

Commodity	Parts per million
Oats, forage	0.15 ppm
Oats, hay	0.04 ppm
Oats, straw	0.07 ppm
Rye, forage	0.15 ppm
Rye, straw	0.07 ppm
Sorghum, grain, forage	0.03 ppm
Sorghum, grain, stover	0.06 ppm
Teosinte, forage	0.15 ppm
Teosinte, hay	0.04 ppm
Teosinte, straw	0.07 ppm
Triticale, forage	0.15 ppm
Triticale, hay	0.04 ppm
Triticale, straw	0.07 ppm
Wheat, forage	0.15 ppm
Wheat, hay	0.03 ppm
Wheat, straw	0.03 ppm

[FR Doc. 2010-20443 Filed 8-17-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0048; FRL-8839-4]

Prohydrojasmon, propyl-3-oxo-2-pentylcyclo-pentylacetate; Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate, on red apple varieties when applied/used as a plant growth-regulator in accordance with the terms of Experimental Use Permit (EUP) No. 62097-EUP-R and when used in accordance with good agricultural practices. Fine Agrochemicals, Ltd., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues

of prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate. The temporary tolerance exemption expires on August 1, 2012.

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-2010-0048. 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: Gina Casciano, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0513; e-mail address: casciano.gina@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://www.gpoaccess.gov/ecfr>.

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-2010-0048 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 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-2010-0048, 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 7, 2010 (75 FR 17715) (FRL-8810-7), 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 tolerance petition (PP 9G7656) by Fine Agrochemicals, Ltd., c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA, 22192. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of prohydrojasmon, propyl-3-oxo-2-pentylcyclo-pentylacetate, (PDJ), for its use in accordance with the terms of Experimental Use Permit (EUP) No. 62097-EUP-R. This notice referenced a summary of the petition prepared by the petitioner Fine Agrochemicals, Ltd., c/o SciReg, Inc., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

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 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 in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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...." Additionally, section 408(b)(2)(D) of FFDCA requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

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.

PDJ is a synthetically made plant growth regulator which is both structurally similar and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator present in all vascular (higher) plants. The jasmonates, of which JA is a member, is a group of plant hormones involved in multiple stages of plant development and defense, including the ability to stimulate fruit ripening (Creelman and Mullet, et al., 1995). The highest levels of naturally occurring JA are found in actively growing plant tissues such as leaves, flowers, and developing fruit (Creelman and Mullet, et al., 1995; Mason et al., 1992), thus JA has always been a natural component of diets containing plant materials. To date, there have been no reported toxic effects associated with the consumption of JA in fruits and vegetables.

PDJ, a synthetic version of JA, is expected to behave in the same manner and have the same low toxicity profile as JA since it is structurally similar and functionally identical to naturally occurring JA. Studies submitted by the applicant and reviewed by EPA indicate that PDJ is not acutely toxic. No toxic endpoints were established, and no significant toxicological effects were observed in any of the acute toxicity studies. In addition, studies submitted indicate that PDJ is not genotoxic, has no subchronic toxic effects, and is not a developmental toxicant. Summaries of the toxicological data submitted in support of this temporary exemption from the requirement of a tolerance follow.

A. Acute Toxicity

Acute toxicity studies on the technical grade active ingredient (TGAI) for PDJ, containing 97.98% PDJ, confirm

a low toxicity profile. The acute toxicity data show virtual nontoxicity for all routes of exposure and it can be concluded that any dietary risks associated with this plant regulator would be negligible.

1. The acute oral median lethal dose (LD₅₀) in rats was greater than 5,000 milligrams per kilogram (mg/kg) bodyweight. There were no observed toxicological effects on the test subjects in the acute oral study submitted (MRID No. 47927825). PDJ is classified as Toxicity Category IV for acute oral toxicity.

2. The acute dermal LD₅₀ in rats was greater than 2,000 mg/kg bodyweight (MRID 47927826). PDJ is classified as Toxicity Category III for acute dermal toxicity.

3. The acute inhalation median lethal concentration (LC₅₀) was greater than 2.8 milligrams per liter (mg/L) in rats and showed no significant inhalation toxicity (MRID 47927827). PDJ is classified as Toxicity Category IV for acute inhalation toxicity.

4. A primary eye irritation study on rabbits indicates that PDJ is minimally irritating to the eye (MRID 47927828). PDJ is classified as Toxicity Category IV for primary eye irritation.

5. A skin irritation study on rabbits indicates that PDJ is not irritating to the skin (MRID 47927829). PDJ is classified as Toxicity Category IV for primary skin irritation.

