BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0265; FRL-9927-65]

n-Butyl benzoate; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of n-butyl benzoate (CAS Reg. No. 136-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals and when used as an inert ingredient in antimicrobial formulations in food-contact surface sanitizer products at a maximum level in the end-use concentration of 15,000 parts per million (ppm). Exponent, Inc., on behalf Huntsman Corp., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of n-butyl benzoate**.**

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-2014-0265, is available at *http://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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, 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 Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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-2014-0265 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-2014-0265, by one of the following methods:

• *Federal eRulemaking Portal*: *http://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 *http://www.epa.gov/dockets/contacts.html*.

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

II. Petition for Exemption

In the **Federal Register** of October 24, 2014 (Vol. 79 FR 63594) (FRL-9916-03), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10682) by Exponent, Inc., 1150 Connecticut Ave., NW, Suite 1100, Washington, DC 20035 on behalf Huntsman Corp., 8600 Gosling Road, The Woodlands, TX 77381. The petition requested that 40 CFR 180.910, 180.930, and

180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of n-butyl benzoate (CAS Reg. No. 136-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals and when used as an inert ingredient in antimicrobial formulations in food-contact surface sanitizer products. That document referenced a summary of the petition prepared by Exponent, Inc., on behalf Huntsman Corp., the petitioner, which is available in the docket, *http://www.regulations.gov*. No tolerance-related comments were received on the notice of filing.

Based on a review of the data submitted in support of this petition, EPA has modified the exemption requested by limiting the amount of n-butyl benzoate allowed in food contact sanitizing solutions to a maximum 15,000 ppm (1.5%). This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document "n-Butyl Benzoate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations," in docket ID number EPA-HQ-OPP-2014-0265.

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...."

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

In acute oral, dermal, and inhalation toxicity studies in rats, n-butyl benzoate was found to be slightly toxic to nontoxic. In primary eye and dermal irritation studies in

rabbits, n-butyl benzoate was found to be minimally irritating. In a dermal sensitization study in guinea pigs, n-butyl benzoate was not a dermal sensitizer.

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, n-butyl benzoate was administered daily to rats by gavage at doses of 0 (vehicle control), 250, 500 and 1,000 mg/kg bw/day. The NOAEL for parental toxicity was 1,000 mg/kg/day; the highest dose tested. The LOAEL for parental toxicity was not observed in this study. The NOAEL for embryo-fetal toxicity was 500 mg/kg bw/day based on increased pup mortality on post-natal day zero observed at the LOAEL of 1,000 mg/kg/day.

No positive mutagenic response was observed for n-butyl benzoate in a reverse bacterial mutation assay.

No chronic toxicity data for n-butyl benzoate are available.

There are no cancer studies available for n-butyl benzoate. n-Butyl benzoate is metabolized by esterase mediated hydrolysis resulting in the formation of two major polar metabolites, n-butyl alcohol and benzoic acid. Each metabolite enters other degradation pathways to be rapidly metabolized and/or excreted. Based on predicted rapid metabolism and excretion, the lack of specific target organ toxicity in the OCSPP Harmonized Test Guideline 870.3650 study, the results of genotoxicity testing being negative, and a Quantitative Structure Activity Relationship (QSAR) expert model, DEREK Nexus, that indicates no structural alerts for carcinogenicity, n-butyl benzote is not expected to be carcinogenic.

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 *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

1. *Acute dietary (all populations)*. There were no adverse effects observed attributable to a single dose for the general population (including infants and children) or females 13-49 years of age.

2. *Chronic dietary (all populations)*. The chronic population adjusted dose (cPAD) of 5 mg/kg/day is established based on the NOAEL of 500 mg/kg/day from a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats. The adverse effects seen in this study were increased pup mortality

observed at the LOAEL of 1,000 mg/kg/day. The Food Quality Protection Act (FQPA) safety factor/database uncertainty factor of 1X and 10X intra- and interspecies uncertainty factors are utilized for dietary risk assessment.

3. *Dermal, short- and intermediate-term*. The level of concern (LOC) for short- and intermediate-term dermal exposure is a margin of exposure (MOE) of 100 and the assessment is based on the NOAEL (500 mg/kg/day) from the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats

4. *Inhalation, short- and intermediate term*. The LOC for short-and intermediate-term inhalation exposure is a MOE of 100 and the assessment is based on the NOAEL (500 mg/kg/day) from the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats.

5. Quantification of cancer risk is not appropriate since there are no concerns for cancer based on data that n-butyl benzoate is metabolized by esterase mediated hydrolysis resulting in the formation of two major polar metabolites, n-butyl alcohol and benzoic acid, neither substance being a concern for cancer. In addition, there is a lack of specific target organ toxicity in the OCSPP Harmonized Test Guideline 870.3650 study, the results of genotoxicity testing for n-butyl benzoate are negative, and QSAR expert model, DEREK Nexus, indicates that there are no structural alerts for carcinogenicity. As such, n-butyl benzote is not expected to be carcinogenic.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to n-butyl benzoate, EPA considered exposure under the proposed exemption from the

requirement of a tolerance. EPA assessed dietary exposures from n-butyl benzoate in food as follows:

The Agency assessed the dietary exposures to n-butyl benzoate as an inert ingredient for use in pesticide formulations applied to growing crops, raw agricultural commodities, and livestock as well as an inert ingredient for use in food-contact surface sanitizing solutions. In the case of dietary exposures to n-butyl benzoate as an inert ingredient used in pesticide formulations applied to growing crops, raw agricultural commodities, and livestock, a chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM-FCID)TM, Version 3.16. EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for n-butyl benzoate. In the absence of specific residue data, EPA has developed an approach that 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 *http://www.regulations.gov* in docket ID number EPA-HQ-OPP-2008-0738.

