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

weed control; therefore, repeat treatments may be necessary for new plants emerging from seed or regrowth of treated vegetation.

Scythe Herbicide contains as the active ingredient 57 percent pelargonic acid and 3 percent related fatty acids (C_6 – C_{12}). One gallon of Scythe contains 4.2 pounds (lbs) of pelargonic acid. The application rate will range from 3 percent to 10 percent v/v delivered at 75 to 200 gallons of spray solution per acre through boom, hand-held, or high volume equipment. Therefore, the rate of use of pelargonic acid will be 9.45 lbs to 84 lbs per acre. Combinations with selected products may further reduce the application rate to a low 0.78 lbs to 2.1 lbs per acre (0.25 percent solution in 75 or 200 gallons spray per acre).

Second, pelargonic acid is used as a fruit blossom thinner that promotes return bloom (annual bearing) and increased fruit size and quality in apple and pear. Thinex® Blossom Thinner (EPA Reg. No. 53219–11) was registered as a biochemical pesticide due to the natural occurrence of pelargonic acid, the low use rates and the unique non-toxic mode of action. Thinex works on contact by damaging the stigma or female flower part of the blossom, thus preventing pollination of a certain percentage of flowers. A blossom that has already been fertilized at the time of application will be undamaged by Thinex. No more than 2 applications per year are made. On February 14, 1996, pelargonic acid was exempt under 40 CFR 180.1159 from the requirement of a tolerance when used as a blossom thinning agent on apple and pear.

Thinex Blossom Thinner contains as the active ingredient 57 percent pelargonic acid and 3 percent related fatty acids (C_6 – C_{12}). The application rate as a blossom thinner ranges from 0.5 pints to 4 pints of product to make 100 gallons of spray solution. One hundred to 400 gallons of spray solution per acre may be used. Therefore, the rate of use of pelargonic acid as a blossom thinning agent ranges from a low 0.26 lbs to a high 8.4 lbs per acre.

B. Product Identity/Chemistry

Pelargonic acid ($C_8H_{17}COOH$), a nine-carbon straight-chain fatty acid commonly referred to as nonanoic acid, is a naturally-occurring fatty acid found in the environment and in our food supply.

Pelargonic acid has been found to occur naturally in low concentrations in soil. The degradation of pelargonic acid applied to soil occurs very rapidly by microbial means, not through hydrolysis or photolysis. Degradation occurs under aerobic conditions with beta-oxidation being the principal pathway of metabolism.

Pelargonic acid has been shown to occur naturally in our food supply. For example, it has been identified in grapes, cheese and milk at levels from 10 parts per million (ppm) to 400 ppm. Some literature references cite its natural occurrence in soybeans (trace levels), oranges (130 ppm), beans (trace levels), tobacco (0.27 ppm) and potatoes (1.18 ppm). In a cross-section of apple varieties analyzed by Mycogen, pelargonic acid was found at levels from 20 parts per billion (ppb) to 320 ppb.

Fatty acids, including pelargonic acid, are metabolized in mammalian systems to produce energy. The oxidative degradation of fatty acids is a central metabolic pathway in humans, animals and plants. Fatty acids of varying chain lengths are metabolized into two-carbon fragments through a sequence of enzyme-catalyzed reactions. The metabolic products are then incorporated into fats, carbohydrates and amino acids.

The magnitude of pelargonic acid residues from applications of Scythe Herbicide anticipated at time of harvest will be insignificant beyond naturally-occurring levels and to normal dietary exposure. Applications of Scythe Herbicide will not directly contact desirable food commodities since exposure will be intentionally avoided by the grower because crop damage may result. Any residues of pelargonic acid on food commodities will only occur as a result of spray drift, thus minimizing residues of pelargonic acid on the food commodity.

An analytical method for detecting and measuring the levels of pelargonic acid residue is not necessary to protect the public health and environment. 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 residue from applications as a herbicide or a blossom thinner.

C. Mammalian Toxicological Profile

Mycogen has submitted to EPA a comprehensive toxicology data package and referenced several published articles concluding that residues of pelargonic acid will be safe to human health.

Although a significant concentration of pelargonic acid can be irritating to eyes and skin, toxicology data confirms that exposure to residues of pelargonic acid beyond naturally occurring background levels will be practically non-toxic to human health. The following mammalian toxicity studies have been conducted to support the tolerance exemption for residues of pelargonic acid:

Acute Oral LD_{50}: >5000 mg/kg
Acute Dermal LD_{50}: >2000 mg/kg
Acute Inhalation LC_{50}: >1.244 mg/L
Dermal Irritation (Rat): Severely Irritating
Eye Irritation (Rabbit): Severely Irritating
Skin Sensitization (Guinea Pig): Not sensitizing

A range finding test to determine dosing concentrations for a 90–Day Rat Oral Toxicity study produced no adverse effects from pelargonic acid at any dose level for 3 weeks, including the highest dose of 20,000 ppm (2 percent), or 1,834 mg/kg/day, for a period of 2 weeks.

