| Inert ingredients | Limits | Uses |
|---|---|---|
| * * * * * | | |
| α-Alkyl (minimum $C_6$ linear, branched, saturated and/or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; minimum oxyethylene content is 2 moles; minimum oxypropylene content is 0 moles (CAS Reg. Nos. 9046–01–9, 37280–82–3, 39464–66–9, 42612–52–2, 50643–20–4, 52019–36–0, 58318–92–6, 60267–55–2, 61837–79–4, 67711–84–6, 68070–99–5, 68071–35–2, 68071–17–0, 68130–47–2, 68186–37–8, 68186–36–7, 68311–02–4, 68425–73–0, 68458–48–0, 68511–37–5, 68610–65–1, 68585–36–4, 68649–29–6, 68815–11–2, 68908–64–5, 68891–13–4, 73038–25–2, 78330–24–2, 108818–88–8, 154518–39–5, 317833–96–8, 873662–29–4, 936100–29–7, 936100–30–0). | Not to exceed 30% of pesticide formulation. | Surfactants, related adjuvants of surfactants |
| * * * * * | | |

■ 4. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

* * * * *

| Inert ingredients | Limits | Uses |
|---|---|---|
| * * * * * | | |
| α-Alkyl($C_6$-$C_{15}$)-ω-hydroxypoly(oxyethylene)sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, poly(oxyethylene) content averages 2–4 moles (CAS Reg. Nos. 3088–31–1, 9004–82–4, 9004–84–6, 13150–00–0, 25446–78–0, 26183–44–8, 32612–48–9, 50602–06–7, 62755–21–9, 68424–50–0, 68511–39–7, 68585–34–2, 68611–55–2, 68891–38–3, 73665–22–2). | Not to exceed 30% of pesticide formulation. | Surfactants, related adjuvants of surfactants |
| * * * * * | | |

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2009–0046; FRL–8428–9]**

### N-alkyl ($C_8$-$C_{18}$) Primary Amines and Acetate Salts; 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-alkyl ($C_8$-$C_{18}$) primary amines and acetate salts where the alkyl group is linear and may be saturated and/or unsaturated, herein referred to in this document as NAPAAS, when used as inert ingredients for pre-harvest uses under 40 CFR 180.920 at a maximum concentration in formulated end-use products of 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products. The Joint Inerts Task Force (JITF), Cluster Support Team Number 25 (CST 25), 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 NAPAAS.

**DATES:** This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 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–2009–0046. 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:** Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: *leifer.kerry@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 those engaged in the following activities:

- 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 to provide 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 directly 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. 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–2009–0046 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 as required by 40 CFR part 178 on or before September 28, 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 this copy, identified by docket ID number EPA–HQ–OPP–2009–0046, 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

In the **Federal Register** of March 4, 2009 (74 FR 9397) (FRL–8401–8), 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 9E7519) by The Joint Inerts Task Force (JITF), Cluster Support Team 25 (CST 25), c/o CropLife America, 1156 15th Street, N.W., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of the inert ingredients N-alkyl ($C_8$-$C_{18}$) primary amines and acetate salts where the alkyl group is linear and may be saturated and/or unsaturated (NAPAAS). Concentration in formulated end-use products not to exceed 8% by weight in herbicide products, 5% by weight in insecticide products, and 30% by weight in fungicide products. That notice referenced a summary of the petition prepared by JITF, CST 25, the petitioner, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the exemption requested by changing the use limitations in pesticide products as follows: A maximum concentration in formulated end-use products of 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products. These limitations are based on the Agency's risk assessment which can be found at *http://www.regulations.gov*, in document N-alkyl ($C_8$-$C_{18}$) Primary Amines and Acetate Salts (NAPAAS - JITF CST 25 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations, in docket ID number EPA–HQ–OPP–2009–0046.

This petition was submitted in response to a final rule of August 9, 2006 (71 FR 45415) (FRL–8084–1) in which the Agency revoked, under section 408(e)(1) of the FFDCA, the existing exemptions from the requirement of a tolerance for residues of certain inert ingredients because of insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009 (73 FR 45311) (FRL–8372–7) to allow for data to be submitted to support the establishment of tolerance exemptions for these inert ingredients prior to the effective date of the tolerance exemption revocation.

## III. Inert Ingredient Definition

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

## IV. Aggregate Risk Assessment and Determination of Safety

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for exemption from the requirement of a tolerance for residues of NAPAAS provided that the concentration of the NAPAAS inerts are limited in formulated end-use product to no more than 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products. 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 mammalian toxicology database for NAPAAS consists of one OPPTS Harmonized Guideline 870.3650 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats); acute oral, dermal, and eye toxicity data; and *in vitro* mutagenicity data.

