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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0479; FRL–8816–5]

Alkyl (C12-C16) Dimethyl Ammonio 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 Alkyl (C_{12}-C_{16}) dimethyl ammonio acetate, herein referred to in this document as ADAA, when used as an inert ingredient (surfactant) in pesticide formulations for pre-harvest uses under 40 CFR 180.920 or applied to animals under 40 CFR 180.930 at a maxiumum concentration of 20% in pesticide product formulations. Technology Sciences Group, Inc., on behalf of Rhodia, 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 ADAA.

DATES: This regulation is effective April 14, 2010. Objections and requests for hearings must be received on or before June 14, 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–2009–0479. 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: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8560; e-mail address: *fertich.elizabeth@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 cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS harmonized test quidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. 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–2009–0479 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 14, 2010.

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–2009–0479, 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 August 19, 2009 (74 FR 41895) (FRL–8429–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7557) by Rhodia, Inc., 5171 Glenwood Avenue, Suite 402, Raleigh, NC 27612. The petition requested that 40 CFR 180.920 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of Alkyl (C_{12}-C_{16}) dimethyl ammonio acetate, herein referred to in this document as ADAA. That notice included a summary of the petition prepared by the petitioner. 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(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) 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 the petitioned-for exemption from the requirement of a tolerance for residues of ADAA when used as inert ingredients in pesticide formulations for pre-harvest uses and on animals at a maximum of 20% by weight in pesticide formulations. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. The nature of the toxic effects caused by ADAA are discussed in this unit.

Acute oral toxicity studies were performed using C_{12}-ADAA and C_{16}-ADAA. ADAA has moderate to low acute toxicity via the oral and dermal routes of exposure. Low acute toxicity is generally associated with C_{16}-ADAA while moderate acute toxicity is associated with C_{12}-ADAA. In acute dermal and eye irritation studies, C_{12}-ADAA was severely irritating to the skin and eyes. A mixture of C_{12}-C_{16} ADAA was used in a local lymph node assay (LLNA) to evaluate the potential to cause skin sensitization, C_{12}-C_{16} ADAA was found to be a sensitizer; however, it gave a negative response for skin sensitization in *in vivo* guinea pigs as determined by Magnusson-Kligman test.

Two developmental studies were available; an oral toxicity study in the rat and a screening level developmental dermal toxicity study in the rabbit. In the developmental toxicity study in the rat, maternal toxicity was manifested as reduced body weight gain, stained and matted haircoats, and respiratory rates at 50 milligrams/kilograms/day (mg/kg/day) and above. Offspring toxicity was manifested as reduced or absent ossification of the skull, sternebrae #5 and/or #6, and other sternebrae at 250 mg/kg/day. The NOAEL for developmental toxicity in rats was 150 mg/kg/day. In the screening level developmental dermal toxicity study in rabbits, maternal toxicity manifested as skin irritation, inhibition of body weight gain, decreased food consumption and resorptions at doses of 100 mg/kg/day and above while offspring toxicity was manifested as increased incidence of resorptions and decreased average litter size at ≥ 100 mg/kg/day. The NOAEL for systemic and developmental toxicity in rabbits via dermal route was 40 mg/kg/day.

A dose range-finding and a main study of Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test according to the OPPTS Harmonized Test Guideline 870.3650 study were available in the rat. In the range-finding study, at ≥ 100 mg/kg/day, a reduction was observed in mean food consumption, body weight, and body weight gain during the pre-pairing period in all animals. Also, animals pushed their heads through the bedding throughout the treatment period at doses ≥ 100 mg/kg/day. At 1,000 mg/kg/day, mortality was observed in all animals within 24 hours. In the main OPPTS Harmonized Test Guideline 870.3650 study, parental toxicity was manifested as microscopic lesions (squamous hyperplasia, hyperkeratosis, submucosal inflammation and edema) in the forestomach at the lowest dose tested (50 mg/kg/day). Reproductive and developmental toxicity was manifested as increased implantation losses, decreased birth and viability indices, and decreased pup weight at 300 mg/kg/day (highest dose tested). The NOAEL for reproductive/developmental toxicity was 150 mg/kg/day.

