ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0783; FRL–9941–49]

Benzyl acetate; 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 benzyl acetate (CAS Reg. No. 140–11–4), when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops only under 40 CFR 180.920. Technology Sciences Group, on behalf of the Huntsman Corporation, 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 benzyl acetate.

DATES: This regulation is effective February 12, 2016. Objections and requests for hearings must be received on or before April 12, 2016, 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–2014–0783, 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.*

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–2014–0783 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 April 12, 2016. 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–2014–0783, 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 Wednesday, March 4, 2015 (80 FR 11611) (FRL–9922–68), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition ((PP) IN–10748) by Technology Sciences Group (TSG) 1150 18th Street NW., Suite 1000, Washington, DC 20036, on behalf of the Huntsman Corporation, 8600 Gosling Road, The Woodlands, TX 77381. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of benzyl acetate (CAS Reg. No. 140–11–4) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops only. That document referenced a summary of the petition prepared by the Huntsman Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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

Benzyl acetate exhibits low levels of toxicity via the dermal route of exposure in rabbits and inhalation and oral routes of exposure in rats. It is mildly irritating to the skin and minimally irritating to the eyes in rabbits. It is not a skin sensitizer in guinea pigs.

In a 13-week feeding study in the rat, atrophic seminiferous tubules were observed in male rats at dose levels of 12,500 parts per millions (ppm) (equivalent to 900 milligrams/kilogram/day (mg/kg/day)). The NOAEL was identified as 6,250 ppm (460 mg/kg/day). In mice, following 13 weeks of exposure via the diet, decreased body weight and food consumption were observed at all doses. The LOAEL was 3,130 ppm (425 mg/kg/day). A NOAEL was not established.

In a developmental toxicity study in the rat, maternal and fetal toxicity were observed at 1,000 mg/kg/day. Maternal toxicity was manifested as decreased body weight and fetal toxicity was manifested as reduced body weights, increased incidence of dilation of the renal pelvis and skeletal variations. Although qualitative fetal susceptibility is observed, fetal effects occur in the presence of maternal toxicity and a clear NOAEL of 500 mg/kg/day was established for maternal and developmental toxicity.

The potential for benzyl acetate to be genotoxic was evaluated in a battery of *in vivo* mammalian genotoxicity studies. It was negative in the Ames assay (with and without metabolic activation), sister chromatid exchange assay, Chinese hamster ovary cell assay, mouse micronucleus assay and in the dominant lethal assay in Drosophila. However, it gave a positive response in the mouse lymphoma assay. Since other chromosomal aberrations assays as well as gene mutation assays and a dominant lethal assay gave a negative response, it is concluded that benzyl acetate is unlikely to be mutagenic.

Evidence of neurotoxicity and neuronal degeneration was identified in the 13-week studies in rats and mice. Signs of neurotoxicity included tremors and ataxia that were associated with the degeneration of the glial cells in the cerebellum and hippocampus at the doses ≥12,500 ppm (≥2,000 mg/kg/day). Since these effects were induced at doses above the limit dose (1,000 mg/kg/day) and the established cRfD of 1.10 mg/kg/day, will be protective of these effects, the concern is low for these effects.

There is evidence that benzyl acetate suppresses immune function in mammalian systems in the rat however this effect occurs only at a dose that is lethal and well above the limit dose. In the 13-week feeding study in the rat, a decrease in the cellular components of the bone marrow, thymus and lymphoid follicles was observed at 50,000 ppm (3,900 mg/kg/day for males and 4,500 mg/kg/day for females), the highest dose tested and well above the limit dose. The NOAEL for this study was 12,500 ppm (900 mg/kg/day). The potential for immunotoxicity is not of concern because the effects occur well above the limit dose and the exposure to benzyl acetate through the proposed use is unlikely to occur at such a high dose.

