



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0514; FRL-13128-01-OCSP]

Rice bran wax in Pesticide Formulations; Exemption from the Requirement for 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 rice bran wax (CAS Reg. No. 8016-60-2) when used as an inert ingredient (lubricant) on growing crops and raw agricultural commodities pre- and post-harvest, when applied to animals, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Micro Powders, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of rice bran wax when used in accordance with the terms of those exemptions.

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-2023-0514, is available online 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: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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 proposed 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 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 FFDCCA 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 FFDCCA 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, FFDCCA 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 FFDCCA 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 EPA, you must identify the docket ID number EPA-HQ-OPP-2023-0514 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 November 21, 2023 (88 FR 81021, FRL-10579-10-OCSP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11778) by Micro Powders, Inc. (EPA Company Number 102655, 580 White Plains Road, Tarrytown, NY 10591 USA). The petition requested that 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of rice bran wax (CAS Reg. No. 8016-60-2) when used as an inert ingredient (lubricant) in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest under 40 CFR 180.910, when applied to animals under 40 CFR 180.930, and when used in antimicrobial formulations (food-contact surface sanitizing solutions) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and

utensils under 40 CFR 180.940(a). That document referenced a summary of the petition prepared by Micro Powders, Inc., the petitioner, which is available in the docket (EPA-HQ-OPP-2023-0514) available online at <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all substances (or groups of similar substances) that are intentionally included in a pesticide product, other than active ingredients as defined in 40 CFR 153.125. Inert ingredients include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm 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 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(c)(2)(A), and the factors specified in FFDCA

section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for rice bran wax including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with rice bran wax follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies 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. Specific information on the studies received and the nature of the adverse effects caused by rice bran wax as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicological database of rice bran wax is supported by data regarding surrogates (Carnauba wax, D-002, D-003, γ -Oryzanol, Docosanoic Acid). EPA has determined that it is appropriate to bridge surrogate (Micro Powders, Inc.) data to assess rice bran wax due to similarities in the functional groups/structure (long-chain aliphatic esters, fatty acids, and alcohols), composition (natural plant wax mixtures), and physical/chemical properties (high molecular weight, low water solubility, low vapor pressure), and the available human health toxicity and ecological toxicity data of the five surrogate substances.

Rice bran wax has low acute toxicity via the oral route, and it is anticipated to have low toxicity via the dermal and inhalation routes. Rice bran wax is not an acute eye or dermal irritant, nor a skin sensitizer. Repeated dose toxicity was evaluated comprehensively using surrogate data. Subchronic toxicity studies with D-002 and D-003 in rats (90-day gavage) showed no adverse effects at doses up to 1,500 milligrams per kilogram per day (mg/kg/day). Carnauba wax administered in rat diet at up to 10 percent (approximately 8,800 to 10,200 mg/kg body weight

per day) for 13 weeks produced no treatment-related effects. A three-generation reproductive toxicity study with carnauba wax in rats demonstrated no reproductive or developmental toxicity at dietary concentrations up to 1 percent (approximately 10,000 mg/kg/day). Chronic toxicity studies with carnauba wax (28 weeks in dogs) and D-003 (9 months in dogs, 18 months in mice, 24 months in rats) at doses up to 1,500 mg/kg/day showed no treatment-related adverse effects.

Mutagenicity was assessed using an Ames bacterial reverse mutation test with rice bran wax oxidized in *Salmonella typhimurium* and it showed no evidence of mutagenic activity in any tested strain. Carcinogenicity was evaluated using surrogate data. Two-year dietary carcinogenicity bioassays with γ -oryzanol in Fischer 344 rats and B6C3F1 mice showed no increase in tumor incidence at doses up to 2,000 mg/kg/day. Carcinogenicity studies with D-003 in Sprague-Dawley rats (24 months) and OF1 mice (18 months) at doses up to 1,500 mg/kg/day showed no evidence of carcinogenic potential. These data support a determination that rice bran wax is not likely to be carcinogenic to humans.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the NOAEL dose and the LOAEL dose. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The hazard profile of rice bran wax is adequately defined. Overall, rice bran wax is of low acute, subchronic, and developmental toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, the Agency performed a qualitative risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to rice bran wax, EPA considered exposure under the proposed exemption from the requirement of a tolerance. Dietary exposure (food and drinking water) to rice bran wax may occur following ingestion of foods with residues from their use in accordance with this exemption. However, a quantitative dietary exposure assessment is not necessary since a toxicological endpoint for risk assessment was not identified.

2. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Rice bran wax may be present in pesticide and non-pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment is not necessary since a toxicological endpoint for risk assessment was not identified.

3. *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.”

Based on the lack of toxicity in the available database, EPA has not found rice bran wax to share a common mechanism of toxicity with any other substances, and rice bran wax does not

appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that rice bran wax 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. 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 (10X) 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on an assessment of rice bran wax, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with rice bran wax, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to rice bran wax residues.

F. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is

establishing an exemption from the requirement of a tolerance without any numerical limitation.

G. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of rice bran wax (CAS Reg. No. 8016-60-2) when used as an inert ingredient (lubricant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910; when applied to animals under 40 CFR 180.930; and when used in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a).

V. 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.

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 V.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 tolerance actions 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 the pesticide-specific review documents, located in the applicable docket at <https://www.regulations.gov>.

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 does not meet the criteria set forth in 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: February 9, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons stated in the preamble, the EPA amends 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. In §180.910, amend Table 1 to §180.910 by adding, in alphabetical order, an entry for “rice bran wax” to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.910

Inert ingredients	Limits	Uses
* * * * *		
Rice bran wax (CAS Reg. No. 8016-60-2)	None	Lubricant
* * * * *		

3. In § 180.930, amend Table 1 to §180.930 by adding, in alphabetical order, an entry for “rice bran wax” to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

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Table 1 to 180.930

Inert ingredients	Limits	Uses
* * * * *		
Rice bran wax (CAS Reg. No. 8016-60-2)	None	Lubricant
* * * * *		

4. In §180.940, amend Table 1 to paragraph (a) by adding, in alphabetical order, an entry for “rice bran wax” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial

formulations (Food-contact surface sanitizing solutions).

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Table 1 to Paragraph (a)

Inert ingredients	CAS Reg. No.	Limits
* * * * *		
Rice bran wax	8016-60-2	None
* * * * *		

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