Product Name: AC 303,630 Technical. Technical. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1-pyrrole-3-carbonitrile at 93 percent. Proposed classification/Use: For technical manufacturing.

2. File Symbol: 241-GAI. Applicant: American Cyanamid Company.Product Name: Alert. Insecticide/Miticide. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1*H*-pyrrole-3-carbonitrile at 21.44 percent. Proposed classification/Use: Restricted. For use on cotton.

3. File Symbol: 241-GAT. Applicant: American Cyanamid Company. Product Name: Pirate. Insecticide/Miticide. Active ingredient: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-1*H*-pyrrole-3-carbonitrile at 30.83 percent. Proposed classification/Use: Restricted. For use on cotton.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

II. Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPP–30464] (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 official notice record is located at the address in ''ADDRESSES'' at the beginning of this document.

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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–30464]. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: November 13, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–31682 Filed 12–1–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–847; FRL–6043–2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–847, must be received on or before January 4, 1999.

ADDRESSES: By mail submit written comments to: Public Information and Records Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Joanne I. Miller (PM 13)	Rm. 237, CM #2, 703–305–6224, e-mail: Miller.joanne@epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA 22202
Cynthia Giles-Parker (PM 22).	Rm. 247, CM #2, 703–305–7740, e-mail: giles-parker.cynthia@epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–847 (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 official record is located at the address in ''ADDRESSES''.

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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF–847 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 21 U.S.C. 346a.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 13, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below petitioner summaries of the pesticide petitions are printed as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. BASF Corporation

PP 7F4870

EPA has received a pesticide petition (PP 7F4870) from BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina 27709–3528 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 quinclorac (3,7-dichloro-8-quinolone carboxylic acid), in or on the raw agricultural commodity wheat and sorghum raw agricultural and food/feed commodities: 0.5 parts per million (ppm) in or on wheat grain, 0.1 ppm in or on wheat straw, 1.0 ppm in or on wheat forage, 0.5 ppm in or on wheat hay, 1.0 ppm in or on wheat bran, 1.5 ppm in or on wheat germ, 0.75 ppm in or on wheat shorts, 0.5 ppm in or on sorghum grain, 0.2 ppm in or on sorghum forage and 0.05 ppm in or on sorghum fodder. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the 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.

A. Residue Chemistry

1. *Plant and animal metabolism*. The metabolism of quinclorac in plants and animals is well understood. Based on a nature of the residue study in wheat and supported by similar studies in rice and sorghum, the residue of concern from quinclorac use in non-oily grains consists only of the parent compound.

2. *Analytical method*. An adequate analytical method for enforcement of the tolerances exists. The analytical method used for quantitative determinations was designed to measure quinclorac residues present as the parent compound.

3. *Magnitude of residues* —(i) *Raw agricultural commodities*. Crop field trials were conducted in wheat and sorghum and treatments were made at the maximum proposed label rate. The maximum amount of quinclorac residue found in wheat and sorghum raw agricultural commodities are: wheat forage 0.88 ppm, wheat hay 032 ppm, wheat grain 0.25 ppm, wheat straw 0.08 ppm, sorghum forage 0.15 ppm, sorghum grain 0.26 ppm, sorghum fodder 0.05 ppm.

(ii) *Processed fractions*. Processing studies were conducted for both wheat and sorghum to determine whether quinclorac residues concentrate during the commercial processing of these commodities. In sorghum, no concentration of residues was found in the production of flour and starch. In wheat, no concentration was found in the production of middlings and flour. Quinclorac residues concentrated 2-fold in the production of bran, 3-fold in the production of germ, and only slightly, 1.3-fold, in shorts. No additional data were needed in support of residues in meat, milk, poultry, and eggs. Maximum residue levels in wheat and sorghum raw agricultural commodities and process fractions were well below levels of current rice tolerances (5 ppm for grain, 12 ppm for straw, and 15 ppm for bran) which originally dictated the animal feeding study dosing levels and subsequent setting of animal product tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data quinclorac does not pose any acute toxicity risks. Several acute toxicology studies place technical-grade quinclorac in Toxicity Category III for acute oral, acute dermal, acute inhalation toxicity, and for eye irritation. Technical 3,7-dichloro-8-quinoline carboxylic acid is in category IV for primary dermal irritation and is a skin sensitizer. The currently registered end use formulations of quinclorac (50% wettable powder and 75% dry flowable formulations) have tested negative for skin sensitization.

