

an additional uncertainty factor of 10 for incompleteness of data until a rat 2-generation reproduction study was completed. The study was a condition of registration of the subject active ingredient, and was submitted to the Agency by Abbott Laboratories on September 27, 1999.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Abbott Laboratories submitted a summary of information, data, and arguments in support of their pesticide petition which was published in the **Federal Register** of March 10, 1999 (64 FR 11872) (FRL-6067-5). EPA has not republished the summary of information initially submitted by Abbott Laboratories and published in the March 10, 1999 **Federal Register**, except where EPA believes such information would be helpful in understanding the new data. Valent BioSciences Corporation is, however, relying on the previously submitted information in addition to the new data summarized below in support of this pesticide petition to extend the temporary tolerance. EPA will take into account all available data when giving due consideration to Valent BioSciences Corporation's petition. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Valent BioSciences Corporation has submitted the following summary of new information, data, and arguments in support of their pesticide petition. This summary was prepared by Valent BioSciences Corporation and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

#### A. Product Name and Proposed Use Practices

AVG is a plant regulator useful in the management practices of stone fruit. It is applied once during the season at low rates (50 grams active ingredient per acre) using airblast sprayers. The product is recommended to be applied to stone fruit 7-14 days prior to the beginning of normal harvest. The proposed, amended, experimental use program will be conducted in Alabama, Arkansas, California, Georgia, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Virginia and Washington. The proposed, amended, experimental program would utilize 146 pounds of

active ingredient on 1,325 acres, in each year of the proposed 2-year program.

#### B. Mammalian Toxicological Profile

1. *Reproductive toxicity.* AVG was evaluated in a rat 2-generation reproduction study submitted by Abbott Laboratories. Rats were dosed at levels of 0, 0.8, 2.5, 4.0, and 8.0 mg ai/kg bwt/day. Based on reductions in body weight, changes in organ weights, and increased incidence of microscopic findings, the parental LOEL was established at 2.5 mg ai/kg bwt/day. The parental NOAEL was established at 0.8 mg ai/kg bwt/day. The NOAEL for reproductive toxicity was established at 4.0 mg ai/kg bwt/day. The NOAEL for neonatal toxicity was established at 2.5 mg ai/kg bwt/day.

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Expected dietary exposures from residues of AVG would occur through raw and processed commodities of treated stone fruit. There are no home and garden uses for AVG. Based on the additional information derived from the rat 2-generation reproduction study, Valent BioSciences Corporation proposes that the NOAEL of 0.8 mg ai/kg bwt/day and a safety factor of 100 be incorporated into the chronic risk assessment. The resulting RfD is 0.008 mg ai/kg bwt/day. The proposed temporary tolerance on stone fruit in addition to tolerances on apples and pears would utilize approximately 1.7% RfD for the U.S. population in general, and approximately 12.7% for the non-nursing infants.

ii. *Drinking water.* Spray drift may potentially lead to exposure to residues in drinking water.

2. *Non-dietary exposure.* The only non-dietary exposure expected is to applicators. Exposure to AVG resulting from its application according to label directions is not expected to present risks of adverse health or environmental effects, based on its toxicology profile and occupational risk assessment. Non-occupational exposures (home/garden uses) are not applicable to this experimental use permit.

#### D. Safety Determination

1. *U.S. population.* AVG is an amino acid derived from a naturally occurring soil microorganism. Based on the toxicology profile and the low to no detectable residues in the agricultural commodities, Valent BioSciences Corporation concludes that there is a reasonable certainty of no harm resulting from aggregate exposure of AVG to the general population.

2. *Infants and children.* The effects demonstrated in the developmental and immune toxicity studies are considered secondary to the adverse effects upon body weight gain, food consumption and food efficiency in the treated rats. In the rat reproduction study, decreased neonatal survival, decreased pup body weights and other effects associated with reduced pup weights were observed only at doses greater than those producing effects on the parental animals. The NOAEL for neonates in the reproduction study, 2.5 mg ai/kg bwt/day, was 3 times greater than the NOAEL for parental animals, 0.8 mg ai/kg bwt/day NOAEL, providing an additional built-in safety factor of 3 for the subpopulation of infants and children. The company concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure.

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-1003; FRL-6773-5]

### Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical 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 a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-1003, must be received on or before April 27, 2001.

**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-1003 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6224; e-mail address: miller.joanne@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 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-1003. 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-1003 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, 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](mailto: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-1003. 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 a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions 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 petitions. Additional data may be needed before EPA rules on these petitions.

### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: March 19, 2001.

**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 FFDCFA. The summaries of the petitions were prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petitioner's summaries 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.

