ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0431; FRL–9402–4]

Endothall; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of endothall in or on apple and apple, pomace. United Phosphorus, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 18, 2013. Objections and requests for hearings must be received on or before February 18, 2014, 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–2012–0431, 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), EPA West 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: Lois Rossi, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 703–305–5447; email address: *Rossi.Lois@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–2012–0431 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 18, 2014. 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–2012–0431, 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.htm.*

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 July 25, 2012 (77 FR 43562) (FRL–9353–6), 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 2F8023) by United Phosphorus, Inc., 630 Freedom Business Center, Suite 402 King of Prussia, PA 19406. The petition requested that 40 CFR 180.293 be amended by establishing tolerances for residues of the herbicide, endothall, mono (N,N-dimethylalkylamine) salt of endothall, and the dipotassium salt of endothall, in or on apples at 0.05 parts per million (ppm), and apple, pomace at 0.15 ppm. That document referenced a summary of the petition prepared by United Phosphorus, Inc., the registrant, which is available in the docket, EPA–HQ–OPP–2012–0431 at *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed definition for apple pomace to ''apple, wet pomace'' and updated the current tolerance expression so that metabolites and degradates of endothall are included. The reasons for these changes are explained in Unit IV.D.

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 endothall including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with endothall 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.

Endothall is a caustic chemical with toxicity being the result of a direct degenerative effect on tissue. By acute exposure, endothall is a skin sensitizer and an extreme irritant by the acute oral and ocular routes of administration. The most sensitive effect of endothall following chronic oral administration is direct irritation of the gastrointestinal system. This effect was evident in several species and in several studies. The dog is particularly sensitive to endothall toxicity. Endothall caused gastric epithelial hyperplasia in dogs treated with an oral dose of 6.5 mg/kg/day for 52 weeks (a dose level that was one order of magnitude lower than doses associated with clinical signs of toxicity (subdued behavior, poor condition, thin appearance and distended abdomen). Besides gastric irritant effects, decreased body weight in the dog was also a sensitive effect following 13 weeks of endothall administration. The decreased body weights were most likely attributable to the constant and direct irritation of the gastric lining. In the rat, gastric irritation was noted at a dose level that was 1 to 2 orders of magnitude lower than doses resulting in kidney lesions. Proliferative lesions of the gastric epithelium were observed in F1 parental male and female rats treated orally with 2 mg/kg/day endothall in a 2-generation reproduction study (a NOAEL was not identified). In a developmental rat study, pregnant rats exhibited decreased body weight and decreased body weight was also noted in a 90-day dietary study in the rat.

Dermally, endothall destroys the stratum corneum and then the underlying viable epidermis. In the 21-day dermal rat study, systemic toxicity (hematology and clinical chemistry alterations) was noted at a dose level that was one order of magnitude greater than that causing dermal irritation. Available studies clearly demonstrate that local irritation (portal of entry effect) is the most sensitive and initial effect, occurring at dose levels lower than those associated with systemic toxicity.

Acute inhalation toxicity of endothall is low; however, nasal and pulmonary toxicity were evident in the 5-day and 28-day inhalation toxicity studies in the rat including rales, labored respiration, pale lungs (gross necropsy), increased absolute and relative lung weights, subacute inflammation, alveolar proteinosis, and nasal hemorrhage inflammation, erosion, and ulceration.

Endothall does not cause pre-natal toxicity following *in utero* exposure to rats nor pre-and postnatal toxicity following exposures to rats for two generations. In the developmental mouse study, there was severe maternal toxicity (i.e., greater than 30% mortality) at the highest dose tested; at this dose level, a slight increase in vertebral and rib malformations was observed in the offspring indicating that these effects were most likely secondary to severe maternal toxicity. The hazard data for endothall indicate no evidence of quantitative or qualitative increased susceptibility of rat fetuses exposed *in utero* to endothall in the developmental toxicity studies. In addition, no evidence of quantitative or qualitative increased susceptibility of rat fetuses or neonates was observed in the 2-generation reproduction study.

Available studies showed no evidence of neurotoxicity and do not indicate potential Immunotoxicity. Endothall does not belong to the class of compounds (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system. Endothall is classified as ''not likely to be carcinogenic to humans'' based on lack of evidence of carcinogenicity in mice or rats. It has no mutagenic potential.

Specific information on the studies received and the nature of the adverse effects caused by endothall 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 document ''Endothall. Human Health Risk Assessment to support proposed Use on Apples'' at 30–34 in docket ID number EPA–HQ–OPP–2012–0431.

