(*1*) Rule 1144, "Vanishing Oils and Rust Inhibitors," adopted on March 6, 2009.

(*2*) Rule 1145, "Plastic, Rubber, Leather, and Glass Coatings," amended on December 4, 2009.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0533; FRL–8833–2]

Residues of Quaternary Ammonium Compounds, N-Alkyl (C_{12-14}) Dimethyl Ethylbenzyl Ammonium Chloride; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing exemption from the requirement of a tolerance for residues of n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. The regulation will exempt from the requirement of tolerance residues in food resulting from contact with surfaces treated with antimicrobial solutions where the end-use concentration of active quaternary compound does not exceed 400 parts per million (ppm).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0533. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Velma Noble, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6233; e-mail address: *noble.velma@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 dairy cattle milk producer, food manufacturer, or beverage manufacturer. Potentially affected entities may include, but are not limited to:

- Dairy cattle milk production (NAICS code 11212).
- Food manufacturing (NAICS code 311).
- Beverage manufacturing (NAICS code 3121).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr*.

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–2008–0533 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 September 13, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0533, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility 's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Exemption

In the **Federal Register** of November 28, 2007 (72 FR 67299) (FRL–8141–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7323) by Stepan Company, 22 West Frontage Rd., Northfield, IL 60093. The petition requested that 40 CFR 180.940(a) be amended by increasing concentration limits for n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride in end-use solutions eligible for tolerance exemption. That notice referenced a summary of the petition prepared by Stepan Company, the registrant, which is available in the docket, *http://www.regulations.gov*.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which 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."

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in section 408(c)(2)(B) of FFDCA, 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 residues of n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride on food contact surfaces when applied/used in public eating places, dairy processing equipment, and/or food processing equipment and utensils. EPA's assessment of exposures and risks associated with amending the exemption from the requirement for a tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The alkyl dimethyl benzyl ammonium chlorides (ADBAC) chemical case is comprised of 24 compounds that are structurally similar and are a subgroup of the class of chemicals known as quaternary ammonium compounds. Quaternary ammonium compounds are a class of salts derived from ammonium in which nitrogen atom is attached to four organic groups. ADBAC is characterized by having a positively charged nitrogen atom covalently bonded to three alkyl group substituents (two methyls and R component) and a benzyl substituent. The R component represents the different number of hydrocarbon carbon moieties delineated by different percentages (e.g., Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride). In finished form, these quaternary ammonium compounds are salts with the positively charged nitrogen (cation) balanced by a negatively charged anion. The most common anion for the quaternary ammonium compounds in this cluster is chloride. However, other anions, such as saccharide and bromide are also used. The Agency clustered these chemicals together because variance in the length and conformation of alkyl carbon chains between 12 and 18 does not appear to significantly affect the toxicity or fate of the ADBAC compound. In all ADBACs, it is the positive entity (quaternized nitrogen) that is of relevance from toxicology and exposure perspectives. The negative part of ADBAC (counter ion) is a relatively non-toxic entity (chloride). Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride (PC code 069105) was chosen by the Agency as the representative chemical for the ADBAC subgroup of quaternary ammonium compounds, and the toxicology database for alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride is considered representative of the hazard for the ADBAC subgroup. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC compound was used on 100% of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the ADBAC compounds when used in combination.

Quaternary ammonium compounds are corrosive on contact with the skin and eyes. They typically cause highly-irritating localized effects which occur at the portals of entry. On the other hand, ADBACs are only moderately toxic systemically by oral, dermal, and inhalation routes of exposure. Systemic toxicity occurs after absorption and distribution of the chemical to tissues in the body. Such toxicity is dependent on physiological factors within the tissue/organ, and also how the body eliminates the chemical (Kinetics). These chemicals are classified as "not likely" to be human carcinogens based on negative carcinogenicity studies in both rats and mice. There is no evidence of these chemicals being associated with increased susceptibility to developmental toxicity or reproductive toxicity based on two developmental toxicity studies and a 2–generation reproductive study. Lastly, they are negative for mutagenicity and neurotoxicity. Specific information on the studies received and the nature of the toxic effects caused by ADBAC, can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2005–0339, Alkyl dimethyl benzyl ammonium chloride (ADBAC)- Report of Antimicrobials Division Toxicity Endpoint Committee (ADTC) and the Hazard Identification Assessment Review Committee (HIARC).

B. Toxicological Points of Departure/Levels of Concern

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. The Level of Concern (LOC) is a reference value expressed as either a reference dose/population adjusted dose (RfD/PAD) or margin of exposure (MOE). Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by

dividing the POD by all applicable uncertainty/safety factors. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded. For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of a cancer occurrence greater than that expected in a lifetime. Generally, cancer risks are considered non-threshold. 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*.

