and responsibilities established by Congress in the preemption provisions of section 408(a)(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) (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 8, 2010.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grape</td>
<td>* * * * *</td>
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</tbody>
</table>

(b) Section 18 emergency exemptions. Time-limited tolerances are established for residues of hexythiazox, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, calculated as the stoichiometric equivalent of hexythiazox. These tolerances will expire and are revoked on the dates specified in the following table:

* * * * *

(c) Tolerances with regional registrations. Tolerances with regional registrations as defined by 40 CFR 180.1(n), are established for residues of hexythiazox, 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 hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, calculated as the stoichiometric equivalent of hexythiazox. [FR Doc. 2010–5692 Filed 3–16–10; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA—HQ—OPP—2009–0845; FRL—8814–3]

Tetraethoxysilane, Polymer with Hexamethyldisiloxane; 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 tetrathoxysilane, polymer with hexamethyldisiloxane, minimum number average molecular weight (in AMU) 2,500 (CAS Reg. No. 104133–09–7) when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Wacker Chemical Corporation 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 tetrathoxysilane, polymer with hexamethyldisiloxane, on food or feed commodities.

DATES: This regulation is effective March 17, 2010. Objections and requests for hearings must be received on or before May 17, 2010, 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–2009–0845. All documents in the
docket are listed in the docket index
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:
Deirdre Sunderland, Registration
Division (7505P), Office of Pesticide
Programs, Environmental Protection
Agency, 1200 Pennsylvania Ave., NW.,
Washington, DC 20460–0001; telephone
number: (703) 603–0851; e-mail address:
sunderland.deirdre@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 Access Electronic Copies
of this Document?

You may access a frequently updated
electronic version of 40 CFR part 180
through the Government Printing
Office’s pilot e-CFR site at http://
www.gpoaccess.gov/ecfr.

C. Can I File an Objection or Hearing
Request?

Under section 408(g) of FFDCA, 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. The EPA procedural
regulations which govern the
submission of objections and requests
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–2009–0845, in the subject line on
the first page of your submission. All
requests must be in writing, and must be
mailed or delivered to the Hearing Clerk
on or before May 17, 2010.

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 that is described in
ADDRESS.

ADDRESS:
Information not marked
confidential pursuant to 40 CFR part 2
may be disclosed publicly by EPA
without prior notice. Submit your
copies, identified by docket ID number
EPA–HQ–OPP–2009–0845, 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 January 6,
2010 (75 FR 864) (FRL–8801–5), EPA
issued a notice pursuant to section 408
of FFDCA, 21 U.S.C. 346a, announcing
the receipt of a pesticide petition (PP
980634) filed by Wacker Chemical
Corporation, 3301 Sutton Rd., Adrian,
MI 49221–9397. The petition requested
that 40 CFR 180.960 be amended by
establishing an exemption from the
requirement of a tolerance for residues
of tetraethoxysilane, polymer with
hexamethyldisiloxane, minimum
number average molecular weight (in
AMU) 2,500, (CAS No. 104133–09–7).
That notice included a summary of the
petition prepared by the petitioner and
solicited comments on the petitioner’s
request. The Agency did not receive any
comments.

Section 408(c)(2)(A)(i) 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 tolerance 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,
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


exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of FFDCA, 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 present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Tetraethoxysilane, polymer with hexamethyldisiloxane, conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.
3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(i).
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).
7. The polymer’s number average MW of 2,500 daltons is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, tetraethoxysilane, polymer with hexamethyldisiloxane, meets the criteria for a polymer 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 tetraethoxysilane, polymer with hexamethyldisiloxane.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that tetraethoxysilane, polymer with hexamethyldisiloxane 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 tetraethoxysilane, polymer with hexamethyldisiloxane is 2,500 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since tetraethoxysilane, polymer with hexamethyldisiloxane 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

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider “available information” concerning the cumulative effects of a particular chemical’s residues and “other substances that have a common mechanism of toxicity.” For the purposes of this tolerance action, EPA has not assumed that tetraethoxysilane, polymer with hexamethyldisiloxane has a common mechanism of toxicity with other substances, based on the anticipated absence of mammalian toxicity. 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 the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website 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 tetraethoxysilane, polymer with hexamethyldisiloxane, 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 tetraethoxysilane, polymer with hexamethyldisiloxane.

VIII. Other Considerations

A. Endocrine Disruptor

EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under Agency’s EDSP have been developed tetraethoxysilane, polymer with hexamethyldisiloxane
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, or otherwise have any unique impacts or 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) (Public Law 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.

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 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.

Dated: March 8, 2010.

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(g), 346a and 371.

2. In §180.960, in the table, add alphabetically the following polymers to read as follows:

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

* * * * *

<table>
<thead>
<tr>
<th>Polymer</th>
<th>CAS No.</th>
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</thead>
<tbody>
<tr>
<td>Tetraethoxysilane, polymer with hexamethyldisiloxane, minimum number average molecular weight (in AMU) 2,500.</td>
<td>* * * * *</td>
</tr>
</tbody>
</table>

[FR Doc. 2010–5691 Filed 3–16; 8:45 am]

BILLING CODE 6560–50–S