

Dated: March 8, 2001.

Margaret H. McFarland,

Deputy Secretary.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301105; FRL-6770-8]

RIN 2070-AB78

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of clethodim in or on tuberous and corm vegetables, sunflower seed, sunflower meal, fruiting vegetable group, carrots, radish roots, radish tops, leaf petioles subgroup, melon subgroup, squash/cucumber subgroup, cranberry, strawberry, clover forage, and clover hay. In addition, this regulation amends tolerances for combined residues of clethodim in or on sugar beet tops, sugar beet molasses, and potato granules/flakes. Interregional Research Project Number 4 (IR-4) and Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective March 14, 2001. Objections and requests for hearings, identified by docket control number OPP-301105, must be received by EPA on or before May 14, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301105 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 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 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" "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301105. The official record consists of the documents specifically referenced in this action, 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 Hwy., 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.

II. Background and Statutory Findings

In the **Federal Register** of March 29, 2000 (65 FR-1660-2)(FRL-6495-5), and December 3, 1997 (62 FR-63942)(FRL-5756-1), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of pesticide petitions (PP) for tolerances by 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. These notices included a summary of the petitions prepared by Valent USA Corporation, the registrant.

The petitions requested that 40 CFR 180.458 be amended by establishing tolerances for combined residues of the herbicide clethodim, (E)-(±)-2-[1-[[[3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, on various commodities with the following tolerance levels at parts per million (ppm): tuberous and corm vegetables at 1.0 ppm, potato granules/flakes at 2.0 ppm, sugar beet tops at 1.0 ppm, sugar beet molasses at 1.0 ppm, sunflower seed at 5.0 ppm, sunflower meal at 10.0 ppm, fruiting group, vegetable at 1.0 ppm, carrots at 0.50 ppm, radish roots at 0.50 ppm, radish tops at 0.70 ppm, leaf petioles subgroup at 0.50 ppm, melon subgroup at 2.0 ppm, squash/cucumber subgroup at 0.50 ppm, cranberry at 0.50 ppm, strawberry at 3.0 ppm, clover forage at 10.0 ppm, and clover hay at 20.0 ppm.

The petitioner, IR-4 subsequently revised the petition to propose a tolerance for the leaf petiole vegetable subgroup at 0.60 ppm.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the

legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For

further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for combined residues of clethodim on tuberous and corm vegetables at 1.0 ppm, potato granules/flakes at 2.0 ppm, sugar beet tops at 1.0 ppm, sugar beet molasses at 1.0 ppm, sunflower seed at 5.0 ppm, sunflower meal at 10.0 ppm, fruiting group, vegetable at 1.0 ppm, carrots at 0.50 ppm, radish roots at 0.50 ppm, radish tops at 0.70 ppm, leaf

petioles subgroup at 0.60 ppm, melon subgroup at 2.0 ppm, squash/cucumber subgroup at 0.50 ppm, cranberry at 0.50 ppm, strawberry at 3.0 ppm, clover forage at 10.0 ppm, and clover hay at 20.0 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by clethodim are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline Number	Study Type	Results
870.3100	Subchronic-Feeding-Rat	NOAEL= 25 milligrams/kilograms/day (mg/kg/day). LOAEL= 134 mg/kg/day based on decreased body weights, body weight gains, food consumption, and increased absolute and relative liver weights, and centrilobular hypertrophy of liver in both sexes
870.3150	Subchronic-Feeding-Dog	NOAEL= 25 mg/kg/day LOAEL= 75 mg/kg/day based on increased absolute and relative liver weights, severity of liver lesions in both sexes, and increased serum cholesterol and alkaline phosphatase in females
870.3200	21-Day Dermal Toxicity-Rat	Systemic NOAEL= 100 mg/kg/day LOAEL= 1,000 mg/kg/day based on anogenital discharge and staining in both sexes, decreased food efficiency and body weight gain in males, and increases in absolute and relative liver weights in females Dermal NOAEL= not established LOAEL= 10 mg/kg/day based on observed dermal irritation
870.3700	Developmental Toxicity-Rat	Maternal NOAEL= 100 mg/kg/day LOAEL= 350 mg/kg/day based on decreased body weight gain and clinical signs Developmental NOAEL= 100 mg/kg/day LOAEL= 350 mg/kg/day based on decreased fetal body weight and increased skeletal anomalies
870.3700	Developmental Toxicity-Rabbit	Maternal NOAEL= 25 mg/kg/day LOAEL= 100 mg/kg/day based on decreased weight gain and food consumption and clinical signs Developmental NOAEL < 300 mg/kg/day LOAEL= Not determined because no developmental toxicity observed