2. *Chronic feeding — Nonrodent*. A 1-year feeding study in dogs fed 0, 34, 142, and 513 (males) and 0, 35, 140, and 469 (females) milligrams/kilogram/day (mg/kg/day) resulted in a No Observed Adverse Effect Level (NOAEL) of 140 mg/kg/day based on reduced body weight gains, adverse effect on food efficiency, hematological and clinical chemistry values, increased liver and kidney weights, and microscopic findings in liver and kidneys at 513 mg/kg/day (males) and 469 mg/kg/day (females), the highest dosages tested (HDT).

3. *Chronic feeding/oncogenicity - Rats*. A chronic feeding/carcinogenicity study in rats fed dosages of 1, 56, 186, 385, and 487 mg/kg/day (males) and 0, 60, 235, 478, and 757 mg/kg/day (females) resulted in a NOAEL of 478 mg/kg/day (females) and 385 mg/kg/day (males) based on slight decreases in weight for females at 757 mg/kg/day (HDT) and an equivocal (uncertain) increase in acinar cell hyperplasia of the pancreas in males at 487 mg/kg/day (HDT). There were no carcinogenic effects noted for female rats under the conditions of the study up to 757 mg/kg/day (HDT).

4. *Oncogenicity - Mice*. A carcinogenic study in mice fed dosages of 0, 37.5, 150, 600, and 1,200 mg/kg/day resulted in no carcinogenic effects observed under the conditions of the study up to and including 1,200 mg/kg/day (HDT) and a systemic NOAEL of 37.5 mg/kg/day based on a reduction of body weight at 150 mg/kg/day.

5. *Teratology - Rats*. A developmental study in rats fed dosages of 0, 24.4, 146, and 438 mg/kg/day (HDT) resulted in developmental toxicity NOAEL of 438 mg/kg/day and a maternal toxicity NOAEL of 146 mg/kg/day based on reduced food consumption, increased water intake, and mortality at 438 mg/kg/day (HDT). Under the conditions of this study, quinclorac did not produce any sign of embryo/fetal toxicity and

did not alter fetal morphological development.

6. *Teratology - Rabbits*. A developmental study in rabbits fed dosages of 0, 70, 200, and 600 mg/kg/day resulted in a developmental toxicity NOAEL of 200 mg/kg/day based on an increase in resorptions and postimplantation loss; a decrease in the number of live fetuses and decreased fetal body weights at the 600 mg/kg/day dose level (HDT). At all other treatment levels no embryo/fetal toxicity was observed. The maternal toxicity NOAEL is 70 mg/kg/day based on decreased body weight gain and food consumption at 200 mg/kg/day; and increased water consumption, increased mortality, and discoloration of the kidney at 600 mg/kg/day.

7. *Two-generation reproduction - Rats*. A 2-generation reproduction study with rats fed dosages of 0, 50, 200, and 600 mg/kg/day resulted in a reproductive NOAEL of 200 mg/kg/day based on reduced pup viability and pup weight, and delay in development (pinna unfolding and eye opening) at 600 mg/kg/day with a maternal NOAEL of 200 mg/kg/day based on reduced body weights at 600 mg/kg/day. At treatment levels of 50 and 200 mg/kg/day no substance related finding were noted either in the parent animals or the offspring.

8. *Mutagenicity*. All *Salmonella* Assays testing the appropriate technical 3,7-dichloro-8-quinoline carboxylic acid were negative. The 3,7-dichloro-8-quinoline carboxylic acid was negative in the *in vivo* cytogenetics (Chinese hamster) at dose levels ranging from 2,000 to 8,000 mg/kg and did not induce unscheduled DNA synthesis in the UDS assay at levels ranging from 101 to 1,520 –ug/ml.

9. *Metabolism - Rat*. A metabolism study with rats receiving dosages of 15, 100, 600 and 1,200 mg/kg/day resulted in more than 90% of the administered radioactivity eliminated in the urine within 5 days (most within 24 hours) and 0.7 – 3.7% in the feces. Radioactivity was mainly associated with the unchanged parent compound. The glucuronic acid conjugate of quinclorac was a minor (2 – 5%) metabolite in urine.

10. *Reference dose*. The established Reference Dose (RfD) for quinclorac is based on the 2-year feeding study in mice with a threshold NOAEL of 37.5 mg/kg/day. Using an uncertainty factor of 100, the RfD has been calculated to be 0.38 mg/kg/day.

11. *Cancer classification and risk assessment*. The cancer classification of quinclorac has been reviewed by the FIFRA Scientific Advisory Panel (SAP). The Panel recommended that the compound be classified as a Group D carcinogen (not classifiable as to human carcinogenicity). The EPA Health Effects Peer Review Committee (PRC) evaluated the carcinogenic potential of quinclorac and the conclusions of the SAP and has classified quinclorac as a Group D carcinogen. Since quinclorac is not classified as a carcinogen, a cancer risk assessment was not necessary for approval of the currently established tolerances. Therefore, a cancer risk assessment for the proposed tolerances on wheat and sorghum is also not necessary.

