

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2018-0091; FRL-9986-06]

**Calcium Formate; 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 calcium formate (CAS Reg. No. 544-17-2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only. ADAMA Agan, Ltd. c/o Makhteshim Agan of North America, 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 calcium formate.

**DATES:** This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019, 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-2018-0091, 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), West William Jefferson Clinton 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:** Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfrNotices@epa.gov](mailto:RDfrNotices@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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0091 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, 2019. 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 Confidential Business Information (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-

2018-0091, 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 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.html>.

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 April 11, 2018 (83 FR 15528) (FRL-9975-57), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11075) by ADAMA Agan, Ltd. c/o Makhteshim Agan of North America, Inc., 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of calcium formate (CAS Reg. No. 544-17-2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only. That document referenced a summary of the petition prepared by ADAMA Agan, LTD, the petitioner, which is available in the docket, <http://www.regulations.gov>.

This is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in document: Calcium Formate; Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2018-0091. No comments were received in response to the notice published by EPA.

**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 calcium formate including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with calcium formate 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.

The toxicity database on calcium formate is somewhat limited. Consequently, studies on appropriate surrogates were used to supplement the database on calcium formate. Formic acid, sodium formate, potassium formate and ammonium formate were selected as appropriate surrogates since they are either the acid form of calcium formate or other salts of formic acid.

Calcium formate is not expected to be acutely toxic based on acute toxicity data. There are no subchronic or chronic studies on calcium formate, although there are studies on potassium formate. These studies show effects based on reduced body weight gain. A two-year study with potassium formate indicates the compound is not carcinogenic to Wistar rats.

In mutagenicity studies with calcium formate, sodium formate and methyl formate, results of the test were negative for all chemicals. The weight-of-evidence suggests that calcium is not expected to be mutagenic.

There are no available developmental toxicity studies on calcium formate; however, both a rat and rabbit developmental toxicity study have been conducted on sodium formate. In the rat study, the maternal and developmental no-observed-adverse-effect-level (NOAEL) was considered the highest dose tested at 945 milligram/kilogram/day (mg/kg/day). In the rabbit study, the maternal and developmental toxicity NOAEL was also the highest dose tested at 1,000 mg/kg/day. A five-generation rat reproductive toxicity study on calcium formate has been conducted with a NOAEL of >200 mg/kg/day (only dose tested). In a three-generation reproduction study in rats via drinking water, no treatment related effects were

observed in the parental animals and offspring at doses up to 200 mg/kg/day.

No studies were submitted for immunotoxicity. However, the toxicity studies available did not show any signs of immunotoxicity up to limit doses. Therefore, immunotoxicity is not of concern.

There are no available studies for neurotoxicity. However, the functional observation battery performed in the 90-day oral toxicity study did not show any signs of neurotoxicity up to limit doses. Therefore, neurotoxicity is not of concern.

A metabolism study is available in the toxicity database. Calcium formate breaks down into calcium and formate ions. Calcium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard. Formate ions are readily converted to carbon dioxide in the environment by biodegradation or photooxidation.

Specific information on the studies received and the nature of the adverse effects caused by calcium formate as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document Calcium Formate Risk Assessment at page 7 in docket ID number EPA-HQ-OPP-2018-0091.

##### 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>.

No toxicological endpoints of concern were identified for calcium formate based on available toxicity studies on surrogate chemicals. Formic acid, sodium formate, potassium formate and ammonium formate were selected as appropriate surrogates since they are either the acid form of calcium formate or other salts of formic acid. Most of the available studies on these substances were not conducted up to the limit dose. The highest dose of 200 mg/kg/day in a lifelong study in rats via drinking water did not produce any systemic toxicity (IUCLID, Calcium formate, 2001). Therefore, a conservative risk assessment was conducted using a NOAEL of 200 mg/kg/day for chronic dietary and short- and intermediate-term dermal exposure risk estimates. An uncertainty/safety factor of 100X (10X for interspecies variability and 10X for interspecies extrapolation) was used. The Food Quality Protection Act (FQPA) factor of 10X was reduced to 1X, therefore, the chronic Reference Dose (cRfD) of 2 mg/kg/day is equal to the chronic Population Adjusted Dose (cPAD). A 100% dermal absorption factor is assumed for converting oral to dermal equivalent doses in the absence of dermal toxicity or dermal absorption studies.