A developmental toxicity screen study in rats produced a NOEL of 1,500 mg/kg/day (only dose tested). Pelargonic acid was tested at one dose administered by gavage in corn oil to 22 CD rats (20 pregnant) on days 6 through 15 of gestation. No evidence of maternal or developmental toxicity was seen.

A chronic dermal toxicity study in mice resulted in no evidence of severe dermal or systemic toxicity. Fifty mice were treated twice-weekly with 50 mg doses of undiluted pelargonic acid for 80 weeks. Histopathology revealed no tumors of the skin or the internal organs.

A gene mutation assay in mouse lymphoma cells (L5178Y TK <plus-minus>) concluded that pelargonic acid was negative for inducing mutations without metabolic activation, and was considered weakly positive for inducing mutations at the TK locus of culture mouse (L5178Y TK <plus-minus>) cells in the presence of S9-induced metabolic activation. Mutations were induced at levels greater than or equal to 50 mg/ml. However, this occurred in the presence of increasing moderate-to-severe cytotoxicity and small colony development and may reflect gross chromosomal changes or damage rather than actual mutational changes within the TK gene locus.

In an *in-vivo* mouse micronucleus assay, groups of ICR mice (15/sex/dose) were administered single oral doses of 1,250, 2,500, or 5,000 mg/kg pelargonic acid. The bone marrow cells were harvested 24, 48, and 72 hours post-treatment. No significant increases in the frequency of micronucleated polychromatic erythrocytes (PCEs) were observed in either sex at any dose; thus, pelargonic acid was negative in the micronucleus assay.

A reverse gene mutation assay (Ames Test) concluded that pelargonic acid was not mutagenic under the conditions of the study.

D. Aggregate Exposure

Pelargonic acid is a naturally-occurring fatty acid found in our food supply. Mycogen Corporation has estimated the potential worst case dietary exposure of pelargonic acid beyond existing natural background levels after an application of Scythe Herbicide between grape vine rows. The commodity grape was selected because the use of Scythe Herbicide between grape vine rows is a representative and major use pattern intended for the product. In an effort to make a worst case scenario for residue calculations, Mycogen has suggested a 10 percent deposition on the crop, even though such a drift rate will be intentionally avoided by the grower because crop damage may result. Drift deposition would likely be less than 1 percent of applied spray volume.

The worst case human daily consumption level of pelargonic acid from treated grapes has been estimated to be 0.397 mg/kg/day. This exposure dose after applications of Scythe Herbicide must be compared to the highest dose level tested in the dietary range-finding toxicology study. In this study, a daily feeding dose of 1,834 mg/kg/day (20,000 ppm) did not produce any signs of toxicity or abnormalities for a period of 2 weeks.

Exposure to drinking water will be minimal. Scythe Herbicide will not be applied directly to water. The proposed label includes applications to dry ditches, dry canals, ditch banks, and for use above the water line or after draw-down of agricultural irrigation water and ditch systems, industrial ponds and disposal systems, and impounded water areas. Taking potential spray drift into consideration, the rapid degradation of pelargonic acid to naturally-occurring background levels in our environment will mitigate the exposure of residues to drinking water to insignificant amounts. In addition, the degradation of pelargonic acid will ensure that no contamination to groundwater will occur.

If residues of pelargonic acid do occur in food or in drinking water, information on the metabolism of fatty acids in the body confirms that residues of pelargonic acid would present minimal risk to humans. Fatty acids are digested in mammalian systems through normal metabolic pathways. While pelargonic acid is not as widespread in our diet as other fatty acids, the only difference is that most dietary fatty acids have even-numbered carbon chains and are ingested initially in the form of triglycerides. It is likely that pelargonic acid, when it is absorbed from the gastrointestinal tract into the blood, would be treated little differently from the free fatty acids released from adipose tissue.

Non-dietary exposure of pelargonic acid will be mitigated through the use of proper personal protective equipment. For non-occupational uses or exposure to sites not associated with food or drinking water, data on the natural occurrence and rapid microbiological degradation of pelargonic acid in the environment confirms that exposure will be minimal. EPA has waived all environmental fate data requirements for the current registration of Scythe Herbicide.

E. Cumulative Exposure

No cumulative exposure through other pesticides and substances with common mode of toxicity is expected. Pelargonic acid has a unique mode of action. Residues will not increase or sustain as a result of exposure to other materials. Pelargonic acid will degrade by microbial action to background levels over a period of 24 - 48 hours regardless of contact with substances either through pesticide tank mixing or exposure to other chemical residues in the environment. Normal use patterns will not lead to accumulation of pelargonic acid in the environment.

