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.

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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: 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 [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-6-methyl-*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.

*D. International Tolerances*

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of cyprodinil in or on raw agricultural commodities.

*E. Toxicological Profile of Cyprodinil*

The following mammilian toxicity studies have been conducted to support the tolerances of cyprodinil:

A rat acute oral study for cyprodinil with a $LD_{50}$ of 2,796 mg/kg. A rat acute dermal study for cyprodinil with a $LD_{50}$ >2,000 mg/kg.

A rat inhalation study for cyprodinil with a $LC_{50}$ >1.2 mg/liter air.

A primary eye irritation study in rabbits showing cyprodinil as minimally irritating.

A primary dermal irritation study in rabbits showing cyprodinil as slightly irritating.

A skin sensitization study in guinea pigs showing cyprodinil as a weak sensitizer.

A 28–day dermal study in the rat with a No-Observed Effect Level (NOEL) of 5 mg/kg based on clinical signs.

A 90–day feeding study in the dog with a NOEL of 1,500 ppm (37.5 mg/kg) based on reduced food intake and body weight.

A 90–day feeding study in the mouse with a NOEL of 500 ppm (75 mg/kg) based on liver histologic changes.

A 90–day feeding study in the rat with a NOEL of 50 ppm (5 mg/kg) based on hematologic and histologic findings.

A 12–month feeding study in the dog with a NOEL of 2,500 ppm (62.5 mg/kg) based on liver histologic changes.

An 18–month oncogenicity feeding study in the mouse with a NOEL of 2,000 ppm (300 mg/kg). The MTD was 5,000 ppm based on reduction in body weight gain and no evidence of oncogenicity was seen.

A 24–month chronic feeding/oncogenicity study in the rat with a NOEL of 75 ppm (3.75 mg/kg) based on hematologic and histologic findings. The MTD was 2,000 ppm based on liver histopathology and no evidence of oncogenicity was seen. An oral teratology study in the rat with a maternal NOEL of 200 mg/kg based on reductions in body weight gain and food consumption and a fetal NOEL of 200 mg/kg based on decreased pup weight and delayed skeletal growth at 1,000 mg/kg. An oral teratology study in the rabbit with a maternal NOEL of 150 mg/kg based on reduction in body weight gain and a fetal NOEL of 400 mg/kg based on the absence of any fetal effects.

A 2–generation reproduction study in the rat with a systemic NOEL of 100 ppm and a fetal NOEL of 1,000 ppm (100 mg/kg).

A slight decrease in pup weight at birth and subsequent body weight gain during the lactation phase was observed only at the maternally toxic dose of 4,000 ppm without any effects on reproduction and fertility.

*In vitro* gene mutation test: Ames assay - negative; Chinese hamster V79 cell test - negative; rat hepatocyte DNA repair test - negative.

*In vitro* chromosome test: Chinese hamster ovary cell cytogenetic test - negative. In *vivo* mutagenicity test: mouse bone marrow test - negative.

*F. Threshold Effects*

1. *Chronic effects*. Based on the available chronic toxicity data, Ciba believes the Reference Dose (RfD) for cyprodinil is 0.0375 mg/kg/day. This RfD is based on a 2–year feeding study in rats with a NOEL of 3.75 mg/kg/day (75 ppm) and an uncertainty factor of 100. No additional modifying factor for the nature of effects was judged to be necessary as liver sinusoidal dilatation was the most sensitive indicator of toxicity in that study.

2. *Acute toxicity.* The risk from acute dietary exposure to cyprodinil is considered to be very low. The lowest NOEL in a short-term exposure scenario, identified as 150 mg/kg in the rabbit teratology study, is 40–fold higher than the chronic NOEL. Since chronic exposure assessment did not result in any margin of exposure (MOE) less than 400 for even the most impacted population subgroup, Ciba believes the MOE is greater than 100 for any population subgroups; EPA considers margins of exposure of 100 or more as satisfactory.

*G. Non-threshold Effects*

Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), Ciba believes cyprodinil to be in Group ''E''( no evidence of carcinogenicity). There was no evidence of carcinogenicity in an 18–month feed study in mice and a 24–month feeding in rats. Dosage levels in both the mouse and the rat studies were adequate for identifying a cancer risk.

