The applications were approved on November 15, 1996, for an end-use and a technical product as listed below:

1. Able Biological Insecticide (EPA Reg. No. 100–776) for control of lepidopteran insect of tree fruits, terrestrial small fruits and vegetables, tree nuts, alfalfa, herbs, cranberries, corn, cotton, and soybeans.

2. Technical CGA-269941 (EPA Reg. No. 100–775) for formulating into end-use products for control of lepidopterus insect pests of tree fruits, terrestrial small fruits and vegetables, tree nuts, herbs, spices, cranberries, alfalfa, corn, peanuts, cotton, and soybeans.

The Agency has considered all required data on risks associated with the proposed use of *Bacillus thuringiensis* var. *kurstaki* strain M-200, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health safety determinations which show that use of *Bacillus thuringiensis* var. *kurstaki* strain M-200 when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on these registrations is contained in an EPA Pesticide Fact Sheet on *Bacillus thuringiensis* var. *kurstaki* strain M-200.

A copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Regulatory Action Leader. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 1132, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, D.C. 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: February 5, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 97–3929 Filed 2–18–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–703; FRL–5585–6]

Ciba-Geigy Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of tolerances for residues of difenoconazole in or on raw agricultural commodities of barley. This notice includes a summary of the petition that was prepared by the petitioner, Ciba-Geigy Corporation.

DATES: Comments, identified by the docket control number [PF–703], must be received on or before March 21, 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: Crystal Mall #2, Room 1132, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically be 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 in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–703]. Electronic comments on this notice 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 a comment concerning this notice 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 Room 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, Cynthia Giles-Parker, Product Manager (PM 22), Registration Division, 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, Room 229, 1921 Jefferson Davis Highway, Arlington, VA, 703–305–5540, e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP–6F4748)) from Ciba-Geigy Corporation, 410 Swing Rd., Greensboro, NC 27401, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide, difenoconazole, in or on the raw agricultural commodities barely forage, hay, and straw at 0.05 parts per million (ppm) and barley grain at 0.01 ppm.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of FFDCA; 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 (FQPA) Pub. L. 104-170, Ciba-Geigy Corporation (Ciba-Geigy) 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-Geigy. EPA is in the process of evaluating the petition. As required by section 408(d)(3) of the FFDCA, 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

The analytical method AG–575B (MRID 42806504) was used to determine residues of difenoconazole in or on barley matrices. This method is proposed as the regulatory enforcement method for barley. It is a revised version of AG–575A that incorporates specificity data and methodology for megabore column gas chromatography. The procedures in AG–575A remain unaltered in the revised method, AG–575B. Procedural recoveries on barley substrates, fortified prior to extraction at levels ranging from 0.01 ppm to 5.0 ppm, ranged from 70% to 125% using AG–575B.

One-year freezer storage stability was demonstrated in lettuce, soybeans, and wheat forage. A 2-year stability study including wheat forage, grain, and straw is now in progress.

A. Chemical Uses

Difenoconazole is the active ingredient in dividend® 3FS, a fungicide that offers broad-spectrum control of several seed, soil borne, and foliar pathogens of wheat. In the current petition, dividend is being developed as a seed treatment for barley and triticale. It is highly active at rates of 0.5 to 1.0 fl. oz. of 3FS formulation/100 lb of seed (0.0125 to 0.025 lb active ingredient (ai)/100 lb seed). In barley, dividend controls barley stripe, general seed rots, fusarium seed scab, and covered smut. Dividend also partially controls take-all, common root rot, fusarium root rot, and fusarium crown rot. Dividend controls general seed rots of triticale.

B. Difenoconazole Safety

1. Ciba-Geigy has submitted over 20 toxicity studies in support of tolerances for difenoconazole. Difenoconazole has a low order of acute toxicity, minimal irritation potential, and no sensitization potential. There was no evidence of genotoxicity, and it is not fetotoxic, embryolethal, or teratogenic. It is not a reproductive toxin. The main target organ of toxicity was the liver in the species tested. There was an increase in liver tumors only in mice, and only, according to the EPA's Carcinogenicity Peer Review Committee (CPRC), at doses considered excessively high for carcinogenicity testing. EPA has concluded that for the purpose of risk characterization, the margin of exposure (MOE) approach (threshold model) should be used for quantification of human risk. MOEs are extremely high for the U.S. population and all population subgroups for both chronic effects and acute toxicity.