The carcinogenicity of benzyl acetate in $F_3$44/N rats, and B6C3F_1 mice using was evaluated using the gavage method of administration and corn oil as a vehicle. There were indications that benzyl acetate increased the incidences of pancreatic acinar cell adenomas in male rats and the incidences of hepatocellular adenomas and forestomach neoplasms in male and female mice. Because of the confounding effects of corn oil on the incidences of pancreatic neoplasm and because of the controversy over the use of the gavage route of administration, the National Toxicology Program (NTP) decided to re-study benzyl acetate using the dosed feed route of administration. In 1993, the NTP conducted a second set of carcinogenicity studies in rats and mice using the dose feed route of administration. Benzyl acetate was administered via the diet to rats and mice at doses up to 12,000 ppm (510/575 mg/kg/day, male/female). Toxicity was not observed in rats at any dose. In mice, males and females exhibited reduced body weight throughout the entire study at 345/375 mg/kg/day. There was no evidence of carcinogenicity in mice and rats. Since the exposure to benzyl acetate is likely to occur via the dietary route in humans and there is some uncertainty about the use of corn oil in the gavage study, it is concluded that benzyl acetate is

unlikely to be carcinogenic to humans via the dietary route of exposure.

In metabolism studies approximately 90% of benzyl acetate is excreted as metabolites primarily in the urine after oral or percutaneous administration. None was detected in the adipose tissue, blood, kidney, liver, lung, muscle, skin or stomach. The major metabolite in the urine was hippuric acid and 95 to 99% of the excreted dose was in this form. Less than 4% remained in the carcass.

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.*

The point of departure for benzyl acetate is 110 mg/kg/day from the NTP 2-year carcinogenicity study in mice (dietary study) based on decreased in body weights in both sexes at the LOAEL of 345/375 mg/kg/day. There was no NOAEL observed in a 90-day toxicity study in mice based on the effects on body weights seen at all doses (lowest dose tested was 3,130 ppm; equal to 425 mg/kg/day); however, in a carcinogenicity study in mice no effects on body weight were seen at 110 mg/kg/day, therefore, the NOAEL for the carcinogenicity study would be protective of decreased body weights seen in a 90-day study in mice. Therefore, 90-day toxicity study in mice was not selected. This endpoint was used for all exposure scenarios. The dermal absorption and inhalation factors were 100%. The Agency applied an interspecies uncertainty factor (10X) and an intraspecies uncertainty factor (10X); the FQPA safety factor was reduced to 1X.

C. Exposure Assessment

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

An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model DEEM–FCID™, Version 3.16, which includes 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. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model that assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. 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. Nonpesticidal dietary exposure to benzyl acetate (*e.g.,* use as a food additive (flavoring agent) were also considered as part of aggregate chronic dietary risk 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 benzyl acetate, 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).

Based upon the requested use of benzyl acetate, the Agency does not expect non-occupational, non-dietary exposures. However, there is a potential for residential exposure via non-pesticidal uses such as use in cosmetics and other, pesticide uses, once it is approved. The residential exposure could occur via ingestion products containing benzyl acetate, and via dermal and inhalation routes of exposure through use of products containing benzyl acetate in residential settings. These residential pesticide exposures are considered short-term and intermediate-term in nature. Residential exposures to benzyl acetate as the result of its use as a cosmetic ingredient may be short-, intermediate- or long-term in nature. The aggregate-short term exposure assessment for benzyl acetate considers exposures from the pesticidal and nonpesticidal uses (*i.e.,* flavoring agent and cosmetic ingredient) and would be protective of any potential long-term exposure to benzyl acetate resulting from its use in cosmetics as the same toxicological point of departure is used for all exposure durations and the average daily exposure estimates for cosmetic use is conservatively applied to all exposure durations.

