ephemeral reproductions of sound recordings.

DATES: *Effective Date:* January 1, 2017.

Applicability Dates: These rates are applicable to the period January 1, 2017, through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Kimberly Whittle, Attorney Advisor, by telephone at (202) 707–7658 or by email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Sections 112(e) and 114(f) of the Copyright Act, title 17 of the United States Code, create statutory licenses for certain digital performances of sound recordings and the making of ephemeral reproductions to facilitate transmission of those sound recordings. On May 2, 2016, the Copyright Royalty Judges (Judges) adopted final regulations governing the rates and terms of copyright royalty payments under those licenses for the license period 2016–2020 for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. *See* 81 FR 26316.

Pursuant to those regulations, at least 25 days before January 1 of each year, the Judges shall publish in the **Federal Register** notice of a COLA applicable to the royalty fees for performances of sound recordings via eligible transmissions by commercial and noncommercial noninteractive webcasters. 37 CFR 380.10(a)(1)–(2).

The adjustment in the royalty fee shall be based on a calculation of the percentage increase in the CPI–U from the CPI–U published in November 2015 (237.838),[1] according to the formula (1 + $(C_y - 237.838)/237.838) \times R_{2016}$, where C_y is the CPI–U published by the Secretary of Labor before December 1 of the preceding year and R_{2016} is the royalty rate for 2016 (*i.e.,* $0.0022 per subscription performance or $0.0017 per nonsubscription performance). The adjustment shall be rounded to the nearest fourth decimal place. 37 CFR 380.10(c) (as revised herein). The CPI–U published by the Secretary of Labor from the most recent index published before December 1, 2016, is 241.729.[2] Applying the formula in 37 CFR 380.10(c) and rounding to the nearest fourth decimal place results in no adjustment in the rates for 2017.

The 2017 rate for eligible transmission of sound recordings by commercial webcasters remains unchanged at a rate of $.0022 per subscription performance and $.0017 per nonsubscription performance.

Application of the formula to rates for noncommercial webcasters results in an unchanged rate of $.0017 per performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

As provided in 37 CFR 380.1(d), the royalty fee for making ephemeral recordings under section 112 of the Copyright Act to facilitate digital transmission of sound recordings under section 114 of the Copyright Act is included in the section 114 royalty fee and comprises 5% of the total fee.

List of Subjects in 37 CFR Part 380

Copyright, Sound recordings.

Final Regulations

In consideration of the foregoing, the Judges amend part 380 of title 37 of the Code of Federal Regulations as follows:

PART 380—RATES AND TERMS FOR TRANSMISSIONS BY ELIGIBLE NONSUBSCRIPTION SERVICES AND NEW SUBSCRIPTION SERVICES AND FOR THE MAKING OF EPHEMERAL REPRODUCTIONS TO FACILITATE THOSE TRANSMISSIONS

■ 1. The authority citation for part 380 continues to read as follows:

Authority: 17 U.S.C. 112(e), 114(f), 804(b)(3).

■ 2. Section 380.10 is amended by:

■ a. Revising paragraph (a).

■ b. In paragraph (c), removing ''237.336'' wherever it appears and adding in its place ''237.838''.

The revision reads as follows:

§ 380.10 Royalty fees for the public performance of sound recordings and the making of ephemeral recordings.

(a) *Royalty fees.* For the year 2017, Licensees must pay royalty fees for all Eligible Transmissions of sound recordings at the following rates:

(1) *Commercial Webcasters:* $0.0022 per performance for subscription services and $0.0017 per performance for nonsubscription services.

(2) *Noncommercial webcasters.* $500 per year for each channel or station and $0.0017 per performance for all digital audio transmissions in excess of 159,140 ATH in a month on a channel or station.

* * * * *

Dated: November 29, 2016.

Suzanne M. Barnett,

Chief Copyright Royalty Judge.

[FR Doc. 2016–29019 Filed 12–2–16; 8:45 am]

BILLING CODE 1410–72–P

[1] The current regulations erroneously state that 237.336 was the CPI–U published in November 2015. That was actually the CPI–U *for* November 2015 that was published in December 2015. See *BLS News Release—Consumer Price Index November 2015, available at http://www.bls.gov/news.release/archives/cpi_12152015.pdf.* The correct figure for this part of the calculation is 237.838 because it was the CPI–U *published in* November 2015. *See BLS News Release—Consumer Price Index November 2015, available at http://www.bls.gov/news.release/archives/cpi_11172015.pdf.* The Judges have corrected the figure in text of the regulations published herein.

