version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES''at the beginning of this document

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300615]. No CBI should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

This final rule extends a time-limited tolerancethat was previously extended by EPA 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). IN addition, 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).

Since this extension of an existing time-limited tolerance does 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.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. *801 et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This 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: February 6, 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.

§ 180.356 [Amended]

2. In § 180.356, by amending paragraph (b) in the table, for the commodities ''Grasses, Bermuda, Forage'' and ''Grasses, Bermuda, Hay'' by removing the date ''November 30, 1998'' and by adding in its place ''11/30/99''.

[FR Doc. 98–4522 Filed 2–24–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300614; FRL–5769–9]

RIN 2070–AB78

Kaolin; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of anhydrous kaolin when used in or on food commodities to aid in the control of insects, fungi, and bacteria (food/feed use). This regulation was requested by Engelhard Corporation.

DATES: This regulation becomes effective February 25, 1998. Objections and requests for hearings must be received by EPA on or before April 27, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300614], may 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, Pittsburg, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Intregrity 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 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@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 in 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 number [OPP–300614]. 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: Driss Benmhend, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5–W61, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703) 308–9525; e-mail: benmhend.driss@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 26, 1997 (62 FR 63168)(FRL–5753–3), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition for the new active ingredient kaolin (PP 7E4908) by Engelhard Corporation, Research Center, 101 Wood Avenue, Iselin, NJ 08830. The notice included a summary of the petition prepared by the petitioner. The summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested the establishment of a permanent tolerance exemption for kaolin for all food commodities. Kaolin is a naturally occurring aluminosilicate, used as an indirect food additive for paperboard food contact, adhesives, cellophane, etc. It is also used in pharmaceuticals (tablet diluents poultices), and in toiletries (toothpaste, etc.). Prior to the current petition request, EPA authorized the issuance of an experimental use permit (EUP) to the registrant for the end-use product, M-96-018 Kaolin (70060-EUP-R), containing 98.8% active ingredient. In conjunction with the EUP, EPA approved a petition for a temporary tolerance exemption (PP 7G4793) for the active ingredient when applied to all food commodities. The exemption from a temporary tolerance for kaolin on all food commodities was granted for purposes of the EUP (April 23, 1997, 62 FR 19683) (FRL–5712–8).

There were no comments or requests for referral to an advisory committee, received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated and were considered in support of this tolerance.

I. Toxicological Profile

The submitted toxicology studies are acceptable for these new registrations. No additional toxicology data are required. The data reported in the acute oral toxicity studies demonstrated that the acute oral LD_{50} for kaolin in rats is >5,000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the acute dermal toxicity study demonstrated that the acute dermal LD_{50} for kaolin in rats is >5,000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the primary eye irritation study demonstrate that the test substance was minimally irritating. Kaolin was not corrosive and all eye irritation effects cleared within 72 hours postdosing; Toxicity Category III. The data reported in the primary-skin irritation study demonstrated that the test substance caused no dermal irritation in rabbits treated with 0.5 g kaolin for 4 hours. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV.

Kaolin is used as an indirect food additive for paper/paperboard dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used in pharmaceuticals, tablet diluents, poultices, and surgical dusting powders. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized as Safe) status under 21 CFR 186.1256 and is generally recognized as safe ''as an indirect human food ingredient with no limitation other than current good manufacturing practice.''

II. Aggregate Exposure

1. *Dietary exposure and risk characterization*. Dietary exposure of kaolin via food or water is difficult to estimate due to the use of kaolin in thousands of products. Kaolin is an inert mineral and has no known toxicological effects

2. *Non-dietary exposure, non-occupational exposure*. The amount of kaolin currently used in the U.S. pesticide industry as an inert is between 2 million lbs. and 10 million lbs. per year.

3. *Aggregate exposure from multiple routes including dermal and inhalation*. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for kaolin showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

III. Safety Considerations

The lack of toxicity of kaolin is demonstrated by the above summary. Based on this information, the aggregate exposure to kaolin over a lifetime should not pose appreciable risks to human health. There is a reasonable certainty that no harm will result from aggregate exposure to kaolin residues. Exempting kaolin from the requirement of a tolerance is safe.

Consistent with section 408(b)(2)(c) of the FFDCA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with the common mechanism of toxicity. Based on the available information, the Agency concludes that kaolin is ubiquitous in all foods including those consumed by infants and children. Furthermore, kaolin is used as an additive in several food and non food products. Like adults, infants and children are also exposed to kaolin in these products, and there is no evidence that suggests that such exposure may lead to any harm.

IV. Cumulative Effects

Kaolin has no mode of toxicity and therefore no common mechanism of toxicity with other substances.

V. International Tolerances

No international tolerance exemptions are known to exist.

VI. Summary of Findings

Kaolin is considered as GRAS by FDA under 21 CFR 186.1256. EPA has not

identified any toxicity or clinical abnormalities. Moreover, the ecological effects studies demonstrated that there were no adverse effects. As a result, the Agency concludes that the exemption from the requirement of a tolerance is safe. Therefore, the tolerance exemption is established as set forth below.

VII. 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 (1)(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 April 27, 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 issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Docket

EPA has established a record for this rulemaking under docket number [OPP–300614] (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 Rm. 119 of the Public Information and Records Intregrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

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 address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of 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: February 6, 1998.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

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

2. Section 180.1180 is amended by removing the paragraph heading for paragraph (a), revising paragraph (b), and removing paragraphs (c) and (d) to read as follows:

§ 180.1180 Kaolin; exemption from the requirement of a tolerance.

* * * * *

(b) Kaolin is exempted from the requirement of a tolerance for residues when used on or in food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

[FR Doc. 98–4652 Filed 2–24–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300603; FRL–5766–4]

RIN 2070–AB78

Bensulfuron Methyl (methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl) amino] carbonyl] amino] sulfonyl] methyl] Benzoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of bensulfuron methyl in or on crayfish. In addition, this regulation raises the tolerance for residues of bensulfuron methyl on rice straw. E.I. duPont de Nemours and Company, Inc. requested this tolerance 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 February 25, 1998. Objections and requests for hearings must be received by EPA on or before April 27, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300603], 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–300603], 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 5.1/6.1 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–300603]. 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: Jim Tompkins, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 1997 (62 FR 27033) (FRL-5717–7), 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 pesticide petitions (PP) 4F4367 and 5F4490. This notice included a summary of the petitions prepared by E.I. duPont de Nemours and Company, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.445 be amended by establishing a tolerance for residues of the herbicide bensulfuron methyl, in or on rice (grain) at 0.02 parts per million (ppm), rice straw at 0.05 ppm, and crayfish at 0.05 ppm.

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.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of