behavioral changes were observed in either F_1 or F_2 offsprings in the two-generation reproduction study). Moreover, as the NOELs for fetal/developmental toxicity are significantly higher than those for maternal toxicity, the results indicate that chlorfenapyr is neither a developmental toxicant nor a teratogenic agent in either the Sprague-Dawley rat or New Zealand white rabbit. Thus, there is no reliable information to indicate that there would be a variability in the sensitivities of infants and children and adults to the effects of exposure to chlorfenapyr.

Therefore, a chronic dietary exposure analysis for the residues of chlorfenapyr in cotton, meat, and milk, using the "worst case" proposed tolerance-level residues, demonstrates that these levels are well below the RfD of 0.03 mg/kg b.w./day and thus the proposed use of chlorfenapyr is toxicologically supported.

F. International Tolerances

Section 408(b)(4) of the amended FFDCA requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission.

There is neither a Codex proposal, nor Canadian or Mexican tolerances/limits for residues of chlorfenapyr in/on cottonseed. Therefore, a compatibility issue is not relevant to the proposed tolerance.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket control number [PF-697]. All written comments filed in response to this petition will be available, in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket control numbers [PF-697] (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 8:30 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 ASCII file avoiding the use of special characters and any form of encryption. The official record for this notice, 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 record which will also include all comments submitted directly in writing.

The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this notice.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Dated: January 24, 1997.

Stephen L. Johnson, Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–2466 Filed 2–4–97; 8:45 am] BILLING CODE 6560–50–F

[PF-695; FRL-5584-1]

Ciba-Geigy Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice announces the refiling of a pesticide petition proposing the establishment of a regulation for residues of [4-(2,2-difluoro-1,3benzodioxol-4-yl)-1*H*-pyrrole 3 carbonitrile] (fludioxonil) in or on the raw agricultural commodity (RAC) potatoes. The notice contains a summary of the petition prepared by the petitioner, Ciba-Geigy Corporation. **DATES:** Comments, identified by the docket number [PF-695], must be received on or before March 7, 1997. 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 Hwy., Arlington, VA 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 [PF–695]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in unit II of this document.

Information submitted as comments 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 address given above from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, PM 21, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm 227, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 305-6226, e-mail: welch.connie@epamail.epa.gov. SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 6F4694) from Ciba-Geigy Corporation ("Ciba"), 410 Swing Road, Greensboro, NC 27401, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide, fludioxonil, in or on the raw agricultural commodity potatoes at 0.02 parts per million (ppm).

The proposed analytical method is Method AG–597B. The Limit of Detection is 0.5 ng and the Limit of Quantitation for potatoes is 0.01 ppm. In AG–597, a subsample of potato substrate or processed fraction is homogenized twice with 90 percent acetonitrile (ACN)/10 percent water. Both extracts are filtered through Whatman 2V and Reeve Angel 802 paper. A 40–mL aliquot (2–g equivalent) is taken and the

ACN is evaporated using rotary evaporation. The sample is diluted with a saturated salt solution and partitioned twice with methyl tert-butyl ether (MTBE). Toluene is added to the organic phase, the MTBE is evaporated and hexane is added to the sample. Samples are cleaned up on a 0.5-g silica Bond Elut column that has been preconditioned with 10 percent isopropyl alcohol/90 percent hexane and rinsed with hexane. The sample is loaded onto the column and CGA-173506 is eluted with 50 percent DCM/ 50 percent toluene. The silica column eluate is evaporated to dryness. The residue remaining is dissolved in methanol and water and then loaded onto a preconditioned 0.5-g phenyl Bond Elut column. Fludioxonil is eluted with acetone. The acetone solution is evaporated to dryness, and the residue is dissolved in an appropriate amount of mobile phase. Residues of fludioxonil are determined by using an Amino column with normal phase HPLC and ultraviolet absorbance detection at 268

EPA has determined that the petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

