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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0048; FRL-9347-9]

Prohydrojasmon; Amendment of Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises the temporary exemption from the requirement of a tolerance for residues of Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate, by including grapes and extending the date of expiration of the temporary tolerance exemption from August 1, 2012, to August 1, 2014, when used as a plant growth regulator pre-harvest and in accordance with good agricultural practices and with the terms of Experimental Use Permit (EUP) No. 62097-EUP-1. Fine Agrochemicals, Ltd., submitted a petition to the U.S. Environmental Protection Agency (EPA or the Agency) under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the amendment to the temporary tolerance exemption.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0048; FRL-9347-9, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Gina Burnett, 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; email address: *burnett.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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections.You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 online 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 February 15, 2012, (77 FR 8755) (FRL-9335-3), 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 1G7947) by Fine Agrochemicals, Ltd., c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192. The petition requested that 40 CFR 180.1299 be amended by including grapes in the

temporary exemption from the requirement of a tolerance for residues of Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate, and that the expiration date for the tolerance exemption be extended by 2 years in order to coincide with a 2-year extension of the petitioner's Experimental Use Permit (EUP) for this biochemical. The petitioner requests the tolerance exemption expiration date extension and EUP extension in order to better assess the effects of application timing, geography, and apple variety on efficacy (color enhancement). Fewer red apple sites will be treated as compared to the two initial growing seasons (2010 and 2011), but more acres will be treated per site, increasing statistical power and confidence, and providing the applicant with more useful data. Under the EUP extension, the petitioner will also be approved to test PDJ on grapes. This notice referenced a summary of the petition prepared by the petitioner, Fine Agrochemicals, Ltd., which is available in the docket via *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.

The Agency established a temporary tolerance exemption for PDJ in a Final Rule published in the **Federal Register** on August 18, 2010, (75 FR 50922-50926) (FRL-8839-4), to coincide with the approval of an Experimental Use Permit (EUP) granted to Fine Agrochemicals, Ltd. The temporary tolerance exemption supported uses on red apple varieties, and will expire on August 1, 2012. This amendment proposes to expand the crops covered by including grapes, and by extending the expiration date of the

tolerance exemption to August 1, 2014, to coincide with the extension of the petitioner's EUP for the same time period. Since the establishment of the temporary tolerance exemption, no new toxicology data have been generated. As such, the toxicological profile as stated in the August 18, 2010, issue of the **Federal Register**, and referenced herein, has not changed. Copies of the August 18, 2010, document (75 FR 50922-50926), and the studies cited therein, are located under docket identification (ID) number EPA-HQ-OPP-2010-0048.

As discussed in the August 18, 2010, **Federal Register**, (75 FR 50923), PDJ is a synthetic plant growth regulator that is structurally similar and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator present in all vascular plants. The jasomates, 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 (Ref. 1). The highest levels of naturally occurring JA are found in actively growing plant tissues such as leaves, flowers, and developing fruit (Refs. 1 and 3), 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 because it is structurally similar and functionally identical to naturally occurring JA. Studies submitted by the applicant in support of this temporary exemption from the requirement of a tolerance, and reviewed by the Agency, indicate that PDJ is not acutely toxic. These studies and the Agency's conclusions are summarized at 75 FR 50922-50926, August 18, 2010. Specifically, no toxic endpoints

were established, and no significant toxicological effects were observed in any of the acute toxicity studies (75 FR 50923-50924, August 18, 2010). In addition, studies submitted indicate that PDJ is not genotoxic, has no subchronic toxic effects, and is not a developmental toxicant (75 FR 50924, August 18, 2010).

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 residues of PDJ is expected to be insignificant, even in the event of exposure. In a worst case scenario, such as no degradation of the applied compound, PDJ residues consumed by a 70 kg person are four orders of magnitude below the No Observed Adverse Effect Level (NOAEL) that was calculated for this compound (75 FR 50924, August 18, 2010).

1. *Food*. PDJ is structurally similar to the naturally occurring plant growth regulator jasmonic acid (JA). JA is naturally present in fruits and vegetables at various levels, generally not exceeding 2 parts per million (ppm), and has always been a component of any diet containing plant materials (Refs. 1 and 2). Dietary exposure to residues of PDJ via exposure to treated fruit or foliage is not expected to exist above background levels of naturally occurring JA (75 FR 50924-50925, August 18, 2010).

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 (Ref. 3). In addition, 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 $LD_{50} > 5,000$ milligrams per kilogram (mg/kg); developmental toxicity NOAEL > 500 mg/kg) (75 FR 50925, August 18, 2010).

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 not expected because the compound is intended only for agricultural use as a plant growth regulator applied to apples and grapes 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.

Relevant data and information indicate that PDJ has negligible acute, subchronic, and developmental toxicity (75 FR 50922-25, August 18, 2010). In addition, PDJ is structurally similar to jasmonic acid, which is present in all fruits and vegetables and for which there is no reported history of toxicological incident (EPA, 2010). Therefore, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. 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

An analytical method is not required for enforcement purposes for the reasons stated above and because EPA 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 Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate.

VIII. Conclusion

The Agency acknowledges the need to extend the temporary tolerance exemption to coincide with the approved extension of Fine Agrochemical, Ltd.'s EUP for PDJ. In addition, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of PDJ. Therefore, the temporary exemption is amended for residues of PDJ on red apples to include grapes, when used pre-harvest as a plant growth regulator, in accordance with good agricultural practices and with the terms of EUP No. 62097-EUP-1, and will expire on August 1, 2014**.**

IX. References

The references used in this document are in the OPP docket listed under docket ID EPA-HQ-OPP-2010-0048, and may be seen by accessing the regulatory.gov web site.

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. 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.

3. EPA (2010) Environmental Protection Agency (EPA) Risk Assessment: Application for Experimental-Use Permit and Temporary Tolerance Exemption for FAL 1800 (Prohydrojasmon). May 18, 2010.

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: May 3, 2012.

Keith Mathews,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1299 is revised 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 as a plant growth regulator on red apples varieties and grapes pre-harvest, in accordance with good agricultural practices and the terms of Experimental Use Permit No. 62097-EUP-1, and will expire on August 1, 2014.

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