#### Valent U.S.A. Corporation

PP 5F4440 and 5F4572

EPA has received amended pesticide petitions (5F4440 and 5F4572) from Valent U.S.A. Corporation, 1333 N. California Blvd., Ste. 600, Walnut Creek, CA 94596-8025 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by extending time-limited tolerances for residues of clethodim in or on the raw agricultural commodities (RACs) alfalfa forage at 6 parts per million (ppm), alfalfa hay at 10 ppm, dry beans at 2 ppm, peanut hay at 3 ppm, peanut meal at 5 ppm, peanuts at 3 ppm, tomato paste at 3 ppm, and tomato puree at 2 ppm. Time-limited tolerances on these commodities would expire on April 30, 2003, to allow EPA sufficient time to evaluate new residue data. Valent USA Corporation is not proposing to extend the time-limited tolerance for residues on tomatoes at 1.0 ppm because tolerances are to be issued for residues on fruiting vegetables (except cucurbits), which includes tomatoes, at 1.5 ppm through a separate pesticide petition (0E6097). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; 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. This notice includes a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant.

#### A. Residue Chemistry

1. *Plant metabolism.* The metabolism of <sup>14</sup>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, a high performance liquid chromatography (HPLC) method capable of distinguishing clethodim from the structurally related herbicide sethoxydim.

3. *Magnitude of residues—i. Fruiting vegetables.* There is an existing time-limited tolerance for tomatoes of 1.0 ppm and Valent U.S.A. Corporation is proposing to replace this tolerance with a 1.5 ppm tolerance for fruiting vegetables based on residue trials conducted on peppers (bell and non-bell) and tomatoes. Six field trials for bell peppers were treated with two post-emergent applications of 0.25 lb. a.i./acre each. Bell pepper fruit was harvested approximately 21 days after the last application. Residues in/on bell pepper fruit samples ranged from 0.11 ppm to 0.89 ppm total clethodim. The highest average field trial (HAFT) residue was 0.79 ppm. The average residue level was 0.46 ppm. Five field trials for non-bell peppers were treated with two post-emergent applications of 0.25 lb. a.i./acre each. Non-bell pepper fruit was harvested approximately 21 days after the last application. Residues in/on non-bell pepper fruit samples

ranged from 0.12 ppm to 0.92 ppm total clethodim. The HAFT residue was 0.90 ppm. The average residue level was 0.55 ppm.

Twelve residue trials for tomatoes were treated with two post-emergent applications of 0.25 lb. a.i./acre each. Tomatoes were harvested approximately 20 days after the last application. Clethodim residues ranged from <0.1 to 0.79 ppm. The HAFT residue was 0.77 ppm. The average residue level was 0.37 ppm. To support permanent tolerances on tomatoes, Valent U.S.A. Corporation agreed to conduct four additional residue trials in EPA Region X to bring the total number of trials up to 16. In these four additional trials, tomatoes were treated with two post-emergent applications of 0.25 lb. a.i./acre each. Tomatoes were harvested approximately 20 days after the last application. Clethodim residues ranged from 0.34 to 1.07 ppm. The average residue level for all 16 tomato residue trials was 0.42 ppm. The HAFT residue was 1.04 ppm.

Combining the pepper residue data and the tomato residue data gives an overall average residue in fruiting vegetables of 0.45 ppm. These data from bell and non-bell peppers and tomatoes support a tolerance for fruiting vegetables (except cucurbits, crop group 8) of 1.5 ppm.

ii. *Dry beans.* There is an existing time-limited tolerance for dry beans of 2.0 ppm. This tolerance was supported by nine field trials in which beans were treated with two post-emergent applications of 0.25 lb. a.i./acre each approximately 14 days apart. Beans were harvested approximately 30 days after the last application. Clethodim residues ranged from 0.58 ppm to 1.57 ppm. The HAFT residue was 1.57 ppm. The average residue level for all trials, excluding samples less than the limit of detection, was 0.99 ppm.

To support permanent tolerances on dry beans, Valent U.S.A. Corporation agreed to conduct 3 additional residue trials in EPA Region V to bring the total number of trials up to 12. In these 3 additional trials, beans were treated with two post-emergent applications of 0.25 lb. a.i./acre each approximately 14 days apart. Beans were harvested approximately 30 days after the last application. Clethodim residues ranged from 1.2 ppm to 2.0 ppm. The average residue level for all 12 residue trials, excluding samples less than the limit of detection, was 1.15 ppm. The HAFT residue was 2.0 ppm.

iii. *Peanuts.* There is an existing time-limited tolerance for peanut hay at 3 ppm, peanut meal at 5 ppm, peanuts at 3 ppm. This tolerance was supported by eight field trials in which peanuts were

treated with two post-emergent applications of 0.25 lb. a.i./acre each approximately 14 days apart. Peanuts were harvested approximately 40 days after the last application. Peanuts were dried in the field for 3 to 11 days after which peanuts and peanut hay were sampled. Clethodim residues ranged from <0.05 ppm to 2.7 ppm. The HAFT residue was 1.75 ppm. The average residue level, excluding samples less than the limit of detection, was 0.96 ppm. Residues in peanut hay ranged from 0.22 ppm to 2.6 ppm with a HAFT residue of 2.55 ppm. A processing study was also performed for peanuts and residues were found to concentrate in meal with a concentration factor of 2.78 ppm.

