Corporation concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to flufenacet residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of flufenacet, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Although there is no indication of increased sensitivity to young rats or rabbits following prenatal and/or postnatal exposure to flufenacet in the standard developmental and reproductive toxicity studies, an additional developmental neurotoxicity study, which is not normally required, is needed to access the susceptibility of the offspring in function/neurological development. Therefore, EPA has required that a developmental neurotoxicity study be conducted with flufenacet and a threefold safety factor for children and infants will be used in the aggregate dietary acute and chronic risk assessment. Although there is no indication of additional sensitivity to young rats or rabbits following prenatal and/or postnatal exposure to flufenacet in the developmental and reproductive toxicity studies; the Agency concluded that the FQPA safety factor should not be removed but instead reduced because: (i) There was no assessment of susceptibility of the offspring in functional/neurological developmental and reproductive studies; (ii) there is evidence of neurotoxicity in mice, rats, and dogs; (iii) there is concern for thyroid hormone disruption.

F. International Tolerances

Maximum residue levels are established or proposed for countries of the European Communities in the following commodities: cereals at 0.5 ppm, corn at 0.5 ppm, potato at 0.1 ppm, sunflower at 0.05 ppm, soybean at 0.05 ppm, animal meat at 0.05 ppm, animal edible offal's at 0.05 ppm, animal fat at 0.05 ppm, milk at 0.01 ppm, and eggs at 0.05 ppm.

[FR Doc. 00–7742 Filed 3–28–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–924; FRL–6495–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

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 docket control number PF–924, must be received on or before April 28, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–924 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–924. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–924 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: ''*opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–924. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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 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.

List of Subjects

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

Dated: March 15, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below 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. Interregional research Project Number 4 (IR-4)

0E6097 and 7F4873

EPA has received pesticide petitions (0E6097 and 7F4873) from IR-4, Rutgers, The State University of New Jersey, 681 U.S. Highway No. 1 South, North New Brunswick, NJ 08902, and Valent USA Corporation, Walnut Creek, CA 94596-8025 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 tolerances for residues of clethodim in or on the following raw agricultural commodities (RAC): Root vegetables subgroup at 1.0 parts per million (ppm), leaves of root and tuber vegetables group at 2.0 ppm, leafy petiole vegetables subgroup at 0.5 ppm, melon subgroup at 2.0 ppm, squash/cucumber subgroup at 0.5 ppm, cranberry at 0.5 ppm, clover forage at 10 ppm, clover hay at 20.0 ppm, strawberry at 5.0 ppm, and fruiting vegetables group at 1.0 ppm.

EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petitions prepared by Valent USA Corporation, the registrant, Walnut Creek, CA 94596-8025.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of ^{14}C-clethodim labelled in the ring structure and in the side chain has been studied in carrots, soybeans, and cotton as well as in lactating goats and laying hens. The major metabolic pathway in plants is initial sulfoxidation, forming clethodim sulfoxide, followed by further oxidation to form clethodim sulfone. These reactions are apparently followed by elimination of the chloroallyloxy side chain to give the imine sulfoxide and sulfone, with further hydroxylation to form the 5-OH sulfoxide and 5-OH sulfone. Clethodim sulfoxide and

clethodim sulfone conjugates were also detected as major or minor metabolites, depending on plant species and subfractions. Once the side chain is cleaved from clethodim, the chloroallyloxy moiety undergoes extensive metabolism to eliminate chlorine and incorporate three-carbon moieties into natural plant components.

2. *Analytical method*. Practical analytical methods for detecting and measuring levels of clethodim and its metabolites have been developed and validated in/on all appropriate agricultural commodities, respective processing fractions, milk, animal tissues, and environmental samples. The methods have been validated at independent laboratories, and EPA has successfully performed an analytical method trial. For most commodities, the primary enforcement method is EPA-RM-26D-3, an high performance liquid chromotography method capable of distinguishing clethodim from the structurally related herbicide sethoxydim.