[2] As announced on November 17, 2016, by the Bureau of Labor Statistics in its *News Release—Consumer Price Index October 2016, available at http://www.bls.gov/news.release/pdf/cpi.pdf.*

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0439; FRL–9954–33]

Tau-Fluvalinate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tau-fluvalinate in or on wine grapes. Makhteshim Agan of North America, Inc., d/b/a ADAMA requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2016. Objections and requests for hearings must be received on or before February 3, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0439, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0439 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 3, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0439, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8362) by Makhteshim Agan of North America, Inc., d/b/a ADAMA, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180.427 be amended by establishing a tolerance for residues of the insecticide/miticide tau-fluvalinate in or on wine grapes at 1.0 parts per million (ppm). That document referenced a summary of the petition prepared by Makhteshim Agan of North America, Inc., d/b/a ADAMA, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 for tau-fluvalinate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tau-fluvalinate 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.

Tau-fluvalinate is a member of the pyrethroid class of insecticides. Pyrethroids have historically been classified into two groups, Type I and Type II, based on chemical structure and toxicological effects. Tau-fluvalinate is a Type II pyrethroid. Neurotoxicity was observed throughout the database and clinical signs characteristic of Type II pyrethroids, such as excessive salivation, tremors, pawing, abnormal stance, excessive lacrimation, bulging eyes, ruffling, excessive grooming, vocalization and hyperactivity followed by hypoactivity were seen. Other observed neurotoxic effects included decreased rearing, forelimb grip strength and body temperature, heightened sensitivity to pain, and impaired motor, autonomic, and sensorimotor function.

No increased prenatal susceptibility was observed following developmental toxicity studies in the rat or rabbit. Tau-fluvalinate did not have an effect on fetal development in the prenatal developmental study in rats. In the prenatal developmental study in rabbits, maternal and fetal effects were seen at the highest dose tested. Developmental effects included skeletal anomalies, a lower implantation efficiency, higher incidence of resorption and concurrent lower fetal viability. Maternal effects involved anorexia and general depression. The qualitative susceptibility seen during the prenatal developmental study in rabbits is secondary to maternal toxicity and occurs at the same dose. Evidence of quantitative post-natal sensitivity was

observed in the 2-generation reproduction study in rats. Under the conditions of this study, both the F_1 and F_2 litters experienced tremors during lactation and decreased pup and litter weight in both litters while no effects were noted in the adult animals. However, when considered in the context of the totality of the database, a different pattern emerges regarding this apparent lifestage sensitivity. It appears that the postnatal sensitivity seen in the reproduction study reflects the limited evaluation of adult animals as well as the potential for greater pup exposure through both milk and feed rather than a specific lifestage sensitivity. There are on-going efforts to develop methods to investigate the possibility of increased sensitivity of juvenile rats to pyrethroids as a class at doses near the lowest observed adverse effect level (LOAEL) values. Pending receipt of the additional data, the Agency has conducted an assessment using the available guideline and literature studies. This approach is consistent with assessments performed for other pyrethroid pesticides.

A dermal assessment was not conducted based on the lack of systemic toxicity in the rabbit dermal study at the limit dose and the low potential for dermal absorption. These findings are consistent with the toxicology profile of many pyrethroids. In an acute inhalation neurotoxicity study, neurotoxic effects were observed in the functional observational battery (FOB) including decreased rearing, forelimb grip strength and body temperature in females. This route-specific study provides a robust endpoint for the inhalation route of exposure and was used to estimate human inhalation risks. The standard interspecies extrapolation uncertainty factor is reduced from 10X to 3X due to the human equivalent concentration (HEC) calculation accounting for pharmacokinetic (not pharmacodynamic) interspecies differences. However, due to the lack of a clear no- observed-adverse-effect-level (NOAEL) in the acute inhalation neurotoxicity study, an additional 10X is added to extrapolate a NOAEL from a lowest-observed-adverse-effect-level (LOAEL). The 10X intraspecies factor is also applied. The total uncertainty factor for inhalation exposure is 300X for adults and children >6 years of age. The total inhalation uncertainty factor for children ≤6 years of age is 1,000X since the Food Quality Protection Act safety factor (FQPA SF) of 3X applies.

There was no evidence of carcinogenicity in the combined chronic gavage/carcinogenicity study in rats or the carcinogenicity study in mice. In a battery of mutagenicity studies, there was no evidence of a mutagenic effect.

