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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0141; FRL–7364–1]

Acequinocyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of acequinocyl, 2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione, and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, expressed as acequinocyl equivalents in or on almond; almond, hulls; apple, wet pomace; citrus, oil; fat and liver of cattle, goat, horse, and sheep; fruit, citrus, group 10; fruit, pome, group 11; pistachio; and strawberry. Arvesta Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective July 21, 2004. Objections and requests for hearings must be received on or before September 20, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP–2004–0141. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Marilyn Mautz, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6785; e-mail address:*mautz.marilyn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of February 25, 2004 (69 FR 8645) (FRL–7344–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 2F6440 and 3F6596) by Arvesta Corporation, 100 First St., Suite 1700, San Francisco, CA 94105. That notice included a summary of the petitions prepared by Arvesta Corporation, the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the insecticide acequinocyl, 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate, and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone (acequinocyl-OH), expressed as acequinocyl equivalents, in or on the listed commodities as follows:

PP 2F6440: Fruit, pome group at 0.4 parts per million (ppm); apple, wet pomace at1.0 ppm; fruit, citrus, group at 0.3 ppm; orange, oil at 30 ppm; almond and pistachio at 0.01 ppm; almond, hulls at 1.5 ppm; cattle, meat and kidney at 0.01 ppm; cattle, liver and fat at 0.02 ppm; and milk at 0.01 ppm.

PP 3F6595: Strawberries at 0.4 ppm

The petition, PP 2F6440, was subsequently amended to: Increase the tolerances for almond and pistachio from 0.01 ppm to 0.02 ppm; increase the tolerance for almond hulls from 1.5 ppm to 2.0 ppm; to decrease the tolerance for citrus fruit group from 0.3 ppm to 0.20 ppm; add separate tolerances for fat and liver of goat, horse and sheep; withdraw the proposed tolerances for milk, and meat and kidney of cattle; and to correct the terms for certain commodities as summarized in the Table 1 of this unit.

The almond and pistachio tolerances were increased to account for the combined limit of quantification (LOQ) of the residue analytical method for the parent and its metabolite. The LOQ for each one is 0.01 ppm in/on each plant and livestock commodity, with the exception of citrus oil, where the LOQ for each one is 0.5 ppm. The withdrawal of the proposed milk, kidney and meat commodities and the addition of other livestock commodities are based on the results of the submitted cattle feeding study.

In addition, the chemical name is corrected from 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate to 2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione to be consistent with the nomenclature used in the *Chemical Abstracts Chemical Substance Index*, published by the American Chemical Society.

TABLE 1.—TOLERANCE SUMMARY

Commodity	Proposed tolerance (in ppm)	Amended (in ppm)	Correct commodity term
Almond	0.01	0.02	
Almond, hulls	1.5	2.0	
Apple, wet pomace	1.0		
Cattle, fat	0.02		
Cattle, kidney	0.01	Withdrawn	
Cattle, liver	0.02		
Cattle, meat	0.01	Withdrawn	
Fruit, citrus, group	0.3	0.20	Fruit, citrus, group 10
Fruit, pome group	0.4	0.40	Fruit, pome, group 11
Goat, fat		0.02	
Goat, liver		0.02	
Horse, fat		0.02	
Horse, liver		0.02	
Milk	0.01	Withdrawn	
Orange, oil	30		Citrus, oil
Pistachio	0.01	0.02	
Sheep, fat		0.02	
Sheep, liver		0.02	
Strawberries	0.4	0.40	Strawberry

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of acequinocyl and its metabolite, acequincyl-OH, on almond, pistachio, and the liver and fat of cattle, horse, goat, and sheep at 0.02 ppm; almond hulls at 2.0 ppm; wet apple pomace at 1.0 ppm; citrus fruit crop group 10 at 0.20 ppm; citrus oil at 30 ppm; and pome fruit crop group 11 and strawberry at 0.40 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