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline Number	Study Type	Results
870.3800	Reproductive Toxicity- 2-Generation Rat	Parental/Systemic NOAEL= 51 mg/kg/day LOAEL= 263 mg/kg/day based on decreased body weight in both sexes, and particularly in both generations of males, decreased food consumption Reproductive NOAEL= 263 mg/kg/day HDT LOAEL= Not determined because no effects were noted for fertility, length of gestation or growth and development of offspring Offspring NOAEL= 263 mg/kg/day HDT
870.4100	Chronic-Feeding-Dog	NOAEL= 1 mg/kg/day LOAEL= 75 mg/kg/day based on increased absolute and relative liver weights in both sexes with histopathological changes (males only) and increased liver enzymes
870.4200	Carcinogenicity-Mouse (78-week)	NOAEL= 30 mg/kg/day LOAEL= 150 mg/kg/day based on decreased survival, decreased hematology parameters, increased absolute and relative liver weights (female only), centrilobular hypertrophy, increased pigment and bile duct hyperplasia in both sexes No evidence of carcinogenicity
870.4300	Chronic Toxicity/Carcinogenicity-Rat	NOAEL= 19 mg/kg/day LOAEL= 100 mg/kg/day based on decreased body weight means, body weight gains, food consumption, and food efficiency (males only), and increased absolute and relative liver weights with centrilobular hypertrophy (at 12 months) in both sexes No evidence of carcinogenicity
870.5100	Gene Mutation - <i>Salmonella</i>	Negative for reverse mutation in <i>Salmonella</i> (and <i>E. coli</i>) exposed to cytotoxic levels (10,000 µg/plate) with/without activation
870.5300	CHO Assay	Positive for inducing structural aberrations only in the absence of activation (negative +S9) at dose near limit of solubility and cytotoxicity (1.0 to 1.2 µL/ml)
870.5395	Micronucleus Assay	Negative for chromosomal damage in bone marrow cells of rats treated orally up to toxic doses (1,500 mg/kg)
870.5550	Unscheduled DNA Synthesis	Negative for unscheduled DNA synthesis (UDS) in hepatocytes from mice treated orally up to toxic doses (5,000 mg/kg)
870.6300	Developmental Neurotoxicity Rat	None available
870.7485	Metabolism Rat	Clethodim is readily absorbed and eliminated (87–92%, urine; 9–17%, feces; < 1% expired air) after 7 days. Gastrointestinal absorption estimated at 89–96%. No evidence of bioconcentration. Extensively metabolized with < 1% eliminated as unchanged parent compound. Predominant metabolite is clethodim sulphoxide (48–68%) after 48 hours.
870.7600	Dermal Absorption Rat	At 10 hours after receiving a single dermal application of 0.05 mg/rat the dermal absorption factor was 30%

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL

was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for

interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is

retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of

exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10⁶ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach,