In the case of the proposed use of n-butyl benzoate as an inert ingredient in food-contact sanitizing pesticide products, EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use. This same methodology has been utilized by FDA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of n-butyl benzoate can be found at *http://www.regulations.gov* in document "n-Butyl Benzoate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations," pp. 13-15 in docket ID number EPA-HQ-OPP-2014-0265.

The exposures from food and food contact sanitizing are then added together for the final dietary exposure assessment.

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 n-butyl benzoate, 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).

There are no current or proposed residential uses for n-butyl benzoate, however it is possible that n-butyl benzoate may be used as an inert ingredient in pesticide products that may have uses resulting in potential residential exposures. A complete description of the approach used to assess possible residential exposures from n-butyl benzoate can be found at *http://www.regulations.gov* in document "n-Butyl Benzoate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations," pp. 16 in docket ID number EPA-HQ-OPP-2014-0265.

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."

EPA has not found n-butyl benzoate to share a common mechanism of toxicity with any other substances, and n-butyl benzoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that n-butyl benzoate 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 *http://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.

2. *Prenatal and postnatal sensitivity*. There is an evidence of increased susceptibility of infants and children in the OECD 422 study in rats. In this study, the NOAEL for parental toxicity was 1,000 mg/kg/day; the highest dose tested while the NOAEL for embryo-fetal toxicity was 500 mg/kg/day based on increased pup mortality on post-natal day zero seen at the LOAEL of 1,000 mg/kg/day. However, the concern for this susceptibility is low because there is clear NOAEL established in the study protecting the offspring, and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility. The endpoints and doses selected for the dietary risk assessment of n-butyl benzoate are protective of adverse effects in both offspring and adults.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for n-butyl benzoate contains acute toxicity, subchronic toxicity, reproductive toxicity, developmental toxicity, and genotoxicity data. No

immunotoxicity or neurotoxicity study is available; however, there was no evidence of any triggers for immunotoxicity or neurotoxicity in the database. Therefore, there is no need for immunotoxicity or neurotoxicity study at this time and no need for additional uncertainty factor for the lack of those studies.

ii. Although there is evidence that n-butyl benzoate results in increased susceptibility in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats, that study identified a clear NOAEL for offspring effects, which the Agency is using as the endpoint for its assessment. Therefore, the concern for these effects is low and there is no need for an additional uncertainty factor.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues, as well as conservative assumptions for food-contact surface sanitizers. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to n-butyl benzoate in drinking water. These assessments will not underestimate the exposure and risks posed by n-butyl benzoate.

E. Aggregate Risks and Determination of Safety

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, n-butyl benzoate 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 n-butyl benzoate from food and

water will utilize 21.0% of the cPAD for the U.S. population and 94.1% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure

3. *Short-and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). While n-butyl benzoate is not currently used as an inert ingredient in pesticide products that are registered for uses that could result in short- or intermediate-term residential exposure, it is possible that n-butyl benzoate could be used in such products and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with potential short-and intermediate-term residential exposures to n-butyl benzoate.

Using the exposure assumptions described in this unit for short-and intermediate-term exposures, EPA has concluded the combined food, water, and residential exposures result in aggregate short- and intermediate-term MOEs of 320 for adults and 100 for children (1-2 years old). EPA's level of concern for n-butyl benzoate is a MOE of 100 or below; however these MOEs are not of concern based on the highly conservative assumptions made regarding residential and dietary exposures to n-butyl benzoate as described in Unit IV. Section C.

4. *Aggregate cancer risk for U.S. population*. Based on data that n-butyl benzoate is metabolized by esterase mediated hydrolysis resulting in the formation of two major polar metabolites, n-butyl alcohol and benzoic acid. Each metabolite enters other degradation pathways to be rapidly metabolized and/or excreted, n-butyl benzoate is not expected to pose a cancer risk to humans.

5. *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 n-butyl benzoate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method for enforcement purposes is not required for n-butyl benzoate in pesticide formulations that include uses on crops for pre- and post-harvest, and on animals, since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

An analytical method is also not required for enforcement purposes for n-butyl benzoate on food-contact surfaces in antimicrobial applications since the Agency is not establishing a numerical tolerance for residues of n-butyl benzoate in or on any food commodities. EPA is establishing a limitation on the amount of n-butyl benzoate that may be used in food-contact surface antimicrobial applications. That 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 food-contact surface antimicrobial applications for sale or distribution that contains greater than 15,000 ppm (1.5%) of n-butyl benzoate by weight.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910, 180.930, and 180.940(a) for n-butyl benzoate (CAS Reg. No. 136-60-7) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals, and when used as an inert ingredient in antimicrobial formulations in food-contact surface sanitizer products at a maximum level in the end-use concentration of 15,000 parts per million (ppm).

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.*), 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 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

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: May 29, 2015.

Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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, add alphabetically the inert ingredient to the table to read as follows:

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

***** ***** ***** ***** *****

Inert ingredients	Limits	Uses
* * * * * * *		
n-Butyl benzoate (CAS Reg. No.136-60-7)		Solvent
* * * * * * *		

3. In §180.930, add alphabetically the inert ingredient to the table to read as follows:

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

***** ***** ***** ***** *****

Inert ingredients	Limits	Uses
* * * * * * *		
n-Butyl benzoate (CAS RN 136-60-7)		Solvent
* * * * * * *		

4. In §180.940(a) add alphabetically the inert ingredient to the table to read as follows:

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

***** ***** ***** ***** *****

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* *	* *	* * *
n-Butyl benzoate	136-60-7	When ready for use, the end-use concentration is not to exceed 15,000 ppm
* *	* *	* * *

* * * * *

[FR Doc. 2015-13818 Filed: 6/4/2015 08:45 am; Publication Date: 6/5/2015]