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 acequinocyl are discussed in Table 2 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study type	Results
870.3100	90-Day oral toxicity—rodents; mouse	NOAEL = Male/Female (M/F); 16/21 milligrams/kilogram/day (mg/kg/day) LOAEL = M/F; 81/100 mg/kg/day based on hepatocyte vacuolation
870.3100	90-Day oral toxicity—rodents; rat	NOAEL = M/F; 30.4/32.2 mg/kg/day LOAEL = M/F; 119.5/129.2 mg/kg/day based on increased prothrombin times in males and increased activated partial thromboplastin times in both sexes
870.3150	90-Day oral toxicity—nonrodents	NOAEL = M/F; 40/40 mg/kg/day LOAEL = M/F; 160/160 mg/kg/day based on decreased body weight gains and reduced food efficiencies in males and for female beagle dogs based on increased platelet counts
870.3200	21/28-Day dermal toxicity	Systemic NOAEL = 200 mg/kg/day Systemic LOAEL = 1,000 mg/kg/day based on increased clotting factor times Dermal NOAEL= 1,000 mg/kg/day Dermal LOAEL not established
870.3700	Prenatal developmental—rodents	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 500 mg/kg/day based on signs of internal hemorrhage and increased incidence of clinical signs (pale eyes, piloerection, red vaginal discharge) Developmental NOAEL = 500 mg/kg/day Developmental LOAEL = 750 mg/kg/day based on increased resorptions
870.3700	Prenatal developmental—nonrodents	Maternal NOAEL = 60 mg/kg/day Maternal LOAEL = 120 mg/kg/day based on treatment-related clinical signs leading to premature sacrifice (hematuria, reduced fecal output, body weight loss, and reduced food consumption) and gross necropsy findings (pale lungs and liver, hemorrhaging uterus, fluid in the cecum, fur in the stomach, blood stained vaginal opening, blood-stained urinary bladder contents/urine, and hair loss) Developmental NOAEL = 60 mg/kg/day Developmental LOAEL =120 mg/kg/day based on increased number of complete resorptions
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = M/F; 7.3/134 mg/kg/day Parental/Systemic LOAEL = Males; 58.9 mg/kg/day based on increased incidences of hemorrhagic effects in F_1 males. Parental/Systemic LOAEL was not established for females Reproductive NOAEL = M/F; 124/136 mg/kg/day Reproductive LOAEL = was not established Offspring NOAEL = M/F; 7.3/8.7 mg/kg/day Offspring LOAEL = M/F; 58.9/69.2 mg/kg/day based on hemorrhagic effects, swollen body parts, protruding eyes, clinical signs, delay in pupil development, and increased mortality post weaning
870.4100	Chronic toxicity—dogs	NOAEL = M/F; 80/80 mg/kg/day LOAEL = M/F; 320/320 mg/kg/day based on premature sacrifice (inappetence, body weight loss)
870.4300	Combined chronic/carcinogenicity—rats	NOAEL = M/F; 2.25/46.20 mg/kg/day LOAEL = M/F; 9.02/93.56 mg/kg/day based on enlarged eyeballs in male and female rats (coagulopathy) No evidence of carcinogenicity
870.4300	Combined chronic/carcinogenicity—mouse	NOAEL = M/F; 2.7/3.5 mg/kg/day LOAEL = M/F; 7.0/8.7 mg/kg/day based on clinical chemistry and microscopic non-neoplastic lesions (brown pigmented cells and perivascular inflammatory cells in liver) No evidence of carcinogenicity
870.5100	Gene mutation	There was no evidence of induced mutant colonies over background
870.5300	Gene mutation	There was no clear evidence of biologically significant induction of mutant colonies over background
870.5375	Chromosome aberration	There was no evidence of chromosome aberrations induced over background
870.5395	Mammalian erythrocyte micronucleus test in mice	There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or harvest time

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study type	Results
870.7485	Metabolism and pharmacokinetics	Acequinocyl exhibits marginal absorption, relatively rapid and complete excretion primarily via the bile and feces, and undergoes nearly complete metabolism to hydrolysis products and a glucuronide conjugate. There was no evidence for selective tissue accumulation or sequestration of acequinocyl or its metabolites in rats
870.7600	Dermal penetration	Percent of dose absorbed decreased with exposure concentration indicating that saturation of absorption at/or about the high dose. Absorption at 168 hours was 12.23%, 19.75%, and 14.77% for the 0.1, 0.01, and 0.001 mg/centimeter squared (cm^2 dose groups, respectively

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or 1 in 10 million (1×10^{-7}). 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 acequinocyl used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ACEQUINOCYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any iraditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Acute dietary	Not applicable	None	An endpoint of concern attributable to a single dose was not identified. An aRfD was not established

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ACEQUINOCYL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure scenario	Dose used in risk assessment, interspecies and intraspecies and any iraditional UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Chronic dietary (all populations)	NOAEL = 2.7 UF = 100X cRfD = 0.027	FQPA SF = 1X [1] cPAD = 0.027	18-month carcinogenicity study in mice; LOAEL = 7.0 mg/kg/day based on clinical chemistry and microscopic nonneoplastic lesions (brown pigmented cells and perivascular inflammatory cells in liver)

NOTE: UF = uncertainty factor; FQPA SF = special FQPA safety factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (c = chronic) RfD = reference dose.
[1] cPAD = cRfD÷FQPA SF.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* There are no tolerances established for residues of acequinocyl. Risk assessments were conducted by EPA to assess dietary exposures from acequinocyl 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 one-day or single exposure.