6. Data indicate that PDJ is not a dermal sensitizer (MRID 47927830).

B. Mutagenicity

Two mutagenicity studies, using the TGAI of PDJ (97.98% PDJ) as the test substance, were performed. These studies are sufficient to confirm that there are no expected dietary or non-occupational risks of mutagenicity with regard to new food uses.

1. A Bacterial Reverse Gene Mutation Test (MRID No. 47927833) investigating doses of test substance up to those that were cytotoxic, both with and without metabolic S9 activation, found no incidences of a 2-fold or greater increase in the number of revertants compared to the corresponding solvent control. Therefore, PDJ is considered to be non-mutagenic under the conditions of this assay.

2. An *in vitro* Mammalian Cell Chromosome Aberration Test (MRID No. 47927834) tested PDJ genotoxicity on Chinese hamster lung cells (CHL/IU) up to the cytotoxic dose level (80 micrograms per milliliter [μg/mL], based on reduced mitotic activity) without S9 activation, and up to the limit concentration of 5,000 μg/mL with S9 activation. None of the test substance

concentrations induced a significant increase in the incidence of cells with chromosomal abnormalities, either in the absence or presence of S9 activation. In both experiments, the fraction of cells with chromosomal aberrations was below 5%, indicating a negative response of the test substance. There was also no indication of a dose-response effect either with or without metabolic activation. All of the negative, solvent, and positive controls gave appropriate responses. Therefore, under the conditions of this assay, PDJ is considered to be non-mutagenic and does not cause chromosome aberrations.

C. Subchronic Toxicity

In a subchronic toxicity study using the TGAI of PDJ (97.98% PDJ) as the test substance, no clinically or toxicologically significant effects were found in any treatment group (MRID 47927831). Therefore, the no observed adverse effect level (NOAEL) for PDJ has been established as the highest test substance dose, 10,000 parts per million (ppm) (equivalent to 566 mg/kg bw/day for male test animals and 587 mg/kg bw/day for female test animals). A lowest observed adverse effect level (LOAEL) was not established, suggesting that the test animals could have tolerated a higher dose. In sum, the data submitted to the Agency indicate that PDJ has no subchronic toxicological effect.

D. Developmental Toxicity

In a developmental toxicity study, using the TGAI of PDJ (97.98% PDJ) as the test substance (MRID 47927832), there were no treatment-related effects found at necropsy in maternal animals nor were there effects on copra lutei, number of implantations, sex ratio, fetal body weight, or preimplantation embryonic mortality. The Agency does not consider the transient decrease in body weight or food intake as adverse and establishes the NOAEL for this study as 500 mg/kg bw/day. A LOAEL was not identified for maternal effects, suggesting that the test animals could have tolerated a higher dose. No treatment-related developmental effects were found on external examination of the fetuses. Visceral examination showed a slight increase in the incidence of thymic remnants; however, the increase was within the range of the performing laboratories historical control data. Therefore, the Agency does not consider this a treatment-related effect. There was also a slight increase in the incidence of a 14th rib, a common variation in this strain of rat and is therefore not considered an adverse effect. It was not accompanied by an increased incidence of abnormal

embryos, either on external, skeletal, or visceral examination, and did not appear at a higher than normal rate. Based on the study results, the developmental effects NOAEL for the study is the highest dose tested 500 mg/kg bw/day. A LOAEL was not identified for developmental effects, suggesting that the test animals could have tolerated a higher dose. In sum, the data submitted to the Agency indicate that PDJ is not a developmental toxicant.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Dietary exposure to the residues of PDJ is expected to be insignificant, even in the event of exposure. Based on subchronic toxicity data submitted in support of this petition, the Agency has calculated the possibility of dietary exposure and concludes that in a worst case scenario, such as no degradation, PDJ residues consumed by a 70 kg person are four orders of magnitude below the NOAEL that was calculated for this compound (EPA, 2010). Moreover, based on the fate and distribution data (absorption/desorption, hydrolysis, photodegradation in water, and aerobic soil metabolism) submitted by the applicant and reviewed by EPA, PDJ, when applied to plant material such as fruit and foliage, is expected to degrade rapidly, with calculated environmental concentrations ranging from 0.77 to 0.06 ppm on the day of application and declining to 0.0 by two days post application. In addition, these studies indicate that PDJ is relatively unstable in the environment with an aerobic soil half-life of 1.6 – 2.3 hours, and upon consumption breaks down under gastric condition with a half-life of 0.8 days.