3. *Magnitude of residues*. A summary of field residue data supporting the proposed tolerances on root vegetables subgroup (carrot and radish), leaves of root and tuber vegetables (sugarbeet tops and radish tops), leafy petioles (celery), cucurbits (cantaloupe, summer squash, and cucumber), strawberry, cranberry, and clover is presented below.

i. *Root and tuber vegetables*. Eight field trials for carrots were treated with two post-emergent applications of 0.24 lb. to 0.26 lb. active ingredient/acre (a.i./acre) and harvested approximately 29 to 31 days after the application. Residues in carrots ranged from < 0.25 ppm to 0.39 ppm total clethodim. Four field trials, radishes were treated with one post-emergent application of 0.25 lb. a.i./acre and harvested approximately 14–15 days after application. All residues in radish roots were less than 0.45 ppm.

ii. *Leaves of root and tuber vegetables*. Twelve field trials for sugarbeets were treated with two post-emergent applications of 0.25 lb. each. Sugar beet tops were harvested approximately 40 days after the last application. Clethodim residues in/on sugarbeet tops ranged from < 0.10 ppm to 0.88 ppm total clethodim.

iii. *Leafy petioles*. Five field trials for celery was treated with two post-emergent applications of 0.25 lb. a.i./acre each, approximately 14 days apart, and harvested approximately 30 days after the last application. Residues in celery ranged from < 0.1 ppm to 0.33 ppm total clethodim.

iv. *Cucurbits*. Seven field trials for cantaloupes were treated with two post-emergent applications of 0.25 lb. a.i/acre each and harvested approximately 13–20 days after the last application. Residues in/on cantaloupe ranged from < 0.10 ppm to 1.2 ppm total clethodim. Six field trials for summer squash were treated with two post-emergent applications of 0.25 lb. a.i./acre each and harvested approximately 13–14 days after the last application. Total clethodim residues ranged from < 0.10 ppm to 0.11 ppm.

v. *Strawberry*. Seven field trials for strawberries were treated with two post-emergent applications of 0.23 lb. to 0.27 lb. a.i./acre each. Strawberry fruit was harvested approximately 4–7 days after the last application. Clethodim residues in/on sugar beet tops ranged from 0.38 ppm to 2.28 ppm total clethodim.

vi. *Cranberry*. Three field trials for cranberries were treated with two post-emergent applications of 0.24 lb. to 0.28 lb. a.i./acre each. Cranberries were harvested 29–30 days after the last application. Residues ranged from 0.13 ppm to 3.2 ppm total clethodim.

vii. *Clover*. Three field trials for clover was treated with one post-emergent application of 0.25 lb. a.i./acre. Clover forage and hay were harvested 5 days after the last application. Residues in forage ranged from 3.3 ppm to 6.1 ppm total clethodim and residues in hay ranged from 12.2 ppm to 15.3 ppm total clethodim.

viii. *Fruiting vegetables*. Six field trials for bell peppers were conducted using two applications of 0.25 lb .a.i./acre and harvested 19 to 21 days after application. Residues in bell peppers ranged from 0.14 ppm to 0.89 ppm total clethodim. Five non-bell pepper field trials were conducted using two applications of 0.25 lb. a.i./acre and harvested 20 to 22 days after application. Residues in non-bell peppers ranged from 0.12 ppm to 0.92 ppm total clethodim. Combining the data with previously conducted field trials for tomatoes gives an overall average residue in fruiting vegetables of 0.42 ppm and supports a tolerance for fruiting vegetables (except cucurbits) of 1.0 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Clethodim technical is slightly toxic to animals following acute oral (Toxicity Category III), dermal (Toxicity Category IV), or inhalation exposure (Toxicity Category IV). Clethodim is a moderate eye irritant (Category III), a skin irritant (Category II), and does not cause skin sensitization in the modified Buehler test in guinea pigs. In addition, an acute oral no-observed adverse effect level (NOAEL) has been determined in rats to be 300 milligrams/kilograms (mg/kg).

2. *Genotoxicity*. Clethodim does not present a genetic hazard. Clethodim technical did not induce gene mutation in microbial *in vitro* assays. A weak response in an *in vitro* assay for chromosome aberrations was not confirmed when clethodim was tested in an *in vivo* cytogenetics assay up to the maximally tolerated dose level, nor was the response observed *in vitro* using technical material of a higher purity. No evidence of unscheduled DNA synthesis was seen following *in vivo* exposure up to a dose level near the lethal doese LD_{50} (1.5 g/kg). This evidence indicates that clethodim does not present a genetic hazard to intact animal systems.

