560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0743; FRL 13377-01-OCSPP]

Calcium Carbonate; Exemption from the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of calcium carbonate (CAS # 471-34-1), in or on all food commodities when used in accordance with label directions and good agricultural practices. Columbia River Carbonates, 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 calcium carbonate in or on all food commodities, in accordance with the terms of the 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-2022-0743, 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 (7511P), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1606; email address: *BPPDFRNotices@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:

- 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, 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 docket ID number EPA-HQ-OPP-2022-0743 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 Administrative Law Judges Division (ALJD), 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* "Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.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 ALJD electronically, a person should utilize the ALJD 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. Summary of Petitioned-For Tolerance

In the ***Federal Register*** of September 23, 2022 (87 FR 58047) (FRL-9410-05-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F9018) by Columbia River Carbonates, 300 North Pekin Road, Woodland, Washington 98674. The petitioner requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of calcium carbonate.

The notice of filing referenced a summary of the petition prepared by Columbia River Carbonates, which is available in the docket at https://www.regulations.gov. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing a tolerance exemption, as explained in Unit III.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." 21 U.S.C. 346a(c)(2)(A)(i). 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." *Id*. at 346a(c)(2)(A)(ii). 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) and (D). FFDCA section 408(b)(2)(C) 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. . . . " It 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 Food Quality Protection Act (FQPA) safety factor. 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 supports the choice of a different factor.

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."

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 calcium carbonate, including exposure resulting from

the tolerance exemption established by this action.

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, "HH Assessment Calcium Carbonate." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

A. *Toxicological Profile and Endpoints*

Calcium carbonate is of low acute toxicity. Calcium carbonate is of low acute oral toxicity (Toxicity Category III), of low acute dermal toxicity (Toxicity Category III) and inhalation toxicity (Toxicity Category IV). It is not an eye irritant (Toxicity Category IV), not a dermal irritant (Toxicity Category IV) and is not a dermal sensitizer in mice. A non-occupational and occupational short- and intermediate-term (1 day to 6 months) inhalation endpoint was found. The endpoint was derived from the 90-day inhalation toxicity study in rats. The no observed adverse effect level (NOAEL) of 0.123 mg/L and lowest observed adverse effect concentration (LOAEC) of 0.212 mg/L for portal of entry effects are based on increased bronchoalveolar lavage (BAL) derived enzymes changes (ALP and LDH) and increased neutrophil and protein levels in females. It was noted that the LOAEC was selected conservatively, and likely reflects an inflection point for the effects observed at the highest dose tested, due to the lack of measurements in the percent viable cells after the recovery period for the three middle doses and lack of weight information in the other two lung regions. There were no systemic effects up to the highest dose tested (0.399 mg/L). The level of concern (LOC) for short- and intermediate-term inhalation exposure is 30 (3X for interspecies extrapolation and 10X for intraspecies variation). The standard interspecies extrapolation uncertainty factor can be reduced from 10X to 3X due to the HEC calculation accounting for pharmacokinetic interspecies differences and not pharmacodynamic, interspecies differences. The total UF of 30X for occupational inhalation exposure scenarios includes: 3X for interspecies extrapolation, and 10X for intraspecies variability (LOC=30).

B. *FQPA Safety Factor for Infants and Children*

EPA concluded that an FQPA safety factor is not required at this time as the

calcium carbonate toxicology database is complete and adequate to characterize potential pre- and post-natal toxicity to infants and children, there is no indication of increased quantitative or qualitative susceptibility in the developmental or reproduction toxicity studies, and no dietary endpoints have been identified.

C. *Exposure Assessment*

In accordance with the FFDCA, EPA must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In evaluating dietary exposure to calcium carbonate from pesticide chemical residues in food or feed, EPA considered exposure under the petitioned-for tolerance exemption. Given that no toxicological endpoints were identified, EPA conducted a qualitative dietary exposure and risk assessment. EPA's dietary exposure assessment also includes exposure to pesticide residues in drinking water. Finally, as required under the FFDCA, EPA assessed the potential for "residential exposure," which refers to non-occupational, non-dietary exposure. EPA did not conduct a quantitative aggregate exposure assessment as no endpoints were selected for oral and dermal exposures. While an inhalation endpoint was selected, the exposures cannot be combined as no endpoints were selected for oral and dermal exposures.

D. *Cumulative Effects*

Based on the lack of toxicity in the available data, calcium carbonate and its metabolites are not expected to share a common mechanism of toxicity with other chemicals. For the purposes of this action, therefore, EPA has assumed that calcium carbonate does not have a common mechanism of toxicity with other substances.

E. *EPA's Safety Determination*

EPA determines whether chronic dietary pesticide exposure is safe by comparing estimated aggregate food and drinking water exposure to the chronic population adjusted dose. Short-, intermediate-, and chronic-term risks are evaluated by comparing the

estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists.

Based on the data summarized in the calcium carbonate Human Health Risk Assessment, EPA has concluded that calcium carbonate does not pose any risks of concern to the U.S. population, including any subpopulations, based on aggregate exposure to calcium carbonate, for any exposure scenario. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general U.S. population, or to infants and children, from aggregate exposure to calcium carbonate residues.

F. *Analytical Enforcement Methodology*

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

IV. 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 calcium carbonate. Therefore, an exemption from the requirement of a tolerance is established for residues of calcium carbonate in or on all food commodities.

V. Statutory and Executive Order Reviews

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, 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 2026 *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 exempt from review 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: August 11, 2026.

Elizabeth Vizard,

Acting Director, Office of Pesticide Programs.

For the reasons set forth in the preamble, 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 § 180.1423 to subpart D to read as follows:

§180.1423 Calcium carbonate; Exemption from the Requirement of a Tolerance.

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

[FR Doc. 2026-16720 Filed: 8/14/2026 8:45 am; Publication Date: 8/17/2026]