For short and intermediate term inhalation exposure, the route specific study was used. The NOAEL of 0.62 mg/l (32 parts per million (ppm)) was observed in a 90-day inhalation toxicity study in rats (IUCLID, Formic acid, 2000). The uncertainty factor is 100X (10X for interspecies variability and 10X for interspecies extrapolation). The FQPA factor of 10 X was reduced to 1X.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to calcium formate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from calcium formate in food as follows:

Because no endpoint was identified for acute exposure, an acute exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM-FCID™, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, what we eat in America, (NHANES/WWEIA). This dietary survey was conducted from

1994–98. As to residue levels in food, no residue data were submitted. 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 ingredients in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

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, that a single inert ingredient or class of ingredients would be present at the level of the

active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient.

In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, and 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.

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 calcium formate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for 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).

There are no known or anticipated residential uses for calcium formate and therefore, residential exposure is not expected.

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 calcium formate to share a common mechanism of toxicity with any other substances, and calcium formate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that calcium formate 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

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 pre-natal and post-natal 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 is available to EPA to support the choice of a different factor.

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:

1. Toxicological studies were identified for calcium formate in the publicly available databases. However, calcium formate breaks down into calcium and formate ions. Calcium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard risk. The toxicological database for calcium formate is limited. There is available data on formic acid and related formate compounds (such as ammonium, sodium and methyl formate), which can serve as suitable surrogates for calcium formate. Studies conducted with methanol are also applicable to formate compounds, since methanol is metabolized into formic acid. Therefore, the database is considered adequate for FQPA assessment.

2. There is no evidence of increased susceptibility of infants and children in the available reproduction and developmental toxicity studies with

calcium formate and/or sodium formate. No developmental or maternal systemic toxicity was observed in rats at doses up to 200 mg/kg/day when calcium formate was administered via drinking water.

No developmental or maternal toxicity was observed in mice at doses up to 750 mg/kg gavage dose of sodium formate on gestation day 8. No evidence of increased susceptibility was observed following pre- and post-natal exposure to calcium formate. In a multigeneration reproduction study (three to five generations), no parental, reproductive or offspring toxicity was observed at doses up to 200 mg/kg/day.

3. No neurotoxicity studies are available in the database. However, there is no evidence of clinical signs of neurotoxicity in the database, nor evidence of susceptibility in the young in the database. Therefore, EPA concluded that the developmental neurotoxicity study is not required. There is no evidence of immunotoxicity in the available database.

4. The dietary food exposure assessment utilizes highly conservative default assumptions that would not underestimate the dietary risk to all populations. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ammonium formate, a value of 100 ppb for drinking water based on screening level modeling was used for the chronic dietary risk assessment. The value of 100 ppb is considered to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

Taking into consideration the available information, EPA concludes the additional 10X FQPA safety factor can be reduced to 1X. These assessments will not underestimate the exposure and risks posed by calcium formate.

#### E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on calcium, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to calcium formate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of calcium formate when used as an inert ingredient in pesticide formulations applied is safe under FFDCA section 408.

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, calcium formate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure analysis, EPA has concluded that risk estimates for chronic exposure to calcium formate from food and water are not of concern (<100% cPAD with a risk estimate at 31.2% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for calcium formate.

3. *Short- and intermediate term risk.* Short- and intermediate-term toxicological endpoints were established; however, calcium formate is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for calcium formate.

4. *Aggregate cancer risk U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, calcium formate is not expected to pose a cancer risk to humans.

5. *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 calcium formate residues.

#### V. 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.

#### VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for calcium formate (CAS Reg. No. 544–17–2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only.

**VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of 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 action has been exempted from review under Executive Order 12866, this action 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), or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action 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 exemption in this final rule, do not

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

This action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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 14, 2018.

**Donna Davis,**

*Acting 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, add alphabetically the inert ingredient 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 |
|---|---------|------|
| * * * * *                                     | *       | *    |
| Calcium formate (CAS Reg. No. 544-17-2) ..... | Carrier | *    |
| * * * * *                                     | *       | *    |

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2016-0538; FRL-9982-42]

**Bixafen; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of bixafen in or on multiple commodities which are identified and discussed later in this document. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019 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-2016-0538, 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), West William Jefferson Clinton 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