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[FR Doc. 2010–20299 Filed 8–17–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0046; FRL–8836–4]

N-alkyl (C8-C18) 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 (C8-C18) 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 a surfactant and related adjuvants of surfactants for pre-harvest and post-harvest uses under 40 CFR 180.910 and application to animals under 40 CFR 180.930 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 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an establishment of 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 August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0046. 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: *austin.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the Harmonized Test Guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0046 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 October 18, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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

In the **Federal Register** of February 4, 2010, (75 FR 5793) (FRL–8807–5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7627) by The JITF, Cluster Support Team 25 (CST 25), 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 an exemption from the requirement of a tolerance for residues of NAPAAS when used as at surfactant and related adjuvants of surfactants in pesticide formulations applied to pre-harvest and post-harvest crops and animals. These uses are considered inert ingredients in pesticide products. The concentration in formulated end-use products not to exceed 10% by weight in herbicide products, 4% by weight in other pesticidal products. That notice referenced a summary of the petition prepared by the JITF, Cluster Support Team Number 25 (CST 25), the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(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 NAPAAS including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with NAPAAS 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 NAPAAS as well as the NOAEL and the LOAEL from the toxicity studies are discussed in this unit.

The available mammalian toxicology database for NAPAAS consists of one Harmonized Test 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.

The 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 the NAPAAS. In the Harmonized Test 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 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 C8–C10 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 NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document "*N*-Alkyl (C8–C18) Primary Amines and Acetate Salts (NAPAAS - JITF CST 25 Inert Ingredients). Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pp. 8-12 and 19-22 in docket ID number EPA–HQ–OPP–2009–0046.

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 NAPAAS used for human risk assessment is discussed in Unit IV.A of the final rule published in the **Federal Register** of July 29, 2009, (74 FR 37578) (FRL–8428–9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to NAPAAS, EPA considered exposure under the proposed 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 concentration 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 (to no more than 10% by weight in herbicide products, 4% by weight in insecticide products, and 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. 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 structure activity relationship (SAR) database, DEREK 11, 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 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 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 compound. 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).

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 required 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 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NAPAAS does 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 postnatal exposure in the Harmonized Test Guideline 870.3650 reproductive/developmental screening study. Decreased pup body weight was observed at 40 and 80 milligrams/kilogram/day (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 Harmonized Test 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. There is no indication that NAPAAS is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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

iv. There are no residual uncertainties identified in the exposure databases. 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 PCT is assumed for all crops. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to NAPAAS in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by NAPAAS.

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-term, intermediate-term, 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, NAPAAS is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to NAPAAS from food and water will utilize 106% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for NAPAAS.

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

4. *Determination of safety*. EPA notes that the risk for children is slightly above a cPAD of 100%. The dietary exposure estimates overstate dietary risk because it assumes that the NAPAAS are present at the maximum limitation (10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products) because surfactants are generally used at levels far below these percentages. EPA examined several of the pesticide products associated with the tolerance/commodity combinations which are the drivers 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. Therefore, given the exceptionally conservative nature of the exposure assessment, EPA believes that actual risks are significantly lower and are not of concern. Based on this risk assessment, 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 NAPAAS residues.

V. Other Considerations

A. Analytical Enforcement Methodology

EPA is establishing a limitation on the amount of NAPAAS that may be used in end-use 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 a maximum concentration in formulated end-use products of NAPAAS greater than 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products.

B. International Residue Limits

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

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for *N*-alkyl (C8-C18) primary amines and acetate salts where the alkyl group is linear and may be saturated and/or unsaturated when used as an inert ingredient (surfactant and related adjuvants of surfactants) in pesticide formulations applied to pre-harvest and post-harvest crops and animals 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 a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

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

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: August 9, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

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

§ 180.910 N-alkyl (C8-C18) primary amines and accetate salts; Exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
N-alkyl (C8-C18) 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
* * *	* * *	*

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

§ 180.930 N-alkyl (C8-C18) primary amines and accetate salts; Exemption from the requirement of a tolerance.

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Inert ingredients	Limits	Uses
* * *	* * *	*
N-alkyl (C8-C18) 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
* * *	* * *	*

[FR Doc. 2010–20300 Filed 8–17–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8838–9]

Diethylene Glycol (DEG); 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 diethylene glycol (DEG) (CAS No. 111–46–6) when used as an inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations without limitation, under 40 CFR 180.920, for use on growing crops and raw agricultural commodities pre-harvest Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc. 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 DEG.

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0474. 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: *austin.lisa@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to