Specific information on the studies received and the nature of the adverse effects caused by tau-fluvalinate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Tau-fluvalinate. Human Health Risk Assessment for Registration Review and for Establishment of a Tolerance with No U.S. Registrations for Residues in Wine Grapes'' on page 52 in docket ID number EPA–HQ–OPP–2015–0439.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

The database of tau-fluvalinate toxicology studies is complete and provides a robust characterization of the hazard potential for children and adults. In addition to the standard guideline studies, numerous studies from the scientific literature that describe the pharmacodynamic (PD) and pharmacokinetic (PK) profile of the pyrethroids in general have been considered in EPA's assessment. Tau-fluvalinate is rapidly absorbed following an oral dose, and effects are typically observed within the first several hours after dosing. For pyrethroids, as a class, the combination of rapid absorption, metabolism, and elimination precludes accumulation and increased potency following repeated dosing. This is also true of tau-fluvalinate. However, the combined chronic gavage/carcinogenicity neurotoxicity study is more appropriate for point of departure (POD) selection than the acute oral studies, because it is more sensitive. This is likely due to the lower doses tested, and the lower gavage volume used to administer tau-fluvalinate. While acute neurotoxic effects are the most sensitive effects observed in the toxicity database, neurotoxic effects attributable to chronic exposure to tau-fluvalinate have not been identified. The clinical signs in the combined chronic gavage/carcinogenicity neurotoxicity study disappeared each day prior to the next dosing and did not progress in severity across time. This POD is the most protective within the database and will be protective of the acute neurotoxic effects seen in the acute, subchronic and 2-generation reproduction studies in the rat. All exposure durations for the tau-fluvalinate risk assessment are assessed as single-day exposures.

A summary of the toxicological endpoints for tau-fluvalinate used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TAU-FLUVALINATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Children < 6 years old).	NOAEL = 1.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 3x	Acute RfD = 0.01 mg/kg/day. aPAD = 0.003 mg/kg/day.	Combined chronic gavage/carcinogenicity study. LOAEL = 2.5 mg/kg/day. Clinical signs of neurotoxicity including excessive salivation, pawing, abnormal stance, excessive lacrimation, ruffling and hyperactivity followed by hypoactivity.
Acute dietary (Adults and children ≥ 6 years old).	NOAEL = 1.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.01 mg/kg/day. aPAD = 0.01 mg/kg/day.	Combined chronic gavage/carcinogenicity study. LOAEL = 2.5 mg/kg/day. Clinical signs of neurotoxicity including excessive salivation, pawing, abnormal stance, excessive lacrimation, ruffling and hyperactivity followed by hypoactivity.
Chronic dietary (All populations)	Neurotoxic effects, the most sensitive effects observed in the toxicity database, attributable to chronic exposure to tau-fluvalinate have not been identified (neurotoxic effects do not progress over time).		
Inhalation short-term (1 to 30 days).	Inhalation study LOAEC= 20 mg/m^3. UF_A = 3x UF_H = 10x $UF_{L=}$ 10x FQPA SF= 3x (Children <6 years old) FQPA SF= 1x (Adults and children ≥6 years old)	LOC for MOE = 1,000 (Children <6 years old). LOC for MOE = 300 (Adults and children ≥6 years old).	Acute inhalation study. LOAEL = 20 mg/m^3 (LDT). Increased glucose levels and decreased body temperature, rearing and forelimb grip strength in females in addition to soiled fur appearance.
Cancer (Oral, dermal, inhalation).	Tau-fluvalinate has been classified as not likely to be a human carcinogen.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tau-fluvalinate, EPA considered exposure under the petitioned-for tolerances as well as all existing tau-fluvalinate tolerances in 40 CFR 180.427. EPA assessed dietary exposures from tau-fluvalinate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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.

Such effects were identified for tau-fluvalinate. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) 2003–2008 National Health and Nutrition Survey/What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all registered and proposed commodities.

ii. *Chronic exposure.* Neurotoxic effects, the most sensitive effects observed in the toxicity database, attributable to chronic exposure to tau-fluvalinate have not been identified (neurotoxic effects do not progress over time); therefore, a quantitative chronic aggregate risk assessment was not conducted.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that tau-fluvalinate does not pose a cancer hazard to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for tau-fluvalinate. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* As a class of chemicals, the pyrethroids have low water solubility and a high affinity to bind to soils. Given these physical/chemical properties, it is unlikely that dietary exposure from drinking water will be a major pathway of exposure. The existing beehive use and use on wine grapes grown outside of the U.S. will not result in tau-fluvalinate entering drinking water sources. However, the outdoor, non-food uses (including carrots and *Brassica*/cole crops grown for seed, ornamentals and building perimeters) could potentially result in residues in surface or ground water. The limit of water solubility, 2.4 ppb, is used for tau-fluvalinate as an upper-bound estimated drinking water concentration (EDWC) for this assessment.

