as independent diagnostic information to the ordering clinician. Examples are IHC's for immunologic detection and semi-quantitative measurement of specific ligand markers of proliferation, such as Ki-67, or semi-quantitative determination of other analytes, such as hormone receptors, if they are reported for their prognostic implications. However, this classification does not apply to estrogen and progesterone receptors that are classified as class III devices.

(3) Class III for IHC's that generate information that is reported directly to the clinician to be used as the basis for significant medical decisions, and that either provide information substantially independent of other pathological (or cytopathological) aspects of the specimen or that have novel claims not supported by current widely accepted scientific pathophysiologic principles. Examples are markers used to identify clinically significant genetic mutations in tissues that are normal by conventional histopathologic examination.

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established for the requirement for premarket approval for the devices described in paragraph(b)(3) of this section. See § 864.3 for effective dates of requirement for premarket approval.

Dated: May 31, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–15140 Filed 6–13–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 5E4573/P662; FRL–5375–1]

RIN 2070–AC18

Fenarimol; Pesticide Tolerance For Residues in or on Filberts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish a tolerance for residues of the fungicide fenarimol in or on the raw agricultural commodity filberts. The proposed regulation to establish a maximum permissible level for residues of the fungicide was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the docket number [PP 5E4573/P662], must be received on or before July 15, 1996.

ADDRESSES: By mail, submit written comments 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Comments and data may also be submitted to OPP by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 5E4573/P662]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the ''SUPPLEMENTARY INFORMATION'' section of this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above, from 8 a .m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8783; e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 5E4573 to EPA on behalf of the Oregon Filbert Commission.

This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.421 by establishing a tolerance for residues of the fungicide fenarimol [alpha-(2-chlorophenyl)-alpha-(4-chlorophenyl)-5-pyrimidine methanol] in or on the raw agricultural commodity filberts at 0.02 parts per million (ppm).

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance include:

1. A 1–year feeding study with dogs fed diets containing 0, 1.25, 12.5, or 125 milligrams/kilogram (mg/kg)/day. The no-observed-effects level (NOEL) for this study is established at 12.5 mg/kg/day. The high dose level (125 mg/kg/day) caused increased serum alkaline phosphatase, increased liver weights, an increase in *p*-nitroanisole *o*-demethylase activity, and mild hepatic bile stasis.

2. A 2–year chronic feeding/carcinogenicity study in rats fed diets containing concentrations of 0, 50, 130, or 350 ppm (equivalent to 0, 2.5, 6.5, or 17.5 mg/kg/day) with a systemic NOEL of 130 ppm (equivalent to 6.5 mg/kg/day). An increase in fatty liver changes was observed in rats fed diets containing 350 ppm. There were no carcinogenic effects observed under the conditions of the study.

3. A second 2–year chronic feeding/carcinogenicity study in rats fed diets containing 0, 12.5, 25, or 50 ppm (equivalent to 0, 0.63, 1.25, or 2.5 mg/kg/day) with no systemic or carcinogenic effects observed under the conditions of the study.

4. A 2–year carcinogenicity study in mice fed diets containing concentrations of 0, 50, 170, or 600 ppm (equivalent to 0, 7, 24.3, or 85.7 mg/kg/day) with a NOEL for systemic effects at 170 ppm. An increase in fatty liver changes was observed in mice at the 600 ppm dose level. There were no carcinogenic efects observed under the conditions of the study.

5. A developmental toxicity study with rabbits given oral doses of 0, 5, 10, or 35 mg/kg/day with no developmental toxicity observed under the conditions of the study.

6. A developmental toxicity study with rats given oral doses of 0, 5, 13, or 35 mg/kg/day demonstrated hydronephrosis at 35 mg/kg/day. The NOEL for developmental toxicity in this study is established at 13 mg/kg/day.

7. A second developmental toxicity study in rats (with a postpartum evaluation) again demonstrated hydronephrosis at 35 mg/kg/day. Maternal toxicity (decreased body weight gain) was also observed at the 35 mg/kg/day. The NOEL's for developmental and maternal toxicity in this study are established at 13 mg/kg/day.

8. A 3–generation reproduction study in rats fed diets containing 0, 12.5, 25, or 50 ppm (equivalent to 0.625, 1.25, or 2.5 mg/kg/day) demonstrated decreased mating in males at the 25 ppm and delayed parturition and dystocia in females at 25 ppm and 50 ppm. The NOEL for reproductive effects in this study is established at 12.5 ppm. The infertility effect in male rats is considered to be a species-specific effect mediated by the inhibition of testosterone aromatase which catalyzes the conversion of testosterone to estradiol in the hypothalamus. Estradiol plays an essential role in the development and maintenance of sexual behavior of rats but not in man.

