F. Safety Determination

1. *U.S. population in general.* Dekalb believes that the lack of acute toxicity and the rapid digestibility of PAT protein provide evidence for the lack of toxicity and allergenicty and support an exemption from the requirement for a tolerance for PAT protein.

2. *Infants and children.* The use sites for insect protected corn containing PAT protein are all agricultural for control of Lepidopteran insects. Therefore, nondietary exposure to infants and children is not expected. Dekalb believes that the lack of toxicity of PAT protein provides reasonable certainty that no harm will result to infants and children from aggregate dietary exposure to residues of PAT.

G. Existing Tolerances or Tolerance Exemptions

An exemption from the requirement for a tolerance was granted by the EPA for ''Plant-pesticide Inert Ingredient Phosphinothricin Acetyltransferase (PAT) and the Genetic Material Necessary for Its Production (Plasmid Vector pCIBP3064) in Corn,'' Federal Register: August 16, 1995, (60 FR 42450; FRL–4971–2).

III. Administrative Matters

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the document control number [PF–660]. 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 Fridy, except legal holidays.

A record has been established for this notice under docket number [PF–660] (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 Rm. 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 rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

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

List of Subjects

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

Dated: January 17, 1997.

Flora Chow,

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

[FR Doc. 97–1754 Filed 1–23–97; 8:45 am]
BILLING CODE 6560–50–F

[PF–693; FRL–5583–8]

Drexel Chemical Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition proposing the establishment of a tolerance for residues of diuron in or on the edible portions of catfish. The summary was prepared by the petitioner, Drexel Chemical Company.

DATES: Comments, identified by the docket number [PF–693], must be received on or before, February 24, 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 should 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 docket number [PF–693]. Electronic comments on this proposed rule may be filed online at many Federal Depositary Libraries. Additional information on electronic submissions may be found below in this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Phillip V. Errico, Product Manager (PM) 25, 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. 245, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6027; e-mail: errico.phillip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petition (PP) 6F4680 from Drexel Chemical Company, POB 13327, Memphis, TN 38133-0237, proposing to amend 40 CFR 180.106 by establishing a tolerance for residues of the herbicide diuron [3-(3,4-dichlorophenyl)-1,1-dimethylurea] in or on the raw agricultural commodity catfish at 1 part per million (ppm). The proposed analytical method is gas chromatography (GC) with a nitrogen-phosphorous detector.

Pursuant to section 408(d)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended, Drexel Chemical Company has submitted the following summary of information, data and arguments in support of their pesticide petition. The summary was prepared by Drexel Chemical Company and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not

necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

A. Residue Chemistry

1. *Analytical method*. An analytical method is available, a modified form of DuPont Agricultural Products method #5470. The principle of the determination is the hydrolysis of diuron and its metabolites by alkaline reflux to 3,4-dichloroanaline (3,4-DCA), followed by a distillation of the aniline into an acid solution. The acid distillate is made alkaline with concentrated base and subsequently extracted into an organic solvent (hexane) and analyzed by gas chromatography. With the modified method, recoveries exceeded 70% and the limit of quantitation (LOQ) is 0.01 µg/g.

2. *Magnitude of the residues*. Residue trials were conducted in contained catfish ponds on a 30, 60 and 90–day treatment schedule. In the 30–day treatment schedule pond, diuron residues in catfish fillet were between 0.8 and 0.9 ppm after the first week post treatment, and declined to 0.2 ppm after 8 weeks post treatment. Due to mortality from Proliferative Gill Disease (PGD), no catfish were available after the last treatment day for residue determination from the 60–day treatment schedule pond. Diuron residues in catfish fillet from the 90–day treatment schedule pond were 1.2 ppm on the last treatment day, rose slightly to 1.4 ppm by day 7 post treatment, and declined to 1.1 ppm by day 28 post treatment.

Using data from the magnitude of the residue study, a pharmacokinetic model was developed that allowed the prediction of diuron residues in catfish fillet using a treatment schedule of applying 0.01 ppm diuron to the pond every 7 days for 56 days. Based on the model, the maximum mean fillet residue from this treatment schedule is predicted to be 0.75 ppm.

The pharmacokinetic model was validated using data from an efficacy study. Catfish were grown in ponds treated with 0.01 ppm diuron every 7 days. Diuron residues in catfish fillet were determined after 113 days of treatment. The analysis found mean fillet residues of 0.92 ppm. The pharmacokinetic model predicted day 113 diuron residues in catfish fillet of 0.89 ppm. This excellent agreement between prediction and found values demonstrates the utility of the model.