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://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for endothall used for human risk assessment is shown in Table 1.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ENDOTHALL 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 (General population including Females 13–50 years of age, infants and children).	An appropriate endpoint attributable to a single dose was not available from any study, including the prenatal development toxicity study in rats. An acute RfD was not established.		
Chronic dietary (All populations)	LOAEL = 2 mg/kg/day (NOAEL not determined). UF = 300x FQPA SF = 3x	Chronic RfD = 0.007 mg/kg/day cPAD = 0.007 mg/kg/day	Rat 2-generation reproduction study proliferative lesions of the gastric epithelium (both sexes)
Incidental oral short-term (1 to 30 days).	Offspring NOAEL = 9.4 mg/kg/day.	Residential LOC for MOE = 100.	Rat 2-generation reproduction study LOAEL = 60 mg/kg/day based on decreased pup body weight (both sexes) on Day 0 F_1 and F_2 generations Body Weights were also similarly decreased in the dams throughout the study.
Dermal short-term (1 to 30 days) And Intermediate-term (1 to 6 months).	In the 21 day dermal toxicity study, severe dermal effects were observed at 30 mg/kg/day (lowest dose tested). The NOAEL for dermal irritation was not established due to Erythema, edema and fissuring and sloughing off of skin at the lowest tested (30 mg/kg/day) endothall is caustic dermally because it is an acid. Since undiluted endothal is so toxic at the portal of entry (e.g., skin), quantification of systemic toxicity and risk is not necessary to show that direct exposure to endothall poses unacceptable risk. Protection against any potential dermal effects from direct exposure is addressed with precautionary labeling recommending the use of gloves and other personal protection which limits contact of the material with the handler's body. The 30 mg/kg/day dose from the 21 day dermal study was used as a point of reference in assessing potential risk to swimmers from dermal exposure.		
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL = 0.001 mg/kg/day (inhalation absorption rate = 100%). UF_A = 3x^{c}x UF_H = 10xx FQPA SF = 1x	LOC for MOE = 30	Subchronic inhalation toxicity study LOAEL = 0.005 based on clinical signs (rales and labored respiration) observed acutely (0–1 hr post dosing and prior to next exposure).
Cancer (Oral, dermal, inhalation).	Classified as a "Not Likely" 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_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to endothall, EPA considered exposure under the petitioned-for tolerances as well as all existing endothall tolerances in 40 CFR 180.293. EPA assessed dietary exposures from endothall 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.

No such effects were identified in the toxicological studies for endothall; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FID) Version 3.16 which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), conducted from 2003–2008. As to residue levels in food, EPA used average percent crop treated (PCT) estimates for endothall, average field trial residues for all existing and new uses, and DEEM 7.81 default and crop specific processing factors and conservative drinking water estimates to obtain accurate residue data.

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

iv. *Percent crop treated (PCT) information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for new and existing uses as follows: Apple 62%, apple fresh market 76%, apple processing 37%, apple juice 40%, barley for grain 36%, corn for grain 19%, dry beans 32%, grape 95%, grape fresh market 99%, grape processing 94%, green peas 43%, oats for grain 7%, peanut for nuts 42%, rice 100%, sorghum for grain 15%, soybean for beans 9%, strawberry 90%, strawberry fresh market 88%, strawberry processing 100%, sugar beet for sugar 37%, sugarcane for sugar 54%, watermelon 33%, and wheat for grain 14%.

Because endothall will be applied to water in irrigation canals, EPA estimates the percent crop treated for endothall by estimating the percent of the crop that is irrigated. This will serve as an upper bound for crops that may be exposed to endothall in irrigation water. EPA uses two methods to estimate percent crop irrigated. The first method, where data on irrigated production is available, is an estimate of the share of total production that is irrigated. Estimates from this method are provided for barley, corn, dry edible beans, oats, peanuts, rice, sorghum, soybeans, sugar beets, sugarcane, and wheat. For these crops, data on irrigated production is from the 2007 Census of Agriculture. Where data on irrigated production are not available, EPA estimates the percent crop irrigated by determining the percentage of United States production of a crop that is grown in 17 western states where endothall may be used. The 17 western states are Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming. These states are the states where large scale water projects are predominate, and where other chemicals are used in canals for weed control. These types of irrigation projects are relatively rare in other parts of the country. Data on the share of the crop grown in the 17 western states are from USDA/NASS data.

These estimates are conservative because they are the equivalent of assuming 100% of irrigated crops are irrigated with water from endothall-treated canals. This assumption is being made despite the fact that all irrigation canals may not be treated with endothall, even in some areas with surface water delivery systems and other areas with crops (even in the heavily irrigated areas of the West), not being irrigated.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition A, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions B and C, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which endothall may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for endothall in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of endothall. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Simple First-Order Degradation the estimated drinking water concentrations (EDWCs) of endothall for chronic exposures for non-cancer assessments are estimated to be 31 ppb for surface water and ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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). A product containing endothall is currently registered for uses that could result in residential exposures which include aquatic applications on ponds, lakes and garden pools. There is a potential for exposure from registered uses for homeowners who apply endothall products to control aquatic weeds and algae in ponds and garden pools. For residential handlers, exposure scenarios are only considered to be short-term in nature due to the episodic uses associated with homeowner products. There is also a potential for exposure to adults and children from contacting water treated with endothall through swimming, wading, water skiing, etc. Only short-term exposures are expected since these scenarios are expected to be only episodic.