A summary of the toxicological endpoints for ADBAC used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADBAC USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population, females 13+, infants and children)	An acute dietary endpoint was not identified in the database.		
Chronic dietary (all populations)	NOAEL = 44 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.44 mg/kg/day cPAD = 0.44 mg/kg/day	Chronic toxicity/carcinogencity-rat MRID 41947501 LOAEL = 88 mg/kg/day based on decreased body weight and weight gain
Incidental oral short-term (1 to 30 days)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Incidental oral intermediate-term (1 to 6 months)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Developmental Toxicity-Rat MRID 42351501 LOAEL = 30 mg/kg/day based on clinical signs and decrease body weight gain
Dermal short-term (1 to 30 days) (Formulated product (4% ai.))	Dermal study NOAEL = 20 mg/kg/day (333 ug/cm^2)[b] UF_A = 3x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10[d]	21-day dermal toxicity-guinea pigs MRID 41105801 LOAEL = 40 mg/kg/day based on denuded non-vascularized epidermal layer
Dermal intermediate-term (technical grade a.i.) (1 to 6 months)	Dermal study NOAEL= 20 mg/kg/day (80 ug/cm^2)[c] UF_A = 3x UF_H = 3x FQPA SF = 1x	LOC for MOE = 10[d]	90-day dermal in rats MRID 41499601 LOAEL = 20 mg/kg/day based on highest doest tested before irritation became significant. Irritation not observed until day 43
Dermal Short-term (technical grade a.i)	No endpoint identified from the available data on dermal irritation. Dermal irritation in the 90-day dermal toxicity study was not evident until day 43 (MRID 41499601)[d]		
Long-term Dermal (technical grade a.i.)	No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical that could be tested without irritation effects.[d]		
Inhalation (all exposures)	Oral study NOAEL = 3 mg/kg/day 100% UF_A = 10x UF_H = 10x FQPA SF = 10x (UF_{db})[a]	LOC for MOE = 1000	Developmental Toxicity-rabbit MRID 42392801 LOAEL = 9 mg/kg/day based on clinical signs of toxicity in maternal animals

UF_A = extrapolation from animal to human (interspecies).
UF_H = potential variation in sensitivity among members of the human population (intraspecies).
FQPA SF = FQPA Safety Factor.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose.
MOE = margin of exposure.

[a] An additional uncertainity factor of 10x is applied for use of an oral endpoint for route-to-route extrapolation in the absence of an inhalation toxicity study.

[b] Formulated-based dermal endpoint = (20 mg/kg guinea pig x 0.43 kg guinea pig x 1,000 ug/mg)/25.8cm^2 area of guinea pig dosed = 33 ug/cm^2.

[c] TGAI-based dermal endpoint = (20 mg/kg rat x 0.2 kg rat x 1000 ug/mg)/ 50 cm^2 area of rate dosed = 80 ug/cm^2.

[d] For dermal exposures, irritation as the effect was selected for the short-term endpoint and a reduced margin of exposure (MOE) was used to characterize the risk. The use of irritation as a toxic endpoint for assessment of dermal risk is appropriate in this case, as dermal exposure that results in primarily an irritation response is considered a self-limiting type of exposure that is not expected to last for any length of time, and variability in the response is not expected to be as great as systemic toxic responses. For ADBAC, the MOE for short-term dermal risk is reduced to a total factor of 10x (3x for interspecies extrapolation, 3x for intraspecies variation.)

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride, EPA considered exposure under the petitioned-for exemption as well as all existing ADBAC exemptions or tolerances in 40 CFR 180.940(a), and (c). EPA assessed dietary exposures from ADBAC in food as follows:

ADBACs are to be used as a sanitizer on counter tops, utensils, appliances, tables, refrigerators, food packaging, and beverage bottling. The use of these actives in antimicrobial products for use on food or feed contact surfaces, agricultural commodities, and application to food-grade eggs may result in pesticide residues in human food. Residues from treated surfaces, such as utensils, countertops, equipment, and appliances can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

The Agency assessed chronic dietary exposures from the use of ADBAC as a disinfectant and food contact sanitizer on utensils, countertops, and in food/beverage processing facilities. The assessment calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using modified Food and Drug Administration (FDA) methodologies for utensils and Indirect Dietary Residential Exposure Model software (IDREAM) for countertops. IDREAM incorporates consumption data from U.S. Department of Agriculture (USDA) Continuing Surface of Food Intakes by Individuals (CSFII) for 1994–1996, and 1998. The 1994–1996, and 1998 data are based on the reported consumption of more than 20,000 individuals over 2 non-consecutive survey days.

