■ 2. In §180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

* * * * *

Inert Ingredients	Limits	Uses
* * * * * * *		
Mono-, di-, and trimethylnapthalenesulfonic acids and napthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts (CAS Reg. Nos 9008–63–3, 9069–80–1, 9084–06–4, 36290–04–7, 91078–68–1, 141959–43–5, 68425–94–5)		Surfactants, related adjuvants of surfactants
* * * * * * *		

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0690; FRL–8437–3]

C_{10}-C_{18}-Alkyl dimethyl amine oxides; 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 C_{10}-C_{18}-Alkyl dimethyl amine oxides (ADAO) when used as the inert ingredient in pesticide formulations applied to raw agricultural commodities pre- and post-harvest. Exponent on behalf of Stepan Company and Rhodia submitted petitions 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 ADAOs.

DATES: This regulation is effective October 7, 2009. Objections and requests for hearings must be received on or before December 7, 2009, 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–2009–0690. All documents in the dockets 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: *austin.lisa@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also 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 Guidelines referenced in this document, go to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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–2009–0690 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 December 7, 2009.

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–2009–0690, 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

EPA received two petitions requesting that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ADAOs. These two petitions are grouped together because they fall under the same general chemical description criteria.

In the **Federal Register** of February 1, 2006 (71 FR 5322) (FRL–7756–5), 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 petition (PP #5E7003) by Stepan Company, 951 Bankhead Hwy., Winder, GA 30680. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ADAOs (CAS Reg. Nos. 1643–20–5, 2571–88–2, 2605–79–0, 3332–27–2, 61788–90–7, 68955–55–5, 70592–80–2, 7128–91–8, 85408–48–6, and 85408–49–7). Also, in the **Federal Register** of December 3, 2008 (73 FR 73644) (FRL–8390–4), 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 petition (PP #5E7003) by Stepan Company, 951 Bankhead Hwy., Winder, GA 30680. This petition is an addendum to PP #5E7003 and included the submission of new data only. Both notices included a summary of the petition prepared by the petitioner. There were no comments received in response to the notices of filing.

Also, in the **Federal Register** of April 13, 2009 (74 FR 16869) (FRL–8396–6), 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 petition (PP #8E7316) by Rhodia Inc. c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ADAOs. The notice included a summary of the petition prepared by the petitioner. There were no substantial comments received in response to the notice of filing.

Based upon review of the data supporting the petitions (#5E7003 and #8E7316), EPA has modified the exemptions requested by limiting ADAOs to a maximum of 15% by weight in pesticide formulations. In addition, the risk assessment supports the expansion of the exemptions from a requirement of tolerance to include use in pesticide formulations intended for post– harvest as well as pre–harvest application under 40 CFR 180.910. Further details can be found at *http://www.regulations.gov* in document Decision Document for Petition Numbers #5E7003 and 8E7316 ($C_{10–16}$); C_{10}–C_{18}–Alkyldimethylamine oxides CAS Reg. No. 1643–20–5, 2571–88–2, 2605–79–0, 3332–27–2, 61788–90–7, 68955–55–5, 70592–80–2, 7128–91–8, 85408–48–6, 85408–49–7) in docket ID numbers EPA–HQ–OPP–2005–0310 and EPA–HQ–OPP–2008–0858.

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 ploymers 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 ADAOs is limited to no more than 15% by weight in pesticide formulations when used as an inert ingredient in pesticide formulations for pre- and post-harvest uses. EPA's assessment of exposures and risks associated with establishing tolerances 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.

The available toxicology database includes an acute, subchronic (rat and rabbit), 21 and 90 day dermal toxicity (rabbit), developmental (rat and rabbit), reproduction and fertility effects study, an OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests, chronic dermal toxicity (mouse), chronic/carcinogenicity (rat), mutagenicity, and metabolism studies.

ADAOs have moderate acute toxicity via the oral routes and low toxicity via the dermal and inhalation routes. It is moderately irritating to the skin and severely irritating to the eye. It is not a skin sensitizer.

Subchronic studies were available in the rat and rabbit. Following subchronic exposure to rats via the diet, a decrease in body weight was observed in females only while cataracts were observed in males only. In the rabbit, subchronic exposure via the diet resulted in decreased alkaline phosphatase levels and increased liver/body weight ratio.

