

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300477; FRL-5712-8]

RIN 2070-AB78

Kaolin; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a temporary exemption from the requirement of a tolerance for residues of the insecticide Kaolin, when used on crops (apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cranberries, cucurbits, grapes, melons, nuts, ornamentals, peaches, peanuts, pears, peppers, plums, potatoes, seed crops, small grains, soybeans, strawberries, sugar beets, and tomatoes) to control certain insect, fungus, and bacterial damage to plants.

DATES: This regulation is effective April 23, 1997 and expires December 31, 1999. Submit written objections and hearing requests on or before June 23, 1997

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300477; PP-7G4793], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Room 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to: Crystal Mall #2, Room 1132, 1921 Jefferson Davis Highway, Arlington, VA. 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@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 in 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-300477; PP-7G4793]. 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. Additional information on electronic submissions can be found in Unit IV. of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Sheryl K. Reilly, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: Room CS15-W29, 2800 Jefferson Davis Highway, Arlington, VA, 703-308-8265), e-mail: reilly.sheryl@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Engelhard Corporation, Research Center, 101 Wood Avenue, Iselin, NJ 08830-0770 has requested in pesticide petition PP-7G4793 the establishment of an exemption from the requirement of a tolerance for residues of the insecticide Kaolin. A notice of filing (FRL-5585-4) was published in the **Federal Register** (62 FR 6524, February 12, 1997), and the notice announced that the comment period would end on March 12, 1997; no comments were received. This temporary exemption from the requirement of a tolerance will permit the marketing of the above food commodities when treated in accordance with the provisions of experimental use permit 70060-EUP-1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104-170.

I. Summary**A. Proposed Use Practices**

The experimental program will be conducted in the states of Alabama, Arizona, California, Delaware, Florida, Idaho, Indiana, Georgia, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina,

Tennessee, Texas, Virginia, Washington, and West Virginia. Crops to be treated are apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cranberries, cucurbits, grapes, melons, nuts, ornamentals, peaches, peanuts, pears, peppers, plums, potatoes, seed crops, small grains, soybean, strawberries, sugar beets, and tomatoes. Treatment is made shortly after leaf or plant emergence and applied at 7 to 10-day intervals to crops. Treatment will not be applied within 10 days of harvest. Dosage rates are 10 to 100 lbs of the formulated kaolin per acre and are applied with standard commercial spray equipment. The first year target pests are aphids, apple scab, codling moth, fireblight, leaf hoppers, and pear psylla. The second year target pests are aphid complex, apple scab, armyworm, bacteria spot, bollworms, citrus canker, citrus rust, codling moth, Colorado potato beetle, cotton flea hopper, European and spotted red mite, fabrea leaf spot, early and late blight, fireblight, flyspeck, Japanese beetle, leaf hopper complex, leaf rollers, mealybug, mildews, phylloxera, pear psylla, pear rust mites, Pierce's Disease, rots, scales, tarnish plant bug, thrips, wheat stem-saw fly, and whitefly.

B. Product Identity/Chemistry

Kaolin is a white, nonporous, nonswelling, natural aluminosilicate mineral with the chemical formula of $A_1_4Si_4O_{10}(OH)_8$. Kaolin is one of the most highly divided and highly refined naturally occurring minerals. Median particle size of commercial products vary between 0.1-10 microns. Kaolin is chemically inert. Its hydrophilic surface allows kaolin to be easily dispersed in water at neutral pH values of 6-8. Common physical properties of kaolin are: platy shape; high brightness (80-95); specific gravity 2.58-2.63; refractive index 1.56-1.62; and Mohs hardness 2-3.

C. Toxicological Profile

Waivers were requested for acute toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity, and chronic toxicity. The waivers were accepted based on its long history of use by humans without any indication of deleterious effects, and on the following: Kaolin is used as an indirect food additive for paper/paper board in wet and fatty food contact, paper/paper board 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, in toothpaste and in antiperspirants; Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%).