The Estimated Daily Intake (EDI) calculations presented in this assessment for treated indirect dietary exposures resulting from sanitizing utensils assumed that food would contact 4,000 cm^2 (which represents contact with treated silverware, china, and glass used by an individual who regularly eats three meals per day at an institutional or public facility) and that the residual solution remaining on the surface or pesticide migration fraction is 1 mg per square centimeter of treated area. The body weights used for this assessment were 70 kilogram (kg) for an adult male, 60 kg for an adult woman, and 10 kg for an infant. Based on data provided in a new residue study, Transferability Equivalence among Quats and Measured Food Surrogate Transfer Efficiency (MRID 46870703), a conservative transfer rate of 43% was used to estimate the amount of residues on the surface that will be transferred to food and subsequently ingested. The maximum application rate for ADBAC on utensils is 0.0033 lbs a.i per gallon of treatment solution.

There are two levels of refinement for assessing dietary exposure to antimicrobial products used on countertops. The Tier 2 approach, a refined exposure estimate in comparison to the Tier 1, was utilized for this assessment. This conservative approach uses food consumption and preparation patterns as well as data and assumptions that are not chemical-specific. Food ingredients are separated into nine categories based on food preparation, food physical properties, and potential, or likelihood of contact with treated countertops. The nine food categories are liquids, fruit, bread, cheese, vegetable, meat, purees (e.g., pudding, oatmeal), pieces (foods normally consumed in small pieces), and powders (foods normally used in powder/granular forms). Assumed countertop residues are converted to estimated residues contacting the countertops using a translation factor for each food category, and default residue transfer efficiency for a representative food. Therefore, IDREAM combines the estimated countertop residues for surface treatment products, CSFII consumption data, food-specific conversion factors that relate the surface area contacting a countertop with corresponding weight of the food item, and the transfer efficiency of residues from countertops to food. Conservative assumptions for these analyses include: All disinfectants registered to disinfect kitchen countertops are included; all foods are prepared on treated countertops; all prepared foods will come in contact with treated countertops at the maximum active ingredient (a.i.) residues; these residues will not diminish over time (i.e., residue reduction will not occur from cooking or preparation processes); there is a 100% likelihood of contact to account for both commercial and residential scenarios; all commercial facilities and households use the same disinfectant product; all foods are prepared and consumed.

When assessing the food bottling/packaging use, EPA assumed a 100% transfer rate because the food is potentially in contact with the treated surfaces for very long periods of time. The maximum application rate for ADBAC for bottling/packing of food is 0.0103 lbs a.i per gallon of treatment solution. EDI values were calculated using an approach similar to that used for treated food utensils. Exposure was assumed to occur through the ingestion of three food products that might be packaged in treated material: milk, egg products, and beverages (alcoholic and non-alcoholic). A calorie intake modification factor of 0.64 was applied to the EDI for a child to account for the differences between intake values among children and adults.

2. *Dietary exposure from drinking water.* ADBAC is applied to nursery ornamentals and turf as an bactericide and fungicide. The Tier 1 surface water and groundwater model was used to assess Estimated Drinking Water Concentrations (EDWCs). EPA modeled the ornamental plant use because this use has the highest application rate of all labeled uses — 302 lbs. a.i/Acre, and a maximum of 3 applications per year. The EDWCs determined for the nursery ornamental use are also protective of all other uses with lower application rates. The EDWC for surface water is 331 ug/L and groundwater is 5.4 ug/L. There were no major degradates of ADBAC in the laboratory studies.

ADBAC is also used for mosquito control and as an algaecide in decorative ponds and pools. Because the mosquito control and algaecide uses are both periodic in nature and are restricted to a limited use area, EPA expects drinking water exposures from these uses to be minimal in comparison to the ornamental plant exposure estimate for drinking water using the Tier 1 surface and ground water model.

Additionally, antisapstain and cooling water tower uses for ADBAC are potential exposures to drinking water. These uses are also expected to result in minimal exposure in comparison to the modeled EDWCs for the ornamental use taking into account that the Tier 1 model assumed that ADBAC was applied at 302 lbs./Acre across the entire watershed.

Specific information on the dietary and drinking water exposure assessments for ADBAC can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339, Dietary Risk Assessment on ADBAC and Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC).

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).

