



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

6
DATE: June XX, 2005

ACTION MEMORANDUM

SUBJECT: Inert Reassessment of alpha-Pinene and beta-Pinene Polymers

FROM: Dan Rosenblatt, Chief
Minor Use, Inerts, and Emergency Response Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of alpha-Pinene and beta-Pinene Polymers -- Inert Ingredient Exemptions from the Requirement of a Tolerance.

Tolerance Exemption Expression	40 CFR
beta-Pinene polymers	180.910 [formerly 40 CFR 180.1001(c)]
alpha-Pinene	180.920 and 180.930 [formerly 40 CFR 180.1001(d) and (e)]

Summary:

In the Federal Register of May 18, 2005, the Agency published a final rule establishing several tolerance exemptions for various pinene polymers. As part of this action, the entry for pinene polymers in 40 CFR 180.910 was removed and replaced by entries for four alpha- and/or beta-pinene polymers. (A copy of this final rule is attached.) This removal and replacement counts as the reassessment of the one tolerance exemption for beta-pinene polymers.

The final rule was based on a science assessment which is included in the Docket for the above final rule OPP-2005-0110. Based on that science assessment, the two tolerance exemptions for alpha-Pinene are reassessed, as is. The current limitation of "Not more than 2% of formulation by weight" is to remain.

List Reclassification Determination: List 4B

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the three exemptions from the requirement of a tolerance for the inert ingredients alpha-pinene and beta-pinene polymers, and with the List reclassification determinations, as described above. I consider the one tolerance exemption established in 40 CFR 180.910 [formerly 40 CFR 180.1001(a)] for beta-pinene polymers and the two tolerance exemptions established in 180.920 and 180.930 [formerly 40 CFR 180.1001(d) and (e)] to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.



Lois A. Rossi, Director
Registration Division

Date: 6/10/05

cc: Debra Edwards, SRRD
Joe Nevola, SRRD

the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Congressional Review Act

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 final rule in the **Federal Register**. This final 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 record keeping requirements.

Dated: April 29, 2005.

Lois Rossi,
Director, Registration 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. 321(q), 346a and 371.

2. In § 180.950, the table in paragraph (e) is amended by adding alphabetically the following entry to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *
(e) * * *

Chemical Name	CAS No.
Red cabbage color, expressed from edible red cabbage heads via a pressing process using only acidified water.	None

Chemical Name	CAS No.
* * * * *	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0110; FRL-7710-3]

Pinene Polymers; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of several alpha- and/or beta-pinene polymers when used as inert ingredients in or on growing crops and when applied to raw agricultural commodities after harvest. Hercules, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of alpha and/or beta-pinene polymers.

DATES: This regulation is effective May 18, 2005. Objections and requests for hearings must be received on or before July 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0110. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Electronic Documents and Other Related Information?

In addition to using EDOCKET at (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of November 20, 1998 (63 FR 64494) (FRL-6027-6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 6E4782) by Hercules, Inc. 1313 North Market St., Wilmington, DE 19894-0001. The petition requested that 40 CFR part 180 be amended by establishing an

exemption from the requirement of a tolerance for residues of alpha- and/or beta-pinene polymers for use as an inert ingredient in pesticide products. That notice included a summary of the petition prepared by the petitioner.

The Agency interpreted the petitioner's request for an exemption for alpha- and/or beta-pinene polymers, as a request to amend the existing exemption for beta-pinene polymers to include alpha- and/or beta-pinene polymers. In the Notice of Filing the

petitioner used only the generalized term alpha- and/or beta-pinene polymers and did not specifically identify the chemicals by CAS Reg. No. or Name. The alpha- and/or beta-pinene polymers considered by the Agency are in the following Table.

CHEMICALS CONSIDERED

Common chemical name	CAS Nomenclature	CAS No.
Alpha-pinene polymer	Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, homopolymer	25766-18-1
Beta-pinene polymer	Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene-, homopolymer (9CI)	25719-60-2
Copolymer of alpha- and beta-pinene	Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, polymer with 6,6-dimethyl-2-methylenebicyclo [3.1.1]heptane (9CI)	31393-98-3
Polymerized alpha-pinene fraction from turpentine	Terpenes and Terpenoids, turpentine oil, alpha-pinene fraction, polymd.	70750-57-1

There were no comments received in response to the notice of filing.

Section 408(b)(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 tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA 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) of the FFDCA 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.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as

polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. 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. The nature of the toxic effects caused by alpha- and/or beta-pinene polymers are discussed in this unit.