An acute exposure assessment is unnecessary because no such effect was seen in the submitted studies.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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: Tolerance-level residues, DEEM™ ver. 7.76 default processing factors, and 100 percent crop treated (%CT) data were used in the chronic dietary assessment.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for acequinocyl 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 acequinocyl.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 acequinocyl they are further discussed on the aggregate risk in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of acequinocyl for chronic exposures are estimated to be 0.24 parts per billion (ppb) for surface water and 0.003 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).

Acequinocyl is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to acequinocyl and any other substances and acequinocyl 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 acequinocyl 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of FFDCA 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 database on toxicity and exposure unless EPA determines based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to acequinocyl. And, there is no qualitative and/or quantitative evidence of increased susceptibility to acequinocyl following pre/postnatal exposure in a 2-generation reproduction study in rats. There is no concern for developmental neurotoxicity resulting from exposure to acequinocyl; a DNT study is not required.

There is an apparent qualitative increase in susceptibility in the rat and rabbit developmental studies as indicated by increases in resorptions that occurred at the same or higher dose that caused maternal toxicity, but the concern is low since:

- The fetal effects were noted in the presence of maternal toxicity.
- There are no residual uncertainties for pre- and/or postnatal toxicity since the database is complete.

Effects that could be indicative of neurotoxicity were shown in two studies, the 2-generation reproduction study and the subchronic rat oral toxicity study. In the 2-generation reproduction study, significant reduction in startle response in F2 pups was observed in high-dose groups (58.9/69.2 mg/kg/day and 111.2/133.5 mg/kg/day). In the subchronic rat oral toxicity study, neurotoxicity signs such as decreased motor activity, piloerection, and hunched posture were noted at the high dose 252.7/286.0 mg/kg/day.The concern is low since:

- EPA considered these effects as secondary as they were observed at very high doses.
- Other functional development tests (such as pupillary reflex test at 21 days post partum, an open field exploration test at 35–48 days post partum and a water-maze test with a learning phase and a memory phase at 35–48 days post partum) that were performed on pups did not show significant differences as compared to control values even at the highest dosage level.
- Acequinocyl is a known Vitamin K antagonist; neurotoxic compounds of similar structure were not identified.

3. *Conclusion*. There is a complete toxicity database for acequinocyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

In evaluating whether to retain the 10X SF to protect infants and children or to select a different safety factor, EPA considered the following factors:

i. There are no special concerns regarding pre- or postnatal toxicity exposure.

ii. The exposure databases (food and drinking water) are complete and/or employ conservative assumptions.

iii. There is no residential exposure.

iv. The risk assessments cover or approximate all the metabolites and degradates of concern.

v. The assessments do not underestimate the potential risk for infants and children.

vi. The toxicity database is complete.

Therefore, it is concluded that 1X is adequate to protect infants and children.

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 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 (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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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*. Acequinocyl is not expected to pose an acute risk because no acute effects were observed in the submitted studies.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acequinocyl from food will utilize 4.2% of the cPAD for the U.S. population, 14% of the cPAD for all infants less than 1 year old, and 23 % of the cPAD for children 1-2 years old. There are no residential uses for acequinocyl that result in chronic residential exposure to acequinocyl. In addition, there is potential for chronic dietary exposure to acequinocyl 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 Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO ACEQUINOCYL

Population subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.027	4.2	0.24	0.003	910
All infants ≤1year old	0.027	14	0.24	0.003	230
Children 1–2 years old	0.027	23	0.24	0.003	210
Children 3–5 years old	0.027	15	0.24	0.003	230
Children 6– 12 years old	0.027	6.5	0.24	0.003	250
Youth 13–19 years old	0.027	3.2	0.24	0.003	780
Adults 20–49 years old	0.027	2.1	0.24	0.003	920
Females 13–19 years old	0.027	2.3	0.24	0.003	790
Adults 50+ yeas old	0.027	2.4	0.24	0.003	920

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

Acequinocyl 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. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Acequinocyl 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.