ADBAC is currently registered for the following residential non-dietary sites: Homes, swimming pools, humidifiers. EPA assessed residential exposure using the following assumptions: Residential exposure may occur during the application as well as post application of ADBAC to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diaper treated during washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Residential post application scenarios such as children exposure to treated toys and floors were also assessed to determine dermal and incidental oral exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufactures Association Antimicrobial Exposure Assessment Study (USEPA, 1999), and the SWIMODEL 3.0 was utilized to conduct exposure assessments of pesticides found in swimming pools and spas (Versar, 2003). Note that for this assessment, EPA assumed that residential users complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The duration for most residential exposures is believed to be best represented by the short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and post-application scenarios are assumed to be performed on an episodic, not daily basis.

Specific information on the residential exposure assessment for ADBAC Quaternaries can be found at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2006–0339 Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment.

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's risk assessment for any individual ADBAC is based on an assessment of the cumulative exposure to all ADBACs. The individual exposure scenarios in the ADBAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that an ADBAC compound was used on 100% of the surfaces authorized on the label that could result in human exposure and summing the percent active ingredients on the labels for all of the ADBACs when used in combination. Thus, because the risk assessment for ADBAC accounts for exposures to all of the ADBACs, there is no need for a separate cumulative risk assessment for those compounds. The Agency has not identified any other substances as sharing a common mode of toxicity with ADBAC. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemical, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold 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 when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA SF value based on the use of traditional UFs and/or FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence that ADBAC result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1X. That decision is based on the following findings:

i. The toxicity database for ADBAC is complete.

ii. There is no indication that ADBAC is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that ADBAC results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. Conservative ground and surface water modeling estimates were used. Similarly conservative residential standard operating procedures (SOPs) were used 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 ADBAC.

E. Aggregate Risks and Determination of Safety

The chronic dietary aggregate risk assessment includes direct and indirect food contact uses as well as drinking water exposures. Based on the results of the chronic aggregate assessment, the estimated chronic risks for adults and children are 8.4% and 40.9% of the cPAD. Therefore, the chronic dietary aggregate risks are not of concern (i.e., less than 100% of cPAD).

Short-term and intermediate-term aggregate risks were calculated using the total MOE approach. Only the short-term aggregate is presented here because the endpoints for incidental oral as well as inhalation are identical for the short- and intermediate-term durations. The aggregate risks are not of concern for adults for any of the three routes of exposure. The aggregate adult MOEs are 1,200 for oral, 480 for dermal, and 2,000 for inhalation, which are greater than the target MOE of 100 for the oral, 1,000 for inhalation, and 10 for dermal. For children, the aggregate risk estimate for each of the routes of exposure are also above the target MOEs of 100 for the oral, 1,000 for inhalation, and 10 for dermal (MOE=140 for the oral route,

1,200 for the dermal route, and are thus not of concern). There were no inhalation risks identified.

Based on the toxicological and exposure data discussed in this preamble, EPA concludes that will not pose a risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty of no harm will result to the general population, or to infants and children from aggregate exposure to ADBAC residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An analytical method for food is not needed. Food contact sanitizers are typically regulated by the State health departments to ensure that the food industry is using products in compliance with the regulations in 40 CFR 180.940. The end-use solution that is applied to the food contact surface is analyzed not food items that may come into contact with treated surface. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. A titration method is used to determine the total amount of quaternary compound. If the use solution is a mixture of ADBAC and didecyl dimethyl ammonium chloride (DDAC), then High Pressure Liquid Chromatogram–Ultraviolet Visible (HPLC-UV) is used to determine the amount of ADBAC. The amount of DDAC is determined by calculating the difference between the total amount of quaternary compounds and ADBAC.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride.

C. Response to Comments

EPA received no comments in response to the notice of filing for the petition to amend the tolerance exemption for the ADBAC compound addressed in this rulemaking, n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride. However, in October, 2008, EPA received comments on a final rule amending the tolerance exemption for a similar ADBAC compound, n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride. (73 FR 49101) (August 20, 2008). The commenter mistakenly assumed that this final rule was a "proposed EPA action" and urged that EPA require submission of new data on ADBAC, review studies that have recently become available on ADBAC, and conduct a revised risk assessment for the chemical. Because the petition for the current action was pending at the time that the comments on the related final rule were received, EPA considered those comments in ruling on the petition addressed in this action.

The commenter raised several concerns with regard to the earlier tolerance action as to an ADBAC compound: (1) ADBAC and other quaternary ammonium compounds may be reproductive and genetic toxicants; (2) quaternary ammonium compounds are linked with increased occupational asthma and immune system sensitization; and (3) quaternary ammonium compounds are persistent in the environment. The commenter also raised various environmental concerns with the quaternary ammonium compounds but these concerns are relevant only to EPA's decision to register ADBAC under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.*, and not tolerance actions under section 408 of the FFDCA. EPA has prepared a detailed response to each of the commenter's arguments and included that document in the record for this action. EPA's response as to the FFDCA-related comments is summarized below.