Several mutagenicity studies (two Ames assays and chromosome aberration assay) were available for review. The results for these studies were negative. No animal carcinogenicity studies are available in the database. Based on Structure Activity Relationship (SAR) analysis, no structural alerts for carcinogenicity were identified.

Two *in vitro* dermal absorption studies were available in hairless mice. The dermal absorption factor of C_{12}-ADAA and C_{16}-ADAA was estimated to be <1%.

The Agency notes the surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions. The observed toxicity seen in the repeated dose studies, such as microscopic stomach lesions or decreased body weight gain, are attributed to the corrosive and irritating nature of these surfactants.

There are no published or unpublished ADAA metabolism studies. However, ADAA are expected to metabolized via three potential metabolic pathways:

1. Omega oxidation followed by beta oxidation of the carbon chain,

2. Conjugation of ADAA at the carboxylic acid portion of the molecule by any of a number of amino acids, or

3. Glucuronidation at the same site on ADAA, followed by elimination.

Specific information on the studies received and the nature of the adverse effects caused by ADAA, as well as, the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Decision Document for Alkyl (C_{12}-C_{16}) dimethyl ammonio acetate (CAS Reg. Nos. 683–10–3, 2601–33–4 and 693–33–4)," pages 8-16 in docket ID number EPA–HQ–OPP–2009–0479.

B. Toxicological Endpoints

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. 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 UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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*.

For the purpose of this risk assessment, a protective overall NOAEL of 40 mg/kg/day was selected for all exposure scenarios based on weight-of-evidence from three studies in which systemic toxicity was observed at doses of 100 mg/kg/day or above. The different NOAELs observed in these studies are due to the dose selection process. For example, a NOAEL of 33 mg/kg/day and LOAEL of 100 mg/kg/day (based on pushing head through bedding, decreased food consumption and weight gain) were established in a range finding study for a combined reproduction/ developmental toxicity screening test. In the main study, Organization for Economic Cooperation and Development (OECD) combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, the LOAEL was established at 50 mg/kg/day (lowest dose tested). However, the LOAEL was based on irritation in the forestomach of rats due to the physical/chemical properties of ADAA, which was not considered relevant for human risk assessments. Also the NOAEL of 40 mg/kg/day is considered to be protective of marginal decreases in body weights seen at the LOAEL of 50 mg/kg/day in the oral development toxicity study in rats because body weight effects were not observed in the OECD 422 study (main study) at a dose level of 150 mg/kg/day. Additionally, this NOAEL is supported by the developmental dermal toxicity study in the rabbit. In this study, a NOAEL of 40 was established based on the effects (uncoordinated movement, partial paralysis and increased incidence of resorptions) observed at 100 mg/kg/day in the presence of severe skin irritation.

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

TABLE.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADAA FOR 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 (all populations)	The Agency notes the surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Moderate acute toxicity is associated with C12-ADAA. However, these effects are considered local irritations rather than systemic toxicity. Therefore this endpoint is not appropriate for risk assessment. In addition, no endpoint of concern attributed to a single dose was identified in the database.		
Chronic dietary (all populations)	NOAEL = 40 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.40 mg/kg/day cPAD = 0.40 mg/kg/day	Overall NOAEL based on three studies OECD 422 range finding and main study Developmental toxicity study in rabbits via dermal route, Oral developmental toxicity study in rats
Incidental Oral, dermal and inhalation (Short- and Intermediate-Term)	NOAEL= 40 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Overall NOAEL based on three studies OECD 422 range finding and main study Developmental toxicity study in rabbits via dermal route, Oral developmental toxicity study in rats

