additional flexibility for transmix processors who produce locomotive and marine diesel fuel, and allowed solvent yellow 124 marker to transition out of the distribution system. We stated in the direct final rule that if EPA received timely adverse comment or a hearing request on the rule or any specific portion of the rule, we would publish a withdrawal of the rule or a specific portion of the rule in the **Federal Register** informing the public that the rule or portions of the rule with adverse comment will not take effect. We subsequently received adverse comment on the RFS heating oil amendments and the diesel transmix amendments. We did not receive adverse comment on the yellow marker amendments to 40 CFR 80.510, 80.598, 80.610, or the RFS requirement for RIN generation, as amended in 40 CFR 80.1426. Therefore, EPA is withdrawing the direct final rule with respect to the RFS heating oil amendments and the diesel sulfur transmix amendments, but leaving in place the direct final rule with respect to 40 CFR 80.510, 80.598, 80.610, and 80.1426. Those regulatory amendments will take effect on December 10, 2012.

EPA intends to address all comments received on the RFS heating oil and diesel transmix amendments in subsequent final actions, which will be based on the parallel proposed rule also published on October 9, 2012 (77 FR 61313). As stated in the direct final rule and the parallel proposed rule, we will not institute a second comment period on this action.

Dated: November 30, 2012.

Lisa P. Jackson,

Administrator.

Accordingly, the regulatory amendments to 40 CFR 80.511, 80.513, 80.572, 80.597, 80.1401, 80.1450, 80.1451, 80.1453, 80.1454, and 80.1460 published on October 9, 2012 (77 FR 61281) are withdrawn. The regulatory amendments to 40 CFR 80.510, 80.598, 80.610, and 80.1426 will take effect on December 10, 2012.

[FR Doc. 2012–29512 Filed 12–5–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0106; FRL–9369–2]

Alkyl(C_8-C_{18}) dimethylamidopropylamines; 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 the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines where the alkyl group is linear and may be saturated and/or unsaturated when used as an inert ingredient at levels not to exceed 20% in herbicide formulations applied to growing crops. Dow AgroSciences, LLC, 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 the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.

DATES: This regulation is effective December 6, 2012. Objections and requests for hearings must be received on or before February 4, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0106, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: William Cutchin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7990; email address: *cutchin.william@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2012–0106 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 February 4, 2013. 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 (excluding 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 the non-CBI copy of your objection or hearing request, identified by docket ID number

EPA–HQ–OPP–2012–0106, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of May 2, 2012 (77 FR 25957) (FRL–9346–1), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7949) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines where the alkyl group is linear and may be saturated and/or unsaturated (9-octadecenamide, *N*-[3-(dimethylamino)propyl]-,(9Z)-, CAS Reg. No. 109–28–4; dodecanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 3179–80–4; octadecanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 7651–02–7; octanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 22890–10–4; decanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 22890–11–5; hexadecanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 39669–97–1; tetradecanamide, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 45267–19–4; amides, coco, *N*-[3-(dimethylamino)propyl], CAS Reg. No. 68140–01–2; *N*-[3-(dimethylamino)propyl]-C_{12}-C_{18}(even numbered)-alkylamide, CAS Reg. No. 1147459–12–8; amides, C_8-C_{18} and C_{18}-unsatd., *N*-[3-(dimethylamino)propyl], CAS Reg. No. 146987–98–6) when used as an inert ingredient at levels not to exceed 20% in herbicide formulations applied to growing crops. That notice referenced a summary of the petition prepared by Dow AgroSciences, LLC, 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 FFDCA section 408(c)(2)(A), 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with of the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