*H. Aggregate Exposure*

1. *Dietary exposure.* For the purposes of assessing the potential dietary exposure under the proposed temporary tolerance, Ciba has estimated aggregate exposure based upon the Theoretical Maximum Residue Concentration (TMRC) from the requested tolerance for members of the Stone Fruit Crop Grouping at 2.0 ppm. The TMRC is a ''worst case'' estimate of dietary exposure since it assumes 100 percent of all crops for which tolerances are established are treated and that pesticide residues are at the tolerance levels. In conducting this exposure assessment, Ciba has made very conservative assumptions — 100 percent of all stone fruit commodities will contain cyprodinil residues at tolerance levels — which result in an overestimate of human exposure. Ciba has also calculated aggregate exposure based upon the scale of the requested 950–acre EUP. It is estimated that a maximum of 0.25 percent of the stone fruit market would receive applications of cyprodinil under this EUP and that dietary exposure would be proportionately less than under the ''worst case'' assumptions given above.

2. *Drinking water exposure.* Cyprodinil is rapidly degraded in the environment via photolysis and microbial degradation; aqueous and soil photolysis half lives for cyprodinil are 12 days and 67 days, respectively. The aerobic metabolism half life is 25 days and the leaching potential for cyprodinil is low ($K^{oc}$ = 1,550 to 2,030). Based on these data, Ciba does not anticipate exposure to residue of cyprodinil in drinking water.

3. *Non-dietary exposure.* Ciba believes that the potential for non-occupational exposure to the general public is unlikely except for potential residues in food crops discussed above. The proposed uses for cyprodinil are for agricultural crops and the product is not used residentially in or around the home.

Ciba believes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by cyprodinil would be cumulative with those of any other chemicals. Consequently, Ciba is considering only the potential exposure to cyprodinil in its aggregate risk assessment.

*I. Safety To the U.S. Population*

*Reference dose.* Using the conservative exposure assumptions described above (100 percent stone fruit acres treated and tolerance level residues) and based on the completeness and reliability of the toxicity data base for cyprodinil, Ciba has calculated aggregate exposure levels for this chemical. Based on chronic toxicity endpoints, only 2 percent of the RfD will be utilized for the U.S. general population. Under the scale of this EUP (0.25 percent stone fruit acres treated) it is estimated that only 0.005 percent of the RfD will be utilized for the U.S. general population. EPA usually 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 cyprodinil residues.

*J. Safety to Infants and Children*

Developmental delays (reduced pup weight and ossification) were observed in the rat teratology study and 2–generation rat reproduction study at maternally toxic doses. The lowest NOEL for this effect was established in the 2–generation study at 100 mg/kg (1,000 ppm). The finding is judged to be a nonspecific, secondary effect of maternal toxicity. No developmental toxicity was observed in the rabbit teratology study.

*Reference dose.* Using the same conservative exposure assumptions as employed for the determination in the general population (100 percent stone fruit acres treated and tolerance level residues), Ciba has calculated the utilization of RfD by aggregate exposure to residues of cyprodinil to be 9 percent for nursing infants less than 1 year old, 17 percent for non-nursing infants less than 1 year old, 4 percent for children 1 to 6 years old, and 3 percent for children 7 to 12 years old. Under the scale of this EUP (0.25 percent stone fruit acre treated) the utilization of RfD by aggregate exposure to residues of cyprodinil is estimated to be 0.023 percent for nursing infants less than 1 year old, 0.043 percent for non-nursing infants less than 1 year old, 0.011 percent for children 1 to 6 years old, and 0.007 percent for children 7 to 12 years old. Ciba believes that under the worst case assumptions which overestimate exposure to infants and children, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyprodinil residues. Under the scale of this EUP resultant exposure will be proportionately less.

*K. Estrogenic Effects*

Cyprodinil does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that cyprodinil might have any effects on endocrine function related to development and reproduction. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

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–696]. 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 number [PF–696] (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.

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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. 97–2468 Filed 1–4–97; 8:45 am]
BILLING CODE 6560–50–F

**[OPP–181031; FRL 5584–3]**

## Azoxystrobin; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has received a specific exemption request from the Louisiana Department of Agriculture and Forestry (hereafter referred to as the ''Applicant'') to use the pesticide azoxystrobin (CAS 131860–33–8) to treat up to 85,000 acres of rice to control benomyl-resistant rice panicle blast and sheath blight. The Applicant proposes the use of a new chemical; therefore, in accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

**DATES:** Comments must be received on or before February 20, 1997.

**ADDRESSES:** Three copies of written comments, bearing the identification notation ''OPP–181031,'' should be submitted by mail to: Public Response and Program Resource 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, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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Information submitted in any comment concerning this notice 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 comment that does not contain CBI must be provided by the submitter for inclusion in the public record. Information not marked