(*2*) Section IV.B.2, Application for a Construction Permit, and Section IV.H.8, Application for a Final Permit, regarding operating and maintenance plans and recordkeeping formats.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0098; FRL–8861–9]

Sodium and Potassium Salts of N-alkyl (C_8–C_{18})-beta-iminodipropionic acid; 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 sodium and potassium salts of N-alkyl (C_8–C_{18})-beta-iminodipropionic acid where the C_8–C_{18} is linear and may be saturated and/or unsaturated, (CAS Reg. Nos. 110676–19–2, 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, and 97862–48–1), herein referred to in this document as SSNAs, when used as inert ingredients for pre- and post-harvest uses and for application to animals at a maximum of 30% by weight in pesticide formulations. The Joint Inerts Task Force (JITF), Cluster Support Team Number 14, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of SSNAs.

DATES: This regulation is effective February 4, 2011. Objections and requests for hearings must be received on or before April 5, 2011, 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–2009–0098. 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: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8825; *e-mail address: samek.karen@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 harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0098 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0098, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online 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. Petition for Exemption

In the **Federal Register** of March 19, 2010 (75 FR 132771) (FRL–8813–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7631) by The Joint Inerts Task Force, Cluster Support Team 14 (CST 14), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 and 40

CFR 180.930 be amended by establishing exemptions from the requirement of a tolerance for residues of the SSNAs (CAS Reg. Nos. 110676–19–2, 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, and 97862–48–1) when used as inert ingredients as a surfactant in pesticide formulations applied to crops pre- and post-harvest, as well as to animals at a maximum of 30% by weight in pesticide formulations. That notice referenced a summary of the petition prepared by the Joint Inerts Task Force (JITF), Cluster Support Team Number 14 (CST 14), the petitioner, which is available in the docket, *http://www.regulations.gov.* Two comments were received in response to the Notice of Filing. One of the comments was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. A second comment was received regarding endocrine effects from soybeans. Since the subject of this tolerance exemption request is not soybeans, this comment is not relevant to this action.

EPA previously published a final rule to establish a tolerance exemption for sodium salts of SSNA (CAS Reg. Nos. 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, and 97862–48–1) under 40 CFR 180.920 in the **Federal Register** of July 29, 2009 (74 FR 37584) (FRL–8425–5). That final rule established a tolerance exemption for sodium salts of SSNA when used as inert ingredients in pesticide formulations applied to growing crops only.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the SSNAs including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with the SSNAs follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Specific information on the studies received and the nature of the adverse effects caused by the SSNAs, 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 "Sodium Salts of N-Alkyl (C_8–C_{18})-β-iminodipropionic Acid (SSNAs—JITF CST 14 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pages 8–13 and pages 46–49 in docket ID number EPA–HQ–OPP–2009–0098. In this human health risk assessment an exemption from the requirement of a tolerance was assessed for an exemption under 40 CFR 180.920 for pre-harvest use of sodium salts of SSNA where the C_8-C_{18} is linear and may be saturated and/or unsaturated provided that the concentration of the SSNA inert is limited to no more than 30% by weight in pesticide formulations. It was noted in the document that this risk assessment also supports the use of the SSNA inert ingredients in pesticide formulations intended for use post-harvest as well. Because it is likely that the sodium or potassium salts of SSNA readily disassociate in the body to the salt and the active moiety and that the toxicity of the chemical is associated with the active moiety, the Agency concludes that its risk assessment is sufficient to support both the sodium and potassium salts of SSNA. The Agency also concludes that the risk assessment supports the application of these chemicals to animals under 40 CFR 180.930 with the limitation of no more than 30% in pesticide formulations.

The available toxicity data indicate that the SSNAs have low acute oral and dermal toxicity, are potentially

corrosive to the skin, but are also mild to moderate eye irritants. In the OPPTS Harmonized Guideline 870.3650 study with sodium coco β-iminodipropionate in rats, decreased food consumption and body weight gain in males and females at 160 and 600 mg/kg bw/day were observed. Mean liver and kidney weights were increased at the high dose, while testis and epididymides were unaffected. Hypertrophy was found in the livers of males and/or females at the mid- and high-doses as well as renal histopathology in males, acanthosis of the non-glandular stomach in males and females, and inflammation of the glandular and non-glandular stomach in females. In the absence of any evidence of hepatic toxicity, liver hypertrophy was considered an adaptive effect and non-adverse.

No reproduction or developmental effects were noted in the database and there was no evidence of neurotoxicity.

In general, 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. It is possible that some of the observed toxicity seen in the repeated studies, such as inflammation of the glandular stomach, can be attributed to the corrosive and irritating nature of these surfactants.