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). Tau-fluvalinate is currently registered for the following uses that could result in residential exposures: Outdoor residential settings including outside surfaces (crack and crevice), ant mound treatments (spot application) and use on roses, flowers, houseplants, ground covers, vines, ornamentals, shrubs and trees. EPA assessed residential exposure

using the following assumptions: Because a dermal hazard was not identified for tau-fluvalinate, only inhalation exposures were assessed for handlers. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios: (1) Applying ready-to-use (RTU) spray for use on gardens/trees, flowers, and ornamentals; (2) Mixing/loading/applying liquids with pump sprayer/hose-end sprayer for use on gardens/trees, flowers, and ornamentals; (3) Mixing/loading/applying liquids with manually pressurized handwand for use on gardens/trees, flowers, and ornamentals; (4) Mixing/loading/applying liquids with backpack for use on gardens/trees, flowers, and ornamentals; (5) Mixing/loading/applying liquids with a sprinkler can for use on gardens/trees, flowers, and ornamentals; and (6) Applying RTU spray to spot or crack and crevice treatment outdoors.

Although there is potential for post-application exposure to individuals as a result of being in an environment that has been previously treated with tau-fluvalinate, post-application inhalation exposure is anticipated to be negligible due to the combination of low vapor pressure for tau-fluvalinate and the expected dilution in outdoor air. In addition, because no dermal POD was selected for tau-fluvalinate (*i.e.,* there is no dermal hazard), a quantitative residential dermal post-application exposure assessment was not performed.

Post-application non-dietary ingestion exposure was also not quantitatively assessed for young children. Unlike treated grass at home or in recreational areas or indoor floor surfaces, for the tau-fluvalinate registered outdoor uses (*e.g.,* flowers, trees, crack and crevice), the potential for exposure via non-dietary ingestion for young children is greatly diminished. Since the extent to which young children engage in the types of activities associated with these areas (*e.g.,* gardening) or utilize these areas for prolonged periods of play is low, significant non-dietary ingestion exposure is not expected.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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.''

The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity *http://www.regulations.gov;* EPA–HQ–OPP–2008–0489–0006. The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment (CRA) for the pyrethroids/pyrethrins was published on November 9, 2011 and is available at *http://www.regulations.gov;* EPA–HQ–OPP–2011–0746. No cumulative risks of concern were identified, allowing the agency to consider new uses for pyrethroids. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to *http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html.*

Tau-fluvalinate was included in the 2011 pyrethroid CRA. In the cumulative assessment, residential exposure was the greatest contributor to the total exposure. There are currently registered tau-fluvalinate products for outdoor residential uses that have not been previously assessed and were not included in the CRA. In order to determine if the currently registered tau-fluvalinate residential uses will significantly contribute to or change the overall findings in the pyrethroid CRA, the Agency performed a quantitative cumulative screening assessment. This assessment used the currently registered application rates for tau-fluvalinate along with the previous assumptions as used in the 2011 CRA (*i.e.,* unit exposures, body weight, and the relative potency factor (RPF) for tau-fluvalinate). The resulting exposures were then compared to the pyrethroid CRA index point of departure (index POD) to calculate the screening MOEs. These screening MOEs were then be directly compared to the MOEs that were calculated in the CRA. If the screening MOEs are similar to, or are greater than, the CRA MOEs, then it can be concluded that any currently registered residential uses will not have an impact on the pyrethroid CRA.

The outdoor garden uses resulting in the highest residential exposures for tau-fluvalinate are selected for the screening assessment (specifically, the backpack sprayer and RTU hose-end sprayer garden scenarios). As there is no post-application inhalation or child incidental oral exposures expected from the garden uses, and there is no dermal hazard for tau-fluvalinate, it is only necessary to perform an adult handler inhalation assessment.