9. Multi-generation reproduction studies that were negative for reproductive effects at 35 mg/kg/day (highest dose tested) in guinea pigs and 20 mg/kg/day (highest doses tested) in mice.

10. An aromatase inhibition study in rats that showed fenarimol to be a moderately weak inhibitor of aromatase activity.

The adverse reproductive effects observed in the rat multi-generation reproduction study are considered to be a species-specific effect caused by aromatase inhibition. The aromatose enzyme promotes normal sexual behavior in rats and mice, but not in guinea pigs, or primates (including humans). A NOEL of 35 mg/kg/day for reproductive effects relevant to humans was established based on the NOEL from the multi-generation reproduction study in guinea pigs.

11. Fenarimol tested negative in several assay systems for gene mutation, structural chromosome aberration and other genotoxic effects. In a micronucleus test in the mouse, fenarimol did produce a significant increase in the percent of polychromatic erythrocytes with micronucleus at 24 hours, but not at 48 hours or 72 hours. The significance of this finding is not known, but the negative results of the other assays demonstrate that the mutagenic potential of fenarimol is very low.

12. Metabolism studies in rats show that fenarimol is rapidly metabolized and excreted. Major metabolic pathways were oxidation of the carbinol-carbon atom, the phenyl rings and the pyrimidine ring.

Based on the above findings, the Agency concluded that fenarimol was not carcinogenic in long-term studies in rats and mice under the test conditions in which the highest dose tested for both species approached a maximum-tolerated dose as evidenced by increased fatty changes in the liver.

The Reference Dose (RfD) is calculated at 0.065 mg/kg bwt/day. The RfD is based on a NOEL of 6.5 mg/kg/bwt/day from the 2–year rat chronic feeding study and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from previously established tolerances and the proposed tolerance for filberts utilizes less than 1 percent of the RfD for the general population and less than 2 percent of the RfD for children 1 to 6 years of age (the population subgroup most highly exposed to dietary residues of fenarimol). EPA generally has no concern for exposures below 100 percent of the RfD.

The metabolism of fenarimol in plants is adequately understood for the purposes of the proposed tolerance. The residue of concern is fenarimol per se. An adequate analytical method, is available for enforcement purposes. The analytical method is published in the Pesticide Analytical Manual, Volume II (PAM II).

There is no reasonable expectation that secondary residues of fenarimol will occur in milk, egg, or meat, fat, and meat byproducts of livestock or poultry as a result of this action; there are no livestock feed commodities associated with filberts.

There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the docket number [PP 5E4573/P662].

A record has been established for this rulemaking under docket number [PP 5E4573/P662] (including comments and data submitted electronically as described below). 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 a.m. to 4:30 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.

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 all comments 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.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in t his Executive Order. Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

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).

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement explaining the factual basis for this determination was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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 § 180.421, the table in paragraph (a) is amended by adding alphabetically the entry for filberts, to read as follows:

§ 180.421 Fenarimol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Filberts	0.02
* * * * *	

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[FR Doc. 96–15041 Filed 6–13–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300426; FRL–5374–4]

RIN 2070–AC18

Vinyl Pyrrolidone-Acrylic Acid Copolymer; Tolerance Exemption.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish an exemption from the requirement of a tolerance for residues of vinyl pyrrolidone-acrylic acid copolymer when used as an inert ingredient (adhesive, dispersion stabilizer and coating for sustained release granules) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and applied to animals. This proposed regulation was requested by International Specialty Products.

DATES: Written comments, identified by the docket number [OPP–300426], must be received on or before July 15, 1996.

ADDRESSES: By mail, submit written comments 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, deliver comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–300426]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, 6th Floor, Arlington, VA 22202, (703)–308–8380, e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: International Specialty Products, 1361 Alps Road, Wayne, NJ 07470, submitted pesticide petition (PP) 6E04659 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346 a(e)), propose to amend 40 CFR part 180.1001(c) and (e) by establishing an exemption from the requirement of tolerance for residues of vinyl pyrrolidone-acrylic acid copolymer (CAS Reg. No. 28062–44–4), when used as an inert ingredient (adhesive, dispersion stabilizer and coating for sustained release granules) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001(e).

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not to imply nontoxicity; the ingredient may or may not be chemically active.

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), 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