3. *Reproductive and developmental toxicity*. No reproductive toxicity was observed with clethodim technical at feeding levels up to 2,500 ppm. Developmental toxicity was observed in two rodent species, but only at maternally toxic dose levels. Clethodim is therefore, not considered a reproductive or developmental hazard. These studies indicate no unique toxicity to the developing fetus or young, growing animals.

The developmental toxicity study conducted with clethodim technical in the rat resulted in a developmental and maternal NOAEL and lowest observed adverse effect level (LOAEL) of 100 and 350 milligrams/kilograms/day (mg/kg/day), respectively. The NOAEL and LOAEL for developmental toxicity were based on reductions in fetal body weight and increases in skeletal anomalies. The developmental toxicity study conducted with clethodim technical in the rabbit resulted in a maternal toxicity NOAEL and LOAEL of 25 and 100 mg/kg/day, respectively. Maternal toxicity was manifested as clinical signs of toxicity and reduced weight gain and food consumption during treatment. Developmental toxicity was not observed, and therefore, the developmental toxicity NOAEL was 300 mg/kg/day, highest dose tested (HDT). The 2–generation reproduction study conducted with clethodim technical in the rat resulted in parental toxicity NOAEL and LOAEL of 500 ppm and 2,500 ppm, respectively, based on reductions in body weight in males, and decreased food consumption in both generations. The NOAEL for reproductive toxicity was 2,500 ppm, HDT.

4. *Subchronic toxicity*. Subchronic oral toxicity studies conducted with clethodim technical in the rat and dog indicate a low level of toxicity. Effects observed at high dose levels consisted primarily of decreased body weights,

increased liver size (increased weight and cell hypertrophy), and anemia (decreased erythrocyte counts, hemoglobin, or hematocrit) in rats and dogs. The NOAELs from these studies were 500 ppm milligrams/kilograms bodyweight/day (ca. 25 mg/kg bwt day) in rats and 25 mg/kg bwt day in dogs. A 21–day dermal toxicity study in rats with clethodim technical showed a LOAEL at 100 mg/kg bwt day and a NOAEL at 1,000 mg/kg bwt day, HDT.

5. *Chronic toxicity*. Clethodim technical has been tested in chronic studies with dogs, rats and mice. In chronic studies compound-related effects noted at high doses included decreased body weight, increased liver size (liver weight and hypertrophy), and anemia (decreased hemoglobin, hematocrit, and erythrocyte count). Bone marrow hyperplasia was observed in dogs at the HDT. No treatment-related increases in incidence of neoplasms were observed in any study. Chronic NOAELs were 200 ppm for an 18–month feeding study in mice and 500 ppm for a 24–month study in rats. EPA has established a chronic population adjusted dose (cPAD) for clethodim of 0.01 mg/kg bwt day, based on the NOAEL in the 1–year oral dog study and an uncertainty factor of 100. Effects observed at the LOAEL include, alterations in hematology and increased absolute and relative liver weights at 75 mg/kg/day.

6. *Animal metabolism*. Ruminant and poultry metabolism studies demonstrated that transfer of administered ^{14}C-clethodim residues to tissues was low. Total ^{14}C-residues in goat milk, muscle and tissues accounted for less than 0.5% of the administered dose (24 ppm in diet for 3 days), and were less than 0.4 ppm in all cases. In poultry treated at 2.2 mg/kg/day for 5 days, total ^{14}C-residues in eggs, muscle, and most tissues were less than 0.3 ppm, although higher in liver, kidney and the GI tract. Residues in eggs were less than 0.2 ppm.

Comparing metabolites detected and quantified from plant and animal metabolism studies shows that there are no significant aglycones in plants which are not also present in the excreta or tissues of animals. Based on these metabolism studies, the residues of concern in crops and animal products are clethodim and its metabolites containing the cyclohexene moiety, and their sulfoxides and sulfones.

7. *Metabolite toxicology*. Metabolism studies of clethodim in rats, crop plants, goats and hens demonstrate that the parent is very rapidly metabolized and, in animals, eliminated. Because parent and metabolites are not retained in the body, the potential for acute toxicity from *in situ* formed metabolites is low. The potential for chronic toxicity is adequately tested by chronic exposure to the parent at the MTD and consequent chronic exposure to the internally formed metabolites.