A 21/28 day study and 91–day dermal toxicity studies were available in rabbits. Systemic toxicity was not observed at the limit dose in the 21/28 day study and was not observed at the highest dose (2.5 milligrams/kilogram/day (mg/kg bw/day)) tested in the 91–day study.

Three developmental studies were available for review (2–rat, 1–rabbit). In one developmental toxicity study in the rat (Sprague-Dawley), maternal (decreased body weight gain) and offspring (skeletal variation-bifid centrum) toxicity were manifested at 100 mg/kg/day. The NOAEL in this study was 25 mg/kg/day. In a second developmental toxicity study in the rat (CD), maternal and offspring toxicity occurred at the same dose (200 mg/kg/day), the highest dose tested. Effects similar to the previous study were observed. Maternal toxicity was manifested as decreased body weight, food intake and water consumption and offspring toxicity was manifested as a slight reduction in fetal ossification. The NOAEL in this study was 100 mg/kg/day. In the rabbit, maternal and offspring toxicity were not observed at doses up to 160 mg/kg/day (highest dose tested, HDT). In a reproduction and fertility effects study in the rat, neither maternal nor offspring systemic toxicity was not observed at doses up to 40 mg/kg bw/day (HDT). No treatment-related effects were observed on reproductive parameters.

In an OPPTS Harmonized Test Guideline 870.3650 study designed to evaluate developmental, reproduction and neurological parameters, maternal toxicity in the rat [HanRcc:WIST(SPF)] was manifested as hyperkeratosis, parakeratosis, squamous cell hyperplasia, submucosal inflammation and submucosal edema in the forestomach at 100 mg/kg/day (mid dose tested, MDT). Mortality and decreased body weight were observed in the offspring at 250 mg/kg/day (HDT). Reproductive toxicity (decreased gestation index) was also manifested at 250 mg/kg/day. Reduced total locomotor activity was observed in females at 250 mg/kg/day. However, this effect was considered a result of systemic toxicity rather than a result of neurological toxicity since it was transient, occurred at the high dose in one gender only, it was not observed at the lower doses, neuropathologic lesions were not observed and signs of neurotoxicity were not observed in other studies. Changes in absolute and relative thymus weights and atrophy were observed in males at the 250 mg/kg/d (HDT). These were determined to be non-specific changes not indicative of immunotoxicity. In addition, no blood parameters were affected. Furthermore, these compounds do not belong to a class of chemicals that would be expected to be immunotoxic.

Several mutagenicity studies (Ames, chromosome aberration, micronucleus assay, cell transformation, and cell dominant lethal assay) were available for review. The results for these studies were negative.

There were two chronic studies available, a chronic dermal toxicity study in the mouse, and a chronic/carcinogenicity study in the rat. In the dermal toxicity study in the mouse, systemic toxicity and evidence of increased tumors were not observed at the HDT (5.6 mg/kg/day). In the chronic carcinogenicity study in the rat, systemic toxicity was manifested as decreased body weight and cataracts at 107 mg/kg/day (HDT). Evidence of increased tumors was not observed. Based on the lack of evidence of carcinogenicity in these studies and the negative response for mutagenicity ADAOs are not expected to be carcinogenic.

Metabolism studies demonstrated that C_{12} ADAO was absorbed in rats and extensively and rapidly excreted. The distribution of C_{12} ADMO was similar between males and females. Among all the tissues analyzed, the largest amount and the highest concentration of radioactivity were found in the liver. The fractions of dosed radioactivity appearing in the liver, kidney, and blood reached maxima within 1 hour after the oral dose. The excretion of radioactivity was rapid with approximately 70% and greater excreted within 24 hours. The major excretory pathway was urine followed by expired CO_2 with much less found in feces and bile.

Specific information on the studies received and the nature of the adverse effects caused by ADAOs, 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 the document Decision Document for Petition Numbers #5E7003 and 8E7316 ($C_{10–16}$); C_{10}-C_{18}-Alkyldimethylamine oxides CAS Reg. No. 1643–20–5, 2571–88–2, 2605–79–0, 3332–27–2, 61788–90–7, 68955–55–5, 70592–80–2, 7128–91–8, 85408–48–6, 85408–49–7) at pp 7–18 in docket ID numbers EPA–HQ–OPP–2005–0310 and EPA–HQ–OPP–2008–0858.

