum permissible level for residues of 2,6-DIPN. The temporary tolerance exemption will expire on September 22, 2000.

**DATES:** This regulation is effective September 22, 1999. Objections and requests for hearings, identified by docket control number OPP-300918, must be received by EPA on or before November 22, 1999.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided under Unit VIII. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300918 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703-308-9525); and e-mail address: benmhend.driss@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Potato Processors	311	Food manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under "FOR FURTHER INFORMATION CONTACT."

##### B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register-Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300918. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

##### II. Background and Statutory Findings

In the **Federal Register** of November 25, 1998 (63 FR 65204) (FRL-6039-7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Platte Chemical Company, 419 18th Street, Greeley, CO 80632. This notice included a summary of the petition prepared by the petitioner Platte Chemical Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of 2,6-DIPN.

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an

exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(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. . . ." Additionally, section 408(b)(2)(D) requires that 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."

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.

### III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant 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.

1. *Acute toxicity.* Technical 2,6-DIPN exhibits low acute toxicity. It is a toxicity category IV biopesticide. The rat oral LD<sub>50</sub> is greater than 5,000 milligrams/kilograms (mg/kg), the rabbit dermal LD<sub>50</sub> is greater than 5,000 mg/kg, and the rat inhalation LC<sub>50</sub> is greater than 2.60 mg/L at the maximum attainable condition. In addition, 2,6-DIPN is not a skin sensitizer in guinea pigs, shows no dermal irritation at 72 hours in rabbits, and shows minimal ocular irritation in rabbits. The end use formulation is the same as the technical formulation; it contains no intentionally added inert ingredients.

2. *Genotoxicity.* Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vivo/in vitro* unscheduled DNA synthesis in rat primary hepatocyte cultures at two time points, and an *in vivo* mouse micronucleus assay have been conducted for 2,6-DIPN. These studies show a lack of genotoxicity for 2,6-DIPN.

3. *Other tests.* No additional mammalian toxicology testing has been conducted. Platte requested a waiver from the requirement to submit further mammalian toxicology studies on the basis of the favorable toxicological profile for 2,6-DIPN, the low residues observed in treated potatoes, the specific plant growth regulator mode of action, and the confined nature of the proposed use. No data were found in the literature that would indicate 2,6-DIPN has any adverse effect on mammals. No incidents of hypersensitivity or any other adverse effects have been observed in individuals handling the material over the past 6 years.

### IV. Aggregate Exposures

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

#### A. Dietary Exposure

Any dietary exposure resulting from applications made under an experimental use permit (EUP) would be through potato consumption and animal products in which animals are fed potato feed stocks.

1. *Food.* Residues in treated potatoes have been shown to be low (average residue was 0.08 ppm 90 days after treatment). Residues would be expected to continue to decline after potatoes are removed from storage and before consumption. Cooking and/or processing would be expected to further lower the residue level in consumed potatoes or potato products.

2. *Drinking water exposure.* Since 2,6-DIPN would only be used in commercial storage warehouses, there is little if any potential for drinking water exposure.

#### B. Other Non-Occupational Exposure

The EUP would only cover use for direct application to potatoes when stored in commercial warehouses. There are currently no other registered uses of 2,6-DIPN. Non-dietary exposure to 2,6-

DIPN via lawn care, topical treatments, etc., will not occur. Thus, the potential for non-occupational exposure to the general population is virtually non-existent.

### V. Cumulative Effects

EPA also is required to consider the potential for cumulative effects of 2,6-DIPN and other substances that have a common mechanism of toxicity. Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of 2,6-DIPN and no information that indicates toxic effects, if any, would be cumulative with any other compounds. Since, 2,6-DIPN does not exhibit a toxic mode of action in the target plant, it is appropriate to consider only the potential risks of 2,6-DIPN in this exposure assessment.

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

Since there are no anticipated residues in drinking water or from other non-occupational sources, and no reliable information exists on cumulative effects due to a common mechanism of toxicity, the aggregate exposure to 2,6-DIPN is adequately represented by the dietary route. The lack of toxicity of 2,6-DIPN has been demonstrated by the results of acute toxicity testing in mammals in which 2,6-DIPN caused no adverse effects when dosed orally, dermally, and via inhalation at the limit dose for each study. Anticipated residues in consumed potatoes are low. Moreover, 2,6-DIPN exhibits close structural and chemical similarity to other plant-based, naturally occurring methyl and isopropyl naphthalene. Thus, the dietary exposure to 2,6-DIPN should pose negligible risks to human health. Based on the lack of toxicity and low exposure, there is a reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to 2,6-DIPN residues. Exempting 2,6-DIPN from the requirement of a tolerance should pose no significant risk to humans or the environment.

### VII. Other Considerations

#### A. Analytical Method

An analytical method for residues is not applicable, as this proposes an exemption from the requirement of a tolerance.

#### B. Codex Maximum Residue Level

No Codex maximum residue levels are established for residues of 2,6-DIPN in or on any food or feed crop. There are no other established U.S. tolerances or

exemptions from tolerances for 2,6-DIPN food or feed crops in the United States. The Agency has classified 2,6-DIPN as a biochemical pesticide.

### VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new 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 FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

#### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300918 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 22, 1999.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25) as well as other requirements set forth in 40 CFR 178.25. 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). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP-300918, 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 or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid 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. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### B. When Will the Agency Grant a Request for a Hearing?

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).

### IX. Regulatory Assessment Requirements

This final rule establishes a temporary tolerance/exemption under section 408(d) of the FFDCA 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) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under 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). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between

the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the a temporary tolerance/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.

#### **X. 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 this rule in the **Federal Register**. This rule 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: September 15, 1999.

**Marcia E. Mulkey,**

*Director, 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. 321(q), 346(a) and 371.

2. Section 180.1208 is added to subpart D to read as follows:

#### **§ 180.1208 2,6-Diisopropylnaphthalene; temporary exemption from the requirement of a tolerance.**

2,6-Diisopropylnaphthalene is temporarily exempt from the requirement of a tolerance when used to inhibit sprouting in potatoes held in storage in accordance with the Experimental Use Permit 034704-EUP-13. The temporary exemption from the requirement of a tolerance will expire on September 22, 2000.

[FR Doc. 99-24694 Filed 9-21-99; 8:45 am]

BILLING CODE 6560-50-F

### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 180**

[OPP-300919; FRL-6381-6]

RIN 2070-AB78

#### **Tebuconazole; Extension of Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends time-limited tolerances for residues of the fungicide tebuconazole in or on barley grain at 2.0 parts per million (ppm), barley hay at 20 ppm, barley straw at 20 ppm, wheat hay at 15 ppm, wheat straw at 2.0 ppm, and pistachios at 1.0 ppm; and extends time-limited tolerances for combined residues of tebuconazole and its metabolite in milk at 0.1 ppm and in meat byproducts of cattle, goats, hogs, horses, poultry and sheep at 0.2 ppm for an additional 1-year period. These tolerances will expire and are revoked on December 31, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on barley, wheat and pistachios. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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 the Federal Insecticide, Fungicide, and Rodenticide Act.

**DATES:** This regulation is effective September 22, 1999. Objections and

requests for hearings, identified by docket control number OPP-300919, must be received by EPA on or before November 22, 1999.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300919 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-9362; and e-mail address: [schaible.stephen@epa.gov](mailto:schaible.stephen@epa.gov).  
**SUPPLEMENTARY INFORMATION:**

#### **I. General Information**

##### **A. Does this Action Apply to Me?**

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Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section.

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