2. The following mammalian toxicity studies were conducted and submitted in support of tolerances for difenoconazole. No observed effect levels (NOELs) are consistent with those published in the Federal Register of August 24, 1994 (59 FR 43490, FRL–4906–2).

i. A rat acute oral study with an LD_{50} of 1,453 milligram/kilogram (mg/kg).

ii. A rabbit acute dermal study with an LD_{50} of >2,010 mg/kg.

iii. A rat acute inhalation study with an LC_{50} of >3.285 milligram/liter (mg/L).

iv. A primary eye irritation study in the rabbit which showed slight irritation.

v. A primary dermal irritation study in the rabbit which showed slight irritation.

vi. A dermal sensitization study in the guinea pig which showed no irritation.

vii. A 13-week rat feeding study identified liver as a target organ and had a NOEL of 20 ppm.

viii. A 13-week mouse feeding study identified liver as a target organ and had a NOEL of 20 ppm.

ix. A 26-week dog feeding study identified liver and eye as target organs and had a NOEL of 100 ppm.

x. A 21-day dermal study in rabbits had a NOEL of 10 mg/mg/day based on decreased body weight gain at 100 and 1,000 mg/kg/day.

xi. A 24-month feeding study in rats had a NOEL of 20 ppm based on liver toxicity at 500 and 2,500 ppm. There was no evidence of an oncogenic response.

3. An 18-month mouse feeding study had an overall NOEL of 30 ppm based on decreased body weight gain and liver toxicity at 300 ppm. There was an increase in liver tumors only at dose levels that exceeded the maximum tolerated dose (MTD). The oncogenic NOEL was 300 ppm.

4. A 12-month feeding study in dogs had a NOEL of 100 ppm based on decreased food consumption and increased alkaline phosphatase levels at 500 ppm.

5. An oral teratology study in rats had a maternal NOEL of 16 mg/kg/day based on excess salivation, decreased body weight gain, and food consumption. The developmental NOEL of 85 mg/kg/day was based on effects seen secondary to maternal toxicity including slightly reduced fetal body weight and minor changes in skeletal ossification.

6. An oral teratology study in rabbits had a maternal NOEL of 25 mg/kg/day based on decreased body weight gain, death, and abortion.

7. The developmental NOEL of 25 mg/kg/day was based on effects seen secondary to maternal toxicity including slight increase in post-implantation loss and resorptions and decreased fetal weight.

8. A two-generation reproduction study in rats had a parental and reproductive NOEL of 25 ppm based on significantly reduced female body weight gain, and reductions in male pup weights at 21 days.

9. There was no evidence of the induction of point mutations in an Ames test.

10. There was no evidence of mutagenic effects in a mouse lymphomatest.

11. There was no evidence of mutagenic effects in a nucleus anomaly test with Chinese hamsters.

12. There was no evidence of induction of DNA damage in a rat hepatocyte DNA repair test.

13. There was no evidence of induction of DNA damage in a human fibroblast DNA repair test.

C. Threshold Effects

1. *Chronic effects.* Based on the data from chronic studies in rats, mice, and dogs, the reference dose (RfD) for difenoconazole is 0.01 mg/kg/day published in the Federal Register of August 24, 1994 (59 FR 43490). The RfD for difenoconazole is based on the chronic study in rats with a threshold NOEL of 1 mg/kg/day and an uncertainty factor of 100.

2. *Acute toxicity.* i. EPA has concluded that the dietary acute MOE for developmental toxicity was 25,000 for high exposure in the females 13+ subgroup. The agency is generally not concerned unless the MOE is below 100 for substances whose acute NOEL is based on animal studies.

ii. Ciba-Geigy concurs, and has also considered that since the percentage of the RfD utilized in the chronic exposure analysis for all population subgroups is less than 10, it is highly unlikely that any acute dietary exposure scenario would utilize a significant percentage of the RfD.

iii. Since MOEs of 100 or more are considered satisfactory, there is no concern for acute dietary exposure for the U.S. population, for various population subgroups, or for either gender.