There are no published metabolism studies for this series of surfactants. The SSNA mammalian metabolism pathway is based on analogy to well-described pathways for tertiary amines and fatty acids. Overall it is anticipated that the various metabolites are not systemically toxic and would be rapidly conjugated and excreted.

The SSNA surfactants (mono and di-sodium propionates) may be conjugated and excreted directly. Alternatively, the tertiary amine dipropionate may be oxidized in the liver by monoamine oxidases to generate the intact tertiary amine dipropionate N-oxide which may either be conjugated and excreted or metabolically cleaved to a dipropionate oxime type metabolite that is conjugated and excreted. The linear fatty acid is metabolized via successive beta-oxidation cycles to release acetic acid and eventually carbon dioxide and water.

There are no chronic toxicity studies available for this series of nonionic surfactants. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, *see http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THE SSNAS 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	An effect attributable to a single exposure was not identified.		
Chronic dietary (All populations)	NOAEL= 43 mg/kg/ day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.43 mg/kg/day. cPAD = 0.43 mg/kg/ day.	Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test-Rat OPPTS Harmonized Guideline 870.3650 (CAS Reg. No. 3655–00–3). Parental LOAEL = 160 mg/kg/day based on decreased body weight gain in males and females during the pre-mating period, and an increased incidence of microscopic lesions in the kidneys of males and acanthosis of the glandular + non-glandular stomachs of females. Reporductive/Developmental LOAEL was not observed.
Incidental Oral, Dermal and Inhalation (Short-, and Intermediate-, and Long-Term).	NOAEL= 43 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x 5% dermal and 100% inhalation absorption assumed.	LOC for MOE = 100 ..	Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity screening Test-Rat OPPTS Harmonized Guideline 870.3650 (Cas Reg. No. 3655–00–3). Parental LOAEL = 160 mg/kg/day based on decreased body weight gain in males and females during the pre-mating period and an increased incidence of microscopic lesions in the kidneys of males and acanthosis of the glandular + non-glandular stomachs of females. Reproductive/Developmental LOAEL was not observed.
Cancer (oral, dermal, inhalation).	Classification: No animal toxicity data available for an assessment. Based on SAR analysis, the SSNAs are not expected to be carcinogenic.		

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 SSNAs, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from the SSNAs in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of the SSNAs were seen in the toxicity databases; therefore, an acute exposure assessment for the SSNAs is not necessary.

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 SSNAs. 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 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 the SSNAs, EPA made a specific adjustment to this dietary exposure assessment to account for the use limitations of the amount of SSNAs that may be in formulations (no more than 30% by weight in pesticide formulations) and assumed that the SSNAs 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. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. SSNAs are not expected to be carcinogenic. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.

iv. Anticipated residue and percent crop treated (PCT) information.

EPA did not use anticipated residue and/or PCT information in the dietary assessment for SSNAs. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for SSNAs in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of SSNAs. Further information regarding EPA drinking water models used in the pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

A screening level drinking water analysis, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) was performed to calculate the estimated drinking water concentrations (EDWCs) of SSNAs. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of the SSNAs were conducted. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in the document "Sodium Salts of N-Alkyl (C_8–C_{18})-β-iminodipropionic Acid (SSNAs—JITF CST 14 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pages 13–14 and pages 51–53 in docket ID number EPA–HQ–OPP–2009–0098.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the SSNAs, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compounds and for the metabolites of concern. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). SSNAs 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 the SSNAs as inert ingredients. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for indoor and outdoor scenarios with high exposure potential (*i.e.,* exposure scenarios with high end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing SSNAs. Similarly, residential post application dermal and oral exposure assessments were also performed utilizing high end indoor and outdoor exposure 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."

EPA has not found the SSNAs to share a common mechanism of toxicity with any other substances, and the SSNAs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that the SSNAs do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, *see* EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The toxicology database is adequate to assess risk for the SSNAs when used as inert ingredients in pesticide formulations. The toxicity data available on the SSNAs consists of one OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/development toxicity screening test (rat) for the representative surfactant, sodium coco beta-iminodipropionate (CAS Reg. No. 3655–00–3). There was no evidence of increased sensitivity in young animals because no developmental or reproductive toxicity was observed in the OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study. No treatment related effects were observed on litter sizes or on the early development of pups.