The resulting screening MOEs (adult handler) for tau-fluvalinate garden backpack and hose end sprayer scenarios are 1,300,000 and 61,000, respectively. In the CRA, the garden risk driver was identified as the tau-fluvalinate backpack use and the MOE for that scenario was 1,300. However, since the 2011 CRA, it has been determined that there is no dermal hazard for tau-fluvalinate. With the dermal exposures removed, that MOE would now be 780,000 and would no longer be considered the highest risk driver. Therefore, the next highest risk driver for the CRA garden scenario is used which is the cypermethrin backpack use with a total MOE of 1,400. Since the screening MOEs (1,300,000 and 260,000) are much greater than the CRA MOE (1,400), it can be concluded that the currently registered tau-fluvalinate residential uses will not significantly impact the overall findings in the 2011 pyrethroid CRA.

Dietary exposures make a minor contribution to the total pyrethroid exposure. The dietary exposure assessment performed in support of the pyrethroid cumulative was much more highly refined than that performed for the single chemical. The proposed tolerance for residues of tau-fluvalinate on imported wine grape will make an insignificant contribution to dietary risk to the pyrethroids as a whole.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* After reviewing the extensive body of peer-reviewed literature on pyrethroids, the Agency has no residual uncertainties regarding age-related sensitivity for women of child bearing age as well as for all adult populations and children >6 years of age, based on the absence of pre-natal sensitivity observed in 76 guideline studies for 24

pyrethroids and the scientific literature. Additionally, no evidence of increased quantitative or qualitative susceptibility was seen in the pyrethroid scientific literature related to PD. The Agency is retaining a 3X FQPA Safety Factor to protect for exposures of children ≤6 years of age based on the increased quantitative susceptibility seen in studies on pyrethroid PKs and the increased quantitative juvenile susceptibility observed in high dose studies in the literature.

Although sensitivity was observed in the 2-generation reproduction study, there is a clear NOAEL for the effects (tremors), and the PODs selected for risk assessment are 10-fold lower than where sensitivity was observed, and are therefore protective. When considered within the context of the totality of the database, EPA believes that the apparent sensitivity in the multi-generation reproduction toxicity study in rats is a reflection of the study's design rather than a lifestage sensitivity *per se.* In addition, the LOAELs from the maternal rat prenatal developmental study and the offspring 2-generation reproduction study are ~10 mg/kg/day. There is no sensitivity observed across the rat prenatal developmental and 2-generation reproduction studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for adults and the general population and 3X to protect for exposures of children ≤6 years of age based on the increased quantitative susceptibility seen in studies on pyrethroid PKs and the increased quantitative juvenile susceptibility observed in high dose studies in the literature. That decision is based on the following findings:

i. The toxicology database is adequate for the evaluation of risks to infants and children. Acceptable studies include: Rat and rabbit developmental toxicity studies, a rat multi-generation reproduction study and chronic toxicity/carcinogenicity studies in mice and rats. In addition, acceptable acute (non-guideline) and subchronic (guideline) neurotoxicity studies in the rat are adequate to evaluate the neurotoxicity of tau-fluvalinate.

EPA is making best use of the extensive scientific knowledge about the adverse outcome pathway of pyrethroids in the risk assessments for this class of pesticides. In this way, information on a subset of pyrethroids can be used to help interpret and understand the toxicological profile for other members of the class. In that regard, a group of pesticide registrants and product formulators known as the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) has been conducting multiple experiments with permethrin and deltamethrin as model Type I and Type II compounds, respectively, in order to develop an initial extensive database of *in vitro* and *in vivo* toxicology studies and highly refined physiologically-based pharmacokinetic (PBPK) models. In light of the literature studies indicating a possibility of increased sensitivity in juvenile rats at high doses, the agency is expecting additional *in vitro* and *in vivo* data to help elucidate the biological processes underlying the juvenile sensitivity reported in the peer reviewed literature. In 2010, the agency requested proposals for study protocols that could identify and quantify potential juvenile sensitivity and received a single response from the Pyrethrin and Pyrethroids Technical Working Group (PPTWG), a conglomerate of pyrethroid registrants. The PPTWG protocol has been reviewed, the initial study proposal was refined, and the CAPHRA submitted its updated research. Currently, the CAPHRA is continuing to: (1) Develop rat and human PBPK models, including additional PK data, and (2) conduct *in vivo* behavioral testing using auditory startle testing in rats and plans to submit additional data to the agency. For the reasons discussed in Unit III.D.2., the uncertainty regarding the protectiveness of the intraspecies uncertainty factor raised by the literature studies and the absence of the requested data warrant application of an additional 3X for risk assessments for infants and children under 6 years of age.