I. Petition Summary

- 1. Chemical uses. Fludioxonil is a non-systemic, contact fungicide that is being developed as a seed treatment for potatoes. Fludioxonil provides highlevel, broad-spectrum activity against a wide range of seed-borne and soil-borne diseases caused by Ascomycetes, Deuteromycetes and Basidiomycetes. On potatoes, fludioxonil provides control of Fusarium dry rot seed decay, Rhizoctonia stem canker, and silver scurf. Fludioxonil represents a new class of chemistry with a unique mode of action. Fludioxonil is classified as a phenylpyrrole and is structurally related to pyrrolnitrin. Pyrrolnitrin is a secondary metabolite of a soilinhabiting bacterium of the genus Pseudomonas. It has significant activity against economically important soilborne fungi. In European field trials against foliar pathogens, fludioxonil was highly effective against pathogens resistant or insensitive to other chemical classes such as the benzimidazoles and dicarboximides.
- 2. Fludioxonil safety. a. Ciba has submitted over 25 separate toxicology studies in support of tolerances for fludioxonil. According to Ciba,

fludioxonil has a low order of acute toxicity by the oral, dermal, and inhalation exposure routes. The compound is slightly irritating to the eye, non-irritating to skin, and is not a dermal sensitizer. It is not a teratogen and does not affect reproduction or fertility. The kidney and liver have been identified as target organs in subchronic and chronic toxicity studies. No mutagenic activity has been seen in vivo. On September 19, 1996, the Health Effects Division Carcinogenicity Peer Review Committee issued its finding on fludioxonil. The consensus of the committee was that fludioxonil should be placed in Group D - not classifiable as to human carcinogenicity.

b. The following mammalian toxicity studies have been conducted to support the tolerance of fludioxonil:

i. The rat acute oral LD_{50} is >5,000 mg/kg.

ii. The rat acute dermal LD₅₀ is >2,000

iii. The rat acute inhalation LC₅₀ is >2.6 mg/liter air.

iv. The primary eye irritation study in the rabbit showed slight irritation.

v. The primary dermal irritation study showed no irritation.

vi. The primary dermal sensitization study showed no sensitization.

vii. In a 28-day oral study in rats, the no-observed-effect level (NOEL) was 10 mg/kg/day.

viii. In a 28-day dermal study in rats, the NOEL was 40 mg/kg/day.

ix. In a 90–day subchronic dietary toxicity study in rats, the NOEL was 10 ppm based on liver toxicity.

x. In a 90–day subchronic dietary toxicity study in mice, the NOEL was 100 ppm based on blue urine (a metabolite). The maximum tolerated dose was 7,000 ppm.

xi. In a 90–day oral toxicity study in dogs, the NOEL was 200 ppm based on clinical observation. The maximum tolerated dose was clearly exceeded at 15,000 ppm.

xii. In a 1–year chronic toxicity study in dogs, the NOEL was 100 ppm based on body weight effects. The maximum tolerated dose was 8,000 ppm.

xiii. Two 18—month dietary oncogenicity studies were performed in mice. While a NOEL of 1,000 ppm was clearly established in the first study, its highest feeding level (3,000 ppm) did not meet the criteria for a maximum tolerated dose.

xiv. In the second 18-month study, the maximum tolerated dose was determined to be 5,000 ppm. There were no treatment-related increases in neoplasia at any dose level tested. In a combined chronic toxicity/oncogenicity study in rats, the incidence of liver

tumors in top-dose females (3,000 ppm) was marginally higher than the controls. The NOEL for chronic toxicity was 1,000 ppm in both sexes.

xv. *În vitro* point mutation test: Ames assay - negative; Chinese hamster V79 cells - negative; hepatocyte DNA repair

- negative.

xvi. *In vitro* chromosome test: Chinese hamster ovary cells - clastogenic effects and polyploidy at or near precipitating concentration.

xvii. *In vivo* mutagenicity test: rat hepatocyte micronucleus - negative; mouse bone marrow - negative; cytogenetic test on Chinese hamster bone marrow - negative; mouse dominant lethal - negative.

xviii. In a teratology study in rats, fludioxonil was not teratogenic at doses up to 1,000 mg/kg. The maternal NOEL was 100 mg/kg, while the NOEL in the fetus was 1,000 mg/kg.

xix. In a teratology study in rabbits, fludioxonil was not teratogenic at doses up to 300 mg/kg. The maternal and fetal NOELs were 10 mg/kg and 300 mg/kg,

respectively.

xx. In a multigeneration reproduction study, fludioxonil had no adverse effects on the reproductive performance of the rat at doses up to 3,000 ppm. Fetal effects (reductions in pup body weights) were observed only at 3,000 ppm, a dose level at which there were maternal toxic effects. The NOEL was