F. Safety Determination

Mycogen believes that the use of pelargonic acid as a naturally-occurring, lower toxicity, environmentally compatible material fits with EPA's objective to register reduced risk pesticides. The common dietary intake of the U.S. population includes low concentrations of naturally-occurring fatty acids, including pelargonic acid. The rapid environmental breakdown of pelargonic acid will significantly decrease any residues as a result of applications from Scythe Herbicide. Mycogen believes that under worst case exposure calculations, and based on established toxicology data, any increased levels of pelargonic acid will present no adverse effects to the consumer.

Mycogen believes that a determination of safety for infants and children can be made due to the insignificant exposure expected beyond naturally-occurring background levels, the fact that fatty acids are digested in mammalian systems through normal metabolic pathways, and the toxicology data base concludes that pelargonic acid is practically non-toxic when administered orally. The developmental toxicity screen study in rats produced a NOEL of 1,500 mg/kg/day (only dose tested), and no evidence of maternal or developmental toxicity was seen.

G. Existing Tolerances

Pelargonic acid is exempt under 40 CFR 180.1159 from the requirement of a tolerance when used as a blossom thinning agent on apple and pear. Pelargonic acid has been added to the Food and Drug Administration's list of approved chemicals that may be safely used in washing or to assist in the lye peeling of fruits and vegetables in concentrations of up to 1 percent (21 CFR 173.315). The same use is cleared by the United States Department of Agriculture under the USDA List of Authorized Substances, 1990, 7 CFR 5.14, Fruit & Vegetable Washing Compounds. In addition, pelargonic acid is cleared by the Food and Drug Administration as a sanitizer solution to be used on food-contact articles [21 CFR 178.1010(b) (42)], or as a synthetic food flavoring agent and adjuvant (21 CFR 172.515).

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the document control number, [PF–685]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice of filing under docket number [PF–685] (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 Hwy., 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 of filing, 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 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 requirements.

Dated: January 16, 1997.

Flora Chow,

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

[FR Doc. 97–1753 Filed 1–23–97; 8:45 am]
BILLING CODE 6560–50–F

[PF-689; FRL-5582-7]

Rhone-Poulenc Ag Company; 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 extension of the temporary tolerances for the combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] (CAS Number 36734-19-7, PC Code 109801) in or on the raw agricultural commodities tangerines and tangelos at 3.0 ppm. The notice includes a summary of the petition prepared by the petitioner, Rhone-Poulenc Ag Company.

DATES: Comments, identified by the docket control number [PF-689], 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: 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-689]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). The 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: Connie Welch, Product Manager (PM 21), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, Room 227, 1921 Jefferson Davis Highway, Arlington, VA, 703-305-6226, e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 3G4210) from Rhone-Poulenc Ag Company (Rhone-Poulenc), P.O. Box 12014, T.W. Alexander Drive, Research Triangle Park, NC 27709 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDC), 21 U.S.C. 346(d), to extend the temporary tolerances for the fungicide iprodione [3-(3,5-dichlorophenyl)-*N*-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in or on the raw agricultural commodities tangerines and tangelos at 3.0 ppm. The current temporary tolerances expire on April 15, 1997. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDC; 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 FFDC, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104-170), Rhone-Poulenc 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 Rhone-Poulenc. EPA is in the process of evaluating the petition. As required by section 408(d)(3) of the FFDC, 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

There is an extensive data base supporting the registration of iprodione. All the studies required under the reregistration process mandated by FIFRA 88 have been submitted. Most of these studies have been reviewed by the Agency and accepted.

The temporary tolerances for iprodione on tangelos and tangerines at 3.0 ppm are considered adequate to cover residues resulting from the limited use of iprodione in the proposed experimental use program. The tolerance level is based on field trial data with an overall mean residue of 1.19 ppm for tangelos and tangerines. The nature of the residue in plants is adequately defined. Plant metabolism studies have been reviewed in connection with previous petitions for tolerances. The residues of concern are iprodione, its isomer RP 30228, and its metabolite RP 32490. The Phase IV Review concluded that additional plant metabolism studies are not needed.

The nature of the residue in animals is adequately understood considering the limited use of iprodione on tangerines and tangelos as proposed in the experimental use permit (EUP). The residues of concern in animals are iprodione, its isomer RP 30228, its metabolites RP 32490 and RP 36114. The established tolerances for iprodione and its metabolites in meat, milk, poultry, and eggs are adequate to cover secondary residues in animal commodities resulting from the experimental use on tangerines and tangelos. Citrus feedstuff theoretically accounts only for a maximum of 20% of beef and dairy cattle diet. Citrus