Alpha- and beta-pinene are bicyclic terpene hydrocarbons. They are the major components of turpentine. The two chemicals are closely related, having the same empirical formula of C₁₀H₁₆ and the same basic ring structure. Alpha- and/or beta-pinene polymers are manufactured by various processes that increase the molecular weight beyond that of alpha- or beta-pinene and include formation of a dimer (two "pinenes" in a single molecule), formation of a trimer (three "pinenes" in a single molecule), or polymerization.

The data considered in this assessment included information submitted by the petitioner, and information located by OPP on the internet, primarily information prepared by the National Toxicology Program (NTP) and the robust summaries for bicyclic terpene hydrocarbons submitted in 2002 to EPA by the Terpene Consortium of the Flavor and Fragrance High Production Volume Consortia (FFHPVC). The Agency evaluated first the toxicity of the alpha- and beta-pinene chemicals.

The toxicity of alpha- and beta-pinene is defined by studies from open-literature conducted with alpha-pinene, beta-pinene and various alpha- and beta-pinene mixtures. There is also a structure-activity-relationship (SAR) assessment for alpha-pinene. The findings of the SAR assessment are consistent with the studies from open-literature. The overall conclusions are the following; however, greater detail on the Agency's review and evaluation of the submitted studies and articles from open literature are in the Alpha- and Beta-Pinene Science Assessment in EDOCKET at (<http://www.epa.gov/edocket/>).

Alpha- and beta-pinene are of low acute toxicity via the oral, dermal and inhalation routes. Both alpha- and beta-pinene are irritants to the skin, eye and mucous membranes. Alpha- and beta-pinene are well-absorbed by all routes of exposure.

The subchronic toxicity of alpha- and beta-pinene compounds appears to be low. A subchronic oral toxicity study indicated minor changes in liver and thyroid weights at the two higher dose levels, which were not considered treatment related. There were no effects at approximately 800 mg/kg/day.

Genotoxicity study summaries indicated no evidence of mutagenicity in several *Salmonella typhimurium* reverse mutation assays, one unscheduled DNA assay, and one sister chromatid exchange assay. No chronic/carcinogenicity studies were identified; however, alpha- and beta-pinene are not structurally related to any known carcinogens.

A mixture primarily of alpha- and beta-pinene was tested in three developmental toxicity studies. Summaries of the results of these studies report that no maternal or developmental effects were noted in mice, hamsters, or rats at the highest dose levels, 560, 600, or 260 mg/kg/day, respectively. Alpha- and beta-pinene are not structurally related to any known developmental/reproductive toxicants.

The available information does not indicate that any of these chemicals are of higher toxicity. For alpha- and beta-pinene, the irritation effects are the effects of concern. Such effects are handled through use of personal protective equipment. Most of the turpentine produced in the United States is made up primarily of alpha-pinene (75 to 85%). Turpentine is known to act as a central nervous system (CNS) depressant, as is typical of certain organic chemicals. Given the relationship of turpentine to alpha-pinene, and the relationship of alpha- to beta-pinene, by extrapolation, there could be neurotoxicity concerns for pinene chemicals from dermal and inhalation exposures. Such exposures generally need to be "high" and/or "prolonged" for such toxicity effects to occur. Also, for acute exposures, such effects, generally, are reversible. Concerns are for occupational exposures since the potential for day in/day out exposure can occur in the workplace.

Few toxicity studies conducted with alpha- and/or beta-pinene polymers were located. A structure activity relationship (SAR) assessment indicated an overall low concern. The toxicity information on alpha- and beta-pinene indicate that these are not substances of high toxicity. Polymers composed of alpha and beta-pinene monomers are of a low molecular weight, and thus cannot be exempted from the requirement of a tolerance using the criteria specified for defining a low-risk polymer in 40 CFR 723.250. As previously explained, processes used to form an alpha- and/or beta-pinene polymer would increase the molecular weight. Greater molecular weight means decreased absorption. Alpha- and/or beta-pinene dimers, trimers, or polymers should therefore be of even

lower toxicity than pure alpha- and beta-pinene.

V. 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).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Human beings are exposed to a background level of naturally-occurring alpha- and beta-pinene. The two chemicals occur together, but beta-pinene occurs at lower levels than alpha-pinene. Atmospheric concentrations of alpha-pinene have been detected in deciduous and coniferous forests, and suburban and urban areas. Alpha-pinene has been detected in filberts, chicken, mangos, fresh grapefruit juice (0.054 ppm), guava, carrots, pistachio, safflower, sorghum, tomato, walnut, ginger, celery, unpasteurized orange juice (0.10–1.09 ppm), shrimp, and crab.

Neither alpha- nor beta-pinene are persistent in the environment. Given the ready volatilization and rapid degradation of alpha- and beta-pinene, it is unlikely to be present in any significant amounts in sources of drinking water.