EPA does not believe that ADBAC poses unacceptable reproductive risks. In the ADBAC risk assessment, the Agency relied on available, reliable, quantitative animal data to characterize hazards associated with uses of ADBAC including reproductive function and effects on the developing mammalian fetus. In the developmental studies with rats (range-finding MRID 42645101 and main study MRID 42351501) and rabbits (range-finding MRID 42734401 and main study MRID 42392801), there was no increased sensitivity of developing fetuses to ADBAC compared to adult animals. In a 2–generation reproductive toxicity study (MRID 41385001), effects on rat pups were observed in the absence of statistically significant maternal toxicity, but only at the highest dose (160 mg/kg/day). The effects observed were considered to be nonspecific (decreased pup body weight and weight gain during lactation) and there were no effects of ADBAC on reproductive indices. It is important to note that the endpoints selected from the rat oral developmental toxicity study (NOAEL = 10 mg/kg/day) or the 21–day dermal toxicity studies (NOAEL = 20 mg/kg/day) are well below the dose causing these nonspecific effects. Therefore, the endpoints used in risk assessment are protective of infants and children. The commenter relied on a scientific literature article in which a researcher speculated that a severe decline in the fertility of the researcher's laboratory mouse population was due to exposure to quaternary ammonium compounds. EPA concludes that the results of the specific studies designed to examine the reproductive effects of pesticides outweigh the speculative article.

EPA does not believe ADBAC is a genetic toxicant. In evaluating ADBAC's potential mutagenicity, EPA relied on testing results in a battery of mutagenicity studies, including an HGPRT/CHO forward mutation assay (MRID 42290801, reformat of MRID 41012701), an *in vivo* bone marrow chromosomal aberration assay (MRID 40311101, supplement MRID 43037701), and an unscheduled DNA synthesis (UDS) assay (MRID 42290802, reformat of 41012601), all of which demonstrated that ADBAC did not induce mutagenic effects. Further support for this conclusion is provided by carcinogenicity testing in long-term studies using both rats (MRID 41947501) and mice (MRID 41765201). In both studies, ADBAC was tested at adequate dose levels and found to be negative for induction of tumors. In contrast, the commenter relies on the result in an *in vitro* mutagenicity test. The weight of the evidence clearly supports EPA's conclusion. *In vivo* mutagenicity testing (as does carcinogenicity testing in rodents) carries far greater weight than *in vitro* testing because *in vivo* testing is much more likely to simulate the detoxifying effects present in the living animal.

Finally, although EPA would agree that the chemical properties of ADBAC indicate that it will only degrade slowly in the environment, these properties were taken into account in estimating exposure to humans to ADBAC in drinking water in assessing ADBAC

risks. Accordingly, ADBAC's persistence does not render it unsafe.

V. Conclusion

Therefore, the exemption from the requirement of a tolerance in 40 CFR 180.940(a) for Quaternary Ammonium Compounds: n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 85409–23–0) is amended to increase from 200 ppm to 400 ppm the level of the end-use concentration of all quaternary chemicals that may be present in solution when the solution is ready for use.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 8, 2010.

Joan Harrigan-Farrelly,

Director, Antimicrobials 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. Section 180.940 is amended by revising the following entry in the table in paragraph (a) 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
	* * * *	*
Quaternary Ammonium Compounds: n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384.	85409–23–0	When ready for use, the end-use concentration of all quaternary chemicals in solution is not to exceed 400 ppm of active quaternary compound.
	* * * *	*

[FR Doc. 2010–17156 Filed 7–13–10; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0561;FRL–8833–8]

Acetic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for acetic acid by establishing an exemption from the requirement of a tolerance for residues of acetic acid, also known as vinegar in or on all food crops resulting from unintentional spray and drift to non-target vegetation including non-food, food and feed crops when used as a non-selective contact herbicide spray. SummerSet Products c/o SciReg, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of acetic acid, also known as vinegar.

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0561. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Cheryl Greene, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0352; e-mail address: *greene.cheryl@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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2010–0561 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 September 13, 2010. 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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2010–0561, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 19, 2008, (FR 69635) (FRL–8389–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F7319) by SummerSet Products c/o SciReg, Inc., 130 Columbia Court, Chaska, MN 55318. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid. This notice referenced a summary of the petition prepared by the petitioner SummerSet Products, which is available in the docket, *http://www.regulations.gov*. One anonymous comment was received on the notice of filing. However, EPA was unable to address the comment because it was not specific to this action, focusing instead on the registration of pesticides generally, and therefore was not a significant comment.