Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to a SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600, *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

The corrections promulgated herein remove certain provisions from the SIP. However, regardless of EPA's final action, these provisions still apply as a matter of State law, and thus, EPA's action does not affect any existing requirements applicable to small entities. Also, EPA's action does not impose any new Federal requirements. Therefore, EPA certifies that this correction action does not have a significant impact on a substantial number of small entities.

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the corrections promulgated do not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

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

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 26, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: March 5, 1998.

William P. Yellowtail,

Regional Administrator, Region VIII.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

2. Section 52.320 is amended by revising paragraphs (c)(8), (c)(15), and (c)(72)(i)(D) to read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(8) On June 7, 1974, the Governor submitted five Air Quality Maintenance Area designations.

* * * * *

(15) On July 23, 1979, the Governor submitted House Bill 1090 and Senate Bill 1 as part of the plan.

* * * * *

(72) * * *

(i) * * *

(D) Regulation No. 3, Air Contaminant Emissions Notices, 5 CCR 1001–5, revisions adopted 8/18/94, effective 9/30/94, as follows: Part A (with the exception of the last sentence in the definition of ''Federally enforceable'' in Section I.B.22 and with the exception of Section IV.C.) and Part B (with the exception of Sections V.B. and VII.A.5.). This version of Regulation No. 3, as incorporated by reference here, supersedes and replaces all versions of Regulation No. 3 approved by EPA in previous actions.

* * * * *

[FR Doc. 98–7640 Filed 3–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300632; FRL–5779–3]

RIN 2070–AB78

Titanium Dioxide; 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 titanium dioxide when used as an inert ingredient (UV protectant) in microencapsulated formulations of lambda-cyhalothrin. Zeneca AgProducts 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 March 25, 1998. Objections and requests for hearings must be received by EPA on or before April 24, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300632], 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–300632], 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 1B2, 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 of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300632]. 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 (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 4th Floor, Crystal Station 1B1, 2800 Crystal Drive,, Arlington, VA, 22202, (703)–308–8371, e-mail: gairola.indira@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 1997 (62 FR 33641) (FRL–5723–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6E4675) for a tolerance exemption by Zeneca Ag. Products, 1800 Concord Pike, P.O Box 15458, Wilmington, DE 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag. Products, 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 titanium dioxide, when used as an inert ingredient (UV protectant) in microencapsulated formulations of lambda-cyhalothrin applied to growing crops.

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. 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 titanium dioxide 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 titanium dioxide when used as an inert ingredient (UV protectant) in microencapsulated formulations of lambda-cyhalothrin. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

Titanium is the eighth most abundant element in the earth's crust and consequently spontaneously enters the food chain to some degree. Titanium dioxide (TiO2) is a major constituent of a number of minerals, including rutile, which consists of 95% titanium dioxide. The most commercially important of the titanium compounds, titanium dioxide annual worldwide production is estimated to be appoximately two million metric tons. Titanium dioxide is an opaque powder that is approved for use as a colorant in food (21 CFR 73.575), in drugs (21 CFR 73.1575), and in cosmetics (21 CFR 73.2575; 21 CFR 73.3126). It has an extensive range of industrial uses (e.g., paint, paper, and plastics). Titanium dioxide is currently exempt from the requirement for a tolerance when used as a colorant in pesticide formulations (40 CFR 180.1001(d)).

A National Cancer Institute bioassay concluded that titanium dioxide did not affect mortality, and was not carcinogenic at dose levels of 25,000 or 50,000 ppm in rats or mice.

The World Health Organization Committee on Food Coloring Materials has determined that no ADI need be set for the use of titanium dioxide based on the range of acute, subacute and chronic toxicity assays, all showing low mammalian toxicity, including a two year chronic feeding study in mice which was negative for carcinogenicity. Indeed, titanium dioxide is frequently used as a negative control material in *in vivo* chronic dust exposure studies and in *in vivo* assessments of fibrogenic potential of dusts.

B. Exposures and Risks

Titanium dioxide is currently approved for use in a significant number of pharmaceutical, cosmetic, industrial and food products. Therefore, the potential for aggregate exposure from dietary and non-dietary routes does exist for titanium dioxide. While it is difficult to develop a precise estimate of total human exposure to titanium dioxide, its low toxicity at relatively high doses indicate that current exposures are likely to be significantly below levels that may result in adverse health effects. Titanium dioxide is approved for use in food generally up to

1% of the final weight of the food (10,000 ppm). Even the most extreme assumptions regarding its presence in foods following use as an inert ingredient in lambda-cyhalothrin formulations would not result in a measurable increase in potential dietary intake of titanium dioxide.

All registered lambda-cyhalothrin products to which titanium dioxide is added as an inert ingredient are commercial agricultural products not registered for residential use. The potential for non-occupational exposures by the general population above current background levels resulting from the many non-pesticidal uses of titanium dioxide is unlikely.

Section 408(c)(2)(B) requires that, when considering whether to establish, modify, or revoke an exemption from the requirement of a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide chemical's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticide chemicals, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether titanium dioxide has a common mechanism of toxicity with other substances or how to include this pesticide chemical in a cumulative risk assessment. Unlike other pesticide chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, titanium dioxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that titanium dioxide has a common mechanism of toxicity with other substances.

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

Based on its low toxicity, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of titanium dioxide. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because of the inconsequential increases in dietary exposure resulting from its application to growing crops as an inert ingredient in formulations of lambda-cyhalothrin.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects in calculating a dose level that to account for pre-and post-natal 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 the use of margin of exposure analysis or through using uncertainty (safety) in calculating a dose level that poses no appreciable risk to humans.

Due to low toxicity of titanium dioxide, EPA has not used a safety factor analysis in assessing the risk of this compound. For the same reason, application of the additional safety factor for infants and children would not be appropriate.

III. Other Considerations

A. Analytical Enforcement Methodology

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for titanium dioxide.

B. International Residue Limits

No Codex maximum residue levels have been established for titanium dioxide.

IV. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of titanium dioxide when used as an inert ingredient (UV protectant) in microencapsulated formulations of lambda-cyhalothrin at no more than 3% by weight of the formulation.

V. 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 May 26, 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 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300632] (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 1B2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this 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.

VII. Regulatory Assessment Requirements

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 any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

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.

VIII. 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: March 12, 1998.

James Jones,

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. Section 180.1195 is added to read as follows:

§ 180.1195 Titanium dioxide; exemption from the requirement of a tolerance.

Titanium dioxide is exempted from the requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambda-cyhalothrin at no more than 3.0% by weight of the formulation.

[FR Doc. 98–7492 Filed 3–24–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300625; FRL–5776–5]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine and its metabolites in or on pecans. The Bayer Corporation submitted a petition to EPA