NAPAAS are not acutely toxic by the oral route of exposure but are corrosive to the skin and are severe eye irritants. There is no clear target organ identified for NAPAAS inert compounds. In the OPPTS Harmonized Guideline 870.3650 study on the representative surfactant, treatment-related microscopic lesions were observed in both sexes, which included histomorphologic changes in the stomach (hyperplasia and hyperkeratosis of the squamous mucosa of the forestomach), and erosions, ulcers, inflammatory cell infiltrations, and/or edema in the submucosa of the forestomach and glandular areas of the mucosa. The accumulation of macrophages was most prevalent in the mesenteric lymph nodes and small intestine where they were large with an abundant amount of pale foamy cytoplasm. In the mesenteric lymph node and liver, coalescence of the large macrophages occurred forming microgranulomas. Thymic atrophy was observed in both sexes. Histologically, the thymus was smaller due to a decrease in the amount of cortical lymphocytes, which may be an indirect or secondary phenomenon, as thymic atrophy often occurs in animals under stress. No evidence of potential neurotoxicity was observed in the females, and the reduced motor activity observed in the high-dose males was considered to be secondary to the gastrointestinal irritation and general malaise and not a neurotoxic effect.

There was no evidence of increased susceptibility to the offspring following prenatal and postnatal (four days) exposure and reproductive toxicity was not observed. There is no evidence of mutagenicity or carcinogenicity.

Primary amines and primary amine acetates are biologically equivalent and follow the same metabolic pathways of oxidation by monoamine oxidases to generate the $C_8$-$C_{18}$ fatty acid and ammonia. The fatty acid would be degraded by well-known pathways (β-oxidation) to successive releases of acetic acid, which enters into intermediary metabolism or is metabolized ultimately to carbon dioxide and water. The CST 25 NAPAAS primary amines and primary amine acetate salt may also be conjugated, whether by glucuronidation or sulfonation, and excreted directly.

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

Specific information on the studies received and the nature of the adverse effects caused by the NAPAAS, 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 N-alkyl ($C_8$-$C_{18}$) Primary Amines and Acetate Salts (NAPAAS - JITF CST 25 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations at pp. 8–12 and pp. 19–22 in docket ID number EPA–HQ–OPP–2009–0046.

*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 the NAPAAS used for human health risk assessment is shown in Table 1. below:

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

| Exposure/scenario | Point of departure and uncertainty/safety factors[1] | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute dietary (all populations) | No appropriate endpoint was identified for acute dietary assessment | | |
| Chronic dietary (all populations) | NOAEL= 5 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = 0.05 mg/kg/day<br>cPAD = 0.05 mg/kg/day | OPPTS harmonized guideline 870.3650 reproduction/developmental screen in rats<br>LOAEL = 20 mg/kg/day, based on microscopic lesions in the stomach, jejunum, thymus, and lymph nodes in both sexes |
| Incidental oral short- (1–30 days) and intermediate term (1–6 months) | Oral NOAEL= 5 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x 5% dermal and 100% inhalation absorption assumed | Residential LOC for MOE = 100 | OPPTS harmonized guideline 870.3650 reproduction/developmental screen in rats<br>LOAEL = 20 mg/kg/day, based on microscopic lesions in the stomach, jejunum, thymus, and lymph nodes in both sexes |
| Cancer (oral, dermal, inhalation) | Classification: No animal toxicity data available for an assessment. Based on SAR analysis, the NAPAAS are not expected to be carcinogenic | | |

[1]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 NAPAAS, EPA considered exposure under the petitioned-for exemption from the requirement of a tolerance. EPA assessed dietary exposures from NAPAAS in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of the NAPAAS inerts were seen in the toxicity databases; therefore, an acute exposure assessment for the NAPAAS 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 the NAPAAS. 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 is generally at least 50% 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 NAPAAS, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of NAPAAS that may be in formulations (4% by weight in fungicide products) and assumed that the NAPAAS are present at the maximum limitation rather than at equal quantities with the active ingredient. The Agency does not expect that allowing a maximum of 10% in the final formulation for herbicides only will have a significant impact on the dietary exposure. Across the board it appears that selecting the highest fungicide tolerance and correcting for its limitation to 4% by weight as a maximum in the final formulation, results in a higher residue input into the dietary risk assessment than selecting the highest herbicide tolerance and correcting for 10% by weight as a maximum in the final formulation. This remains a very conservative assumption because surfactants are generally used at levels far below this percentage. For example, EPA examined several of the pesticide products associated with the tolerance/commodity combination which are the driver of the risk assessment and found that these products did not contain surfactants at levels greater than 2.25% and that none of the surfactants were NAPAAS.