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 SSNAs is considered adequate for assessing the risks to infants and children (the available studies are described in unit IV.D.2.). The Agency has determined that the OPPTS Harmonized Guideline 870.3650, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in rats is adequate to assess the toxicity of this chemical because the study provides information on systemic toxicity, neurotoxicity and immunotoxicity following repeated exposure, as well as assessing possible developmental and reproductive effects. The study measures various toxicological parameters such as hematology, clinical biochemistry, gross pathology and histopathology. In this study, no treatment related adverse effects were observed in any of the observed or measured parameters at dose levels below the high dose level of 600 mg/kg/day except for decreased body weight gain during the pre-mating period, and increased incidence of microscopic renal lesions in males and congestion and inflammation of the glandular and non-glandular stomachs of females at the mid level dose level of 160 mg/kg/day. Stomach epithelial cell congestion/inflammation is an effect attributable to local irritation rather than systemic activity. 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 are attributable to the corrosive and irritating nature of these surfactants. The Agency has considerable toxicity information on surfactants which indicates that their 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 the SSNAs indicates that the target organ toxicity is occurring at relatively high doses. Based on the above considerations, the Agency concluded that there is no need for additional data and an additional FQPA safety factor is not necessary.

ii. No quantitative or qualitative increased susceptibility was demonstrated in the offspring in the OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats following *in utero* and post-natal exposure.

iii. There are no neurotoxicity studies available for this series of nonionic

surfactants. However a Functional Observation Battery (FOB) to evaluate neurotoxicity was performed in the Combined Repeated Dose/ Developmental Screening study and only a minor decrease in temperature was observed in males at the mid and high doses. The effect was likely due to normal biological variation and; therefore, was not considered treatment-related. Thus, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. 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 SSNAs in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by the SSNAs.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, the SSNAs 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 30% by weight in pesticide formulations, the chronic dietary exposure from food and water to SSNAs is 27% of the cPAD for the U.S. population and 87% of the cPAD for children 1–2 yrs 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). SSNAs 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 SSNAs. 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 160 for both adult males and females respectively. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 100 for children. 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). SSNAs 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 SSNAs. 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 430 and 450 for adult males and females, respectively. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 110 for children. 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 SSNAs.

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 SSNAs.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of the SSNAs in or on any food commodities. EPA is establishing a limitation on the amount of the SSNAs that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution that contains greater than 30% of the SSNAs by weight in food use pesticide formulations.

B. International Residue Limits

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

The codex has not established a MRL for the SSNAs.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 and 40 CFR 180.930 for sodium and potassium salts of N-alkyl (C_8–C_{18})-beta-iminodipropionic acid where the C_8–C_{18} is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 110676–19–2, 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, and 97862–48–1) when used as inert ingredients in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals at a maximum of 30% by weight in pesticide formulations.

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 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) (Pub. L. 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: January 24, 2011.

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 ingredient to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
Sodium and potassium salts of N-alkyl (C_8–C_{18})-beta-iminodipropionic acid where the C_8–C_{18} is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 110676–19–2, 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, 97862–48–1).	Concentration in formulated end-use products not to exceed 30% by weight in pesticide formulations.	Surfactants, related adjuvants of surfactants.

* * * * *

■ 3. In § 180.930, the table is amended by adding 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
Sodium and potassium salts of N-alkyl (C_8–C_{18})-beta-iminodipropionic acid where the C_8–C_{18} is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 110676–19–2, 3655–00–3, 61791–56–8, 14960–06–6, 26256–79–1, 90170–43–7, 91696–17–2, 97862–48–1).	Concentration in formulated end-use products not to exceed 30% by weight in pesticide formulations.	Surfactants, related adjuvants of surfactants.

* * * * *

[FR Doc. 2011–2408 Filed 2–3–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0181; FRL–8860–7]

n-Octyl Alcohol and n-Decyl Alcohol; 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 n-octyl alcohol (CAS Reg. No. 111–87–5); and n-decyl alcohol (CAS Reg. No. 112–30–1) when used as an inert ingredient (solvent or co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under EPA regulations. Technology Sciences Group Inc., on behalf of AMVAC, Chemical Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of n-octyl alcohol and n-decyl alcohol.

DATES: This regulation is effective February 4, 2011. Objections and requests for hearings must be received on or before April 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** section).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0181. 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: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; e-mail address: *debesai.alganesh@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0181 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0181, 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. Petition for Exemption

In the **Federal Register** of March 24, 2010 (75 FR 14154) (FRL–8815–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7671) by AMVAC Chemical Corporation, 4695 MacArthur Court, Suit 1250, Newport Beach, CA 90660. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of n-octyl alcohol (CAS Reg. No. 111–87–5); and n-decyl alcohol (CAS Reg. No. 112–30–1) when used as inert ingredients (solvent or co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by AMVAC Chemical Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.