E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0292; FRL-9420-01-OCSPP]

Polyammonium Bisulfate; 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 Polyammonium bisulfate (PABS) (CAS Reg. No. 10043-02-4), herein referred to as PABS, when used as an inert ingredient (carrier, adjuvant, buffer and stabilizer) in/on growing crops and raw agricultural commodities pre- and post-harvest, limited to 40% in pesticide non-residential formulations and 5% in pesticide formulations for residential use. An exemption is also established for its use in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils, limited to 250 parts per million (ppm). Spring Regulatory Sciences on behalf of Earth Science Laboratories, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PABS.

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-2021-0292, 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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Marietta Echevarria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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, 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-2021-0292 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-2021-0292, 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/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Petition for Exemption

In the *Federal Register* of June 1, 2021 (86 FR 29229) (FRL-10023-95), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11410) by the Spring Regulatory Sciences (6620 Cypresswood Dr, Suite 250 Spring, TX 77379) on behalf of Earth Science Laboratories, Inc., (113 SE 22nd Street, Suite 1, Bentonville, AR 72712). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of PABS (CAS Reg. No. 10043-02-4) when used as an inert ingredient (carrier, adjuvant, buffer and as a stabilizer) in pesticide formulations applied in/on growing crops pre- and post-harvest, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils under 40 CFR 180.940(a). That document referenced a summary of the petition prepared by Spring Regulatory Sciences on behalf of Earth Science Laboratories, Inc., the petitioner, which is available in the docket, *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, EPA has limited the maximum concentration of PABS to not more than 40% in pesticide formulations for non-residential use and not more than 5% in pesticide formulations for residential use under 40 CFR 180.910 and limited the maximum concentration of PABS to 250 ppm under 40 CFR 180.940(a). These limitations are based on the Agency's risk assessment which can be found at *https://www.regulations.gov* in document "Polyammonium Bisulfate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Amendment to the Tolerance Exemption When Used as an Inert Ingredient in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2021-0292.

III. Inert Ingredient Definition

Inert ingredients are all ingredients 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

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 tolerance is "safe." Section 408(b)(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. Section 408(b)(2)(C) of FFDCA 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..." and specifies factors EPA is to consider in establishing an exemption.

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 appreciable risks 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.

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 PABS including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with PABS 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 PABS 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.

Acute toxicity studies were conducted with ET-3000, a mixture containing PABS. According to these studies acute oral toxicity is low, as the lethal dose (LD_{50}) is 1,750 milligrams/kilogram (mg/kg) in rats, and the acute dermal toxicity in rats is also low, the LD_{50} is greater than 5,000 mg/kg. PABS is also not toxic via acute inhalation exposure, as the lethal concentration (LC50) is greater than 2.09 mg/L in rats. PABS is, however, corrosive to rabbit skin and the results were equivocal in a dermal sensitization study in mice.

Based on the available data on surrogate chemicals, PABS is expected to cause anemia and diarrhea at doses greater than 1,000 mg/kg/day following subchronic exposure in rats. In a

chronic and multigeneration toxicity study in which carcinogenicity was also evaluated, hyperplasia of the glandular stomach and occult blood in the feces were observed at 144 mg/kg/day in rats. No reproduction toxicity or fetal susceptibility was observed in this study. In another chronic/carcinogenicity toxicity study in rats, chronic nephropathy was observed at approximately 564 mg/kg/day. No evidence of carcinogenicity was observed in either study.

No mutagenicity, genotoxicity, or chromosomal aberrations were seen in a battery of mutagenicity tests with the surrogate chemicals except in the case of sodium metabisulfite. Sodium metabisulfite was negative in the Ames test and a mammalian bone marrow chromosome aberration test. However, positive results were observed in a mammalian cell chromosome aberration assay and sister chromatid exchange assays in human lymphoctyes, and a questionably positive result was observed in an *in vivo* mammalian cell chromosome aberration assay. The mutagenicity results are equivocal for sodium metabisulfite.

Neurotoxicity and immunotoxicity toxicity studies are not available for review. However, no evidence of neurotoxicity or immunotoxicity was seen in the available studies.

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/pesticides/factsheets/riskassess.htm*.

No acute endpoint was identified; therefore, an acute assessment is not necessary. The combined chronic toxicity/carcinogenicity study in rats was selected for chronic dietary exposure as well as all other exposure scenarios (incidental oral, dermal and inhalation). In this study, the NOAEL is 72 mg/kg/day, and the LOAEL is 144 mg/kg/day based on hyperplasia of the glandular stomachs and occult blood in the feces. This represents the lowest NOAEL in the database in the most sensitive species. The standard uncertainty factors (UFs) were applied to account for interspecies (10x) and intraspecies (10x) variations. The default value of 100% was used for the dermal and inhalation absorption factors.