a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for clethodim used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLETHODIM FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern (LOC) for Risk Assessment	Study and Toxicological Effects
Acute dietary all populations	N/A	N/A	None selected There were no effects observed in oral toxicity studies including developmental toxicity studies in rats and rabbits that could be attributable to a single dose (exposure). Therefore, a dose and endpoint were not selected for this risk assessment.
Chronic dietary all populations	NOAEL= 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.01 mg/kg/day	Chronic Toxicity-Dog (1 year) Alterations in hematology and clinical chemistry parameters and increased absolute and relative liver weights observed at the LOAEL of 75 mg/kg/day.
Short-term dermal (1 to 7 days) (Residential)	Oral study Maternal NOAEL= 100 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE = 100 (Residential)	Developmental Toxicity-Rat LOAEL = 350 mg/kg/day based on decreased body weight gain and clinical signs of toxicity (salivation)
Intermediate-term dermal (1 week to several months) (Residential)	Oral study NOAEL= 25 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE = 100 (Residential)	Subchronic Toxicity-Dog (90 days) LOAEL = 75 mg/kg/day based on increased absolute and relative liver weights
Long-term dermal (several months to lifetime) (Residential)	Oral study NOAEL= 1.0 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE =100 (Residential)	Chronic Toxicity-Dog (1 year) LOAEL = 75 mg/kg/day based on alterations in hematology and clinical chemistry parameters as well as increases in absolute and relative liver weights
Short-term inhalation (1 to 7 days) (Residential)	Oral study Maternal NOAEL= 100 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE =100 (Residential)	Developmental-Rat LOAEL = 350 mg/kg/day based on decreased body weight gain and clinical signs of toxicity (salivation)
Intermediate-term inhalation (1 week to several months) (Residential)	Oral study NOAEL = 25 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Subchronic Toxicity-Dog (90 days) LOAEL = 75 mg/kg/day based on increased absolute and relative liver weights
Long-term inhalation (several months to lifetime) (Residential)	Oral study NOAEL= 1.0 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE =100 (Residential)	Chronic Toxicity-Dog (1 year) LOAEL = 75 mg/kg/day based on alterations in hematology and clinical chemistry parameters as well as increases in absolute and relative liver weights
Cancer (oral, dermal, inhalation)	N/A	N/A	Clethodim is classified as a “Not Likely” carcinogen

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.458) for the combined residues of clethodim and its metabolites containing the 2-cyclohexen-1-one moiety, in or on a variety of RACs: Fat, meat, and meat by products (mbypp) of cattle, goats, hogs, horses, poultry, and sheep at 0.20 ppm, milk at 0.05 ppm, eggs at 0.20 ppm, cottonseed at 1.0 ppm, potatoes at 0.5, soybeans at 10.0 ppm, potato flakes and granules at 1.0 ppm, cottonseed meal at 2.0 ppm, and soybean soapstock at 15.0 ppm. In addition, permanent tolerances are established under 40 CFR 180.458(a)(3) and (6) for the combined residues of clethodim and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in/on dry bulb onions at 0.20 ppm, sugar beet roots at 0.20 ppm, sugar beet tops at 0.50 ppm, and sugar beet molasses at 2.0 ppm. Time-limited tolerances (set to expire April 30, 2001, are established for various commodities under 40 CFR 180.458(a)(2)).

Risk assessments were conducted by EPA to assess dietary exposures from clethodim in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. An endpoint was not identified for acute dietary exposure and risk assessment because no effects were observed in oral toxicity studies including developmental toxicity studies in rats or rabbits that could be attributable to a single dose (exposure). Therefore, an acute dietary exposure assessment was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The 3-day average of consumption for each sub-population is combined with residues to determine average exposure as mg/kg/day.

The chronic analysis was performed using tolerance level residues for all crops and animal commodities. The

weighted average percent crop treated (PCT) data for existing registrations, and 100% crop treated (CT) data (for new uses) were used for the analyses.

iii. *Cancer.* Clethodim has been classified as a group E carcinogen. Therefore, a cancer risk assessment was not performed.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not underestimate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: 3% for cotton, 8% for onions, 3% for peanuts, 4% for soybeans, 15% for sugar beets, and 1% for tomatoes.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an

underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which clethodim may be applied in a particular area.

2. *Dietary exposure from drinking water.* Known environmental characteristics of clethodim depict a compound which is stable to hydrolysis, except in acid conditions, but highly susceptible to photolysis and metabolism.

Parent clethodim is mobile, but has a short metabolic half-life of 1–3 days in soil under aerobic conditions. Therefore, parent compound should not be a ground water concern in most environments. In the event that parent clethodim did reach ground water, the available routes of disappearance would be dilution, some metabolism to persistent degradates, and slow hydrolysis with the rate depending on the pH of the ground water.