B. Toxicological Profile

1. *Acute toxicity*. The rat acute oral single dose LD_{50} is 3.5 g/kg. The rabbit acute dermal single dose LD_{50} is greater than 2 g/kg of bodyweight. The rat acute inhalation LD_{50} is less than 2.5 mg per liter. A primary eye irritation study in the rabbit shows that diuron is moderately irritating to the unwashed eye when instilled undiluted. A primary dermal irritation showed that diuron is not a skin irritant when applied undiluted. A skin sensitization study (Buehler) in the guinea pig shows that diuron is not a skin sensitizer when applied undiluted.

2. *Genotoxicity*. In the CHO/HGBRT assay the results for diuron are negative up to cytotoxic levels in the presence of S9 activation (0.75 mm) and in the absence of S9 metabolic activation (1.25 mm).

For the *in vivo* cytogenic study in rats, diuron is clastogenic at 5,000 mg/kg, the highest dose level tested.

For the *in vitro* unscheduled DNA synthesis assay in primary rat hepatocytes, diuron is negative up to 20 mm, the highest concentration tested.

Diuron was not considered to be mutagenic to TA97, TA98, TA100 and TA1535 strains of *Salmonella typhimurium* (Ames *Salmonella* plate assay) either with or without metabolic activation at the concentrations tested (-S9, 0.5, 1, 2.5, 5 and 10 µg/plate; S9, 10, 25, 100 and 250 µg/plate).

3. *Developmental and reproductive toxicity*. In a reproductive toxicity study in the rat, the no-observed effect level/lowest observed effect level (NOEL/LOEL) for parental/offspring systemic toxicity and developmental toxicity were determined to be 250 and 1,750 ppm (16.9 and 120 mg/kg/day for males and 20.3 and 144 mg/kg/day for females), respectively, based on decreased body weight gain and food consumption in both sexes and generations. There was no evidence that diuron affected reproductive performance in the rat.

In a developmental toxicity study in the rat, the maternal toxicity NOEL/LOEL were considered to be 16 and 80 mg/kg/day, respectively, based on reduction in body weight and food consumption. The developmental toxicity NOEL/LOEL were considered to be 80 and 400 mg/kg/day, respectively, based on statistically significant increases in delayed ossification of the vertebrae and sternebrae and decreased fetal weights.

In a developmental toxicity study in rabbits, the NOEL/LOEL maternal toxicity were considered to be 10 and 50 mg/kg/day, respectively, based on decreased body weight and food consumption. There was no evidence of developmental effects in the study.

4. *Subchronic toxicity*. In a non-guideline subchronic (6-month) oral toxicity study in rats, the systemic NOEL of technical diuron was sought. The scope of the study was primarily restricted to parameters affecting the erythrocytes. Based on the study findings, the systemic NOEL of diuron could not be determined, since some findings were judged to be equivocal.

5. *Chronic toxicity/oncogenicity*. The chronic rat oral toxicity study was acceptable as supplementary data. However, deficiencies exist in the study because several organs were not examined, such as the mammary glands. No NOEL was determined. The LOEL was considered to be 25 ppm (1.02 and 1.69 mg/kg/day for males and females, respectively), the lowest dose level tested in this study based on increased erythrocyte count in females, increased hemosiderin in the spleen, increased spleen weight, bone marrow activation, increased hematopoietic marrow, decreased fat marrow, and thickened urinary bladder wall in males.

The chronic oral toxicity study in dogs was acceptable. The NOEL/LOEL in the study were considered to be 25 and 125 ppm (1.88 and 9.33 mg/kg/day, respectively, for both males and females) based on abnormal blood pigments in the blood.

The oncogenicity phase of the combined chronic toxicity/oncogenicity study in rats was considered to be supplementary. However, deficiencies exist in the study because several organs were not examined, such as the mammary glands.