ii. As with other pyrethroids, tau-fluvalinate causes neurotoxicity from interaction with sodium channels leading to clinical signs of neurotoxicity. Neurotoxicity was observed in several of the toxicity studies for the active ingredient; however, concern is low, because the selected endpoints are protective of the observed effects. The effects are well characterized and adequately assessed by the available guideline and non-guideline studies.

iii. There were no indications of fetal toxicity in the rat developmental toxicity study. In the rabbit developmental toxicity study, there were fetotoxic effects, as indicated by a lower implantation efficiency, higher incidence of resorption and concurrent lower fetal viability in the high-dose group. However, effects were likely secondary to maternal toxicity at the same dose (125 mg/kg/day). There were signs of post-natal sensitivity in the tau-fluvalinate 2-generation reproduction study in rats. The parental generation did not experience any systemic effects up to the highest dose tested, where there were tremors during lactation in both F_1 and F_2 litters, as well as decreased pup body and litter weights in both generations. The degree of concern for these effects in infants is low, because the offspring effects have clearly defined NOAELs/LOAELs and the POD selected for risk assessment is protective of these effects.

iv. There are no residual uncertainties in the exposure database. Dietary exposures to tau-fluvalinate are estimated using tolerance level residues and 100 PCT. The high-end EDWC for tau-fluvalinate is based on the limit of solubility in water. Adequate exposure data are available to assess the residential exposures. These assessments will not underestimate the exposure and risks posed by tau-fluvalinate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tau-fluvalinate will occupy 20% of the aPAD for adults 50 to 99 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Based on the data summarized in Unit III.A., there is no increase in hazard with increasing dosing duration. Furthermore, chronic dietary exposures will be lower than acute exposures. Therefore, the acute aggregate assessment is protective of potential chronic aggregate exposures.

3. *Short-term risk.* Tau-fluvalinate is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to tau-fluvalinate.

An Aggregate Risk Index (ARI) approach was used to aggregate the

dietary and residential (inhalation) exposures since the levels of concern are not the same for those exposures (100 and 300, respectively). Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate ARI of 74 for adults. Because EPA's level of concern for tau-fluvalinate is an ARI of 1 or below, this ARI is not of concern.

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

Because no intermediate-term adverse effect was identified, tau-fluvalinate is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, tau-fluvalinate is not expected to pose a cancer risk to humans.

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, or to infants and children from aggregate exposure to tau-fluvalinate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Acceptable methods are available for enforcement and data collection purposes for both plant and animal commodities. The Pesticide Analytical Manual (PAM) Volume II lists Method I, a GC method with electron capture detection (ECD), for the enforcement of tolerances for fluvalinate in/on plant and animal commodities.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for tau-fluvalinate.

C. Revisions to Petitioned-For Tolerances

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of tau-fluvalinate not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, a tolerance is established for residues of tau-fluvalinate, in or on grape, wine at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), 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).

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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: November 10, 2016.

Michael Goodis,

Acting 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), 346a and 371.

■ 2. In § 180.427:

■ a. Revise the introductory text in paragraph (a); and

■ b. Add alphabetically the entry ''Grape, wine'' and footnote 1 to the table in paragraph (a).

The additions and revisions read as follows:

§ 180.427 Tau-Fluvalinate; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide tau-fluvalinate, including its metabolites and degradates, in or on commodities in the table below. Compliance with the specified tolerance level is to be determined by measuring only tau-fluvalinate, (cyano-(3-phenoxyphenyl)methyl*N*-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate), in or on the commodity.

Commodity	Parts per million
Grape, wine [1]	1.0
* * * * *	

[1] There is no U.S. registration for use of tau-fluvalinate on wine grapes.

* * * * *

[FR Doc. 2016–29111 Filed 12–2–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0049; FRL–9954–69]

Oxathiapiprolin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of oxathiapiprolin in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation amends the established tolerance for vegetable, tuberous and corm, subgroup 1C; and removes existing tolerances for *Brassica,* head and stem, subgroup 5A, and leafy greens subgroup 4A that are superseded by this action. Interregional Research Project Number 4 (IR–4), E.I. du Pont de Nemours & Company (DuPont), and Syngenta Crop Protection, LLC (Syngenta) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2016. Objections and requests for hearings must be received on or before February 3, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0049, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0049 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 3, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0049, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL–9944–86) and May 19, 2016 (81 FR 31581) (FRL–9946–02), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PPs) by DuPont (PP# 5F8435); Interregional Research Project Number 4 (PP# 5E8437) and Syngenta (PP# 5F8441), respectively.

The petition, 5F8437, requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-