The environmental fate data indicate that clethodim, and its sulphoxide and sulphone metabolites may migrate into surface water bodies through run-off which occurs shortly after application (e.g., rainfall). Since they are not adsorbed readily to soil (K_{as} of < 0.1 to 7), they are likely to remain in the aqueous phase, where they are subject to rapid photolysis and biodegradation. They may remain long enough to exert acute effects on resident biota, but are unlikely to cause chronic effects.

Clethodim does not show a significant potential for bio-accumulation in aquatic organisms. Although they have not been individually tested, the primary degradates are highly polar, and would not be expected to bio-accumulate.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clethodim in drinking water. Because the Agency does not have comprehensive monitoring data,

drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of clethodim.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to clethodim, they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models, the EECs of clethodim for chronic exposures are estimated to be 24.2 part per billion (ppb) for surface water and 0.49 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in

this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Clethodim is not registered for use on any sites that would result in residential exposure. Based on clethodim labels, Select® and Select® 2EC are both available for weed control use in residential and/or public areas. However, the registrant has indicated that the product is not for use by homeowners. Therefore, homeowners will not handle clethodim products, and a non-occupational handler exposure assessment is not necessary. Following treatment by professional applicators, the public could potentially come into contact with clethodim residues in areas such as patios, along driveways and around golf courses and fence lines. However, weed control with clethodim in these areas generally consists of a spot treatment, resulting in a very small treated area, and it is unlikely that children would be exposed to these treated areas. Therefore, a non-occupational post-application exposure assessment was not performed.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether clethodim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, clethodim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that clethodim has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (November 26, 1997 62 FR 62961).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* exposure to clethodim.

iii. *Conclusion.* There is a complete toxicity data base for clethodim and exposure data are complete or are estimated based on data that reasonably account for potential exposures. Based on the above, EPA determined that the 1X safety factor to protect infants and children should be removed.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure milligram/kilogram/day (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk

assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in

drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An endpoint for acute dietary exposure was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clethodim from food

will utilize 29% of the cPAD for the U.S. population, 43% of the cPAD for all infants < 1 year, and 60% of the cPAD for children 1–6 years old. There are no residential uses for clethodim that result in chronic residential exposure to clethodim. In addition, there is potential for chronic dietary exposure to clethodim in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLETHODIM

Population Subgroup	cPAD (mg/kg)	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S population (total)	0.01	29	24.2	0.49	250
All infants < 1 year)	0.01	43	24.2	0.49	57
Children 1–6 years	0.01	60	24.2	0.49	40
Children 7–12 years	0.01	42	24.2	0.49	58
Females 13–50 years	0.01	22	24.2	0.49	230

3. *Short-term and intermediate-term risk.* Aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Clethodim is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Clethodim has been classified as a group E carcinogen. Therefore, clethodim is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to clethodim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The method RM-26B-3 (a modification of RM-26B-2) was validated by IR-4 for potatoes, processed potato commodities, sugar beets, sunflowers, bell peppers, non-bell peppers, celery, cantaloupes, and clover. The LOQ was determined to be 0.1 ppm for cantaloupes and bell peppers, 0.2 ppm for potatoes, sugar beets, sunflowers, celery and non-bell

peppers, and 0.5 ppm for clover. Average recoveries for all the commodities were within the acceptable range at all fortification levels tested. The common moiety method RM-26B-3 for the determination of clethodim and its metabolites in potatoes, processed potato commodities, sugar beets, sunflowers, bell peppers, non-bell peppers, celery, cantaloupes, and clover is acceptable.

Method RM-26B-2 was validated by IR-4 for the analyses of residues of clethodim in/on radish, carrots, cucumbers, cranberries, and strawberries. The LOQ was determined to be 0.05 ppm for strawberries and cranberries, 0.1 ppm for carrots, and 0.16 ppm for radish. Average recoveries were within the acceptable range for all fortification levels tested and all commodities. The method RM-26B-2 for the determination of clethodim and its metabolites in radish, carrots cucumbers, cranberries, and strawberries is acceptable for data collection and meets the requirements for a residue analytical method to enforce tolerances.