1. *Food.* PDJ is structurally similar to the naturally occurring plant growth regulator JA. JA is naturally present in fruits and vegetables at various levels, generally not exceeding 10 μM (2 ppm), and has always been a component of any diet containing plant materials (Creelman and Mullet, 1995; Mason et al., 1992). Dietary exposure to residues of PDJ via exposure to treated fruit or foliage (e.g. apples) is not expected to exist above background levels of

naturally occurring JA. The maximum application rate of PDJ will be 0.009 pounds of active ingredient per acre (lbs ai/A) or 200 parts per million active ingredient per acre (ppm ai/A). Using the Terrestrial Exposure Model (T-REX; USEPA), the Agency calculated that, in a theoretical application at the maximum rate, residue levels of PDJ on grasses, broadleaf foliage, fruits, pods, and seeds will range from 0.77 to 0.06 ppm on the day of application and decline to 0.0 ppm by 2 days post application (EPA, 2010). Given PDJ's expected short-lived presence on vegetation, no significant pesticidal residues are anticipated for harvested foods. Furthermore, PDJ is relatively unstable in the environment with an aerobic soil half-life of 1.6 - 2.3 hours, and upon consumption breaks down under gastric condition with a half-life of 0.8 days.

2. *Drinking water exposure.* Exposure of humans to PDJ in drinking water is unlikely since products are labeled for application directly to terrestrial plants and because data demonstrate a soil half-life for this chemical from 1.6-2.3 hours, as well as rapid degradation in water (EPA, 2010). Specifically, PDJ is not to be applied directly to water or to areas where surface water is present. In addition, the Agency estimated environmental concentrations to an aquatic site from PDJ runoff (spray to apple trees) using the GENeric Estimated Environmental Concentration model (GENEEC; EPA, 2001). The expected concentrations in surface water are well below (6 to 7 orders of magnitude) the maximum doses used in laboratory testing, where no toxic effects were seen (e.g. Acute Oral Toxicity LD₅₀ > 5,000 mg/kg; Developmental Toxicity NOAEL > 500 mg/kg).

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because PDJ is not approved for residential uses. The active ingredient is applied directly to commodities and degrades rapidly.

1. *Dermal exposure.* Non-occupational dermal exposures to PDJ are expected to be negligible because of its directed agricultural use as a plant growth regulator applied to red apple varieties pre-harvest. Any dermal exposure associated with this experimental use permit is expected to be occupational in nature.

2. *Inhalation exposure.* Non-occupational inhalation exposures are not expected to result from the agricultural uses of PDJ. Any inhalation exposure associated with this experimental use permit is expected to be occupational in nature.

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 PDJ to share a common mechanism of toxicity with any other substances, and PDJ does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that PDJ 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. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) 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 database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

The acute, subchronic, and developmental toxicity data discussed in Unit III.B. indicate that PDJ has negligible toxicity. In addition, PDJ is structurally similar to jasmonic acid, which is ubiquitous in nature and present in all fruits and vegetables and for which there is no reported history of toxicological incident. Furthermore, based on subchronic toxicity data submitted in support of this petition, the Agency has calculated the

possibility of dietary exposure and concludes that in a worst case scenario, such as no degradation, the PDJ residues consumed by a 70 kg person are four orders of magnitude below the NOAEL that was calculated for this compound (EPA, 2010). Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to the residues of PDJ. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data and information available on PDJ do not demonstrate toxic potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

Through this action, the Agency proposes a temporary exemption from the requirement of a tolerance of PDJ when used on red apple varieties without any numerical limitations for residues. The Agency has determined that residues resulting from PDJ use as a plant growth regulator are unlikely, and that there are no significant toxicity concerns even in the event that residues of this active ingredient are present. As a result, the Agency has concluded that an analytical method is not required for enforcement purposes for PDJ.

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 PDJ.

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

1. Creelman, R.A. and J.E. Mullet (1995) Jasmonic acid distribution and action in plants: Regulation during development and response to biotic and abiotic stress. *Proceedings of the National Academies of Science*, 92: 4114-4119.
2. EPA (2010) Environmental Protection Agency (EPA) Risk Assessment: Application for Experimental-Use Permit and Temporary Tolerance Exemption for FAL 1800 (Prohydrojasmon). May 18, 2010.
3. Mason, H.S., DeWald, D.B., Creelman, R.A., Mullet J.E. (1992) Coregulation of Soybean and Vegetative Storage Protein Gene Expression by Methyl Jasmonate and Soluble Sugars. *Plant Physiology*, 98: 859-867.

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 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) (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 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 180.1299 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]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0272; FRL-8837-5]

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; 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-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-(1,2-diazenediyl)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. Clariant 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-polypropylene glycol ether with propylene glycol monomethacrylate (1:1), and styrene 2,2'-(1,2-diazenediyl)bis[2-methylbutanenitrile]-initiated on food or feed commodities.