Two metabolites of clethodim, clethodim imine sulfone and clethodim 5-hydroxy sulfone, have been tested in toxicity screening studies to evaluate the potential impact of these metabolites on the toxicity of clethodim. In general, these metabolites were found to be less toxic than clethodim technical for acute and oral toxicity studies; reproduction and teratology screening studies; and several mutagenicity studies.

8. *Endocrine disruption*. No special studies to investigate the potential for estrogenic or other endocrine effects of clethodim have been performed. However, a large and detailed toxicology data base exists for the compound including studies in all required categories. These studies include acute, sub-chronic, chronic, developmental, and reproductive toxicology studies including detailed histology and histopathology of numerous tissues, including endocrine organs, following repeated or long-term exposure. The results of all of these studies show no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, Valent USA Corporation concludes that clethodim does not possess estrogenic or endocrine disrupting properties.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Chronic dietary exposure to clethodim residues was calculated for the U.S. population and 26 population subgroups using anticipated residues (average residues from field residue studies) and accounting for the percent of the crop treated. A parallel analysis was performed assuming 100% of the crop treated. In addition to existing tolerances and those tolerances proposed in this notice, potential chronic dietary exposure to the following treated crops and crop groups is also included in this analysis: sunflower, canola, potato, sweet potato, yam (and other corm and tuberous vegetables), tomatoes, peppers (all) and other fruiting vegetables. These additional crops are being proposed for tolerances or registration by Valent USA Corporation in a separate petition. This chronic dietary exposure analysis can therefore be used to support both petitions.

Chronic dietary exposure was at or below 4.5% of the reference dose (RfD) when accounting for the percent of the crop treated. Calculated exposure increased to a maximum of 32.1% non-nursing infants (< 1–year old) using anticipated residues and assuming 100% of the crop treated. Generally speaking, the Agency has no cause for concern if total residue contribution for published and proposed tolerances is less than 100% of the cPAD.

ii. *Drinking water*. Since clethodim is applied outdoors postemergence to growing agricultural crops, the potential exists for clethodim and/or its metabolites to reach ground or surface water that may be used for drinking water. To model very conservative estimates of the potential concentrations of clethodim and its sulfoxide metabolite in drinking water, the Agency used SCI-GROW for ground water, and generic expected environmental concentration (GENEEC) for surface water. The sum of the parent and metabolite estimated concentrations in surface water greatly exceeded those in ground water. Dividing the GENEEC derived 56–day average concentration by three gives 10 micrograms per liter parts per billion (ppb) as the Agency's worse case estimate for drinking water contamination (April 8, 1998, 63 FR 1701) (FRL–5784–9). Using standard assumptions about body weight and water consumption, the chronic exposure from this drinking water would be 0.00029 and 0.001 mg/kg bwt day for adults and children, respectively; 10% of the cPAD for children. Based on this worse case analysis, the contribution of water to the chronic dietary risk exceeds food, but is still acceptable.

2. *Non-dietary exposure*. Clethodim is currently registered for use on the following residential non-food sites: ornamental plants, wooden containers for growing plants, along driveways, patios, golf course turf, walkways, trails, and paths. There are no indoor uses registered for clethodim. Clethodim kills grassey weeds and does not control broadleaf weeds. Therefore, clethodim is not used broadcast on turf, but only on edges and walkways, thus greatly reducing the risk of residential exposure. There is one exception, under several State 24(c) registrations clethodim can be used broadcast on winter dormant perennial turf to control annual grasses. It is conceivable that these outdoor uses could result in acute or short-term residential exposure. However, under current EPA criteria, the registered and proposed uses of clethodim would not constitute a chronic residential exposure scenario. The Agency did calculate that these potential exposures to homeowner

applicators and other potential exposed individuals lead to acceptable Margin of Exposure (MOE) (63 FR 1701). However, because the Agency did not identify short- or intermediate-term dermal toxic endpoints of concern, these risk analyses are no longer necessary.

