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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0157; FRL-13197-01-OCSPP]

PDHP 68949; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of PDHP 68949 in or on all food commodities if used according to the label and good agricultural practices. Plant Health Care, Inc. submitted a petition to the 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 PDHP 68949 under FFDCA when used in accordance with this 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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0157, is available at https://www.regulations.gov. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Shannon Borges, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1400; email address: *BPPDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) 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." FFDCA section 408(c)(2)(A)(ii) 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 FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), 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, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

C. *How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the EPA, you must identify docket ID number EPA-HQ-OPP-2024-0157 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*].**

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf.* Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting

documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf*.

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 (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-for Exemption

In the **Federal Register** of May 3, 2024 (89 FR 36737) (FRL-11682-03-OCSPP), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 3F9091) by Plant Health Care, Inc., 242 South Main Street, Suite 216, Holly Springs, NC 27540. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biochemical pesticide PDHP 68949 in or on all food commodities. That notice referenced a summary of the petition prepared by the petitioner Plant Health Care, Inc., which is available in the docket. EPA did not receive any comments in response to the notice of filing.

III. Final Tolerance Actions

A. *EPA's Safety Determination*

EPA evaluated the available toxicological and exposure data on PDHP 68949 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which the EPA relied and its risk assessment based on those data can be found within the document entitled "Human Health Risk

Assessment in Support of the Registration of PHC 68949 End Use Product Containing the New Active Ingredient PDHP 68949 (1%) and Associated Petition to Establish a Permanent Tolerance Exemption" (Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

PDHP 68949 is a modified peptide derived from a bacterial harpin protein that acts as a plant growth regulator and activates resistance to nematodes in treated plants (PDHP refers to peptide derived from harpin protein). Harpins are naturally occurring proteins expressed by certain phytopathogenic bacteria that stimulate the innate immune response in plants, commonly referred to as systemic acquired resistance (SAR), which increases the general ability of plants to respond to infections and some soil-borne pests.

EPA used a weight-of-evidence approach, considering available hazard and exposure data, to assess the risk to human health from the use of products containing the active ingredient PDHP 68949. The active ingredient is intended for direct applications to a wide range of plants, including ornamentals, turf, conifers and trees in commercial nurseries, plantation forests, landscapes and parks, as well as agricultural crops as foliar, seed, and root treatments. Accordingly, dietary exposure may result from consumption of treated foods. However, any risks associated with dietary exposures are expected to be negligible because PDHP 68949 is of low oral toxicity, does not exhibit protein homology to putative or known allergens, and is readily digested in both simulated gastric fluids and simulated intestinal fluids containing only chymotrypsin. In addition, there is an expectation of lability of PDHP 68949 in the environment. PDHP 68949 is a protein, which is a biological substance that is subject to biodegradation and decay through mechanisms such as photodegradation, hydrolysis, and active degradation through microbial activity in the environment. Further, food crops undergo a post-harvest washing process to remove soil and surface residues, therefore reducing the amounts of PDHP 68949 on the treated crops. Seed and root treatments are expected to result in negligible exposures of above-ground plant parts to PDHP 68949. Exposure through drinking water is expected to be

negligible because the PDHP 68949 peptide is expected to be susceptible to biodegradation, degradation due to environmental conditions, and water treatment processes.

To assess hazard, an acute oral toxicity study was conducted on the end-use product, PHC 68949, 1% active ingredient PDHP 68949, because the product is manufactured using an integrated process, meaning that the active ingredient is never isolated in the process. The acute oral toxicity study found no toxicity or adverse effects from PHC 68949 and was classified as EPA Toxicity Category IV, indicating minimal toxicity.

One method of assessing allergenicity is to search for homologous sequences (i.e., amino acid similarity) of a protein of interest to known allergenic proteins in databases that contain peer-reviewed protein sequences from allergenic proteins. Matches of greater than 35% identity over 80 amino acids are considered to be indicative of a potential for cross-reactivity. Sometimes a contiguous eight amino acid sequence is also used as an indicator. An analysis of PDHP 68949 found no alignments with greater than 35% identity over 80 contiguous amino acids or eight amino acid exact matches. These data indicate that there is negligible likelihood for cross reactivity of PDHP 68949 with any known allergen sequences deposited in these databases.

To further address the potential allergenicity of PDHP 68949, a gastrointestinal stability study of PHC 68949 was conducted. Proteins are broken into their amino acid components upon ingestion and subsequently used as a nutritional source. Some proteins are more stable in the gastrointestinal tract than others, and it is thought that this relative stability may increase the likelihood of sensitization potential to the protein (i.e., its allergenic potential). Therefore, peptide lability was simulated by incubating PHC 68949 peptide in simulated gastric fluids (pepsin) and simulated intestinal fluids (chymotrypsin) to simulate digestion and assess degradation. Pepsin began to digest PHC 68949 quickly within one minute with a fraction present until 20 minutes. Chymotrypsin fully digested PHC 68949 within five minutes, again with digestion starting at one minute. Both enzymatic digestions were not conducted at the recommended body temperature (37 °C) to mimic real-world conditions, but rather at suboptimal

temperatures (between 0°C and 25°C) for both pepsin and chymotrypsin activity, thus skewing the results towards slower digestion in the assay compared to what would be expected to occur upon ingestion of the peptide. Together, the data show that PDHP 68949 is expected to be labile in the gastric system, albeit at a faster rate than indicated by the two assays.

Exposure of bystanders may occur with landscaping, turf, and in field uses, especially when applied aerially. In those cases, exposure may result from spray drift and are likely to be minimal as, per the label instructions, application may only occur in low wind conditions and medium and coarse droplet sizes are to be used. Additionally, both the aerial application rate (0.5 – 3 ounces/acre) and frequency (every 2 – 4 weeks) are low. Should significant non-occupational exposures occur, the results of the mammalian inhalation and oral (and by extension dermal) toxicology testing performed with the end-use product demonstrated PDHP 68949 is of low toxicity. Therefore, a quantitative non-occupational exposure assessment was not performed for PDHP 68949. The proposed end-use product does not include residential (non-occupational) uses of PDHP 68949; therefore, no exposure is expected, and residential and post-application risk assessments have not been conducted.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the negligible hazard of PDHP 68949. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

B. Analytical Enforcement Methodology

An analytical method is not required for PDHP 68949 because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Conclusion

Based upon its evaluation in the Human Health Risk Assessment, the EPA 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 residues of PDHP 68949. Therefore, an exemption

from the requirement of a tolerance is established for residues of PDHP 68949 in or on all food commodities.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA, 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 et seq. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995

dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit IV.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's 2021 Policy on Children's Health applies to this action. This rule finalizes an exemption from the requirement of a tolerance under the FFDCA, which requires 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in Unit III.A.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 et seq., and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action 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: January 26, 2026.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. Add § 180.1422 to subpart D to read as follows:

§ 180.1422 PDHP 68949; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of PDHP 68949 in or on all food commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2026-01901 Filed: 1/29/2026 8:45 am; Publication Date: 1/30/2026]