BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0232; FRL-12153-01-OCSPP]

Potassium Carbonate; 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 potassium carbonate in or on all food commodities when used as a biochemical fungicide in accordance with label directions and good agricultural practices. Biofungitek, S.L. submitted a petition, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance for the biochemical pesticide potassium carbonate. This regulation eliminates the need to establish a maximum permissible level for residues of potassium carbonate 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 the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0232, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., 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 and for the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Chris Pfeifer, 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) 566-1599; 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, greenhouse owner, 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).

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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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. 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-2021-0232, 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0232 by one of the following methods:

• *Federal eRulemaking Portal*: *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.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Background and Statutory Findings

In the **Federal Register** of June 1, 2021 (86 FR 29229) (FRL-10023-95), 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 0F8851) by Biofungitek, S.L, Parque Científico y Tecnológico de Bizkaia, Astondo Bidea (Building 612), 48160 Derio, Spain (c/o Compliance Services International, 7501 Bridgeport Way West, Lakewood, WA 94899). The petition requested that 40 CFR part 180 be amended to establish an exemption from the requirement of a tolerance for residues of potassium carbonate, when used as a biochemical fungicide in or on all agricultural food commodities in accordance with label directions and good agricultural practices. That document referenced a summary of the petition prepared by Biofungitek, S.L., which is available in the docket at *https://www.regulations.gov*. No comments were received on the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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 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 "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

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. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, 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 to potassium carbonate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with potassium carbonate follows.

A. Toxicological Profile

Potassium carbonate is a white, odorless solid that is classified as an inorganic salt. It is used as a leavening agent in pastas and breads, a pH adjustor for chocolate production, a buffering agent for making wine, and a dietary supplement in chicken feed. The Joint Food and Agriculture Organization of the United Nations (FAO)/ World Health Organization (WHO) Expert Committee on Food Additives has determined that potassium carbonate has no limited terms for daily intake when used as a food additive (JFAO/WHO, 1966). Additionally, potassium

carbonate has been granted “Generally Recognized as Safe” (GRAS) status for use as a food additive by the United States Food and Drug Administration (FDA) per 21 CFR 184.1613.

With regard to historical risk, humans have been regularly exposed to potassium carbonate in the environment without known incident. This naturally occurring inorganic salt is ubiquitous in the environment. Potassium carbonate is regularly found in soil, and is a primary constituent of potash, which has been used as a primary ingredient in ceramics, soaps and fertilizers since the Bronze Age. Currently, humans are also regularly exposed to potassium carbonate in cosmetics and foods without known toxic effects. Although humans are regularly exposed to this compound in the home and in the natural environment, sustained exposures of any significant concentration are unlikely in the environment, as this inorganic salt is extremely soluble, readily dissociating into nontoxic ions in the environment. Given humans’ regular exposures to potassium carbonate without incident, its high solubility and its overall low toxicological profile, no significant risks are expected relative to any potential pesticidal exposures.

As an active ingredient in pesticidal end-use products (EPs), potassium carbonate is a biochemical fungicide intended to be applied by spray to crops, turf and ornamentals in both agricultural and residential settings. Potential exposures to potassium carbonate are not expected to result in any risks of toxicological concern. Potassium carbonate is not expected to pose a risk through any pathways for the following reasons. (1) Potassium carbonate is highly water soluble and is expected to dissociate into nontoxic potassium and carbonate ions soon after any pesticidal application. (2) The human body has natural regulation mechanisms for dietarily processing the potassium and carbonate ions that comprise the salt, potassium carbonate. Specifically, the kidneys regulate the concentration of these ions; and excess ions are filtered out and excreted through urine. (3) Potassium and carbonate ions naturally occur and are already ubiquitous in the

environment; and no significant increase in exposure to potassium and carbonate ions are expected relative to pesticidal use of potassium carbonate. (4) With regard to any potential oral toxicity, potassium carbonate showed low acute oral toxicity and no major adverse effects in the available subchronic oral toxicity database. (5) Based on the physicochemical properties, potassium carbonate degrades rapidly in the environment and is not anticipated to be present in any concentration outside potential naturally occurring background levels. (6) No toxicological endpoints have been identified for potassium carbonate. All the data submitted in support of the registration of this potassium carbonate confirm its low risk relative to any pesticidal exposures.