D. Cumulative Effects

There are other pesticidal compounds that are structurally related to clethodim including sethoxydim, cycloxydim, and tralkoxydim. Analytical methods convert some of these herbicides and their metabolites to common moieties. Plant and animal metabolism data demonstrates that no common metabolites are formed. In consideration of potential cumulative effects of clethodim and other substances that may have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by clethodim would be cumulative with those of other chemical compounds. Thus, only the potential risks of clethodim have been considered in this assessment of aggregate exposure and effects.

Valent USA Corporation will submit information for EPA to consider concerning potential cumulative effects of clethodim consistent with the schedule established by EPA on August 4, 1997 (62 FR 42020) (FRL–5734–6), and other subsequent EPA publications pursuant to the Food Quality Protection Act.

E. Safety Determination

1. *U.S. population—chronic exposure and risk*—i. *Adult sub-populations*. Using the dietary exposure assessment procedures described above for clethodim, calculated chronic dietary exposure -- taking into account percent of crop treated and using anticipated residues -- from existing and proposed uses of clethodim is minimal. The estimated chronic dietary exposure from food for the overall U.S. population and many non-child/infant subgroups is 0.000151 to 0.000162 mg/kg bwt day, 1.5 to 1.6% of the cPAD. Addition of the small but worse case potential chronic exposure from drinking water (calculated above) increases exposure by 0.0003 mg/kg bwt day and the maximum occupancy of the cPAD from 1.6% to 4.6%. Generally, the Agency has no cause for concern if total residue contribution is less than 100% of the cPAD. It can be concluded that there is a reasonable certainty that no harm will result to the overall U.S. population and many non-child/ infant subgroups from aggregate, chronic exposure to clethodim residues.

ii. *Acute dietary exposure and risk—Adult sub-populations*. An acute dietary endpoint was not identified. Thus, the risk from acute aggregate dietary exposure to clethodim is considered to be negligible.

iii. *Non-dietary exposure and aggregate risk—Adult sub-populations*. Acute, short-term, and intermediate-term dermal and inhalation risk assessments for residential exposure to clethodim are not required because no significant toxicological effects were observed.

2. *Infants and children*—i. *Safety factor for infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of clethodim, FFDCA section 408 provides that EPA shall apply an additional margin of safety, up to ten-fold, for added protection for infants and children in the case of threshold effects unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicological data base for evaluating prenatal and postnatal toxicity for clethodim is complete with respect to current data requirements. There are no special prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 3-generation reproductive toxicity study in rats. Valent USA Corporation concludes that reliable data support use of the standard 100-fold uncertainty factor and that an additional uncertainty factor is not needed for clethodim to be further protective of infants and children.

ii. *Chronic exposure and risk—Infant and child sub-populations*. Using the conservative exposure assumptions described above (anticipated residues and percent of crop treated), the percentage of the cPAD that will be utilized by dietary (food only) exposure to residues of clethodim ranges from 0.7% for nursing infants (< 1–year old), up to 4.5% for children (1–6 years). Adding the worse case potential incremental exposure to infants and children from clethodim in drinking water (0.001 mg/kg bwt day) greatly increases the aggregate, chronic dietary exposure and the occupancy of the cPAD by 10.0% to 14.5% for children (1–6 years). EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate, chronic exposure to clethodim residues.

iii. *Acute dietary exposure and risk—Infant and child sub-populations*. An acute dietary endpoint was not identified. Thus, the risk from acute aggregate dietary exposure to clethodim is considered to be negligible.

iv. *Non-dietary exposure and aggregate risk—Infant and child sub-populations*. Acute, short-term, and intermediate-term dermal and inhalation risk assessments for residential exposure to clethodim are not required because no significant toxicological effects were observed.

F. International Tolerances

Although some have been proposed, there are no Canadian, Mexican, or Codex tolerances or maximum residue limits established for clethodim. There are no conflicts between this proposed action and international residue limits.

2. Interregional Research Project Number 4 New Jersey Agricultural Station

8E5026 and 9E6049

EPA has received pesticide petitions (8E5026 and 9E6049) from the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. The petitions propose, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of fludioxonil 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3 carbonitrile).

1. *PP 8E5026* proposes the establishment of tolerances for strawberries at 2.0 ppm; dry bulb onion; great-headed garlic; shallot; and welsh onion at 0.2 ppm; and green onion and leek at 7.0 ppm.