The oncogenicity study in mice was considered to be acceptable. The NOEL/LOEL for systemic toxicity were considered to be 250 ppm (50.8 and 77.5 mg/kg/day for males and females, respectively) based on decreased body weight gain, and increased spleen and liver weight in males, elevated leucocyte and reticulocyte counts, mean corpuscular volume and mean corpuscular hemoglobin, and bilirubin values in both sexes; increased incidence of intracellular pigments in renal tubules in females and in the spleen of males and females; increased incidence of hemosiderin deposits in liver cells in males; increased incidence of liver single cell necrosis and cell mitosis in both sexes; increased incidence of enlarged degenerative cells in females and of hepatopathy and Kupffer cells in males; increased incidence of urinary bladder edema and epithelial hyperplasia, thickened mucosa and enlarged uterine horn in females. In the study, a statistically significant increase (14%, ≤ 0.01) of ovarian luteoma was noted in mice of the 2,500 ppm group as compared to the concurrent controls (6%). This value

was higher than the historical control incidence of 1.7% for ovarian luteoma tumor. Combined ovarian sex cord tumors were also increased. Mammary gland tumors (adenocarcinoma type A and B) in the 2,500 ppm group were statistically significantly higher than the concurrent control (12%, $p \leq 0.05$ vs. 4% in the concurrent control) and higher than the historical control of 3.3%.

C. Aggregate Exposure

1. *Dietary exposure.*—a. *Food.* A Registration Eligibility Document (RED) for diuron is not scheduled for completion until outstanding data requirements requested by the EPA's Office of Pesticide Programs Environmental Fate and Effects Division are completed. Therefore, a dietary exposure assessment using anticipated residues is not available. In the absence of a dietary exposure assessment, the petitioners conducted a very conservative exposure assessment with proposed tolerance level residues (maximum residues permitted) for all crops for which the technical registrants intend to provide supporting data. The food, ''freshwater finfish'' was included with an anticipated residue level of 0.75 ppm, to represent catfish consumption.

Since freshwater finfish can come from a number of sources, including sport fishing, commercial catch, and aquaculture, and could be other popular finfish species, such as trout or tilapia, the consumption estimate is extremely conservative. In addition, diuron is applied to contained ponds used in commercial catfish production during a 2 to 4–month period in the summer and fall. However, the fish are harvested from the ponds the year round. Residue estimates for other foods were adjusted to reflect the percent of crop treated, based on USDA data.

Exposure estimates were compared to a Reference Dose (RfD) of 0.003 mg/kg bwt/day (mkd), which was recommended by the RfD Review Committee at their September 26, 1996, meeting.

The maximum total exposure to the U. S. population for all uses of diuron, including the use in catfish ponds, is 0.000593 mkd, which represents 19.8% of the RfD. The most highly exposed subgroup of the U. S. population was non-hispanic other than black or white (e.g., asians), which had a total exposure of 0.000787 mkd, representing 26.6% of the RfD.

Exposure to all infants was 0.001537 mkd (51.2% of the RfD), and exposure to non-nursing infants less than a year old was 0.000675 mkd (63.3% of the RfD). Exposure to children from 1 to 6 years old was 0.001386 (46.2% of the RfD), and exposure to children 7 to 12 years old was 0.000795 mkd (26.5% of the RfD). Exposure to females of childbearing age (13 to 50 years of age) was 0.000435 mkd (14.5% of the RfD).

b. *Drinking water.* Data concerning potential exposure through drinking water is not available. The proposed use in catfish ponds is not expected to add potential exposure to drinking water. Contained catfish ponds are drained for levee repair every 5 to 10 years. The water is returned to the pond to the greatest extent possible after the repair. In some cases, the water may be released to a ditch or a stream. Because market catfish are harvested from the ponds year round as the catfish in a pond reach marketable size, the repair work is not seasonal, but completed on a staggered basis, and does not necessarily occur during the time of year when diuron may be applied to the pond waters. Diuron is moderately toxic, there have been detections in groundwater, and it has low to intermediate mobility in fine to coarse textured soils and freshwater sediment (according to the Diuron Environmental Fate Profile completed for the U.S. EPA by Dynamac, dated June 10, 1982, pp 37–49). Based on these three factors, a conservative 10% of exposure has been reserved for drinking water.

2. *Non-dietary exposure.* Diuron is not expected to be used in residential settings. However, some registered product labels include uses, while not intended for residential use, could conceivably result in residential exposure. These uses include application to ornamentals, use as a wood preservative (algicide in boat paints), or application to turf. A conservative 5% of the total exposure has been reserved to account for the uses which could potentially result in residential or lawn use.