To support permanent tolerances on peanuts, Valent U.S.A. Corporation agreed to conduct 3 additional residue trials in EPA Region V to bring the total number of trials up to 12. In these three additional trials, peanuts were treated with two post-emergent applications of 0.25 lb. a.i./acre each approximately 14 days apart. Peanuts were harvested approximately 40 days after the last application. Clethodim residues ranged from 0.67 ppm to 1.2 ppm in nutmeats and from 0.8 ppm to 2.9 ppm in peanut hay. The average residue level for all 12 residue trials, excluding samples less than the limit of detection, was 0.94 ppm in nutmeats and 1.39 ppm in peanut hay. The HAFT residue was 1.75 ppm and 2.7 ppm in nutmeats and hay, respectively.

### 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/kilogram (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 (UDS) was seen following *in vivo* exposure up to a dose level near the LD<sub>50</sub> (1.5 gram/kilogram (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 (ca. 25 mg/kg body weight/day (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, the 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 (UF) 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 <sup>14</sup>C-clethodim residues to tissues was low. Total <sup>14</sup>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 <sup>14</sup>C-residues in eggs, muscle, and most tissues were less than 0.3 ppm, although higher in liver, kidney, and the gastrointestinal track (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 maximum tolerance dose (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. These studies show no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, Valent U.S.A. 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, tuberous and corn vegetables (crop subgroup 1C), root vegetables (except sugarbeet, subgroup 1B), leaves of root and tuber vegetables (group 2), leaf petioles (subgroup 4B), cucurbits (group 9), cranberry, strawberry, and clover.

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 screening concentration in ground water (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 (63 FR 1701, April 8, 1998), (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, 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 margins 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 U.S.A. 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 (FQPA).

#### E. Safety Determination

1. *U.S. population—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 bw/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.

i. *Acute dietary exposure and risk.* An acute dietary endpoint was not identified. Thus, the risk from acute aggregate dietary exposure to clethodim is considered to be negligible.

ii. *Non-dietary exposure and aggregate risk.* 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.* In assessing the potential for additional sensitivity of infants and children to residues of clethodim, FFDC section 408 provides that EPA shall apply an additional margin of

safety, up to 10-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 U.S.A. Corporation concludes that reliable data support use of the standard 100-fold UF and that an additional uncertainty factor is not needed for clethodim to be further protective of infants and children.

ii. *Chronic exposure and risk.* 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 worst 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.* 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.* 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

Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established or proposed for residues of clethodim in/on sugar beets (0.1 ppm), potatoes (0.2 ppm), rape seed (0.5 ppm), rape seed oils (0.5 ppm), sunflower seed (0.5 ppm), and

sunflower seed oils (0.05 ppm). There are no conflicts between this proposed action and international residue limits. [FR Doc. 01-7640 Filed 3-27-01; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6959-2]

### Proposed Settlement Agreement

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed settlement agreement; request for public comment.

**SUMMARY:** In accordance with section 113(g) of the Clean Air Act, as amended, 42 U.S.C. 7413(g), notice is hereby given of a proposed settlement agreement in *Eramet Marietta, Inc., v. EPA*, No. 99-1290 (D.C. Cir.).

This case concerns a challenge to the rule entitled National Emission Standards for Hazardous Air Pollutants for Ferroalloys Production, published in the **Federal Register** at 64 FR 27450 on May 20, 1999. The proposed settlement provides for EPA to propose revisions to the Ferroalloys rule that would amend the emission standards applicable to ferromanganese and silicomanganese production in open submerged arc furnaces and extend the compliance deadline by six months.

For a period of thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement from persons who were not named as parties to the litigation in question. EPA or the Department of Justice may withhold or withdraw consent to the proposed settlement if the comments disclose facts or circumstances that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Copies of the settlement are available from Phyllis Cochran, (202) 564-5566. Written comments should be sent to Jon Devine at Air and Radiation Division (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and must be submitted on or before April 27, 2001.

**Anna L. Wolgast,**

*Acting General Counsel.*

[FR Doc. 01-7635 Filed 3-27-01; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6959-5]

### Proposed CERCLA Administrative Cost Recovery Settlement; United States Department of the Navy

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice; request for public comment.

**SUMMARY:** In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the Hooper Sands site in South Berwick, Maine with the following settling party: United States Department of the Navy. The settlement requires the settling party to seek Congressional authorization and appropriation to pay \$1,005,478.00 to the Hazardous Substance Superfund. The settlement includes a covenant not to take administrative action against the settling party pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection with the Docket Clerk, U.S. Environmental Protection Agency—New England, Region 1, Suite 1100 (RAA), Boston, Massachusetts 02114-2023, (617) 918-1093 (U.S. EPA CERCLA Docket No. I-98-1041).

**DATES:** Comments must be submitted on or before April 27, 2001.

**ADDRESSES:** The proposed settlement is available for public inspection or may be obtained by mail by contacting Kathleen Woodward, U.S. Environmental Protection Agency—New England, Region 1, Suite 1100 (SEL), Boston, Massachusetts 02114-2023, (617) 918-1780. Comments should reference the Hooper Sands Site, South Berwick, Maine and EPA CERCLA Docket No. I-98-1041.

#### FOR FURTHER INFORMATION CONTACT:

Kathleen Woodward, U.S. Environmental Protection Agency—New England, Region 1, Suite 1100 (SEL),