2 *PP 9E6049* proposes the establishment of a tolerance for stone fruit group at 2.0 ppm.

EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of petitions prepared by Novaris Crop Protection, Inc. (Novartis), Greensboro, North Carolina, 27419.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of fludioxonil is adequately understood

for the purpose of the proposed tolerances.

2. *Analytical method*. Novartis, has developed and validated analytical methodology for enforcement purposes. This method (Novartis Crop Protection Method AG-597B) has passed an Agency petition method validation for several commodities and is currently the enforcement method for fludioxonil. This method has also been forwarded to FDA for inclusion into PAM II. An extensive database of method validation data using this method on various crop commodities is available; acceptable method validation and concurrent method recovery data on stone fruits, strawberry, and onions were submitted. The validated limit of quantitation (LOQ) for residues of fludioxonil in/on stone fruit is 0.05 ppm and in/on strawberry and bulb vegetables is 0.02 ppm. For residues in/on representative rotational crop matrices is 0.01 ppm.

3. *Magnitude of residues*. The magnitude of residues for fludioxonil is adequately understood for the purpose of the proposed tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Fludioxonil and end use formulations have very low toxicity to the mammalian species by the oral, dermal, or inhalation route. The dose needed to kill 50% of animals was calculated to be greater than 5,000 mg/kg (oral), 2,000 mg/kg (dermal), and 2.6 milligrams/liter (mg/L) (inhalation) in these studies. The eye and skin irritations seen in animals upon acute exposure indicate that no more than transient and slight irritation. No sensitizing potential was noted with either the technical material or the formulated product.

2. *Genotoxicity*. Mutagenicity potential of fludioxonil was tested in several studies. In the Chinese hamster ovary (CHO) cell assay, some clastogenic and polyploidogenic effects were seen at or near the precipitating concentration of the test substance. However, results were negative in the Ames assay, CHO V79 cell assay, hepatocyte DNA repair assay, rat hepatocyte micronucleus test, mouse bone marrow test, and Chinese hamster bone marrow test. A dominant lethal test conducted in the mouse was also negative.

3. *Reproductive and developmental toxicity*. Fludioxonil is not a developmental toxicant and does not affect reproduction or fertility. No fetal toxicity was observed even at the HDT in both the rabbit (300 mg/kg) and the rat (1,000 mg/kg) developmental toxicity studies. In a 2–generation rat reproduction study, a reduction of pup body weight was seen at the highest feeding level of 3,000 ppm in the presence of maternal toxicity. The NOAEL was 300 ppm for both maternal and fetal toxicity in this study.

4. *Subchronic toxicity*. In a 90–day dietary toxicity study the kidney and liver have been identified as target organs. In a subchronic study in rats, the NOAEL was 10 ppm based on liver toxicity. In a subchronic study in mice, the NOAEL was 100 ppm based on blue urine (a metabolite); the maximum tolerated dose was 7,000 ppm. In a subchronic study in dogs, the NOAEL was 200 ppm based on clinical observations; the maximum tolerated dose was 8,000 ppm.

5. *Chronic toxicity*. In an 1–year chronic toxicity study in dogs, the NOAEL was 100 ppm based on body weight effects; the maximum tolerated dose was 8,000 ppm. Two 18–month dietary carcinogenicity studies were performed in mice. While a NOAEL of 1,000 ppm was clearly established in the first study, its highest feeding level (3,000 ppm) did not meet the criteria for a maximum tolerated dose. In the second 18–month study, the maximum tolerated dose was determined to be 5,000 ppm based on kidney effects. There were no treatment-related increases in neoplasia at any dose level tested in either study. In a combined chronic toxicity/carcinogenicity study in rats, the incidence of liver tumors in top-dose females (3,000 ppm) was marginally higher than the concurrent controls but within historical control range. The NOAEL for chronic toxicity was 1,000 ppm in both sexes.

6. *Animal metabolism*. The metabolism of fludioxonil in rats is adequately understood.

7. *Metabolite toxicology*. The residues of concern for tolerance setting purposes is the parent compound. Consequently, there is no additional concern for toxicity of metabolites.