With regard to the overall toxicological profile, potassium carbonate is of low toxicity through most routes of exposure.

All acute toxicity data requirements for potassium carbonate were satisfied by either guideline studies or waiver rationales. The guideline studies submitted for potassium carbonate resulted in the active ingredient being classified as Toxicity Category IV for acute dermal and inhalation toxicity, and Toxicity Category III for acute oral toxicity. The data requirements for primary eye and dermal irritation were satisfied by rationales. The applicant observed that because potassium chloride as an inorganic salt has high pH, it is both is severely irritating and corrosive. In recognition of these physical-chemical characteristics, the applicant ascribed Toxicity Category I for both primary eye and primary dermal irritation. However, it must be noted that when potassium carbonate is added to the aqueous end-use product, which has been assessed as part of the assessment for potassium carbonate, the irritating effects are greatly diminished, and the primary eye and primary dermal irritation for that end-use product are Toxicity Category III. Lastly, available data indicate that potassium carbonate is not a skin sensitizer.

All subchronic data requirements for the active ingredient potassium carbonate were

satisfied with acceptable waiver rationales and a non-guideline study. The 90-day dermal toxicity and 90-day inhalation toxicity data requirements were satisfied by waiver rationales based primarily on low exposure and low toxicity. The subchronic oral toxicity data requirement was satisfied by a non-guideline subchronic oral toxicity repeat-dose oral 90-day dietary study using an acceptable surrogate salt, potassium bicarbonate.

In the 90-day oral toxicity on potassium bicarbonate, rats were dosed at 1,480 and 3,130 mg/kg/day (males), and 1,660 and 3,530 mg/kg/day (females) in the diet. The feeding study resulted in a no observed adverse effect level (NOAEL) of 1,480 mg/kg/day in males and 1,660 mg/kg/day in female rats. The dose levels tested were well above the limit dose of 1,000 mg/kg/day. There were no treatment-related adverse effects on mortality, clinical signs, functional observational battery (FOB), body weight, body weight gain, food consumption, ophthalmoscopy, macroscopic findings, testosterone, follicle stimulating hormone, luteinizing hormone levels, organ weights, or histopathology.

A waiver rationale for the 90-day dermal toxicity requirement was assessed by the Office of Pesticide Program's (OPP's) Hazard and Science Policy Council (HASPOC) using a weight of the evidence (WOE) approach that considered all of the available hazard and exposure information. The rationale for 90-day dermal toxicity was determined to be sufficient to satisfy the data requirement based on the following considerations: (1) potassium carbonate has been assigned Toxicity Category IV for acute dermal toxicity and is not a dermal sensitizer; (2) there were no adverse effects observed in the available repeat oral dose toxicity study with similar salts, including potassium bicarbonate; (3) humans have a history of exposure to potassium carbonate and similar carbonate salts without adverse reactions as seen in cosmetics and foods approved for use by the FDA; (4) the physical chemical properties of potassium carbonate such as high pH, high solubility in water, a low partition coefficient and low vapor pressure indicate a

low probability for dermal penetration; (5) the carbonates and bicarbonates are recognized as GRAS by the FDA (21 CFR 184.1619) for use as flavoring agents; (6) potassium carbonate is approved for inert ingredient (buffering agent) use in pesticide products and has an exemption from the requirement of a tolerance (40 CFR 180.920) when applied to growing crops; (7) human health risk from occupational dermal exposure to the proposed pesticide product is expected to be comparatively minimal, as the maximum concentration reported in cosmetics is 93.4% (in rinse-off products), which already exceeds the product formulation concentration (58.04%) of the proposed EP prior to being further diluted into a spray solution; and (8) using a conservative dermal absorption estimate of 10% and an oral point of departure (POD) of 180 mg/kg/day, any potential exposure would be far below the limit dose of 1,000 mg/kg/day.

