2011. The annual report for reporting years 2011 and beyond must be submitted no later than March 31 of each calendar year for GHG emissions in the previous calendar year, except as provided in paragraphs (b)(1) and (b)(5) of this section.

(1) For reporting year 2011, facilities with one or more of the subparts listed in paragraphs (b)(1)(i) through (b)(1)(xi) of this section and suppliers listed in paragraph (b)(1)(xii) of this section are required to submit their annual GHG report no later than September 28, 2012. Facilities and suppliers that are submitting their second annual GHG report in 2012 and that are reporting on one or more subparts listed in paragraphs (b)(1)(i) through (b)(1)(xii) of this section must notify EPA by March 31, 2012, that they are not required to submit their annual GHG report until September 28, 2012.

(i) Electronics Manufacturing (subpart I).

(ii) Fluorinated Gas Production (subpart L).

(iii) Magnesium Production (subpart T).

(iv) Petroleum and Natural Gas Systems (subpart W).

(v) Use of Electric Transmission and Distribution Equipment (subpart DD).

(vi) Underground Coal Mines (subpart FF).

(vii) Industrial Wastewater Treatment (subpart II).

(viii) Geologic Sequestration of Carbon Dioxide (subpart RR).

(ix) Manufacture of Electric Transmission and Distribution (subpart SS).

(x) Industrial Waste Landfills (subpart TT).

(xi) Injection of Carbon Dioxide (subpart UU).

(xii) Imports and Exports of Equipment Pre-charged with Fluorinated GHGs or Containing Fluorinated GHGs in Closed-cell Foams (subpart QQ).

(2) For a new facility or supplier that begins operation on or after January 1, 2010, and becomes subject to the rule in the year that it becomes operational, report emissions starting the first operating month and ending on December 31 of that year. Each subsequent annual report must cover emissions for the calendar year, beginning on January 1 and ending on December 31.

(3) For any facility or supplier that becomes subject to this rule because of a physical or operational change that is made after January 1, 2010, report emissions for the first calendar year in which the change occurs, beginning with the first month of the change and ending on December 31 of that year. For a facility or supplier that becomes subject to this rule solely because of an increase in hours of operation or level of production, the first month of the change is the month in which the increased hours of operation or level of production, if maintained for the remainder of the year, would cause the facility or supplier to exceed the applicable threshold. Each subsequent annual report must cover emissions for the calendar year, beginning on January 1 and ending on December 31.

(4) Unless otherwise stated, if the final day of any time period falls on a weekend or a federal holiday, the time period shall be extended to the next business day.

(5) The annual GHG report for reporting year 2024 must be submitted no later than May 30, 2025.

* * * * *

[FR Doc. 2025–04724 Filed 3–19–25; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0848; FRL–12666–01–OCSPP]

Potassium Polyaspartate in Pesticide Formulations; 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 polyaspartate (CASRN 64723–18–8) when used as an inert ingredient (complexing agent), at a maximum of 10% in formulation, pre-harvest. Rosen's Inc., 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 potassium polyaspartate, when used in accordance with the terms of the exemptions.

DATES: This regulation is effective March 20, 2025. Objections and requests for hearings must be received on or before May 19, 2025 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–20220848, 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: 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 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.''

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 through 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.

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 EPA, you must identify docket ID number EPA–HQ–OPP–2022–0848, 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 May 19, 2025.

EPA's Office of Administrative Law Judges (OALJ), where 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 Service and Filing'', 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/HomePage?ReadForm.*

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. Petition for Exemption

In the **Federal Register** of November 17, 2022 (87 FR 68959, FRL 9410–07–OCSPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11696) by Rosen's Inc., 700 SW 291 Hwy. Suite 204, Liberty, MO 64068. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of potassium polyaspartate (CASRN 64723–18–8) when used as an inert ingredient (complexing agent) at a maximum of 10% in pesticide formulations applied pre-harvest under 40 CFR 180.920. That document referenced a summary of the petition prepared by Rosen's Inc., the petitioner, which is available in the docket. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients in the pesticide, that are not active ingredients as defined in 40 CFR 153.125 and 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

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 potassium polyaspartate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with potassium polyaspartate 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 potassium polyaspartate 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 potassium polyaspartate is also supported by data regarding the analog sodium polyaspartate. EPA has determined that since sodium polyaspartate is likely to mimic the

effects of sodium polyaspartate due to similarities in the functional groups/structure, composition, metabolism, and physical/chemical properties, it is appropriate to bridge sodium polyaspartate data to assess potassium polyaspartate.

Potassium polyaspartate is anticipated to exhibit low levels of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not likely to be a skin or eye irritant or a skin sensitizer. No adverse effects were reported in the 14-day and 90-day study in rats at the limit dose of 1,000 mg/kg/day. Although developmental/reproductive toxicity studies were not available, the 90-day study did not show any adverse effects on reproductive parameters and there were no structural alerts for developmental/reproductive toxicity when evaluated using modeling. The 90-day study also performed a neurotoxicity screening, and no signs of neurotoxicity were reported. No evidence of immunotoxicity was seen in the studies. Furthermore, concern for carcinogenicity is low, based on negative results in mutagenicity studies, and the lack of structural alerts for carcinogenicity.

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 dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). 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 potassium polyaspartate is adequately defined. Overall, potassium polyaspartate 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, a qualitative risk assessment for potassium polyaspartate can be performed.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to potassium polyaspartate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from potassium polyaspartate in food as follows:

Dietary exposure (food and drinking water) to potassium polyaspartate may occur following ingestion of foods with residues from their use in accordance with this exemption. However, a quantitative dietary exposure assessment was not conducted 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). Potassium polyaspartate may be present in pesticide and non-pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. *Cumulative effects from substances with a common mechanism of toxicity.* FFDCA section 408(b)(2)(D)(v) 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 potassium polyaspartate to share a common mechanism of toxicity with any other substances, and potassium polyaspartate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that potassium polyaspartate 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

FFDCA section 408(b)(2)(C) 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 (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 potassium polyaspartate 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 and low toxicity in available studies associated with potassium polyaspartate, EPA conducted a qualitative assessment. As part of that qualitative 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 potassium polyaspartate residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of potassium polyaspartate in or on any food commodities. EPA is establishing a limitation on the amount of potassium polyaspartate that may be used in pesticide formulations applied pre-harvest. This limitation will be enforced through the pesticide registration process under the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 10% potassium polyaspartate in the final pesticide formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of potassium polyaspartate (CASRN 64723–18–8) when used as an inert ingredient (complexing agent) at a maximum of 10% in pesticide formulations applied pre-harvest under 40 CFR 180.920.

VII. Statutory and Executive Order Reviews

This action establishes exemptions 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.*).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions 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 (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a rule report to each the House of Congress, and to the Comptroller General of the United States. This action does 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: March 10, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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. In § 180.920, amend Table 1 to 180.920 by adding, in alphabetical order, an entry for ''Potassium polyaspartate'' to read as follows:

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

* * * * *

TABLE 1 TO § 180.920

Inert ingredients	Limits	Uses
* * *	* * *	*
Potassium polyaspartate (CASRN 64723–18–8)	Maximum of 10% in pesticide formulations	Complexing agent.
* * *	* * *	*

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