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*.

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

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ADAOS 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)	No appropriate endpoints were identified for acute dietary risk assessment.		
Chronic dietary (all populations)	NOAEL = 42.3 mg inert/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = .42 mg/kg/day cPAD = .42 mg/kg/day	Chronic toxicity/oncogenicity study– rat (CAS Reg. No. 70592–80–2) LOAEL = 87.4 mg/kg/day based on decreased body weight and ophthalmological opacities/cataracts
Incidental Oral Short- and Intermediate Term Dermal and Inhalation	NOAEL= 42.3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x (10% Dermal absorption; 100% inhalation and oral toxicity assumed equivalent)	Residential/Occupational LOC for MOE = 100.	Chronic toxicity/oncogenicity study– rat (CAS Reg. No. 70592–80–2) LOAEL = 87.4 mg/kg/day based on decreased body weight and ophthalmological opacities/cataracts
Cancer (oral, dermal, inhalation)	Classification: ADAOs are not expected to be carcinogenic based on the lack of evidence of carcinogenicity in the chronic feeding study in rats or in the chronic dermal study in mice as well as the negative response for mutagenicity.		

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.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effects attributable to a single exposure of ADAOs were seen in the toxicity databases. Therefore, acute dietary risk assessments for ADAOs are not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. 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 ADAOs. 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 ADAOs, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of ADAOs that may be in formulations (to no more than 15% by weight in pesticide products) and assumed that the ADAOs are present at the maximum limitation rather than at equal quantities with the active ingredient.

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*. ADAOs are not expected to be carcinogenic since there was no evidence of carcinogenicity in the chronic feeding studies in mice and rats or in the chronic dermal study in mice as well as the negative response for mutagenicity. Since the Agency has not identified any concerns for carcinogenicity relating to ADAOs, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for ADAOs. Tolerance level residues and/or 100% CT were assumed for all food commodities.

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 ADAOs, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for ADAOs. 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). ADAOs may be used in 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 ADAOs as inert ingredients. The ADAO 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 home cleaning products. The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing ADAOs in pesticide formulations (Outdoor Scenarios) and ADAOs in disinfectant-type uses (Indoor Scenarios). Based on information contained in the petition, ADAOs can be present in consumer cleaning products (maximum concentration 4%). Therefore, the Agency assessed the disinfectant-type products containing ADAOs 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 ADAOs in pesticide formulations (Outdoor Scenarios) and ADAOs 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.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider''available information''concerning the cumulative effects of a particular pesticide's residues and''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ADAOs and any other substances and, this material 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 ADAOs have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see 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/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Qualitative susceptibility was observed in the developmental toxicity studies in the rat. Skeletal variations were observed in rat fetuses at a dose (100 mg/kg/day) that caused maternal toxicity (decreased body weight gain). In a second developmental study in the rat, increased incidence of bifid centrum occurred in fetuses at a dose (100 mg/kg/day) that caused maternal toxicity (decreased body weight gain). However, the concern for qualitative fetal susceptibility is low because NOAELs are well established in these two studies and protective of fetuses. The NOAEL of 25 mg/kg/day established in the developmental study in the rat represents the lowest NOAEL in the database. However, the NOAEL of 42.3 mg/kg/day was selected from the chronic/carcinogenicity study for use in risk assessment. This decision was based on the conclusion that the NOAEL of 25 mg/kg/day is an artifact of dose spread. The doses tested in the developmental study in the rat were 0, 25, 100, and 200 mg/kg/day. The LOAEL for this study was 100 mg/kg/day. In a second rat developmental study and a 2–generation reproduction study, fetal and maternal effects were consistently seen at doses >100 mg/kg/day, the maternal and fetal NOAELs