5. *Aggregate cancer risk for U.S. population*. Acequinocyl is classified as not likely to be carcinogenic to humans and thus is not expected to pose a cancer risk.

6. *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 acequinocyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Method validation data support the following two plant methods and a livestock method: A high-performance liquid chromatography (HPLC)/mass spectrometry (MS)/MS method (Morse Laboratories Method #Meth–133, revision #3) for determining residues of acequinocyl and acequinocyl-OH in/on fruit commodities; an HPLC/MS/MS method (Morse Laboratories Method #Meth–135) for determining residues of acequinocyl and acequinocyl-OH in/on almonds hulls and nut meats; and an HPLC/MS/MS method (Morse Laboratories Method #Meth–139, Revision #2) for determining residues of acequinocyl and acequinocyl-OH in fat, milk, meat, and meat-by-products.

Methods #Meth–135 and #Meth–133, Revision #3 have each undergone successful independent laboratory validation (ILV) trials. An ILV is not required for Method #Meth–139, Revision#2 because the aforementioned ILV's should be sufficient to cover this method based on the similarity of all three methods.

Based on the available method validation data, these methods are adequate for collecting residue data in/on livestock commodities, milk, pome and citrus fruit commodities, strawberries, and tree nuts. Additional confirmatory methods for plants and livestock and specificity testing of the analytical enforcement methods for plants and livestock are required as conditions of registration. The validated LOQ for both acequinocyl and acequinocyl-OH is 0.01 ppm in/on each plant and livestock commodity, with the exception of citrus oil. The LOQ for each analyte in citrus oil is 0.5 ppm.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for acequinocyl.

C. Conditions

The following information must be submitted as conditions for product registration related to these tolerances: the registrant will be required to submit additional confirmatory enforcement analytical methods and specificity testing for plants and livestock; a confined rotational crop study; and a new livestock storage stability study.

V. Conclusion

Therefore, the tolerances are established for combined residues of acequinocyl and its metabolite 2-dodecyl-3-hydroxy-1,4-naphthoquinone expressed as acequinocyl equivalents, in or on almond, pistachio, and fat and liver of cattle, goat, horse and sheep at 0.02 ppm; on almond hulls at 2.0 ppm; wet apple pomace at 1.0 ppm; fruit, citrus, group 10 at 0.2 ppm; citrus oil at 30 ppm; and fruit, pome, group 11 and strawberry at 0.40 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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 ID number OPP–2004–0141in 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 September 20, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th Street NW, Washington, DC. 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) 5646255–.

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 20460–0001.

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 20460–0001.

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 PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0141, 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 20460–0001. In person or by courier, bring a copy to the location of PIRIB described in **ADDRESSES**. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 special considerations 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* (62 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 section 408(d) of FFDCA, 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* (64 FR 43255, August 10, 1999). 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 section 408(n)(4) of FFDCA. 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. Congressional Review Act

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: July 1, 2004.

James Jones,

Director, 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), 346a and 371.

■ 2. Section 180.599 is added to subpart C to read as follows:

§ 180.599 Acequinocyl; tolerances for residues.

(a) *General.* Tolerances for combined residues of the insecticide acequinocyl, 2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione, and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, expressed as acequinocyl equivalents in or on the following commodities:

Commodity	Parts per million
Almond	0.02
Almond, hulls	2.0
Apple, wet pomace	1.0
Cattle, fat	0.02
Cattle, liver	0.02
Citrus, oil	30
Fruit, citrus, group 10	0.20
Fruit, pome, group 11	0.40
Goat, fat	0.02
Goat, liver	0.02
Horse, fat	0.02
Horse, liver	0.02
Pistachio	0.02
Sheep, fat	0.02
Sheep, liver	0.02
Strawberry	0.40

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–16213 Filed 7–20–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 04–2059; MB Docket No. 02–124; RM–10446]

Radio Broadcasting Services; Amboy, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of KHWY, Inc., allots Channel 237A at Amboy, California, as the community's first local FM service. Channel 237A can be allotted to Amboy, California, in compliance with the Commission's minimum distance separation requirements with a site restriction of 7.4 km (4.6 miles) northeast of Amboy. The coordinates for Channel 237A at Amboy, California, are 34–26–00 North Latitude and 115–40–52 West Longitude. The Mexican government has concurred in this allotment. A filing window for Channel 237A at Amboy, California, will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent Order.

DATES: Effective August 23, 2004.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 02–124, adopted June 30, 2004, and released July 8, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *www.bcpiweb.com.*

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.