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 benzyl acetate to share a common mechanism of toxicity with any other substances, and benzyl acetate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that benzyl

acetate 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 Web site 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* Qualitative fetal susceptibility was observed in the developmental study in rats. Maternal (decrease in body weight) and fetal (reduced body weights, increased incidence of dilation of the renal pelvis and skeletal variations) toxicity were observed at 1,000 mg/kg/day, the limit dose. Since fetal toxicity occurs in the presence of maternal toxicity and a clear NOAEL of 500 mg/kg/day was established, the established cRfD (1.10 mg/kg/day) will be protective of these effects. The potential for reproduction toxicity was observed in the 13-week dietary study in rats. Atrophy of seminiferous tubules was observed in males at 12,500 ppm (900 mg/kg/day). However, the concern for reproduction toxicity is low since effects occurred at a high dose and a clear NOAEL of 6,250 ppm (460 mg/kg/day) was established. Therefore, the established cRfD will be protective of this effect. In addition, no female reproductive parameters were affected in the developmental toxicity study in rats.

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 benzyl acetate contains the following studies that are adequate to evaluate the potential toxicity of benzyl acetate for infants and children: A thirteen week feeding study in the rat, a 13-week feeding study in the mouse, a developmental toxicity study in the rat, several *in vivo* and *in vitro* mutagenicity studies, and carcinogenicity studies in mice and rats via gavage and dietary studies.

ii. Evidence of neurotoxicity and neuronal degeneration seen in a thirteen-week study was determined not to exceed levels of concern since the effects occurred at doses that were well above the limit dose (1,000 mg/kg/day). The established cRfD is 1.10 mg/kg/day therefore is protective of these effects.

iii. Qualitative fetal susceptibility was observed in the developmental study in rats. Maternal (decrease in body weight) and fetal (reduced body weights, increased incidence of dilation of the renal pelvis and skeletal variations) toxicity were observed at 1,000 mg/kg/day, the limit dose. Since fetal toxicity occurs in the presence of maternal toxicity and a clear NOAEL of 500 mg/kg/day was established, the established cRfD (1.10 mg/kg/day) will be protective of these effects. The potential for reproduction toxicity was observed in the 13-week dietary study in rats. Atrophy of seminiferous tubules was observed in males at 12,500 ppm (900 mg/kg/day). However, the concern for reproductive toxicity is low since effects occurred at a high dose and a clear NOAEL of 6,250 ppm (460 mg/kg/day) was established.

iv. 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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to benzyl acetate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by benzyl acetate.

E. Aggregate Risks and Determination of Safety Section

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, benzyl acetate 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 benzyl acetate from food and water will utilize 62.9% of the cPAD for children ages 1 to 2, 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).

Benzyl acetate is likely to be 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 through food and water with short-term residential exposures to benzyl acetate. Using the exposure assumptions described in this unit for screening-level short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 150 for children ages 1 to 2 and 260 for adults. Because EPA's level of concern for benzyl acetate is a 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). Because no intermediate-term adverse effect was identified, benzyl acetate is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in the dietary carcinogenicity studies in mice and rats, benzyl acetate 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 benzyl acetate residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the

Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for benzyl aceetate (CAS Reg. No. 140–11–4) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops only.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 4, 2016.

Susan Lewis,

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 § 180.920 add alphabetically the entry ''Benzyl acetate'' to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
Benzyl acetate (CAS Reg. No. 140–11–4).	.....	Solvent
* * *	*	*

[FR Doc. 2016–02815 Filed 2–11–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 14–226; FCC 15–118]

Broadcast Licensee-Conducted Contests

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, information collection requirements adopted in the Commission's Report and Order relating to the Amendment of the Commission's Rules Related to Broadcast Licensee-Conducted Contests. This document is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the rule.

DATES: The amendments to 47 CFR 73.1216, published at 80 FR 64354, October 23, 2015, are effective on February 12, 2016.

FOR FURTHER INFORMATION CONTACT: Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on February 3, 2016, OMB approved information collection requirements contained in the Commission's Report and Order, FCC 15–118, published at 80 FR 64354. The OMB Control Number is 3060–1209. The Commission publishes this document as an announcement of the effective date of those information collection requirements.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on February 3, 2016, for the information collection