C. Exposure Assessment

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

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for PABS. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary

Exposure and Risk Assessments for the Inerts," (D361707, S. Piper, 2/25/09) and can be found at *https://www.regulations.gov* in docket ID number EPA-HQ-OPP-2008-0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. However, due to dietary risk concerns in assessing this petition request, the Agency assumed that a product consisted of 40 percent PABS instead of 50 percent, as mentioned above. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a combination of different inert ingredients used, which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the Agency considers the active ingredient with the highest tolerance level for that commodity as the guide to assess the total potential level of inert ingredient residues on that commodity. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservative assumption is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100

percent of all foods are treated with the inert ingredient at 40% in the pesticide product at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data. EPA did assume that PABS will be limited to 40% in pesticide non-residential formulations that will be applied to crops and raw agricultural commodities pre- and post-harvest.

To assess dietary exposure to PABS due to its use in antimicrobial products, the EPA calculated the daily dietary dose (DDD) and the estimated daily intake (EDI) as described in the Food Drug Administration (FDA) model. The assessment considered: application rates (limited to 250 ppm), residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on FDA Food Contact Surface Sanitizing Solution Dietary Exposure Assessment Model (2003).

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for PABS, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure

model.

3. *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). PABS may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, specifically in antimicrobial formulations applied to food-contact surfaces and utensils. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden with a high-end post application dermal exposure from contact with treated lawns. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). A conservative residential exposure and risk assessments was completed for pesticide products containing PABS as an inert ingredient. Due to risks of concern resulting from aggregate exposure to PABS, the petitioner requested a limitation of 5% in products for residential use. Therefore, the Agency conducted an assessment to represent conservative residential exposure by assessing PABS (outdoor scenarios) and in disinfectant-type uses (indoor scenarios) at no more than 5% in the final formulation. The Agency assessed pesticide products containing PABS using exposure scenarios used by OPP's Antimicrobials Division to represent conservative residential handler exposure. Further details of this residential exposure and risk analysis can be found at *https://www.regulations.gov* in the memorandum entitled: "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA-HQ-OPP-2008-0710).

4. *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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to PABS and any other substances. PABS does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that PABS 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/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. 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.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X for the chronic dietary assessment for the following reasons. The toxicity database for surrogate chemicals to PABS contains a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, multi-generation reproduction toxicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies on surrogate chemicals; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Fetal susceptibility is not

observed in the available studies. In the multi-generation reproduction toxicity study in rats, maternal and offspring toxicity, which manifested as hyperplasia of the fore and glandular stomachs, and occult blood in the feces were observed at the same dose, 144 mg/kg/day. The cRfD of 0.72 mg/kg/day is based on the effects seen in this study. No reproduction toxicity is seen in the available studies. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal susceptibility, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, PABS is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to PABS from food and water will utilize 83% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

PABS is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure from food and water with short-term residential exposures to PABS.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 273 for adults. For children, the aggregate MOE is 115. Because EPA's level of concern for PABS is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

PABS is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to PABS.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 430 for adults. For children the aggregate MOE is 117. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for PABS is an MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, PABS is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, 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 PABS residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of PABS in or on any food commodities. EPA is establishing a limitation on the amount of PABS that may be used in pesticide formulations. 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 where PABS exceeds 40% in the final pesticide formulations for non-residential use or 5% in the final pesticide formulations for indoor and outdoor residential use. EPA will also not register any pesticide formulations for antimicrobials where PABS exceeds 250 ppm.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for PABS (CAS Reg. No. 10043-02-4) when used as an inert ingredient (carrier, adjuvant, buffer, stabilizer) in pesticide formulations applied in/on growing crops pre- and post-harvest, limited to 40% in non-residential formulations and 5% in formulations for residential indoor and outdoor use; and under 40 CFR 180.940(a) in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils, limited to 250 ppm end-use concentration in formulations.

VII. Statutory and Executive Order Reviews

This action establishes 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 tolerance 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: February 24, 2022.

Marietta Echeverria,

Acting Director, Registration Division, 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. In §180.910, amend table 1 to 180.910 by adding in alphabetical order the inert ingredient "Polyammonium Bisulfate (CAS Reg. No. 10043-02-4)" 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
* * * * * * *		
Polyammonium Bisulfate (CAS Reg. No. 10043-02-4)	Not to exceed 40% in non-residential formulations.	Carrier, adjuvant, buffer,

	Not to exceed 5% in outdoor and indoor formulations for residential use	and stabilizer
* * * * * * *		

3. In §180.940, amend table 1 to paragraph (a) by adding in alphabetical order an entry for “Polyammonium Bisulfate” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)

* * * * *

(a) * * *

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* *	*	* * * *
Polyammonium Bisulfate	10043-02-4	When ready for use, the end-use concentration is not to exceed 250 ppm
* *	*	* * * *

[FR Doc. 2022-04368 Filed: 3/2/2022 8:45 am; Publication Date: 3/3/2022]