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

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Dermal short- and intermediate term (1 to 30 days) (1 to 6 months)	NOAEL= 40 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x 10% dermal absorption factor	LOC for MOE = 100	Overall NOAEL based on three studies OECD 422 range finding and main study Developmental toxicity study in rabbits via dermal route, Oral developmental toxicity study in rats
Inhalation short- and intermediate term (1 to 30 days) (1 to 6 months)	100% inhalation absorption	LOC for MOE = 100	Overall NOAEL based on three studies OECD 422 range finding and main study Developmental toxicity study in rabbits via dermal route, Oral developmental toxicity study in rats
Cancer (oral, dermal, inhalation)	Not necessary. No cancer concerns were identified.		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = FQPA Safety Factor. RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

V. Aggregate Exposures

A. Dietary Exposure

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to the ADAA, EPA considered exposure under the petitioned-for exemptions from the requirement of a tolerance. EPA assessed dietary exposures from ADAA in food as follows:

i. *Acute exposure.* The Agency notes the surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Moderate acute toxicity is associated with C_{12}-ADAA. However, these effects are considered local irritations rather than systemic toxicity. Therefore this endpoint is not appropriate for risk assessment. In addition, no endpoint of concern attributed to a single dose was identified in the database.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for ADAA. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

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

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of ADAA, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of ADAA that may be in formulations (to no more than 20% by weight in pesticide products) and assumed that the ADAA are present at the maximum limitation rather than at equal quantities with the active ingredient. This remains a very conservative assumption because surfactants are generally used at levels far below this percentage.

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

conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer*. ADAA is not expected to be carcinogenic since there was no evidence of carcinogenicity in the available studies. Since the Agency has not identified any concerns for carcinogenicity relating to ADAA, a cancer dietary exposure assessment was not conducted.

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 ADAA, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for ADAA. 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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). ADAA may be used as inert ingredients in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessment was completed for products containing ADAA as inert ingredients. The ADAA inerts are used in pesticide formulations that may be used around the home in pesticide formulations used on lawn, turf, or gardens. In addition, these inerts may be present in personal care products. The Agency selected representative scenarios and conducted an assessment to represent worst-case residential exposure by assessing ADAA in pesticide formulations (outdoor scenarios) and ADAA in disinfectant-type uses (indoor scenarios). Based on information contained in the petition, ADAA can be present in personal care products (maximum concentration 5%). Therefore, the Agency assessed the personal care products containing ADAA using exposure scenarios used by OPP's Antimicrobials Division to represent worst-case residential handler exposure. The Agency conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from ADAA in pesticide formulations (Outdoor Scenarios) and ADAA in disinfectant-type uses (Indoor Scenarios). Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA–HQ–OPP–2008–0710.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of FFFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticide ingredients for which EPA has followed as cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ADAA acetate and any other substances and, ADAA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ADAA has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VII. Additional Safety Factor for the Protection of 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 Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data is available to EPA support the choice of a different factor. EPA concluded that the FQPA safety factor should be reduced to 1X for ADAA.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of infants and children in the available developmental toxicity studies via dermal and oral routes of exposure. In these studies developmental toxicity was observed in the presence of maternal toxicity and/or at one dose level higher. There was no evidence of increased susceptibility of infants and children in the OPPTS 870.3650 study (OECD 422) study. In this study, the maternal toxicity was manifested as body weight changes and microscopic changes, while the fetal toxicity was manifested as increased implantation losses and decreased pup weight. The maternal and developmental NOAEL was 150 mg/kg/day.

3. *Conclusion*. EPA has determined that reliable data show that 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 database is considered adequate for FQPA assessment. The following acceptable studies are available:

Developmental toxicity study in rats (1)

Developmental dermal toxicity study in rabbits

Combined development/reproduction repeated dose toxicity study (1)

ii. Fetal susceptibility was not observed in the oral developmental toxicity study in the rat, the

developmental dermal toxicity study in the rabbit or in the OPPTS Harmonized Test Guideline 870.3650 study. In these studies fetal toxicity was observed at doses that were higher than the dose that caused maternal toxicity. Therefore, there are low concerns and no residual uncertainties concerning prenatal and postnatal toxicity.

