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:


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-carboxylic 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.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Banana</td>
<td>0.1</td>
</tr>
<tr>
<td>Berry, low growing subgroup</td>
<td>0.15</td>
</tr>
<tr>
<td>Onion, bulb, subgroup 3–07A</td>
<td>0.1</td>
</tr>
<tr>
<td>Spinach</td>
<td>1.0</td>
</tr>
<tr>
<td>Tomato, paste</td>
<td>3.0</td>
</tr>
<tr>
<td>Vegetable, brassica, leafy, group 5</td>
<td>1.0</td>
</tr>
<tr>
<td>Vegetable, cucumber, group 9</td>
<td>2.0</td>
</tr>
<tr>
<td>Vegetable, fruiting, group 8</td>
<td>1.0</td>
</tr>
<tr>
<td>Vegetable, leafy, group 4</td>
<td>0.25</td>
</tr>
</tbody>
</table>

1 There are no United States registrations for banana.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[FR Doc. 2012–8355 Filed 4–10–12; 8:45 am]

BILLING CODE 6560–50–P

FOR FURTHER INFORMATION CONTACT:

Alhans Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; email address: debesai.alganesh@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?


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 176. To ensure proper receipt by EPA, you must identify the docket number EPA–HQ–OPP–2011–0934 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 June 11, 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–2011–0934, by one of the following methods.


• 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 Thursday, December 8, 2011 (76 FR 76674) (FRL–9328–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP 1E7877) filed by Dow Corning Corporation, 2200 W. Salzburg Road, Midland, MI. The request petitioned that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of Silicic acid, sodium salt, reaction products with chlorotrimethylsilanes and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol. That notice included a summary of the petition prepared by the petitioner and solicited comments on the petitioner’s request. The Agency received one comment. EPA’s response to this comment is discussed in Unit VIII.C.

Section 408(c)(2)(A)(ii) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(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 use 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 an exemption from the requirement of 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 * * *” and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to Silicic acid, sodium salt, reaction products with chlorotrimethylsilanes and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that Silicic acid, sodium salt, reaction products...
with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol is 75,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. 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 Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol to share a common mechanism of toxicity with any other substances, and Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol 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.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol.

VIII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

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.

The Codex has not established a MRL for Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol.

IX. Conclusion

Accordingly, EPA finds that exempting residues of Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these rules 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 involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply.

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 Codex 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, or otherwise have any unique impacts on local governments. 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).

Although this action does not 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

One comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves residue on food. The Agency understands the commenter’s concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

XI. 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 rule in the Federal Register. This 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.


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:


2. In § 180.960, the table is amended by adding alphabetically the following polymer to read as follows:

§ 180.960 Polymer; exemptions from the requirement of a tolerance.

* * * *

<table>
<thead>
<tr>
<th>Polymer</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicic acid, sodium salt, reaction products with chlorotrimethylsilane and iso-propyl alcohol, reaction with poly(oxypropylene)-poly(oxyethylene) glycol, minimum number average molecular weight (in amu), 75,000.</td>
<td>None.</td>
</tr>
</tbody>
</table>

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BILLING CODE 6560–50–P