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.*

The toxicity database for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines includes acute toxicity studies, *in vitro* genotoxicity assays and a repeat dose developmental/reproductive screening test (OECD 422) toxicity study on a representative *N*-alkyl(C_8-C_{18}) dimethylamidopropylamine member, Amides, coco, *N*-[3-(dimethylamino) propyl]; CAS Reg. No. 68140–01–2 (also referred to as CADPMA). The database is augmented by analogue information in the public domain and EPA's High Production Volume (HPV) program. CAPDMA is included in subcategory 3 of Category I amides within the 2004 HPV submission for Fatty Nitrogen Derived Amides class. CAPDMA has moderate acute oral toxicity with an LD_{50} of 300 milligrams/kilogram/body weight (mg/kg/bw) or greater and is corrosive to the skin and eye, respectively. CAPDMA and its broader class of HPV analogues are negative for genotoxicity across a series of *in vitro* assays. A combined repeated dose toxicity and reproduction and developmental toxicity screening test was conducted in rats with CAPDMA via oral gavage under OECD 422 guidelines. No treatment-related effects were observed in the reproductive or developmental parameters examined. No systemic toxicity was observed in this study. The NOAEL for repeat dose toxicity was 15 mg/kg/bw based on localized gastric irritation due to the irritation and corrosive nature of the material, typical of surfactants seen at the LOAEL of 45 mg/kg/day. The NOAEL for reproductive and mg/kg/day developmental toxicity was the highest dose tested (HDT), 45 mg/kg/day. CAPDMA was negative for mutagenicity in the Ames assay and *in vitro* mammalian chromosome aberration assay. No chronic studies are available for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines but negative findings for genotoxicity and no preneoplastic lesions were observed in the OECD 422 study on CAPDMA that would suggest no potential for carcinogenicity for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines. 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 for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines Neither IARC nor other authoritative bodies have classified the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines as carcinogens based on the SAR analysis, negative findings in both the mutagenicity and clastogenicity studies along with the lack of evidence of specific target organ toxicity. The Agency concluded that these inert ingredients are unlikely to pose a cancer risk to humans. No evidence of immunotoxicity or neurotoxicity was observed in the available database.

A summary of the toxicological endpoints for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THE *N*-ALKYL(C_8-C_{18}) DIMETHYLAMIDOPROPYLAMINES FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effect
Acute dietary (General population including infants and children and Females 13–50 years of age).	No POD identified ...	None	No endpoint of concern following a single exposure was identified in the data base.
Chronic dietary (All populations)	NOAEL = 15 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.15 mg/kg/day. cPAD = 0.15 mg/kg/day.	MRID 48621602 Oral (Gavage) Combined Repeat Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test in the Rat, NOAEL 15 mg/kg/day based on localized gastric irritation seen at the LOAEL of 45 mg/kg/day.
All Inhalation Exposure Scenarios.	NOAEL = 15 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x 100% inhalation absorption is assumed.	MOE = 100	MRID 48621602 Oral (Gavage) Combined Repeat Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test in the Rat, NOAEL. 15 mg/kg/day based on localized gastric irritation seen at the LOAEL as of 45 mk/kg/day.
Cancer (Oral, dermal, inhalation).	There is no evidence for carcinogenic concern for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines in food as using the I–Dietary Exposure Evaluation Model (I–DEEM). I–DEEM is a highly conservative model that is based on the assumption 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 between the active and inert ingredient (if any) 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. Model estimates were calculated for oral exposure from the use of the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines at a maximum concentration of 20% in herbicidal formulations for all crops (every food eaten by a person each day has tolerance-level residues; D361707, S. Piper, 2/25/09).

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 the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are not currently used, and are not proposed for use as inert ingredients in residential pesticide products. For the general population some exposure to the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines could occur via cosmetic use (at very low concentrations) including hair care dye kits. There is also potential for exposure to these chemicals through the use of personal soaps and shampoos. Incidential oral exposure to *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines resulting from cosmetic uses is not expected. Therefore, a quantitative oral risk assessment was not conducted. Since reliable data are not available, a quantitative dermal/inhalation exposure assessment was not conducted. The current dietary risk assessment is highly conservative and protective of any uses potential exposure via consumer products because the exposed population, children 1–2 years old utilize only 53% of the cPAD leaving about 47% of the cPAD for exposure via consumer products.

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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines to share a common mechanism of toxicity with any other substances, and the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines 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.* No evidence of developmental or reproductive toxicity was observed at doses up to 45 mg/kg/day in the Reproduction/Developmental Toxicity Screening Test in Rats (OECD 422 study). The corrosive nature of these chemicals precluded testing at higher doses.

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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines is adequate for FQPA assessment. The available data included acute toxicity studies, mutagenicity and the Reproduction/Developmental Toxicity Screening Test in rats (OECD 422). The available OECD 422 study evaluated reproductive parameters and developmental toxicity parameters in rats. In addition, it also evaluated hematology, clinical chemistry, organ weights and histopathological parameters. No effects on these parameters were observed at the HDT.

ii. No effects on Functional Observation Battery and motor activity parameters were observed in the Reproduction/Developmental Toxicity Screening Test in rats (OECD 422). Since there is no indication that the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factor to account for neurotoxicity.

iii. There is no evidence that the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines result in increased susceptibility of infants and children based on the results of the Reproduction/Developmental Toxicity Screening Test in rats, in *in utero* rats or rabbits in the prenatal developmental studies.

iv. There is no evidence of immunotoxicity in the available database. Therefore, there is no need for the immunotoxicity study or additional uncertainty factor.