Endothall registered use patterns and current labeling indicate three likely residential handler exposure scenarios: (1) applying granules by hand for treating garden pools, (2) applying granules by cup for treating ponds and lakes, and (3) applying granules by spoon for treating ponds and lakes. For post-application exposures, the Agency quantitatively assessed inhalation and incidental oral (water ingestion) from the aquatic use (adult and children). Since endothall is caustic dermally because it is an acid the Agency determined quantification of systemic toxicity and risk resulting from dermal exposure is not appropriate. Though swimmers could be exposed to endothall, EPA did not conduct a formal quantitative assessment for this scenario because the maximum concentration of endothall in swimming water is 5 ppm, and this dilutes out very rapidly. In comparison, in the dermal toxicity study, the concentration that caused irritation was substantially higher (2000 ppm). Therefore exposures to endothall in water would not likely result in any irritation to the skin. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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.''

EPA has not found endothall to share a common mechanism of toxicity with any other substances, and endothall does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that endothall does not have 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

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.* There was no indication of increased susceptibility of rats or mice *in utero* and or postnatal exposure in the developmental and reproductive toxicity 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 3X. That decision is based on the following findings:

i. The toxicity database for endothall is complete, with the exception of the immunotoxicity study, which is a toxicology data requirement of the revised 40 CFR Part 158. However, endothall does not belong to the class of compounds (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system and the available studies showed no evidence of potential immunotoxicity.

ii. There is no indication that endothall is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that endothall results in increased susceptibility *in utero* in rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties in the endothall database in regard to dietary (food and drinking water) and residential exposures. Though the chronic dietary exposure and risk assessment was partially refined by using percent crop treated data, the dietary food assessment is still very conservative since field trial rather than monitoring data were used as the residue input, and default as well as measured processing factors were used for some commodities. Also, the drinking water inputs were based on modeled surface water values from the scenario which provides the highest estimated environmental concentration and will not underestimate chronic exposure to residues of endothall present in drinking water. Residential exposure estimates are based on conservative, health-protective assumptions that also ensure exposures are not underestimated.

v. Although all of the above factors support the conclusion that removal of the FQPA factor would be safe for children, an additional 3X FQPA factor is being retained because a LOAEL established in the two-generation reproduction study was used for assessing chronic dietary risks. A 3X factor (as opposed to a 10X) was determined to be adequate since the severity of the lesions were minimal to mild indicating that LOAEL did not far exceed the NOAEL.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and therefore no acute dietary endpoint was selected. Endothall is not expected to pose an acute dietary risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to endothall from food and water will utilize 90% of the cPAD for infants (1–2 years old) which is the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of endothall is not expected.

3. *Short-term risk:* Short-term aggregate exposure takes into account adult and children's post-application inhalation and oral exposure (from swimming in water bodies treated with endothall) combined with the chronic dietary exposure from the mostly highly exposed adult (General US population) and children's (all children 1–2 years old) subpopulations respectively, to determine aggregate exposure and risk. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to endothall.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that combined short-term food, water, and residential exposures result in aggregate MOEs of 1200 and 210 for the most highly exposed subgroups of adults and children, respectively.

Because EPA's level of concern for endothall is a MOE of 100 or below, these MOEs are not of concern. As discussed in Unit III.C.3., the risk to swimmers from dermal exposure to endothall is very low.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC with microcoulometric nitrogen detection and a confirmatory HPLC/MSD method) is available to enforce the tolerance expression.

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

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 endothall.

C. Response to Comments

There were no comments on the petition to establish endothall tolerance on apples and apple pomace. The comment posted in the Endothall Docket, *EPA–HQ–OPP–2012–0431–0005* was published within the incorrect docket and is irrelevant to this action.

D. Revisions to Petitioned-For Tolerances

The proposed commodity definition for apple pomace is being revised to ''apple, wet pomace'' to reflect the Agency's correct commodity definition. In addition EPA is revising the tolerance expression in 40 CFR 180.293(a)(1) for food commodities to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerances cover ''residues of endothall, including its metabolites and degradates,'' and that compliance with the tolerance levels will be determined, for food commodities, by measuring only endothall (7-oxabicyclo [2.2.1] heptanes-2,3-dicarboxylic acid) and its mono-methyl ester. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the legal effect of tolerances as Provided in FFDCA section 408(a)(3).

V. Conclusion

Therefore, tolerances are established for residues of endothall and its mono-methyl ester, in or on apple at 0.05 ppm and apple, wet pomace at 0.15 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 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.*), 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: December 9, 2013.

Lois Rossi,

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 § 180.293 revise paragraph (a)(1) introductory text and add, alphabetically, the following commodities to the table to read as follows:

§ 180.293 Endothall; tolerances for residues.

(a) *General.* (1) Tolerances are established for the residues of endothall, including its metabolites and degradates, in or on the commodities in the table, below. Compliance with the tolerance levels specified, below, is to be determined by measuring only endothall (7-oxabicylco [2.2.1] heptanes-2,3-dicarboxylic acid) and its mono-methyl ester.

Commodity	Parts per million
Apple	0.05
Apple, wet pomace	0.15
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