were established at 100 mg/kg/day (developmental study) and >40 mg/kg/day (2–generation reproduction study, highest dose tested). In a recently conducted combined developmental/reproduction screening study (OPPTS Harmonized Guideline 870.3650), the maternal and offspring NOAELs were 40 and 100 mg/kg/day, respectively, and effects were seen at doses >100 mg/kg/day further supporting the higher NOAEL. Additionally, in the chronic/carcinogenicity study, the NOAEL was 42.3 mg/kg/day, effects (decreased body weight and cataracts) were observed at 87.4 mg/kg/day which is consistent with the dose at which other effects were seen. Given this weight-of-evidence, it was concluded that the NOAEL of 42.3 mg/kg/day most accurately reflected the true NOAEL. Therefore, the established Chronic Reference Dose (cRfD) (0.42 mg/kg/day) is protective of any developmental effects observed at doses as low as 100 mg/kg/day in these studies. There are low concerns for residual uncertainties concerning prenatal and postnatal toxicity.

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

i. The toxicity database for the ADAOs inerts is considered adequate for assessing the risks to infants and children. The toxicity data available on the ADAOs is summarized in Unit IV.A.

ii. Although qualitative susceptibility was observed in the developmental toxicity studies in the rat, the concern for qualitative fetal susceptibility is low for the reasons noted in Unit IV.D.2.

iii. Evidence of neurotoxicity was noted in the combined developmental/reproduction screening test in rats. Total locomotor activity was reduced at the high dose (250 mg/kg/day) in females only. However, EPA concluded that the reduction in locomotor activity was due to excessive systemic toxicity at the high dose rather than due to neurological origin. This conclusion is based on the following: effects were seen only in one sex at the high dose, the effect was transient, neurotoxicity was not observed at the lower doses in this study, there were no neuropathological lesions in the study and clinical signs of neurotoxicity and neuropathology were not observed in any other studies in the database. Thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. The Agency noted changes in thymus weight and thymus atrophy were observed in males at the high dose (250 mg/kg/day) only. These were determined to be non-specific changes not indicative of immunotoxicity. In addition, no blood parameters were affected. Furthermore, these compounds do not belong to a class of chemicals that would be expected to be immunotoxic. Therefore, these identified effects do not raise a concern necessitating an additional uncertainty.

v. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100% crop treated is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ADAOs in drinking water. These assessments will not underestimate the exposure and risks posed by ADAOs.

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.*There was no hazard attributable to a single exposure seen in the toxicity database for ADAOs. Therefore, the ADAOs are not expected to pose an acute risk.

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 limitations of not more than 15% by weight in pesticide formulations, the chronic dietary exposure from food and water to ADAO is 14% of the cPAD for the U.S. population and 45% of the cPAD for children 1 to 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).

ADAOs 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 ADAOs. 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 250 for both adult males and females respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hand 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 200 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).

ADAOs 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 ADAOs. 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 840 for adult males and 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 210 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 ADAOs.

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 ADAOs.

V. 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, ADAOs may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method(s)

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 ADAOs nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

VI. 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 ADAOs. Accordingly, EPA finds that exempting ADAOs from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing crops will be safe.

VII. 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This 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).

VIII. 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: September 25, 2009.

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 §180.910, the table is amended by adding alphabetically the following inert ingredients:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
C_{10}-C_{18}-Alkyl dimethyl amine oxides (CAS Reg. Nos. 1643–20–5, 2571–88–2, 2605–79–0, 3332–27–2, 61788–90–7, 68955–55–5, 70592–80–2, 7128–91–8, 85408–48–6, and 85408–49–7)	15% by weight in pesticide formulation	Surfactant
* * * * * * *		

[FR Doc. E9–24055 Filed 10–06–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0407; FRL–8438–1]

Ammonium chloride; 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 ammonium chloride (CAS Reg. No. 12125–02–9) applied pre-harvest on all raw agricultural commodities when applied/used as a carrier/nutrient. 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 ammonium chloride.

DATES: This regulation is effective October 7, 2009. Objections and requests for hearings must be received on or before December 7, 2009, 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–2008–0407. 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: Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0851; e-mail address: *sunderland.deirdre@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also 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*.

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–2008–0407 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 December 7, 2009.

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–2008–0407, 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 June 13, 2008 (73 FR 33814) (FRL–8367–3), EPA issued a notice pursuant to section 408