v. Although the duration of exposure was short in the OECD 422 study, there is no need for an additional uncertainty factor because the effects observed were related to local irritation due to corrosive nature of these chemicals. Based on the lack of progression of severity of effects with time along with the considerable similarities of effects across the species tested and the observation that the vast majority of the effects observed were related to local irritation and corrosive effects, EPA has previously concluded that an additional uncertainty factor for extrapolation from subchronic toxicity study to a chronic exposure scenario would not be needed for highly irritating substances. As a result, the typical 100-fold uncertainty factor is sufficiently protective since it is not expected that humans' response to local irritation/corrosiveness effects would be markedly different based on duration of exposure.

vi. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments

were performed using the highly conservative I–DEEM model. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines in drinking water and with regard to potential residential exposures. These assessments will not underestimate the exposure and risks posed by the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.

E. Aggregate Risks and Determination of Safety

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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines from food and water will utilize 16.5% of the cPAD for the general population, and 53% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit IV.C.3., regarding residential use patterns, chronic residential exposure to *N*-alkyl(C_8-C_{18}) could occur via cosmetic use. While the lack of reliable exposure data precluded the ability to perform a quantitative risk assessment for these uses, the highly conservative nature of the chronic dietary risk assessment would be protective of any uses potential chronic exposure via consumer uses.

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). A short-term adverse effect was identified; however, the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Based on the explanation in Unit IV.C.3., regarding residential use patterns, short-term residential exposure to *N*-alkyl(C_8-C_{18}) could occur via cosmetic use. While the lack of reliable exposure data precluded the ability to perform a quantitative risk assessment for these uses, the highly conservative nature of the chronic dietary risk assessment would be protective of any uses potential short-term residential exposure via consumer uses, and EPA has determined that there are no concerns for short-term aggregate risk for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.

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). An intermediate-term adverse effect was identified; however, the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Based on the explanation in Unit IV.C.3., regarding residential use patterns, intermediate-term residential exposure to *N*-alkyl(C_8-C_{18}) could occur via cosmetic use. While the lack of reliable exposure data precluded the ability to perform a quantitative risk assessment for these uses, the highly conservative nature of the chronic dietary risk assessment would be protective of any intermediate-term residential exposure via consumer uses and EPA has determined that there are no concerns for intermediate-term aggregate risk for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.

5. *Aggregate cancer risk for U.S. population.* Based on the SAR analysis, negative findings in both the mutagenicity and clastogenicity studies along with the lack of evidence of specific target organ toxicity, the Agency concluded that the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines are unlikely to pose a cancer risk to humans.

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 the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines residues.

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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines in or on any food commodities. EPA is establishing a limitation on the amount of the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines 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 20% of the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines by weight in the pesticide formulation.

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 United Nation 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 *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for the *N*-alkyl(C_8-C_{18}) dimethylamidopropylamines when used as an inert ingredient in herbicide formulations applied to growing crops at levels not to exceed 20% of the formulation.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: November 21, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, alphabetically add the following inert ingredients to the table 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}) dimethylamidopropylamines where the alkyl group is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 109–28–4, 3179–80–4, 7651–02–7, 22890–10–4, 22890–11–5, 39669–97–1, 45267–19–4, 68140–01–2, 1147459–12–8, 146987–98–6).	Not to exceed 20% by weight in herbicide formulations.	Surfactants, related adjuvants of surfactants.
* * * *	* *	*

[FR Doc. 2012–29106 Filed 12–5–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8

RIN 0930–AA14

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Proposed Modification of Dispensing Restrictions for Buprenorphine and Buprenorphine Combination as Used in Approved Opioid Treatment Medications

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule amends the federal opioid treatment program regulations by modifying the dispensing requirements for buprenorphine and buprenorphine combination products approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs. In particular, this rule would allow opioid treatment programs more flexibility in dispensing take-home supplies of buprenorphine—removing restrictions on the time a patient needs to be in treatment in order to receive take-home supplies—after the assessment and documentation of a patient's responsibility and stability to receive opioid addiction treatment medication. Opioid treatment programs that use these products in the treatment of opioid dependence will continue to adhere to all other federal treatment standards established for methadone.

DATES: This rule is effective January 7, 2013.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies, SAMHSA, 1 Choke Cherry Road, Room 2–1063, Rockville, MD 20857, (240) 276–2716, email: *Nicholas.Reuter@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Regulatory Action

This final rule will modify the way that the narcotic treatment medication buprenorphine will be dispensed by treatment programs to individuals who are dependent on heroin or on certain prescription pain relievers by reducing