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% 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 SAR database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. The Agency has not identified any concerns for carcinogenicity relating to the inerts NAPAAS. 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 NAPAAS. Tolerance level residues and/or 100% crop treated 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 NAPAAS in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of NAPAAS. 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 NAPAAS. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of the NAPAAS were conducted. Modeled acute drinking water values ranged from 0.001 parts per billion (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 N-alkyl ($C_8$-$C_{18}$) Primary Amines and Acetate Salts (NAPAAS - JITF CST 25 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations at pp. 13 and 25–27 in docket ID number EPA–HQ–OPP–2009–0046.

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 NAPAAS, 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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

The Agency has reviewed the submitted petition as well as all available data on the use of these inert ingredients in pesticide formulations, and concludes that the NAPAAS inerts are not used in formulations that would be applied in and around the home or in a way that would result in residential exposures; therefore, a residential exposure risk assessment is not necessary for the NAPAAS inerts.

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 NAPAAS to share a common mechanism of toxicity with any other substances, and NAPAAS do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NAPAAS 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 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*. In the case of the NAPAAS, there was no increased susceptibility to the offspring of rats following prenatal and post-natal exposure in the OPPTS Harmonized Guideline 870.3650 reproductive/developmental screening study. Decreased pup body weight was observed at 40 and 80 mg/kg/day where maternal/paternal toxicity was manifested as microscopic lesions in the stomach, jejunum, thymus, and lymph nodes at 20, 40, and 80 mg/kg/day. Since the rat reproduction/developmental study identified a clear NOAEL of 20 mg/kg/day for offspring effects, and the selected point of departure of 5 mg/kg/day (parental NOAEL for stomach/jejunum/thymus/lymph node lesions) for the dietary risk assessment is protective of the offspring effects, there are no residual concerns.

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 NAPAAS inerts is considered adequate for assessing the risks to infants and children. The toxicity data available on

the NAPAAS consists of one OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/development toxicity screening test (rat); acute oral, dermal, and eye toxicity data; and *in vitro* mutagenicity data. The Agency noted changes in thymus weight and thymus atrophy. However, 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.

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 prenatal and postnatal exposure.

iii. Although the available mammalian toxicity database does not include any chronic toxicity data, the effects observed in the parental animals following gavage dosing are mainly portal-of-entry effects (stomach irritation), and gavage dosing is not a relevant exposure condition in humans. The effects observed would not be expected to occur at a lower dose with increased duration of exposure under relevant exposure conditions. Also, based on the very conservative exposure assessment, the 10X interspecies and 10X intraspecies uncertainty factor would be adequately protective, and no additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure.

iv. No neurotoxicity was demonstrated in the OPPTS Harmonized Guideline 870.3650 study. Thus, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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 NAPAAS in drinking water. These assessments will not underestimate the exposure and risks posed by NAPASS.

*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. No residential aggregate exposure assessment was conducted because no residential uses for NAPAAS are anticipated. Therefore, the aggregate risk for these inerts includes exposures through food and drinking water only.

1. *Acute risk*. There was no hazard attributable to a single exposure seen in the toxicity database for NAPAAS. Therefore, the NAPAAS 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 to no more than 4% in fungicide and insecticide formulations and 10% in herbicide formulations, the chronic dietary exposure from food and water to NAPAAS is 36% of the cPAD for the U.S. population and 106% of the cPAD for children 1–2 yrs old, the most highly exposed population subgroup. While the Agency notes that the risk for children is slightly above a cPAD of 100%, given the exceptionally conservative nature of the exposure assessment detailed above, the Agency believes that actual risks are significantly lower and are not of concern.

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

4. *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 NAPAAS.

## V. Other Considerations

*A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation..

*B. International Residue Limits*

The Agency is not aware of any country requiring a tolerance for NAPAAS nor have any CODEX maximum residue levels been established for any food crops at this time.

## VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of N-alkyl ($C_8$-$C_{18}$) primary amines and acetate salts where the alkyl group is linear and may be saturated and/or unsaturated when used as inert ingredients for pre-harvest uses under 40 CFR 180.920 at a maximum concentration in formulated end-use products of 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products.

## VII. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule,

the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

### 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: July 21, 2009.

**G. Jeffrey Herndon,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 is amended as follows:

## PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

* * * * *

| Inert ingredients | Limits | Uses |
|---|---|---|
| * * * | * * | |
| N-alkyl ($C_8$-$C_{18}$) primary amines and their acetate salts where the alkyl group is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 61790–57–6, 61790–58–7, 61790–59–8, 61790–60–1, 61788–46–3, 61790–33–8, 68155–38–4). | Concentration in formulated end-use products not to exceed 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products.. | Surfactants, related adjuvants of surfactants |
| * * * | * * | |

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2009–0098; FRL–8425–5]**

### Sodium 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 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, herein referred to in this document as SSNAs when used as an inert ingredient for pre-harvest uses under 40 CFR 180.920 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 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 July 29, 2009. Objections and requests for hearings must be received on or before September 28, 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–2009–0098. 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:** Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: *leifer.kerry@epa.gov*.