D. Cumulative Effects

Linuron is the only chemical, registered in the United States as a pesticide, which is chemically similar to diuron. Despite the structural similarity, based on publicly available information, some of their toxicological activities differ significantly. In the carcinogenicity studies, mice treated with 2,500 ppm diuron developed mammary adenocarcinomas and ovarian luteomas. Rats treated with 2,500 ppm diuron developed urinary bladder carcinomas. Mammary glands were not evaluated in this study. For linuron, mice in the carcinogenicity study developed hepatocellular adenomas. Rats developed testicular carcinomas which were not hormone dependant. The carcinogen classification of diuron is currently under review. Linuron is considered a Group C carcinogen (without Q*) Non-tumor lesions in rats administered diuron included anemia and an increased reticulocyte count. In the chronic linuron study, there was a decrease in the reticulocyte count.

Based on these considerations, there is insufficient evidence to determine if cumulative toxicity will occur.

E. Safety Determination

1. *U. S. population.* Maximum exposure to the U. S. population resulting from the use of diuron, including the use in catfish ponds, is not expected to exceed 0.000593 mkd, representing 19.8% of the RfD. After adding 10% for potential drinking water and 5% for potential residential/lawn exposure, the total exposure represents only 34.8% of the RfD. Therefore, there is a reasonable certainty of no harm resulting from aggregate exposure of diuron to the general population.

2. *Infants and children.* Maximum exposure to the most highly exposed infants and children subgroup, non-nursing infants less than a year old, is not expected to exceed 0.001900 mkd, which represents 63.3% of the RfD. After adding 10% for potential drinking water exposure, and 5% for potential residential/lawn exposure, the total exposure to this subgroup represents only 78.3% of the RfD. Therefore, there is a reasonable certainty of no harm resulting from aggregate exposure of diuron to infants and children.

These results represent very conservative consumption and residue levels. An exposure estimate based on anticipated residues for all foods, and consumption of farm-raised catfish only, would result in a greatly diminished risk.

F. International Tolerances

A maximum residue level has not been established for diuron by the Codex Alimentarius Commission.

II. Public Record

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number, [PF–693].

A record has been established for this notice of filing under docket control number [PF–693] (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 Rm. 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 may 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 to printed, paper form as they are received and will place the paper copies in the official notice record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

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

Dated: January 16, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–1751 Filed 1–23–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–685; FRL–5579–3]

Mycogen 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 a regulation establishing an exemption from the requirement of a tolerance for residues of the pesticide pelargonic acid on all raw agricultural commodities. This notice includes a summary of the petition that was prepared by the petitioner, Mycogen Corporation.

DATES: Comments, identified by the docket control number [PF–685], must be received by EPA on or before February 24, 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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 docket number [PF–685]. No ''Confidential Business Information'' (CBI) should be submitted through e-mail. Electronic comments on this notice of filing 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 document 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 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: Michael Mendelsohn, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor, CS #1, 2805 Jefferson Davis Highway, Arlington, VA, 703–308–8715; e-mail: mendelsohn.michael@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petition (PP) 6F4625 from Mycogen Corporation, 4980 Carroll Canyon Road, San Diego, CA 92121. The petition proposes, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of pelargonic acid on all raw agricultural commodities. 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

Mycogen has stated that an analytical method for the detection and measurement of pelargonic acid residues is not necessary to protect the public health and environment. They state that the natural occurrence of pelargonic acid in our food supply and environment, and the rapid metabolism and degradation of pelargonic acid to background levels in humans, plants and soil, eliminate the need to quantify pelargonic acid residues.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Mycogen 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 Mycogen; EPA, as mentioned above, 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 may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

This unit summarizes information cited by Mycogen to support the proposed tolerance.

A. Pelargonic Acid Uses

Pelargonic acid is currently used as the active ingredient in two unique pesticide products. First, it is used as a contact, non-selective, broadspectrum, foliar-applied herbicide. As the active ingredient in Scythe® Herbicide (EPA Reg. No. 53219–7), registered by EPA for non-crop uses on April 7, 1994, pelargonic acid will only control actively growing emerged green vegetation. Pelargonic acid provides burndown of both annual and perennial broadleaf and grass weeds, as well as most mosses and other cryptogams. The spray quickly penetrates plant tissue and disrupts normal cell membrane permeability and cellular physiology. The disruption of the cell membrane results in cell leakage and death of all contacted tissue. The product does not translocate, and it will burn only those plant parts that make contact with spray solution. Scythe provides no residual