12. In addition to the data described above, BASF is submitting a 21 day dermal study in the rat to supplement the quinclorac toxicology database. Results indicate that the NOAEL for quinclorac in this study is greater than 1,000 mg/kg body weight.

C. Aggregate Exposure / Cumulative Effects

1. *Chronic dietary exposure*. BASF has estimated aggregate dietary exposure based on the Theoretical Maximum Residue Contribution (TMRC) calculation. The TMRC is a ''worst case'' estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are established are treated and that residues are at the tolerances level. Since the proposed label prohibits use in many wheat and sorghum producing states, the TMRC calculation results in a significant overestimate of human dietary exposure.

The quinclorac TMRC for the overall U.S. population from the currently established rice and animal tolerances is 0.001485 mg/kg bwt/day which represents 0.39% of the RfD. A preliminary estimate of dietary exposure to residues of quinclorac from the proposed tolerances in wheat and sorghum increases the TMRC by 0.000836 mg/kg bwt/day and accounts for approximately 0.22% of the RfD for the overall U.S. population.

2. *Acute dietary exposure*. BASF has reviewed the toxicity database for quinclorac and has concluded that there is no acute dietary concern since there is no indication of any significant toxicity from a one day or single event oral exposure. The LD_{50} for technical quinclorac has been determined to be 3,060 mg/kg for males and 2,190 mg/kg for females.

3. *Drinking water exposure*. Other potential sources of exposure for the general population to residues of quinclorac are residues in drinking water and exposure from non-occupational sources. Based on the available studies used in EPA's assessment of environmental risk, BASF does not anticipate exposure to residues of quinclorac in drinking water. There is no established Maximum Concentration Level (MCL) for residues of quinclorac in drinking water under the Safe Drinking Water Act (SDWA).

4. *Non-occupational exposure*. Quinclorac is not currently labeled for any nonagricultural use. An application for use of quinclorac on turfgrass is currently pending. The proposed turf registration restricts use of the product to certified commercial applicators and those under their direct supervision. Use of the product by typical uncertified homeowners will be prohibited. Therefore, potential for non-occupational exposure to the general population is significantly reduced compared to general use turf products. BASF is a member of the industry wide Outdoor Residential Exposure Task Force. The Task Force is currently generating data to assess exposure resulting from the use of turf products.

D. Cumulative Effects

BASF has considered the potential for cumulative effects of quinclorac and other substances that have a common mechanism of toxicity. BASF is not aware of any other EPA registered active ingredient that is structurally similar to quinclorac or has a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that aggregate exposure to quinclorac will utilize approximately 0.22% of the RfD for the U.S. population. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of quinclorac, including anticipated dietary exposure and non-occupational exposures.

2. *Infants and children*. No signs of teratogenicity were observed in either the rat or rabbit Developmental studies. The NOAEL values from the Developmental studies are significantly higher than the NOAEL from the 2-year feeding study in mice (threshold NOAEL of 37.5 mg/kg/day) used to establish the RfD.

In the Reproductive Toxicity study, Quinclorac elicited signs of embryotoxicity only at dose levels where clear maternal toxicity was observed. Fertility and reproduction parameters were not affected even at the highest treatment levels (1,155 mg/kg/

day). The NOAEL values from the Reproduction study are significantly higher than the NOAEL from the 2-year feeding study in mice (threshold NOAEL of 37.5 mg/kg/day) used to establish the RfD.

Based on the demonstrated lack of significant developmental or reproductive toxicity, BASF believes that the RfD used to assess safety to the general population is adequate to assess safety to children. The EPA evaluation of the established rice and animal tolerances concluded that for the subgroup exposed to the highest dietary risk, nonnursing infants less than 1 year old, the TMRC is 0.010065 mg/kg bwt/day or 2.65 % of the RfD. The addition of the wheat and sorghum tolerances increases the TMRC for this subgroup to approximately 0.100726 mg/kg bwt/day or 2.82 % of the RfD. BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of quinclorac, including all anticipated dietary exposure and all other non-occupational exposures.

F. Endocrine Effects

No specific tests have been conducted with quinclorac to determine whether the chemical may have an endocrine like effect in humans. However, there were no significant findings in other relevant tests (developmental and reproductive toxicity tests) which would suggest that quinclorac produces endocrine like effects.