3. Threshold effects— a. chronic effects. Based on the available chronic toxicity data, Ciba believes that the Reference Dose (RfD) for fludioxonil is 0.025 mg/kg/day. This RfD is based on a 1–year feeding study in dogs with a NOEL of 2.5 mg/kg/day (100 ppm) and an uncertainty factor of 100. No additional modifying factor for the nature of effects was judged to be necessary as body weight was the most sensitive indicator of toxicity in that study.

b. Acute toxicity. Based on the available acute toxicity data, EPA has determined that fludioxonil does not pose any acute dietary risks. The lowest NOEL in a short term exposure scenario, identified as 10 mg/kg in the rabbit teratology study, is actually higher than the chronic NOEL (see above). Ciba anticipates that the margin of exposure would be in the thousands for any population group (margins of exposure of 100 or more are considered satisfactory).

4. Non-threshold effects. Using the Guidelines for Carcinogenic Risk Assessment published on September 24, 1986 (51 FR 33992), the USEPA has classified fludioxonil in group D for carcinogenicity. The compound was

tested in two mouse oncogenicity studies and a 24-month rat chronic study. Dosage levels in both the mouse and the rat studies were adequate for identifying cancer risk.

5. Aggregate exposure. For purposes of assessing the potential dietary exposure under the proposed tolerance, Ciba has estimated aggregate exposure based on the tolerance level of 0.02 ppm in or on the RAC potatoes (potato tubers). This is a worse case estimate of dietary exposure since it is assumed that 100 percent of all crops for which tolerances are established are treated and that pesticide residues are present at the tolerance levels.

Fludioxonil's current registered use for seed treatment on corn and sorghum seeds does not contribute to dietary exposure because there are no detectable residues. EPA has ruled that these uses are food uses not requiring tolerances. For potato seed treatment, the use described in this petition, a residue tolerance level of 0.02 ppm is being proposed although the highest actual level seen in field trials is around 0.01 ppm. In conducting this exposure assessment, very conservative assumptions—100 percent of potatoes will contain fludioxonil residues and those residues would be at the level of the tolerance—have been used, resulting in an overestimate of human exposure.

Exposures of the general population to residues of this pesticide from other potential sources, drinking water and other non-occupational sources, Ciba considers to be unlikely. The movement of fludioxonil into groundwater is highly unlikely. The EPA has not established a Maximum Contaminant Level for residues of fludioxonil in drinking water. Non-occupational exposure for fludioxonil has not been calculated since the current registration for fludioxonil is limited to commercial crop production. Since the chemical is not used in or around the home, Ciba considers the potential for nonoccupational exposure to the general population to be non-existent.

Consideration of a common mechanism of toxicity is not appropriate at this time since Ciba is unaware of any reliable information that indicates that toxic effects produced by fludioxonil would be cumulative with those of any other chemical compounds.

Consequently, Ciba is considering only the potential risks of fludioxonil in its

aggregate exposure assessment.
6. Determination of safety for U.S. population. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base for fludioxonil, Ciba has calculated

aggregate exposure levels for this chemical. The calculation shows that only 0.09 percent of the RfD will be utilized for the U.S. population based on chronic toxicity endpoints. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Ciba concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fludioxonil residues.

7. Determination of safety for infants and children. Developmental toxicity (decreased pup weight) was observed in the 2–generation rat reproduction study at a maternally toxic dose. The NOEL for this effect was established at 30 mg/kg (300 ppm). This finding is judged to be a nonspecific, secondary effect of maternal toxicity. No developmental toxicity was observed at all in any of the teratology studies conducted. Ciba concludes that infants and children are not uniquely sensitive to fludioxonil.

Using the same conservative exposure assumptions used for the determination in the general population, Ciba has concluded that the percentage of the RfD that will be utilized by aggregate exposure to residues of fludioxonil is 0.03 percent for nursing infants less than 1 year old, 0.11 percent for nonnursing infants, 0.18 percent for children 1 to 6 years old, and 0.13 percent for children 7 to 12 years old. Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Ciba concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to fludioxonil residues.

- 8. Estrogenic effects. No specific tests have been conducted with fludioxonil to determine whether the pesticide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.
- 9. Chemical residues. The nature of the residue is adequately understood in animals and plants. The metabolism of fludioxonil in plants has been characterized in potatoes, rice, and spring wheat. Residues of fludioxonil do not concentrate in processed commodities. There are no Codex maximum residue levels established for residues of fludioxonil on potatoes. Ciba has submitted a practical analytical method for detecting and measuring levels of fludioxonil in or on food with the limit of quantitation that allows monitoring of food with residues at or above the levels set in the proposed

tolerances. EPA will provide information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from the Field Operations Division, Office of Pesticide Programs.