D. Non-Threshold Effects

1. The Health Effects Division, CPRC evaluated the weight of the evidence on difenoconazole with reference to its carcinogenic potential. The CPRC concluded that difenoconazole should be classified a Group C carcinogen, and

for the purpose of risk characterization the MOE approach should be used for quantification of human risk.

2. In the 18-month study with CD-1 mice, there was a statistically significant increase in hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes, but only at dose levels which were considered excessively high for carcinogenicity testing. This is considered very weak evidence of carcinogenic potential. Additionally, there was no evidence of carcinogenicity in either sex of CD rat after 24 months, and there was no evidence of genotoxicity. Therefore, a threshold model should be used for estimating risk. The CPRC determined that a NOEL of 4.7 mg/kg/day, based on endpoints related to hepatic tumor development, should be used for calculating MOEs. The calculated margin of exposure, using worst case assumptions, was 9,958 for the U.S. population.

E. Aggregate Exposure

1. When the potential dietary exposure to difenoconazole is calculated, the theoretical maximum residue concentration (TMRC) of 0.00041 mg/kg/day utilizes 4% of the RfD for the overall U.S. population. For the most exposed population subgroups, children and non-nursing infants, the TMRC is 0.000946 mg/kg/day, utilizing 9% of the RfD published in the Federal Register of August 24, 1994 (59 FR 43490).

2. Ciba-Geigy has conducted another exposure analysis using additional crops and similar conservative assumptions. In this analysis, oats, barley, and bananas (pending import tolerance) were included in addition to wheat. Tolerances or proposed tolerances were 0.1 ppm each for wheat, oats, and barley, and 0.2 ppm for bananas. Tolerances were 0.01 ppm for milk and 0.05 ppm for all other commodities: beef, goat, horse, rabbit, sheep, pork, turkey, eggs, chicken, and other poultry. Very conservative assumptions were used to estimate residues (i.e. 100% of all wheat, oats, barley, and imported bananas used for human consumption or forage was treated and all raw agricultural commodities contained tolerance level residues). These estimates result in a extreme overestimate of human dietary exposure. Calculated TMRC values from these assumptions utilize 4.7% of the RfD for the U.S. population and 12.51% of the RfD for non-nursing infants.

3. Other potential sources of exposure of the general population to residues of pesticides are drinking water and non-occupational sources. Difenoconazole is currently used as a seed treatment and residues are, therefore, incorporated into the soil at very low rates (0.0125 to 0.025 lb ai/100 lb of seed). The likelihood of contamination of surface water from run-off is essentially negligible. In addition, parent and aged leaching, soil absorption/desorption, and radiolabeled pipe studies indicated that difenoconazole has a low potential to leach in the soil and it would not be expected to reach aquatic environments. For these reasons and because of the low-use rate, exposures to residues in ground water are not anticipated.

4. Non-occupational exposure for difenoconazole has not been estimated since the current registration is limited to seed treatment. Therefore, the potential for non-occupational exposure to the general population is insignificant.

5. Ciba-Geigy has considered the potential for cumulative effects of difenoconazole and other substances of common mechanism of toxicity. Ciba-Geigy has concluded that consideration of a common mechanism of toxicity in aggregate exposure assessment is not appropriate at this time. Ciba-Geigy has no information to indicate that the toxic effects (generalized liver toxicity) seen at high doses of difenoconazole would be cumulative with those of any other compound. Thus, Ciba-Geigy is considering only the potential risk of difenoconazole from dietary exposure in its aggregate and cumulative exposure assessment.

F. Determination of Safety for U.S. Population

1. Using the very conservative exposure assumptions described in Unit I.E. of this document, and based on the completeness of the toxicity data base for difenoconazole, Ciba-Geigy calculates that aggregate exposure to difenoconazole utilizes <5% of the RfD for the U.S. population based on chronic toxicity endpoints (NOEL = 1 mg/kg/day). When using the carcinogenic NOEL of 4.7 mg/kg/day and the MOE approach recommended by the CPRC, approximately 1% of the RfD is utilized.

2. If more realistic assumptions were used to estimate anticipated residues and appropriate market share, this percentage would be considerably lower, and would be significantly lower than 100%, even for the highest exposed population subgroup. EPA generally has no concern for exposures below 100% of the RfD. Therefore, Ciba-Geigy concludes that there is reasonable certainty that no harm will result from daily aggregate exposure to residues of difenoconazole over a lifetime.