8. *Endocrine disruption*. Fludioxonil does not belong to a class of chemicals known for having adverse effects on the endocrine system. No estrogenic effects have been observed in the various short- and long-term studies conducted with various mammalian species.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For purposes of assessing the potential dietary exposure under the proposed tolerance, Novartis has estimated aggregate exposure based on a Tier I assessment from the proposed tolerance level of 2.0 ppm in or on stone fruit and strawberry and 8.0 ppm in or on bulb vegetables including in these petitions, a pending 1.0 ppm grape tolerance, and all the currently established fludioxonil tolerances. This is deemed a worse case estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are proposed or established are treated except for strawberry and bulb vegetables where 50% and 28% market share estimates were utilized. Further, it was assumed that pesticide residues are present at the tolerance levels.

ii. *Drinking water*. Exposure of the general population to residues of fludioxonil from drinking water is considered unlikely since field dissipation studies demonstrate the movement of fludioxonil into ground water does not occur. In addition, EPA has not established a maximum contaminant level for residues of fludioxonil in drinking water.

2. *Non-dietary exposure*. Non-occupational exposure for fludioxonil has not been calculated since the current registration for fludioxonil is limited to commercial crop production. Since the chemical is not used in or around the home, Novartis considers the potential for non-occupational exposure to the general population to be non-existent.

D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since Novartis is unaware of any reliable information that indicates that toxic effects produced by fludioxonil would be cumulative with those of any other chemical compounds. Consequently, Novartis is considering the potential risks of only fludioxonil in its aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. The risk from acute dietary exposure to fludioxonil is considered to be very low. Using an acute reference dose (RfD) of 0.1 mg/kg taken from the maternal toxicology NOAEL from a rabbit teratology study and a 100 fold safety factor and highly conservative exposure assumptions, 43.4% of the aRfD is utilized for the general U.S. population.

ii. *Chronic risk*. Based on the available chronic toxicity data, EPA has set the RfD for fludioxonil at 0.03 mg/kg/day. This RfD is based on a 1–year feeding study in dogs with a NOAEL of 3.3 mg/kg/day (100 ppm) and an uncertainty factor of 100. No additional uncertainty factor was judged to be necessary as body weight was the most sensitive indicator of toxicity in that study. Based on the highly conservative exposure assumptions described above, only 7.5% of the RfD will be utilized by the U.S. general population. Therefore,

based on the completeness and reliability of the toxicity data supporting these petitions, there is a reasonable certainty that no harm will result from aggregate exposure to residues of fludioxonil as a result of these requested tolerances.

2. *Infants and children*. Infants and children are not expected to show any particular sensitivity to fludioxonil. This can be demonstrated by referencing several data points, including the equivalence of the maternal and fetal toxicity NOAEL in the fludioxonil 2–generation rat study.

i. *Acute risk*. The risk from acute dietary exposure to fludioxonil is considered to be very low. Under the highly conservative exposure assumptions of residue levels being at tolerance level and 100% market share for the majority of crops with proposed and established fludioxonil registrations, the utilization of the acute RfD of the most exposed group is 83.4% (children, 1–6 years).

ii. *Chronic risk*. Using highly conservative aggregate exposures 23.0% and 19.2% of the RfD were obtained for the most sensitive sub-populations, non-nursing infants (< 1–year old) and children (1–6 years), respectively. Therefore, a reasonable certainty exists that no harm will result from aggregate exposure to fludioxonil if the proposed uses are registered.

F. International Tolerances

There are no Codex maximum residue levels established for residues of fludioxonil in or on strawberrry, dry bulb onion, green onion, and stone fruit crop fruit.

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ENVIRONMENTAL PROTECTION AGENCY

PF–919; FRL–6493–8

Notice of Filing Pesticide Petitions To Establish a Tolerance for Certain Pesticide Chemicals in or on Food

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 docket control number PF–919, must be received on or before April 28, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–919 in the subject line on the first page of your response.

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

Product Manager	Office location/telephone number/e-mail address	Address	Petition number(s)
Mary Waller (PM 21)	Rm. 249, CM #2, 703-308-9354, e-mail:waller.mary@epamail.epa.gov	1921 Jefferson Davis Hwy, Arlington, VA	PP 9F3727
Joe Travano (PM 10)	Rm. 214, CM #2, 703–305–6411, e-mail: travano.joe@epamail.epa.gov.	Do.	PP 0F6069

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–919. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is