The common moiety method RM-26B-3 for the determination of clethodim and its metabolites is similar to the common moiety method RM-26B-2. The method RM-26B-2 and RM-26D-2 have completed an Independent Laboratory Validation (ILV) and also have completed Tolerance Methods Validations (TMVs) in the Agency's

laboratory. Additionally, the compound specific method, EPA-RM-26D-2 is also available and is suitable for residue data collection and as a residue analytical method to enforce tolerances. Both methods have been forwarded to the Food and Drug Administration for inclusion in a future edition of the Pesticide Analytical Manual, Volume II (PAM II).

The methods may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort George G. Mead, Maryland, 20755–5350; telephone number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no established Codex maximum residue limits (MRLs) for residues of clethodim and its metabolites in/on the commodities discussed in the subject petition; therefore, there are no questions with respect to Codex/U.S. tolerance compatibility.

C. Conditions

Registration for members of the tuberous and corm vegetable, subgroup and fruiting vegetables crop group will be made conditional pending the submission of additional residue field trials.

V. Conclusion

Therefore, these tolerances are established for combined residues of clethodim, [(E)-(±)-2-[1-[[3-chloro-2-propenyl]oxylimino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-(ethylthiopropyl)cyclohexene-3-one and 5-(2-(ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, in or on tuberous and corm vegetables at 1.0 ppm, potato granules/flakes at 2.0 ppm, sugar beet tops at 1.0 ppm, sugar beet molasses at 1.0 ppm, sunflower seed at 5.0 ppm, sunflower meal at 10.0 ppm, fruiting vegetable group, at 1.0 ppm, carrots at 0.50 ppm, radish roots at 0.50 ppm, radish tops at 0.70 ppm, leaf petioles subgroup at 0.60 ppm, melon subgroup at 2.0 ppm, squash/cucumber subgroup at 0.50 ppm, cranberry at 0.50 ppm, strawberry at 3.0 ppm, clover forage at 10.0 ppm, and clover hay at 20.0 ppm. Tolerances are amended for combined residues of clethodim in or on sugar beet tops at 1.0 ppm and sugar beet molasses at 1.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301105 in the subject line on the first page of your submission. All requests must be in writing, and must be

mailed or delivered to the Hearing Clerk on or before May 14, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request 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 information 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.

Mail your written request to: Office of the Hearing Clerk 1900, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of

Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301105, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (October 4, 1993 58 FR 51735). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates

Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior special consultations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629 February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (FR 19885 April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (August 10, 1999 64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure

"meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 26, 2001.

James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.458 Clethodim ((E)-(-)-2-[1-[[[3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.

2. Section 180.458 is amended by revising the table in paragraph (a)(3), removing paragraphs (a)(4) and (a)(6), and redesignating paragraph (a)(5) as paragraph (a)(4) to read as follows:

(a) * * *
(3) * * *

Commodity	Parts per million
Beet, sugar, molasses	1.0
Beet, sugar, roots	0.20
Beet, sugar, tops	1.0
Carrot	0.50
Cranberry	0.50
Clover, forage	10.0
Clover, hay	20.0
Fruiting group, vegetable	1.0
Leaf petioles subgroup	0.60
Melon subgroup	2.0
Onion, dry bulb	0.20
Potato, granules/flakes	2.0
Radish, roots	0.50
Radish, tops	0.70
Squash/cucumber subgroup	0.50
Strawberry	3.0
Sunflower, meal	10.0
Sunflower, seed	5.0
Vegetable, tuberous and corm group	1.0

* * * * *
[FR Doc. 01-6185 Filed 3-13-01; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301106; FRL-6766-9]

RIN 2070-AB78

Pymetrozine; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of pymetrozine in or on pecans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pecans. This regulation establishes a maximum permissible level for residues of pymetrozine in this food commodity.