VIII. Conclusion

Therefore, a temporary exemption is established for residues of PDJ when used on red apple varieties pre-harvest and in accordance with good agricultural practices.

IX. References


X. Statutory and Executive Order Reviews

This final rule establishes 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 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 requirement 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 62729, 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).

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 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: August 6, 2010.

Steven Bradbury,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter 1 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. Section 180.1299 is added to subpart D to read as follows:

§ 180.1299 Prohydrojasmon; temporary exemption from the requirement of a tolerance.

A temporary exemption from the requirement of a tolerance is established for residues of prohydrojasmon, propyl-3-oxo-2-pentylcyclo-pentylacetate, when used on red apples varieties pre-harvest and when used in accordance with good agricultural practices and will expire on August 1, 2012.

[FR Doc. 2010–20177 Filed 8–17–10; 8:45 am]

BILLING CODE 6560–00–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypolypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyli)bis[2-methylbutanenitrile]-initiated; 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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypolypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyli)bis[2-methylbutanenitrile]-initiated, number average molecular weight (in AMU) 4000; when used as an inert ingredient in a pesticide chemical formulation 40 CFR 180.960. Clarient 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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypolypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyli)bis[2-methylbutanenitrile]-initiated on food or feed commodities.
DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 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–2010–0272. 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: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8560; e-mail address: fertich.elizabeth@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 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0272 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 October 18, 2010. 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 178 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–2010–0272, 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).

II. Background and Statutory Findings

In the Federal Register of June 8, 2010, (75 FR 32463) (FRL–8827–5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP 067702) filed by Clariant Corporation, P.O. Box 866, 625 East Catawba Avenue, Mount Holly, NC 28120. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-propanoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2′-(1,2-diazenediyldi)bis[2-methylbutanenitrile]-initiated, number average molecular weight (in AMU) 4,000; CAS No. 950207–35–9. 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 in response to this notice.

Section 408(c)(2)(A)(j) 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 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). 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated conforms to the definition 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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated 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)(ii).
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.
7. The polymer's number average MW of 4,000 is greater than 1,000 and less than 10,000. 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.
8. Thus, 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated.
9. 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, 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.

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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, 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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, that is different from a Codex MRL;

required by FFDCA section 408(b)(4).

Alimentarius Commission (Codex), as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish 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 2-propenoic acid, 2-methyl-, C12-16-alkyl esters, telomers with 1-dodecanethiol, polyethylene-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2’-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated, that is different from a Codex MRL; 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) (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. If you received specific comments - consider addressing them here.

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).
DEPARTMENT OF THE ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258


Final Determination To Approve
Alternative Final Cover Request for the Lake County, Montana Landfill

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency Region VIII is making a final determination to approve an alternative final cover for the Lake County landfill, a municipal solid waste landfill (MSWLF) owned and operated by Lake County, Montana on the Confederated Salish and Kootenai Tribes’ Flathead Reservation in Montana. EPA is promulgating a site-specific rule proposed on February 10, 2010, that approves an alternative final cover for the Lake County, Montana landfill.

DATES: This final rule is effective on August 18, 2010. The incorporation by reference of certain publications listed in this rule has been approved by the Director of the Federal Register on August 18, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–RCRA–2009–0621. All documents in the docket are available at http://www.regulations.gov. Although listed in the index, some information may not be publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at http://www.regulations.gov or in hard copy at the Environmental Protection Agency Region VIII, Montana Office, 10 West 15th Street, Suite 3200, Helena, Montana. The Environmental Protection Agency Region VIII Montana Office is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays, and is located in a secure building. To review docket materials at this location, it is recommended that the public make an appointment by calling (406) 457–5000 during normal business hours.

FOR FURTHER INFORMATION CONTACT: Susanna Trujillo, Solid and Hazardous Waste Program, 8P–HW, Environmental Protection Agency, 1595 Wynkoop St., Denver, CO 80202; telephone number: (303) 312–7008; fax number: (303) 312–6341; e-mail address: trujillo.susanna@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What did EPA propose?

After completing a review of Lake County’s final site-specific flexibility application request, dated July 11, 2007, and March 17, 2008, and the amendments to that application, dated January 22, 2009, EPA proposed to approve in the Federal Register on February 10, 2010, (75 FR 6597) Lake County’s site-specific flexibility request to install an alternative final cover that varies from the final closure requirements of 40 Code of Federal Regulations (CFR) 258.60(a), but meets the criteria at 40 CFR 258.60(b). This approval would apply to the 15.4 acres of the landfill that have not been previously closed.

B. What is a site-specific flexibility request?

Under Sections 1008, 2002, 4004, and 4010 of the Resource Conservation and Recovery Act of 1976 (RCRA) as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA established revised minimum Federal criteria for MSWLFs, including landfill location restrictions, operating standards, design standards and requirements for ground water monitoring, corrective action, closure and post-closure care, and financial assurance. Under RCRA Section 4005(c), States are required to develop permit programs for facilities that may receive household hazardous waste or waste from conditionally exempt small quantity generators, and EPA determines whether the program is adequate to ensure that facilities will comply with the revised criteria.

The MSWLF criteria are at 40 CFR part 258. These regulations are self-implementing and apply directly to owners and operators of MSWLFs. For many of these criteria, 40 CFR part 258 includes a flexible performance standard as an alternative to the self-implementing regulation. The flexible standard is not self-implementing, and use of the alternative standard requires approval by the Director of a State with an EPA-approved program.

Because EPA’s approval of a State program does not extend to Indian country, owners and operators of MSWLF units located in Indian country cannot take advantage of the flexibilities available to those facilities subject to an approved State program. However, the EPA has the authority under Sections 2002, 4004, and 4010 of RCRA to promulgate site-specific rules that may provide for use of alternative standards in Indian country.

List of Subjects in 40 CFR Part 180

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