This petition is supported by 23 field residue tests where fludioxonil, in the form of Maxim T Potato Seed Protectant, was applied to potato seed pieces. These trials indicate that the maximum residue of fludioxonil will be at or below 0.011 ppm at the 0.7X rate of 1.75g a.i./100 kg. A tolerance of 0.02 ppm is proposed for raw agricultural commodities (tubers) of potatoes.

No residues greater than or equal to 0.01 ppm were detected in the tubers before processing, in peeled and rinsed potatoes, sliced and peeled potatoes, potato chips, or potato granules from field trials conducted in Michigan and North Dakota.

The results from all four processed field trials indicate that residues in potato processing waste (wet peel and trimmings) and potato culls will not exceed the tolerance established for potato tubers.

Based on the results of rotational crop studies, Ciba proposes a 1–year restriction on rotation to crops other than leafy vegetables, root and tuber vegetables, and registered crops (potatoes, corn, and sorghum).

Using the worst case theoretical diet for beef and dairy cattle, no detectable residues would be expected in tissues or milk. Processed potato products are not fed to poultry. Therefore, there is no need for tolerances in meat, milk or eggs.

10. Environmental fate. Since the Agency classifies seed treatment uses as "Indoor," the only environmental fate data requirement is hydrolysis. Fludioxonil is hydrolytically stable in solution at 25°C at pH 5, 7, or 9. At pH 1 and 13, fludioxonil is extensively degraded.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket number [PF–695].

A record has been established for this notice under docket numbers [PF-695] (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 8:30 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 ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

List of Subjects

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

Dated: January 22, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–2711 Filed 2–4–97; 8:45 am] BILLING CODE 6560–50–F

[PF-696; FRL-5584-2]

Ciba-Geigy Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the establishment of a regulation for residues of cyprodinil in or on members of the stone fruit crop grouping under an experimental use permit (EUP). This notice contains a summary prepared by the petitioner, Ciba-Geigy Corporation. DATES: Comments, identified by the docket number [PF-696], must be received on or before March 7, 1997. 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.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 [PF-696]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as comments concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). No CBI should 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 address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail, Connie Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6226; e-mail: welch.connie@epamail.epa.gov. SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 5G4553 from Ciba Crop Protection, Ciba-Geigy Corporation ("Ciba"), P.O. Box 18300, Greensboro, NC 27419, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C 346a, to amend 40 CFR part 180 by establishing a temporary tolerance for residues of the fungicide cyprodinil (4-cyclopropyl-6methyl-N-phenyl-2-pyrimidinamine) in or on the agricultural commodities for the stone fruit crop grouping at 2.0 ppm. The proposed analytical method is by high performance liquid chromatography with UV detection.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (Pub. L. 104-170), Ciba included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Ciba; EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA has made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Cyprodinil Uses

Cyprodinil is the first fungicide in a new chemical class known as the anilinopyrimidine and is active against important Monilinia diseases of stone fruit when applied at rates of 0.25 to 0.5 lb active ingredient per acre. Cyprodinil has a unique mode of action which controls pathogens resistant to other chemical classes of fungicides.

B. Metabolism and Analytical Method

- 1. *Metabolism*. Ciba believes the metabolism of cyprodinil has been well characterized in plants and animals. The metabolism profile supports the use of an analytical enforcement method that accounts for parent cyprodinil.
- 2. Analytical methodology. Ciba has submitted a practical analytical method involving extraction, filtration, and solid phase cleanup of samples with analysis by HPLC and UV. The limits of quantitation (LOQ) for fruit is 0.02 ppm.

C. Magnitude of Residue

This petition is supported by field residue trials conducted on representative members of the Stone Fruit Crop Grouping. All samples were analyzed for parent residues of cyprodinil. In stone fruit, maximum residues ranged from 0.82 ppm to 1.7 ppm. A temporary tolerance of 2.0 ppm has been proposed for the Stone Fruit Crop Grouping under this EUP. Since stone fruit commodities are not fed to animals, potential transfer of cyprodinil into milk and meat is not anticipated and tolerances in milk, meat, poultry, and eggs are not required.