

## Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

## Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

## Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

## Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human

environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule fits the category selected from paragraph (34)(g), as it establishes a temporary security zone for a limited period of time.

An environmental analysis checklist and a categorical exclusion determination are available and accessible in the docket as indicated in the **ADDRESSES** section.

## List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.06–1, 6.05–6 and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Section 165.T08–040 is added to read as follows:

### § 165.T08–040 Moving Security Zone, Escorted Vessels.

(a) *Location.* The following areas are security zones: Navigable waters of the Lower Mississippi River, from mile marker 90.0 to mile marker 110.0, extending 300 yards in all directions of escorted vessels. Escorted vessels will be escorted by one or more Coast Guard assets or other federal, state, or local law enforcement agency assets clearly identifiable by lights, vessel markings, or with agency insignia.

(b) *Effective period.* This rule is effective May 23, 2012 through August 15, 2012. Beginning April 1, 2012 this rule is enforced through actual notice.

(c) *Regulation.* (1) Under the general regulations in § 165.33 of this part, vessels are prohibited from entering or transiting the security zones described in paragraph (a) of this temporary section, § 165.T08–040.

(2) If granted permission to enter a security zone, a vessel must operate at the minimum speed necessary to maintain a safe course, unless required to maintain speed by the Navigation Rules, and shall proceed as directed by the Coast Guard. When within the security zone, no vessel or person is allowed within 50 yards of the escorted vessel unless authorized by the Coast Guard.

(3) Persons or vessels requiring deviations from this rule must request permission from the Captain of the Port New Orleans through the on-scene Coast Guard or other agency asset, via VHF Ch. 67 or the Coast Guard Vessel Traffic Center at (504) 365–2230.

(4) All persons and vessels granted permission to enter a security zone must comply with the instructions of the Captain of the Port New Orleans and designated personnel. Designated personnel include commissioned, warrant and petty officers of the U.S. Coast Guard, and local, state, and federal law enforcement officers on clearly identified law enforcement agency vessels.

(d) *Informational broadcasts.* The Captain of the Port or a designated representative will inform the public through marine safety information bulletins or broadcast notices to mariners of this regulation.

Dated: April 1, 2012.

**John J. Arenstam,**

*Captain, U.S. Coast Guard, Acting, Captain of the Port New Orleans.*

[FR Doc. 2012–12313 Filed 5–22–12; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2011–0674; FRL–9349–3]

### Acibenzolar- S -methyl; Time-Limited Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of acibenzolar-S-methyl in or on grapefruit, apples and pears. Syngenta Crop Protection LLC. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 23, 2012. Objections and requests for hearings must be received on or before July 23, 2012, 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–2011–0674, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA

West, 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:** Rose Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-5611; email address: [kearns.rosemary@epa.gov](mailto:kearns.rosemary@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](http://ecfr.gpoaccess.gov/cgi/t/text/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-2011-0674 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 July 23, 2012. 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-2011-0674, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 2822T, 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 September 7, 2011 (76 FR 55331) (FRL-8886-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition 1G7889 by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.561 be amended by establishing temporary tolerances for residues of the fungicide, acibenzolar-S-methyl, in or on apples,

grapefruit and pears 0.05 parts per million (ppm) in conjunction with approval of an experimental use permit. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure 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 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.

General information on the toxicity of acibenzolar-S-methyl can be found in a recent tolerance rulemaking for this pesticide in the **Federal Register** of April 11, 2012 (77 FR 21670) (FRL-

9343–3). Specific information on the studies received and the nature of the adverse effects caused by acibenzolar-S-methyl 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 “Acibenzolar-S-methyl Human Health Risk Assessment,” on page 15 in docket ID number EPA–HQ–OPP–2011–0674.

#### *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 Acibenzolar-S-Methyl used for human risk assessment is shown in the recent tolerance rulemaking document for acibenzolar-S-methyl in the **Federal Register** of April 11, 2012 (77 FR 21670).