D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* Dietary exposure of kaolin via food or water is difficult to estimate due to the use of kaolin in thousands of products and its ubiquitous presence in nature. Kaolin has no known mammalian toxicity. The low toxicity, low application rate, and the use patterns leads the Agency to conclude that residues from use of the biochemical pesticide kaolin will not pose a dietary risk of concern under reasonably foreseeable circumstances. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure under this temporary exemption.

2. *Non-dietary, non-occupational exposure.* Increased non-dietary exposure of kaolin via lawn care or ornamental use will be minimal. Kaolin is already widely used in the cosmetic, pharmacological, and other products listed above. 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.

E. Cumulative Exposure

Kaolin has no mode of toxicity and is used in thousands of products used by humans. Cumulative exposure would be difficult to calculate due to its ubiquitous nature in the environment. Because of its low toxicity, low rate of application, and its use patterns, the Agency believes that there is no reason to expect any cumulative effects from kaolin.

F. Endocrine Disruptors

The Agency has no information to suggest that kaolin will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

G. Safety

For the U.S. population, including infants and children, kaolin has no known adverse effects. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that kaolin is not toxic to mammals, including infants and children, and thus there are no threshold effects. As a result, the provision requiring an additional margin of exposure (safety) do not apply, and under reasonable, foreseeable circumstances, kaolin does not pose a dietary risk.

H. Analytical Method

The Agency proposes to establish a temporary 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 kaolin residues.

I. Codex Maximum Residue Level

There are no CODEX tolerances nor international tolerance exemptions for Kaolin at this time. Kaolin is listed as exempt from tolerance "when used in accordance with good agricultural practice as an inert (or occasionally active) ingredient in pesticide formulations applied to growing crops or to food commodities after harvest." 40 CFR 180.1001 (subpart D).

II. Conclusion

Based on its long history of use by humans without any indication of deleterious effects, there is reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of kaolin. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for kaolin. As a result, EPA establishes a temporary exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for kaolin, on the condition that Kaolin be used in accordance with the experimental use permit 70060-EUP-1, with the following provisions:

The total amount of the active ingredients to be used must not exceed the quantity authorized by the experimental use permits.

Engelhard Corporation must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration (FDA).

This temporary exemption from the requirement of a tolerance expires and is revoked December 31, 1999. Residues remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the pesticides are legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary exemption from the requirement of a tolerance. This temporary exemption from the requirement of a tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

III. Objections and Hearing Requests

The new FFDAC section 408(g) provides essentially the same process for persons to "object" to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. 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 adversely affected by this regulation may on or before June 23, 1997 file written objections to the 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 under ADDRESSES at the beginning of this rule (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 genuine and substantial issue of fact; there is 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 "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.

IV. Public Record

A record has been established for this rulemaking under the docket control number [OPP-300477; PP-7G4793] (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 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), 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

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 rule.

V. Regulatory Assessment Requirements

The Office of Management and Budget has exempted this notice from the requirement of section 3 of Executive Order 12866. This action does not impose any enforceable duty or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A), EPA submitted 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 General Accounting Office prior to publication in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(a).

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 15, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

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 added to subpart D to read as follows:

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

(a) *General.* The biochemical pesticide kaolin is temporarily exempted from the requirement of a tolerance for residues of the insecticide Kaolin, when used on crops (apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cranberries, cucurbits, grapes, melons, nuts, ornamentals, peaches, peanuts, pears, peppers, plums, potatoes, seed crops, small grains, soybeans, strawberries, sugar beets, and tomatoes) to control certain insect, fungus, and bacterial damage to plants. This temporary exemption from the requirement of a tolerance will permit the marketing of the food commodities in this paragraph when treated in accordance with the provisions of experimental use permit 70060-EUP-1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked December 31, 1999. This temporary exemption from the requirement of a tolerance may be revoked at any time if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97-10536 Filed 4-22-97; 8:45 am]

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