Exposure to alpha- and beta-pinene can occur from use as a fragrance in consumer products (both are components of many essential oils) and as a flavoring in foods. However, the naturally-occurring exposures to alpha- and beta-pinene are more extensive than

such anthropogenic exposures. The uses regulated by EPA are much smaller than the naturally-occurring exposures.

For greater detail see the Alpha- and Beta-Pinene Science Assessment in EDOCKET at (<http://www.epa.gov/edocket/>).

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to alpha-pinene, beta-pinene, or any alpha- and/or beta-pinene polymers. These chemicals do not appear to produce a toxic metabolite produced by other substances. These are lower toxicity chemicals; therefore, the resultant risks separately and/or combined should also be low. For the purposes of this action, therefore, EPA has not assumed that alpha-pinene, beta-pinene, or any alpha- and/or beta-pinene polymers have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

VII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data unless EPA concludes that a different margin of safety will be safe for infants and children. Three developmental toxicity studies (rat, mouse and hamster) conducted using a mixture of alpha- and beta-pinenes at high dose levels did not identify either maternal or developmental no observed adverse effect levels (NOAELs). There are no indications of increased susceptibility. These pinene chemicals are not structurally related to any known

developmental/reproductive toxicants. Therefore, EPA has not used a safety factor analysis to assess the risk. For the same reasons a tenfold safety factor is unnecessary.

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

The database considered for this action included mostly toxicity data derived using alpha- and beta-pinene. Alpha- and beta-pinene exhibit low acute toxicity by the oral, dermal and inhalation routes, and low subchronic toxicity. Polymers composed of alpha and beta-pinene monomers, even those of low molecular weight, should be even less toxic than alpha- and beta-pinene considering that their absorption is decreased. Based on the available information on toxicity and exposure, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of alpha-pinene, beta-pinene, and alpha- and/or beta-pinene polymers. EPA finds that amending the existing exemption from the requirement of a tolerance for beta-pinene polymers to include alpha- and/or beta-pinene polymers will be safe for the general population including infants and children.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect * * *" EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing alpha-pinene, beta-pinene, or any alpha- and/or beta-pinene polymers for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Exemptions

There is an existing tolerance exemption for B-pinene polymers in 40 CFR 180.910 when applied to growing crops or to raw agricultural commodities after harvest.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for alpha- and/or beta-pinene polymers nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Therefore, exemptions from the requirement for a tolerance are established for alpha-pinene polymer (CAS Reg. No. 25766-18-1), beta-pinene polymer (CAS Reg. No. 25719-60-2), copolymer of alpha- and beta-pinene (CAS Reg. No. 31393-98-3), and terpenes and terpenoids, turpentine oil, alpha-pinene fraction, polymd. (CAS Reg. No. 70750-57-1).

XI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old FFDCA sections 408 and 409 of FFDCA. 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 ID number OPP-2005-0110 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 July 18, 2005.

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). 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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in ADDRESSES. Mail your copies, identified by docket ID number OPP-2005-0110, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in ADDRESSES. You may also send an electronic copy of your request via e-mail to: 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 6.1/8.0 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).

XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 any special considerations 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 OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and 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. In addition, 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 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the 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." This final rule 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct

effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Congressional Review Act

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 final rule in the **Federal Register**. This final 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: April 27, 2005.

Betty Shackleford,
Acting Director, Registration 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. 321(q), 346a and 371.

■ 2. In § 180.910, the table is amended by removing the current B-pinene polymer entry and by alphabetically adding the following entries to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, homopolymer (Alpha-pinene, homopolymer) (CAS Reg. No. 25766-18-1),.	Surfactants, related adjuvants of surfactants
Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene-, homopolymer (Beta-pinene, homopolymer) (CAS Reg. No. 25719-60-2),.	Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, polymer with 6,6-dimethyl-2-methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393-98-3).	Surfactants, related adjuvants of surfactants
Terpenes and terpenoids, turpentine oil, alpha-pinene fraction, polymd. (CAS Reg. No. 70750-57-1).	Surfactants, related adjuvants of surfactants

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 [FR Doc. 05-9479 Filed 5-17-05; 8:45 am]
 BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2005-0095; FRL-7711-9]

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-H-pyrrole-3-carbonitrile) in or on pomegranate. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 18, 2005. Objections and requests for hearings must be received on or before July 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP-2005-0095. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may

access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 2004 (69 FR 12680) (FRL-7347-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6803) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.516 be amended by establishing a tolerance for residues of the fungicide fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-H-pyrrole-3-carbonitrile) in or on pomegranate at 2.0 parts per million (ppm). This petition has subsequently been amended to propose pomegranate (post-harvest) at 5.0 ppm. That notice included a summary of the petition prepared by Syngenta Crop Protection, the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a 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) of FFDCA 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) of FFDCA 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 * * *."