#### *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 40 CFR 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 assumed a distribution of residues based on field trial data and tolerance level residues for apple, grapefruit and pear. 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, EPA used a conservative chronic dietary exposure analysis for the general U.S. population and various population subgroups. Tolerance level residues and 100 crop treated 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 certain conditions are met. PCT data was not used for conducting the chronic dietary risk assessment.

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) in drinking water. These simulation model 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 the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of acibenzolar-S-methyl for acute exposures are estimated to be 45 parts per billion (ppb) for surface water and 0.08 ppb for ground water, for chronic exposures for non-cancer assessments are estimated to be 19.1 ppb for surface water and 0.08 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 45 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 19.1 ppb was used to assess the contribution 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 were 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 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 Food Quality Protection Act Safety Factor (FQPA 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.* The toxicology database for acibenzolar-S-methyl is complete and adequate for assessing increased susceptibility under FQPA. The pre- and postnatal toxicity database for acibenzolar-S-methyl includes developmental toxicity studies in rats and rabbits, a 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. However, the degree of concern for the increased susceptibility seen in these studies is low as there are no residual uncertainties with regard to pre- and/or postnatal toxicity since NOAELs and 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. Additionally, the dietary and residential risk assessments are conservative and will not underestimate dietary exposure and there are no residual uncertainties in the exposure database.

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.
- ii. 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, tolerance level residues for the Experimental Use Permit (EUP) uses 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 water 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. 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 37% 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 12% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for acibenzolar-S-methyl. 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 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 level of concern 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 pattern 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 at least one 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.

Because no intermediate-term adverse effect was identified, acibenzolar-S-methyl 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, 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 using ultra-violet detection ((HPLC/UV) Method AG–617A) 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](mailto: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 U.N. 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.

There are no established Codex, Mexican, or Canadian maximum residue

limits for acibenzolar-S-methyl in/on any commodity. Therefore, international harmonization is not an issue for acibenzolar-S-methyl.

#### V. Conclusion

Therefore, time-limited tolerances are established for residues of acibenzolar-S-methyl, in or on apple, grapefruit and pear at 0.05 ppm. A time limitation been imposed because these tolerances are being established in conjunction with approval of an EUP to use acibenzolar-S-methyl on apple, pear and grapefruit. The EUP approval period and time-limited tolerances will expire 12/31/2015 which provides ample time for all treated crops to be harvested, stored, and out of channels of trade.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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 section 408(n)(4) of FFDCA. 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) (Pub. L. 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: May 14, 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 as follows:

- a. Redesignate paragraph (a) as (a)(1); and
  - b. Add paragraph (a)(2).
- The amendments read as follows:

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

(a) *General.*

(1) \* \* \*

(2) 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	Expiration/revocation date
Apple .....	0.05	12/31/2015
Grapefruit .....	0.05	12/31/2015
Pear .....	0.05	12/31/2015

\* \* \* \* \*

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BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0014; FRL-9349-1]

#### 1,2-Ethanediamine, N1-(2-aminoethyl)-, polymer with 2, 4-diisocyanato-1-methylbenzene; Tolerance Exemption

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of 1,2-ethanediamine, N1-(2-aminoethyl)-, polymer with 2,4-diisocyanato-1-methylbenzene, when used as an inert ingredient in a pesticide chemical formulation. ICR, Inc., on behalf of Triton Systems, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1,2-ethanediamine, N1-(2-aminoethyl)-, polymer with 2,4-diisocyanato-1-methylbenzene on food or feed commodities.

**DATES:** This regulation is effective May 23, 2012. Objections and requests for hearings must be received on or before July 23, 2012, 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-2012-0014, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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:** Anthony Britten, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-8179; email address: [britten.anthony@epa.gov](mailto:britten.anthony@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this action apply to me?

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

- Crop production (NAICS 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 provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may access a frequently updated electronic version of 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](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

###### C. 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-2012-0014 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 July 23, 2012. 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-2012-0014, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line 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. Background and Statutory Findings

In the **Federal Register** of April 4, 2012 (77 FR 20334) (FRL-9340-4), EPA