A waiver rationale for the 90-day inhalation toxicity requirement was assessed by the OPP's HASPOC using a WOE approach that considered all of the available hazard and exposure information. The rationale for 90-day inhalation toxicity was determined to be sufficient to satisfy the data requirement based on the following considerations: (1) the physical-chemical properties of potassium carbonate show negligible vapor pressure because it is a solid powder that dissociates into K^+ and CO_3^{2-} ions when mixed with water; (2) the toxic effects of potassium carbonate are low based on the acute inhalation toxicity study (Toxicity Category IV); (3) during a non-guideline 21-day inhalation study for a potassium carbonate-based scrubbing solution, male and female rats dosed at 0.1, 0.2, and 0.4 mg/L showed no adverse systemic or neurotoxic effects; (4) no adverse effects or evidence of irritation were identified in the publicly available repeat-dose oral toxicity or developmental toxicity studies; and (5) although a qualitative risk assessment approach was taken, relevant margins of exposure (MOEs) were calculated from an oral POD of 180 mg/kg/day to represent worst-case scenarios. The occupational and residential handler MOEs ranged from 13,000 to 90,000,000 which are above 10X the Agency's Level of

Concern (LOC) of 100.

The data requirements for developmental toxicity were satisfied with the submission of four acceptable non-guideline developmental toxicity studies. No adverse effects on maternal or developmental parameters up to the highest doses tested were reported in the test ani. One developmental study administered potassium carbonate via oral gavage at 290 mg/kg/day to mice and at 180 mg/kg/day to rats. No discernible effects were observed on implantation, maternal or fetal survival; and no abnormalities were observed in soft or skeletal tissues. Another study using an accepted surrogate, potassium bicarbonate, was conducted on pregnant animals up to 330 mg/kg/day in rabbits, 340 mg/kg/day in rats, and 580 mg/kg/day in mice. No adverse effects were observed for any animals. In a third study, sodium carbonate, a carbonate which is significantly similar to potassium carbonate, was administered via oral gavage at dose levels up to 179 mg/kg/day in mice, 245 mg/kg/day in rats, and 340 mg/kg/day in rabbits with no adverse effects observed. In a fourth study, calcium carbonate, another carbonate which is significantly similar to potassium carbonate, was administered to rats up to 2,188 mg/kg/day in the diet showed no evidence of maternal toxicity or embryotoxic/teratogenic effects. In short, potassium carbonate is of low toxicity and significant exposure from use as a pesticide is not anticipated and, as such, is not expected to pose any risks with regard to developmental toxicity.

Genotoxicity and mutagenicity data requirements were satisfied through a variety of studies from the open scientific literature on potassium carbonate and similar carbonate/bicarbonate salts indicated that potassium carbonate and related carbonates are not genotoxic. (All the similar carbonate and bicarbonate salts referenced were determined to be acceptable surrogates as they were considered to be both structurally and functionally similar.) In a non-guideline Ames test, potassium carbonate tested negative and did not induce mutations in the *Salmonella typhimurium* strains TA92, TA1535, TA1000, TA 1537, TA94, and TA98 in the

presence or absence of metabolic activation. In the same non-guideline report, potassium carbonate did not induce chromosome aberrations in a mammalian cell line (Chinese hamster fibroblasts) in the presence and absence of S9 metabolic activation. In another study, potassium bicarbonate and sodium bicarbonate, two carbonates considered similar to potassium carbonate, both tested negative and did not induce mutations in the *S. typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA100 in the presence or absence of metabolic activation. An *in vitro* gene mutation guideline study in bacteria, showed calcium carbonate, another carbonate considered to be similar to potassium carbonate, was determined to be non-mutagenic to the *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* WP2 uvrA with and without metabolic activation. Calcium carbonate did not induce chromosome aberrations in a mammalian cell line (L5178Y) in the presence or absence of S9 metabolic activation. Lastly, a guideline bacterial reverse mutation assay (OCSPP 870.5100) was submitted using potassium carbonate (MRID 50898908). In the guideline Ames test, potassium carbonate did not induce mutations in the *S. typhimurium* strains TA98, TA100, TA1535, TA 1537, and *Escherichia coli* WP2 uvrA in the presence or absence of metabolic activation. All submitted data indicate that potassium carbonate is non-genotoxic and non-mutagenic.

