essential-use allowances by means of a confidential letter and would subsequently publish a notice of the allocation in the **Federal Register**, (7) the addition of 40 CFR 82.4(u)(3) for an exemption process for national security interests for HCFC–141b, (8) the addition of paragraph (a)(5) in revised 40 CFR 82.9(a) for granting 15 percent of baseline production allowances as Article 5 allowances for class I, Group VI controlled substances, (9) the addition of 40 CFR 82.9(g) establishing the petition process for national security allowances, (10) the addition of 40 CFR 82.12(a)(3) for transfers of essential-use allowances for metered-dose inhalers in emergency situations, (11) the addition of 40 CFR 82.13(f)(2)(xvii), 40 CFR 82.13(g)(1)(xvii), and 40 CFR 82.13(g)(4)(xv) and the revision of newly designated 40 CFR 82.13(b)(3)(xiii) for the certification of purchases of controlled substances that will be used as a process agent, (12) the revision of paragraphs in 40 CFR 82.13(g)(2) and 40 CFR 82.13(g)(3) for petitioning to import used class I controlled substances, and (13) the revision to 40 CFR 82.13(u) for the reporting by holders of essential-use holders. EPA will address the comments received in a subsequent final action on these thirteen provisions in the near future and issue a final rule based on the parallel proposal also published on August 4, 1998. As stated in the parallel proposal, EPA will not institute a second comment period on this action. The thirty-eight amendments that did not receive adverse comments will become effective on October 5, 1998, as provided in the August 4, 1998 direct final rule. EPA will make the text of the thirty-eight amendments that did not receive adverse comments available at the following website address: www.epa.gov/ozone/title6/phaseout/.

List of Subjects in 40 CFR Part 82

Environmental protection, Administration practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and recordkeeping requirements.

Dated: September 29, 1998.

Robert Perciasepe,

Assistant Administrator for the Office of Air and Radiation.

[FR Doc. 98–26456 Filed 10–2–98; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300728; FRL–6032–2]

RIN 2070–AB78

Alder Bark; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of alder bark when used as an inert ingredient (seed germination stimulator) in pesticide formulations applied to growing crops. Platte Chemical Company requested this tolerance exemption under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective October 5, 1998. Objections and requests for hearings must be received by EPA on or before November 4, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300728], 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), 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–300728], 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300728]. No Confidential Business Information (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.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. #707G, Crystal Mall #2, 1921 Crystal Drive, Arlington, VA, 22202. Telephone No. (703)–308–8371, e-mail: gairola.indira@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 29,1998 (63 FR 23438)(FRL–5783–4) EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a announcing the filing of a pesticide petition (PP) 6E4742 for a tolerance exemption from Platte Chemical Company, 419 18th Street, P.O. Box 667, Greeley, CO 80632, This notice included a summary of the petition prepared by Platte Chemical Company, the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(d) be amended by establishing an exemption from the requirement of a tolerance for residues of the inert ingredient alder bark when used as an inert ingredient (seed germination stimulator) in pesticide formulations applied to growing crops only.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the 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) 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 based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

II. 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; surfactant 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.

III. Risk Assessment and Statutory Findings

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 ingredient in conjunction with possible exposure to residues of the inert ingredient in food, drinking water, and other nonoccupational exposures. 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.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of alder bark and to make a determination on aggregate exposure, consistent with section 408(b)(2), an exemption from the requirement of a tolerance for residues of alder bark when used as an inert ingredient in pesticide formulations applied to growing crops. EPA's assessment of the dietary exposures and risks associated with establishing an exemption from the requirement of a tolerance follows.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL–3190–1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient.

A. Toxicological Profile

Alder bark is the bark of an alder tree (*Alnus glutinosa*) that has been dried and ground into a powder or flour form. The use of alder bark as an inert ingredient in pesticide formulations is not expected to result in adverse effects since it is primarily comprised of lignin, hemicellulose and cellulose, each of which has been extensively studied and been found not to exhibit any adverse toxicological effects.

B. Exposures and Risks

1. *From food and feed uses, drinking water, and non-dietary exposures.* For the purposes of assessing the potential dietary exposure, EPA considered that under this tolerance exemption alder bark could be present in all raw and processed agricultural commodities and drinking water and that non-occupational, non-dietary exposure was possible. However, based on the use of alder bark as a seed germination stimulator, it is likely that residues of alder bark would not be present in or on food or drinking water. EPA therefore concludes that, based on the lack of expected adverse effects and the lack of expected residues of alder bark in or on raw agricultural commodities or drinking water, there are no concerns for risks associated with any exposure scenarios that are reasonably foreseeable.

2. *Cumulative exposure to substances with common mechanism 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.''Because EPA has concluded that alder bark is basically non-toxic, EPA has not assumed that alder bark has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

Based on the lack of expected adverse effects resulting from the use of alder bark, EPA concludes that there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to alder bark. EPA believes this compound presents no dietary risk under reasonably foreseeable circumstances.

D. Aggregate Risks and Determination of Safety 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 pre-and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

In this instance, the Agency believes that there are reliable data to support that fact that alder bark would be expected to be practically nontoxic to humans, and thus EPA has not used a safety factor analysis in assessing the risk of this compound. For the same reasons the additional safety factor is unnecessary.

E. International Residue Limits

No Codex maximum residue levels have been established for alder bark.

V. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of alder bark when used as

an inert ingredient in pesticide formulations applied to growing crops.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) 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 govern 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 December 4, 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 above (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 on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (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 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 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 Confidential Business Information (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.

VII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300728] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

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.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the requirement of a tolerance 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 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).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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. Nevertheless, the Agency has 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.

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.

IX. 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 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 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 24, 1998.

Arnold E. Layne,

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. 346a and 371.

2. In § 180.1001 the table in paragraph (d) is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Alder bark		Seed germination stimulator
* * * * * * *		

[FR Doc. 98–26618 Filed 10–2–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300725; FRL–6031–5]

RIN 2070–AB78

Pyridaben; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of pyridaben and its metabolites PB–7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3 (2*H*)-one) and PB–9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl) benzylthio]-chloropyridazin-3 (2*H*)-one) in or on cranberries. 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 cranberries. This regulation establishes a maximum permissible level for residues of pyridaben in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 1999.

DATES: This regulation is effective October 5, 1998. Objections and requests for hearings must be received by EPA on or before December 4, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300725], 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), 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–300725], 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 also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies