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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0086; FRL-9343-3]

Acibenzolar-*S*-methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of acibenzolar-*S*-methyl in or on berry, low growing, subgroup 13-07G. The Interregional Research Project No. 4 (IR-4) requested the tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0086. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket

at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I 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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, go to: *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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-2011-0086 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0086, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 6, 2011 (76 FR 39358) (FRL-8875-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E7818) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, in or on low growing berry subgroup 13-07G at 0.15 parts per million (ppm), and by amending the tolerance expression to read, "tolerances are established for residues of acibenzolar-*S*-methyl,

benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, including its metabolites and degradates, in or on the commodity(s) listed. Compliance with the tolerance level is to be determined by measuring only those acibenzolar-*S*-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-*S*-methyl. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*.

One comment on the notice of filing was received. EPA's response to this comment is discussed in Unit IV.C.

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 acibenzolar-*S*-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acibenzolar-*S*-methyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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.

Acibenzolar-*S*-methyl showed no significant toxicity in a battery of acute toxicity tests. Considerable skin sensitizing (contact allergenic) potential was demonstrated in a dermal sensitization study in guinea pigs.

In subchronic and chronic oral studies in rats, dogs and mice, signs of mild regenerative hemolytic anemia were consistently observed in all three species. Additional toxic effects observed in these same studies included decreases in body weight, body weight gain and/or food consumption. In a 28-day dermal study in rats, no systemic or dermal effects were observed at dose levels up to 1,000 milligrams/kilogram/day (mg/kg/day), the limit dose. No neurotoxic effects were observed at any dose in a subchronic neurotoxicity study in rats.

Prenatal and postnatal toxicity data are available including developmental toxicity studies in rats and rabbits, a developmental neurotoxicity (DNT) study in rats, and a 2-generation reproduction toxicity study in rats. Based on the developmental toxicity in

rats and the developmental neurotoxicity studies in rats, there is concern for increased qualitative and/or quantitative susceptibility following *in utero* exposure to acibenzolar-*S*-methyl. In the rat developmental toxicity study, treatment related visceral malformations and skeletal variations were observed in fetuses at 200 mg/kg/day, the no observed adverse effect level (NOAEL) for maternal toxicity. In the developmental neurotoxicity study, offspring toxicity was observed at 82 mg/kg/day while no maternal toxicity was observed at 326 mg/kg/day, the highest dose tested (HDT). Additional developmental toxicity studies in rats and rabbits and reproduction studies in rats provided no indication of increased susceptibility of rat or rabbit fetuses or neonates compared to adult animals. In a dermal developmental toxicity study in rats, no maternal or developmental toxicity was observed at dose levels up to 500 mg/kg/day, the HDT.

Acibenzolar-*S*-methyl was classified by the Agency as "not likely" to be a human carcinogen based on negative carcinogenicity studies in male and female rats and mice and generally negative results in an acceptable battery of mutagenicity studies.

An immunotoxicity study required as part of new 40 CFR part 158 data requirements for registration of a pesticide has been submitted and is being reviewed by the Agency. Based on a preliminary review, the study is acceptable and indicates no evidence of immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by acibenzolar-*S*-methyl as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Acibenzolar-*S*-methyl Human Health Risk Assessment for Proposed Use of Acibenzolar-*S*-methyl on Low Growing Berries Crop

Subgroup 13-07G, dated February 23, 2012", on pages 28-33 in docket ID number EPA-HQ-OPP-2011-0086-0007.

B. Toxicological Points of Departure (POD)/Levels of Concern (LOC)

Once a pesticide's toxicological profile is determined, EPA identifies toxicological POD and LOC 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 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 acibenzolar-*S*-methyl used for human risk assessment is shown in the following table.

Table – Summary of Toxicological Doses and Endpoints for Acibenzolar-*S*-methyl for Use in Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population)	NOAEL = 8.2 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	aRfD = 0.082 mg/kg/day aPAD = 0.082 mg/kg/day	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal LOAEL = was not observed NOAEL = 326.2 mg/kg/day HDT
Chronic Dietary (Females 13-49 years & Young Children)	NOAEL = 8.2 mg/kg/day	UF_A= 10x. UF_H=10x FQPA SF= 1x	aRfD = 0.082 mg/kg/day aPAD = 0.082 mg/kg/day	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal LOAEL = was not observed NOAEL = 326.2 mg/kg/day HDT
Chronic Dietary (Adult Males and Females 50+ yrs)	NOAEL = 25 mg/kg/day	UFA= 10x UFH=10x FQPA SF= 1x	cRfD = 0.25 mg/kg/day cPAD = 0.25 mg/kg/day	Chronic Toxicity - Dog; Co-critical; Chronic/Cancer - Rat & Mouse, Reproduction Toxicity - Rat LOAEL = 105 mg/kg/day based on hemolytic anemia with compensatory response.
Incidental Oral	NOAEL = 8.2 mg/kg/day	UFA =10x UFH= 10x	Occupational LOC for MOE= 100	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal LOAEL = was not observed NOAEL = 326.2 mg/kg/day HDT

Dermal Short (1-30 days) and Intermediate (1-6 months) Term DAF = 40%	NOAEL= 8.2 mg/kg/day	UF_A= 10x UF_H=10x	Occupational LOC for MOE = 100	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal LOAEL = was not observed NOAEL = 326.2 mg/kg/day HDT
Inhalation Short (1-30 days) and Intermediate (1-6 months) Term	NOAEL= 8.2 mg/kg/day	UF_A= 10x UF_H=10x	Occupational LOC for MOE = 100	Developmental Neurotoxicity Toxicity - Rat Developmental LOAEL = 82 mg/kg/day based on changes in brain morphometrics in the cerebellum in offspring. Maternal LOAEL = was not observed NOAEL = 326.2 mg/kg/day HDT
Cancer (all routes)	A "not likely" human carcinogen			

Point of Departure = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DAF = Dermal Absorption Factor. Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure (100% absorption factor). mg/kg/day = milligram/kilogram/day. HDT = highest dose tested.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to acibenzolar-*S*-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing acibenzolar-*S*-methyl tolerances in §180.561. EPA assessed dietary exposures from acibenzolar-*S*-methyl 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 acibenzolar-*S*-methyl. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA performed a refined (probabilistic) acute dietary exposure analysis for the general population and all population subgroups. The acute analysis assumed a distribution of residues based on field trial data. Empirical and Dietary Exposure Evaluation Model (DEEM) default processing factors were used to modify the field trial data. Maximum screening-level percent crop treated (PCT) estimates were used for commodities for which data were available. If no PCT data were available, 100 PCT was assumed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, the chronic analysis incorporated tolerance level residues and 100 PCT assumptions were used. DEEM default and empirical processing factors were used to modify the tolerance values.

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

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of

pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

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. EPA did not use PCT data in assessing chronic exposure.

2. *Dietary exposure from drinking water*. The residues of concern for drinking water are acibenzolar-*S*-methyl, benzo(1,2,3) thiadiazole-7-carbothioic acid-*S*-methyl

ester, convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007). The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acibenzolar-*S*-methyl and CGA-210007 in drinking water. These simulations models take into account data on the physical, chemical, and fate/transport characteristics of acibenzolar-*S*-methyl. 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 Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of acibenzolar-*S*-methyl and CGA-210007 for acute exposures are estimated to be 0.72 and 20.02 parts per billion (ppb), respectively, for surface water and 0.0000125 and 0.0812 ppb, respectively, for ground water. EDWCs of acibenzolar-*S*-methyl and CGA-210007 for chronic exposures for non-cancer assessments are estimated to be 0.02 and 8.09 ppb, respectively, for surface water and 0.0000125 and 0.0812 ppb, respectively, for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. CGA-210007 drinking water residues were included in the dietary exposure assessment as acibenzolar-*S*-methyl equivalents. CGA 210007 residues were converted to acibenzolar-*S*-methyl equivalents based on molecular weight (MW), i.e., (MW of acibenzolar (210) ÷ MW of CGA 210007 (180) x EDWC for CGA 210007). The acute analysis incorporated the entire time distribution of estimated drinking water concentrations adjusted to account for CGA-210007. For chronic dietary risk

assessment, the water concentration of value 9.44 ppb was used to assess the contribution of CGA 210007 to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acibenzolar-*S*-methyl is currently registered for the following uses that could result in residential exposures: Turfgrass use on sodfarms, golf courses, collegiate athletic fields, and lawns around commercial and industrial buildings. Residential exposure was assessed for adult handlers and for adult and child post-application activities. Exposure for adult and child golfers was used to aggregate adult post-application dermal exposure with dietary and drinking water exposure. The aggregate exposure assessment for children combines dermal and incidental oral post-application exposure with food and water exposure. 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 acibenzolar-*S*-methyl to share a common mechanism of toxicity with any other substances, and acibenzolar-*S*-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance

action, therefore, EPA has assumed that acibenzolar-*S*-methyl 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 website 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicity database for acibenzolar-*S*-methyl includes adequate developmental toxicity studies in rats and rabbits, a DNT study in rats, and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A., several of these studies indicate that the young are quantitatively and qualitatively more sensitive to acibenzolar-*S*-methyl. Nonetheless, there are no residual uncertainties with regard to prenatal and/or postnatal toxicity since the NOAELs and the LOAELs have been identified for all effects of concern, a clear dose response has been well defined, and the PODs selected for risk assessment are protective of the fetal/offspring effects.

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. That decision is based on the following findings:

i. The toxicity database for acibenzolar-*S*-methyl is complete except for finalization of EPA's review of an immunotoxicity study. Recent changes to 40 CFR part 158 require immunotoxicity testing (OPPTS Guideline 870.7800) for pesticide registration and tolerance establishment. An immunotoxicity study has been submitted to EPA and is currently under review. The study is acceptable and preliminary review results show no evidence of immunotoxicty. In the absence of a completed assessment of the immunotoxicity study at this time, EPA evaluated available acibenzolar-*S*-methyl toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. There are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by acibenzolar-*S*-methyl and acibenzolar-*S*-methyl does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Therefore, EPA does not believe that the ultimate findings of the submitted immunotoxicity study will result in a POD lower than those already selected for acibenzolar-*S*-methyl risk assessment, and an additional database uncertainty factor is not needed to account for the lack of this study.

ii. There is concern for increased qualitative and/or quantitative susceptibility following *in utero* exposure to acibenzolar-*S*-methyl based on developmental toxicity and developmental neurotoxicity studies in rats. However, for the reasons noted above, the degree of concern for the increased susceptibility seen in these studies is low.

iii. There are no residual uncertainties identified in the exposure databases. The dietary risk assessment is conservative and will not underestimate dietary and/or non-dietary residential exposure to acibenzolar-*S*-methyl. The acute analysis assumed a distribution of residues based on field trial data and maximum PCT estimates were used for commodities for which data were available. The chronic dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acibenzolar-*S*-methyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acibenzolar-*S*-methyl.

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 acibenzolar-*S*-methyl will occupy 35% of the aPAD for children 3-5 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acibenzolar-*S*-methyl from food and water will utilize 11% of the cPAD for children 1-2 and children 3-5 years old, the population groups receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acibenzolar-*S*-methyl is not expected.

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

Acibenzolar-*S*-methyl 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 acibenzolar-*S*-methyl.

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 aggregate MOEs of 700 for females 13-49 years old from handler activities, and 1,600 for females 13-49 years old, and 800 - 1,000 for children 1-2 and 6-12 years old, respectively, from post-application exposure. Because EPA's LOC for acibenzolar-*S*-methyl is a MOE of 100 or below, these short-term aggregate MOEs are 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).

An intermediate-term adverse effect was identified; however**,** acibenzolar-*S*-methyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for acibenzolar-*S*-methyl**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acibenzolar-*S*-methyl 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 acibenzolar-*S*-methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High-performance liquid chromatography with ultraviolent detection (HPLC/UV) Method AG-617A) is available to enforce the tolerance expression. This method has undergone a successful tolerance method validation by the Agency.

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 acibenzolar-*S*-methyl in or on berry, low growing, subgroup 13-07G.

C. Response to Comments

One comment was received from a private citizen who opposed authorization by EPA to allow "all of these toxic chemicals since this Agency does not test their reaction with thousands of other chemicals that are already present……."

The Agency has received this same comment on numerous previous occasions. Refer to **Federal Register** of January 7, 2005, 70 FR 1349 for the Agency's response to this comment.

V. Conclusion

Therefore, a tolerance is established for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, including its metabolites and degradates, in or on the berry, low growing, subgroup 13-07G at 0.15 ppm. Compliance with the tolerance level specified is to be determined by measuring only those acibenzolar-*S*-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-*S*-methyl.

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) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report

to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 27, 2012

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. Section 180.561 is amended by revising paragraph (a) to read as follows:

§ 180.561 Acibenzolar-*S*-methyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of acibenzolar-*S*-methyl, benzo(1,2,3)thiadiazole-7-carbothioic acid-*S*-methyl ester, 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 those acibenzolar-*S*-methyl residues convertible to benzo(1,2,3)thiadiazole-7-carboxylic acid (CGA-210007), expressed as the stoichiometric equivalent of acibenzolar-*S*-methyl, in or on the following raw agricultural commodities.

Commodity	Parts per million
Banana[1]	0.1
Berry, low growing, subgroup 13-07G	0.15
Onion, bulb, subgroup 3-07A	0.1
Spinach	1.0
Tomato, paste	3.0
Vegetable, brassica, leafy, group 5	1.0
Vegetable, cucurbit, group 9	2.0
Vegetable, fruiting, group 8	1.0
Vegetable, leafy, group 4	0.25

[1]There are no United States registrations for banana.

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