B. Toxicological Points of Departure/Levels of Concern

No toxicological endpoints have been identified for potassium carbonate. The active ingredient is of low toxicity, and significant exposure is not expected based on the low application rates and rapid degradation in the environment.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water*. As part of its qualitative risk assessment for potassium carbonate, the Agency considered the potential for dietary exposure to residues of the chemical. EPA concludes that dietary (food and drinking water)

exposures are expected to be negligible, as significant residues of the substance are not anticipated on treated commodities at the time of consumption based on its physical and chemical properties. Foremost, potassium carbonate, an inorganic salt, is highly water soluble and is expected to dissociate into potassium and carbonate ions soon after any pesticidal application. Notably, potassium and carbonate ions naturally occur and are already ubiquitous in the environment; and no significant increase in exposure to potassium and carbonate ions are expected relative to the proposed use of the EP. Equally important, the human body has natural regulation mechanisms for potassium and carbonate ions that enter the body. The kidneys regulate the concentration of these ions; and excess ions are filtered out and excreted through urine. Minimal exposure and compensatory regulation notwithstanding, no dietary risks of concern are anticipated for any potential pesticidal exposure, as no toxicological endpoint of concern was identified for potassium carbonate through the oral route of exposure.

2. *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). Potassium carbonate is intended for use in residential (non-occupational) settings. However, significant residential exposure is not expected because potassium carbonate is an inorganic ionic salt that does not easily volatilize and readily dissociates into potassium and carbonate ions in water. Both potassium and carbonate ions are ubiquitous in the environment; and data indicate that no significant increase in exposure to potassium carbonate is expected from use of potassium carbonate pesticide products. In addition, the ions K^+ and CO_3^{2-} resulting from the ionization (dissociation) of K_2CO_3 will not influence the natural K^+ or CO_3^{2-} level in the body due to how the kidneys regulate the ion concentration found in the blood. Given the physicochemical properties and rapid dissociation of the ionic salt, residential handler and post-application

exposures are not expected.

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." EPA has not found that potassium carbonate shares a common mechanism of toxicity with any other substances, and it does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed potassium carbonate 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. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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 support the choice of a different factor. An FQPA safety factor is not required at this time for potassium carbonate because no toxicological endpoints have been established and the qualitative risk assessment has concluded that Potassium Carbonate is of low toxicity and that no significant exposures are

expected.

E. Aggregate Risk

In accordance with the FFDCA, OPP must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources that have the same toxicological endpoints are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. A qualitative aggregate risk assessment has been conducted for the proposed use of potassium carbonate based on the lack of identified endpoints in the toxicological database and minimal exposure to the active ingredient. No risks of concern have been identified.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the May 31, 2023, document entitled "Product Chemistry Review and Human Health Risk Assessment for FIFRA Section 3 Registration of the Manufacturing-Use Product, Potassium Carbonate (99.5% Fine Powder) Containing Potassium Carbonate (99.5%) as its Active Ingredient." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of potassium carbonate.

V. Other Considerations

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.

VI. Conclusion

Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of potassium carbonate in or on all food commodities when used as a biochemical fungicide in accordance with label directions and good agricultural practices.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), such as the exemption 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), 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 the rule in the **Federal Register**. 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: July 29, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated 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 § 180.1413 to subpart D to read as follows:

§ 180.1413 Potassium Carbonate; exemption from the requirement of a tolerance.

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