G. Determination of Safety for Infants and Children

Developmental toxicity and two-generation toxicity studies were evaluated to determine if there is a special concern for the safety of infants and children from exposure to residues of difenoconazole. There was no evidence of embryotoxicity or teratogenicity, and no effects on reproductive parameters, including number of live births, birth weights, and post-natal development, at dose levels which did not cause significant maternal toxicity. In addition, there were no effects in young post-weaning animals that were not seen in adult animals in the two-generation reproduction study. Therefore, Ciba-Geigy concludes that it is inappropriate to assume that infants and children are more sensitive than the general population to effects from exposure to residues of difenoconazole.

H. Estrogenic Effects

1. Developmental toxicity studies in rats and rabbits and a two-generation reproduction study in rats gave no specific indication that difenoconazole may have effects on the endocrine system with regard to development or reproduction. Furthermore, histologic investigations were conducted on endocrine organs (thyroid, adrenal, and pituitary, as well as endocrine sex organs) from long-term studies in dogs, rats, and mice. There was no indication that the endocrine system was targeted by difenoconazole, even when animals were treated with maximally tolerated doses over the majority of their lifetime.

2. Difenoconazole has not been found in raw agricultural commodities at the limit of quantitation (LOQ). Based on the available toxicity information and the lack of detected residues, it is concluded that difenoconazole has no potential to interfere with the endocrine system, and there is no risk of endocrine disruption in humans.

I. Chemical Residues

1. The nature of the residue is adequately understood in plants and animals. The metabolism of difenoconazole has been studied in wheat, tomatoes, potatoes, and grapes. The metabolic pathway was the same in these four separate and distinct crops. There are no Codex maximum residue levels established for residues of difenoconazole in barley. Ciba-Geigy has submitted a practical analytical method for detecting and measuring levels of difenoconazole in or on food with a LOQ 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 the Food and Drug Administration (FDA). The method is available to anyone who is interested in pesticide residue enforcement from EPA's Field Operations Division, Office of Pesticide Programs.

2. Nine-barley trials were conducted in eight states. Fifty-four one-time treated grain, hay, and straw samples (fed commodities) were analyzed. In addition, eighteen one-time treated forage samples were analyzed. Residues of difenoconazole in barley grown from seed treated with difenoconazole were below the LOQ in forage, hay, and straw (<0.05 ppm), and grain (<0.01 ppm). The feeding of difenoconazole-treated barley products to beef or dairy cattle will not require an increase in existing beef tissue or milk tolerances. Similarly, the feeding of difenoconazole-treated barley grain to poultry will not require increasing existing established poultry tissue and egg tolerances.

J. Environmental Fate

Since the Agency classifies seed treatment uses as ''indoor,'' the only environmental fate data requirement is hydrolysis. Difenoconazole is hydrolytically stable in solution at 25 °C at pH 5, 7, or 9.

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–703].

A record has been established for this notice under docket control number [PF–703] 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 an 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, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 4, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–3930 Filed 2–18–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–699; FRL–5585–5]

Zeneca Ag Products; 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 lambda-cyhalothrin and its epimer in or on rice. The names for lambda-cyhalothrin and its epimer are as follows: lambda-cyhalothrin, a 1:1 mixture of *(S)*-alpha-cyano-3-phenoxybenzyl-*(Z)*-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and *(R)*-alpha-cyano-3-phenoxybenzyl-*(Z)*-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. Epimer of lambda-cyhalothrin, a 1:1 mixture of *(S)*-alpha-cyano-3-phenoxybenzyl-*(Z)*(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and *(R)*-alpha-cyano-3-phenoxybenzyl-*(Z)*-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. The summary was prepared by the petitioner, Zeneca Ag Products.

DATES: Comments, identified by the docket control number [PF–699], must be received on or before March 21, 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: Crystal Mall #2, Room 1132, 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 in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–699]. Electronic comments on this notice 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 a comment concerning this notice 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 Room 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, George LaRocca, Product Manager, (PM 13), Registration Division, 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 Highway, Arlington, VA, 703-305-6100, e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP–6F4769) from Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850-5458. The petition proposes, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for residues of the insecticide lambda-cyhalothrin in or on the raw agricultural commodities rice