G. International Tolerances

A maximum residue level has not been established under the Codex Alimentarius Commission for quinclorac in wheat and sorghum. (Joanne I. Miller)

2. Novartis Crop Protection, Inc.

PP 2F4107

EPA has received a pesticide petition (PP 2F4107) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 28479-8300. 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 Difenconazole, [(2*S*,4*R*)/(2*R*,4*S*)]/[2*R*,4*R*/2*S*,4*S*)] 1–(2–4–(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan2yl-methyl)-1*H*-1,2,4-triazole in or on the raw agricultural commodity wheat grain, forage, and straw at 0.1 parts per million (ppm); cattle, eggs, goats, hogs, horses, poultry and sheep 0.05; and milk 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 the 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.

A. Residue Chemistry

1. *Plant metabolism*. 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.

2. *Analytical method*. Novartis has submitted a practical analytical method for detecting and measuring levels of difenoconazole 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.

3. *Magnitude of residues*. Data has been provided from fourteen spring and winter wheat residue trials conducted in major wheat growing states. Application rates were 24 grams a.i. and 48 grams a.i./100 kg seed (10.9 and 21.8 grams a.i./ 100 lb seed, respectively). A processing study was also conducted in which two foliar applications were made in addition to the seed treatment, in an attempt to generate grain samples containing measurable residues. Bran, middlings, shorts and germ, and patent flour were tested for residues.

No residues of difenoconazole (<0.1 ppm) were detected in wheat grain or in any of the processed milled fractions, even when the higher seed treatment rate was coupled with two foliar treatments. The use of difenoconazole as a seed treatment will not result in detectable residues in grain or processed commodities. Similarly, no residues of difenoconazole (0.05 ppm) were detected on wheat forage or straw.

No food additive tolerances are necessary for grain commodities. Tolerances in meat, milk, poultry or eggs were established for enforcement purposes.

B. Toxicological Profile

The following mammalian toxicity studies were conducted and submitted in support of tolerances for difenoconazole.

1. *Acute toxicity*. Difenoconazole has a low order of acute toxicity. The oral rat LD_{50} is 1,453 mg/kg. The rabbit acute dermal LD_{50} is > 2,010 mg/kg and the rat inhalation LC_{50} is > 3.285 mg/L. It is not a skin sensitizer in guinea pig and shows slight eye and dermal irritation in the rabbit.

2. *Genotoxicty*. There was no evidence of the induction of point mutations in an Ames test.

There was no evidence of mutagenic effects in a mouse lymphoma test.

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

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

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

3. *Reproductive and developmental toxicity*. An oral teratology study in rats had a maternal NOAEL of 16 mg/kg/day based on excess salivation and decreased body weight gain and food consumption. The developmental NOAEL 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.

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

A 2-generation reproduction study in rats had a parental and reproductive NOAEL of 25 ppm based on significantly reduced female body weight gain, and reductions in male pup weights at 21 days.

4. *Subchronic toxicity*. A 13-week rat feeding study identified liver as a target organ and had a NOAEL of 20 ppm.

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

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

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

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

An 18-month mouse feeding study had an overall NOAEL 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 NOAEL was 300 ppm.

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

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

An 18-month mouse feeding study had an overall NOAEL 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 NOAEL was 300 ppm.

7. *Animal metabolism*. The metabolism of difenoconazole is well understood. Studies with 14C-difenoconazole in the rat, goat, and hen demonstrate that the majority of the administered dose (76 to > 98%) is eliminated via the excreta as parent and metabolites. Very low concentrations of radioactivity, accounting for <1 to 4% of the applied dose, remain in tissues. The liver and kidney typically show the highest radioactivity, but in the rat, the highest concentration in any tissue was found in the fat.

Concentrations in goat milk reached a plateau on Day 6 of the study at 0.043 ppm for the triazole label and 0.007 ppm for the phenyl label when goats were fed approximately 5 ppm for 10 days. Similarly, very little radioactivity was deposited in eggs; radioactivity reached a plateau of 0.248 to 0.299 ppm in yolks after 7 to 8 days, and 0.007 to 0.153 ppm in whites after 5 days, in hens fed at a rate equivalent to 5 ppm in the diet for 14 consecutive days. CGA–205375, an alcohol resulting from the deskelitalization of the dioxolane ring of difenoconazole, is a major metabolite found in animal tissues, excreta, milk, and eggs. The presence of CGA–71019, containing only the triazole ring, and CGA–189138, containing only the phenyl ring, indicates that bridge cleavage can occur in animals as well as plants. The metabolite patterns in the excreta of hens, goats, and rats were similar.

8. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent compound. Metabolites of difenoconazole are considered to be of equal or lesser toxicity than the parent.

9. *Endocrine disruption*. 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.