iii. Clinical signs of neurotoxicity (uncoordinated movement, partial paralysis) were observed in the developmental dermal study in the rabbit. However, no effects on Functional Observation Battery (FOB) parameters were observed at doses up to and including 300 mg/kg/day in the OPPTS 870.3650 study (OECD 422 study). Therefore, EPA concluded that the developmental neurotoxicity study is not required.

iv. No evidence of immunotoxicity was observed in the database.

v. No chronic toxicity or carcinogenicity studies are available in the database, however the Agency notes that surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions. The observed toxicity seen in the repeated dose studies, such as microscopic lesions or decreased body weight gain, are attributed to the corrosive and irritating nature of these surfactants. The Agency has considerable toxicity information on surfactants which indicates that the effects do not progressively increase in severity over time. In addition, use of the full 10X interspecies factor will actually provide an additional margin of safety because it is not expected that humans' response to local irritation/corrosiveness effects would be markedly different from animals. The database on ADAA indicates that the target organ toxicity is occurring at relatively high doses. Based on the consideration in this unit, the Agency concluded that an additional FQPA safety factor for the lack of a chronic study is not necessary.

vi. The dietary food exposure assessment utilizes highly conservative default assumptions and would not underestimate the dietary risk to all populations. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ADAA, a value of 100 ppb based on screening level modeling was used for the chronic dietary risk assessment. The value of 100 ppb is considered to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

Taking into consideration the available information, EPA concludes the additional 10X FQPA safety factor can be reduced to 1X.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. The Agency notes the surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Moderate acute toxicity is associated with C_{12}-ADAA. However, these effects are considered local irritations rather than systemic toxicity. Therefore this endpoint is not appropriate for risk assessment. In addition, no endpoint of concern attributed to a single dose was identified in the database.

2. *Chronic risk*. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure and the use limitation of not more than 20% by weight in pesticide formulations, the chronic dietary exposure from food and water to ADAA is 19.5% of the cPAD for the U.S. population and 62.9% of the cPAD for children 1-2 years old, the most highly exposed population subgroup.

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).

ADAA are used as inert ingredients in pesticide products that are currently 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 ADAA. Using the exposure assumptions described in this unit, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in aggregate MOEs of 110 for adult males and adult females. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hard surface wiping with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 130 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, 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).

ADAA are currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to ADAA. Using the exposure assumptions described in this unit, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 450 for adult males and adult females. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 150 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency has not identified any concerns for carcinogenicity relating to ADAA.

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 residues of ADAA when used as inert ingredients in pesticide formulations for pre-harvest uses and on animals at a maximum of 20% by weight in pesticide formulations.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, ADAA may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method

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.

C. International Tolerances

The Agency is not aware of any country requiring a tolerance for ADAA nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

IX. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of ADAA. Accordingly, EPA finds that exempting ADAA (at a maximum of 20% by weight in formulation) from the requirement of a tolerance will be safe.

X. 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).

XI. 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: April 1, 2010.

Lois Rossi,

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

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * * *	
Alkyl (C_{12}-C_{16}) dimethyl ammonio acetate (CAS Reg. Nos. 683–10–3, 2601–33–4 and 693–33–4	20% by weight in pesticide formulation	Surfactant
* * *	* * * *	

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

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * * *	
Alkyl (C_{12}-C_{16}) dimethyl ammonio acetate (CAS Reg. Nos. 683–10–3, 2601–33–4 and 693–33–4	20% by weight in pesticide formulation	Surfactant
* * *	* * * *	

[FR Doc. 2010–8298 Filed 4–13–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0695; FRL–8808–7]

Kasugamycin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of kasugamycin, 3-O-[2-amino-4-[(carboxyiminomethyl)amino]-2,3,4,6-tetradeoxy-α-D-arabino-hexopyranosyl]-D-chiro-inositol in or on apples. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the agricultural bactericide on apples. This regulation establishes a maximum permissible level for residues of kasugamycin in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2012.

DATES: This regulation is effective April 14, 2010. Objections and requests for hearings must be received on or before June 14, 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–2008–0695. All documents in the docket are listed in the docket index available in *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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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*. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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. 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–2008–0695 in the subject line on the first page of your submission. All