Difenoconazole has not been found in raw agricultural commodities at the limit of quantification. 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.

C. Aggregate Exposure

1. *Dietary exposure — Food*. When the potential dietary exposure to difenoconazole from established and pending tolerances is calculated, the theoretical maximum residue concentration (TMRC) of 0.000473 mg/kg/day utilizes 4.73% of the RfD for the overall U.S. population. For the most exposed population subgroups, children and non-nursing infants, the TMRC is 0.001252 mg/kg/day, utilizing 12.52% of the RfD followed by children (1–6 years) exposed to 11.24% of the RfD.

Novartis has conducted another exposure analysis using additional crops and similar conservative assumptions. In this analysis, oats, barley, cotton 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 RACs contained tolerance level residues). These estimates result in a extreme overestimate of human dietary exposure. Calculated TMRC values from these assumptions utilize 4.73% of the RfD for the U.S. population and 12.52% of the RfD for non-nursing infants.

2. *Drinking water*. 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. The likelihood of contamination of surface water from run-off is essentially negligible. In addition, parent and aged leaching, soil adsorption/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.

3. *Non-dietary exposure*. 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.

Novartis has considered the potential for cumulative effects of difenoconazole and other substances of common mechanism of toxicity. Novartis has concluded that consideration of a common mechanism of toxicity in aggregate exposure assessment is not appropriate at this time. Novartis 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, Novartis is considering only the potential risk of difenoconazole from dietary exposure in its aggregate and cumulative exposure assessment.

D. Safety Determination

1. *U.S. population*. 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.

Novartis has considered the potential for cumulative effects of difenoconazole and other substances of common mechanism of toxicity. Novartis has concluded that consideration of a common mechanism of toxicity in aggregate exposure assessment is not appropriate at this time. Novartis 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, Novartis is considering only the potential risk of difenoconazole from dietary exposure in its aggregate and cumulative exposure assessment.

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, Novartis concludes that there is reasonable certainty that no harm will result from daily aggregate exposure to residues of difenoconazole over a lifetime.

2. *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 embryo toxicity or teratogenicity, and no effects on reproductive parameters, including number of live births, birth weights, and post-natal development, at dose levels that 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 2-generation reproduction study. Therefore, Novartis 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.

E. International Tolerances

There are no Codex maximum levels established for residues of difenoconazole. (Cynthia Giles-Parker)

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–66260; FRL 6035–9]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn by June 1, 1999, orders will be issued cancelling all of these registrations.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery, telephone number and e-mail: Rm. 216, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5761; e-mail: hollins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provides that a pesticide registrant may, at any time, request that any of its pesticide registrations be cancelled. The Act further provides that EPA must publish a notice of receipt of any such request in the **Federal Register** before acting on the request.

II. Intent to Cancel

This Notice announces receipt by the Agency of requests to cancel some 25 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and 24(c) number) in the following Table 1.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
000070–00055	Kill-Ko Bean Beetle Dust 1% Rotenone	Rotenone
		Cube Resins other than rotenone
000070–00133	Kill Ko Thro Pac Rat Killer	2-(Diphenylacetyl)-1,3-indandione
000070–00170	Kill Ko Rat Killer	2-(Diphenylacetyl)-1,3-indandione
000070–00292	Rigo 3–In–1 Vegetable Dust	Manganese ethylenebis(dithiocarbamate)
		Methoxychlor (2,2-bis(*p*-methoxyphenyl)-1,1,1-trichloroethane)
		Rotenone
		Cube Resins other than rotenone
000491–00265	Bug Blitz	*O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl) phosphorothioate
		(Butylcarbityl)(6-propylpiperonyl) ether 80% and related compounds 20%
		Pyrethrins
000655–00688	Prentox Cube Flea & Tick Dip	Rotenone
		Cube Resins other than rotenone
000769–00309	Fish-Tox-5 (5% Rotenone)	Rotenone
		Cube Resins other than rotenone
000769–00653	Kills Rats with Para Blox Weather Proof Paraffinized Rat	2-(Diphenylacetyl)-1,3-indandione
000769–00656	SMCP Zinc Phosphide	Zinc phosphide (Zn3P2)
000769–00659	SMCP Singe-Kil	Cacodylic acid
000769–00741	Zinc Phosphide (Rumetan) 90%	Zinc phosphide (Zn3P2)
000769–00743	AFC Zinc Phosphide 80 (Rumetan)	Zinc phosphide (Zn3P2)
000769–00756	Zinc Phosphide Rodenticide for Controlling Orchard Mice	Zinc phosphide (Zn3P2)
000769–00832	Miller V–75 A Dust	Rotenone