[FR Doc. E9–24055 Filed 10–06–09; 8:45 am] BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0407; FRL-8438-1]

Ammonium chloride; 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 ammonium chloride (CAS Reg. No. 12125–02–9) applied pre-harvest on all raw agricultural commodities when applied/used as a carrier/nutrient. SciReg, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ammonium chloride.

DATES: This regulation is effective October 7, 2009. Objections and requests for hearings must be received on or before December 7, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0407. 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:

Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0851; e-mail address: sunderland.deirdre@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at http://www.regulations.gov, you may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at http://www.epa.gov/fedrgstr. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at http://www.gpoaccess.gov/ecfr.

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-2008-0407 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before December 7, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA—HQ—OPP—2008—0407, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 13, 2008 (73 FR 33814) (FRL–8367–3), EPA issued a notice pursuant to section 408

of FFDCA, 21 U.S.C. 346a, as amended by FOPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 8E7329) by SciReg Inc., 12733 Director's Loop, Woodbridge, VA 22192. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium chloride when used as an inert ingredient in pesticide formulations applied pre-harvest. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing

Section 408(b)(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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

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 ploymers 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. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 nature of the toxic effects caused by ammonium chloride are discussed in this unit. The following provides a brief summary of the risk assessment and conclusions for the Agency's review of ammonium chloride. The Agency's full decision document for this action is available in the Agency's electronic docket (regulations.gov) under the docket ID number EPA-HQ-OPP-2008-

Ammonium and chloride are integral components of normal human metabolic processes. Ingested ammonium chloride is rapidly absorbed from the gastrointestinal tract with almost complete absorption occurring in 3 to 6 hours. It is utilized by the liver to form amino acids and proteins.

Acute oral studies on mice and rats given ammonium chloride showed LD₅₀ values ranging from 1,220 milligrams/ kilogram (mg/kg) to 1,630 mg/kg. No acute dermal or inhalation studies are available; however, skin irritation and eye irritation studies revealed moderate transient irritation effects. Skin sensitization studies showed that ammonium chloride has no sensitizing potential. According to the World Health Organization (WHO), "The ingestion of ammonium chloride in doses of around 500-1,000 mg/kg body weight/day (bw/day), for periods ranging from 1 to 8 days, has induced metabolic acidosis in mice, guinea-pigs, rats, rabbits, and dogs. However, one study did not report any toxic effects at doses of up to 1 gram/kg bw in rats, rabbits, guinea-pigs, and cats (50 animals per group)." It is also noted that susceptibility to ammonium chloride differs among species.

In one study, male Fisher 344 rats given a diet containing 580 mg/kg/day for 56 days produced no clinical signs of toxicity and no histopathological changes were attribute to this chemical.

Another study administered 684 mg/kg/day of ammonium chloride to male Sprague-Dawley rats for 70 days. Treated animals showed a reduction in urinary pH (6.04 vs. ≥7.56 in controls) and an increase in urinary calcium; however, no crystals were found in the urine. Other urinary parameters were not affected by treatment. In addition, no histopathological changes were noted in the stomach, bladder, or kidneys. The no observed adversed effect level (NOAEL) for these studies are 580 mg/kg/day and 684 mg/kg/day, respectively.

An 8-day dog study administered 200 mg/kg/day of ammonium chloride. Metabolic acidosis occurred in the blood and the plasma; however, there were no changes in the acid-base system in erythrocytes. This study indicates that ammonium chloride causes substantial acidification of the blood and urine but does not affect the acidbase system of erythrocytes. A 330-day study which administered 0 or 1.5% ammonium chloride in drinking water to rats showed the development of osteoporosis in test animals due to loss of organic bone substance and bone minerals. The effect was reversible with the supplement of bicarbonate. The release of bone mineral by resorption is thought to provide additional buffering capacity, sparing bicarbonate.

Renal effects were also observed at high doses in some of the studies. One study administered 0 or 1.28 g/kg/day of ammonium chloride via drinking water or gavage to Sprague-Dawley rats for 5 days. Renal hypertrophy was observed; however, no increase in uptake of radioactive thymidine was seen, implying that no increase in DNA synthesis or cell division occurred.

No evidence of tumors were observed in mice and rats administer ammonium chloride at doses up to 1% of their diet or drinking water for up to 652 days. Ammonium chloride is not expected to be carcinogenic. Based on available mutagencity studies, EPA concludes that ammonium chloride is not mutagenic.

No clinical signs of neurotoxicity were seen in any of the repeat dose studies. Although evidence of neurotoxicity was observed in two specialized studies at high doses, the scenarios presented are not likely to occur in a natural setting (i.e. the chemical injected directly into the brain) and do not include the oral, dermal, or inhalation routes of exposure. After evaluating the available data and the expected exposure from the intended use pattern of this inert ingredient, the Agency does not feel that

a developmental neurotoxicity study is needed.

The primary effect of ammonium chloride is related to the subsequent metabolic acidosis that occurs as a result of ingesting high concentrations of the chemical. Fortunately, the body has compensatory mechanisms used to return it to homeostasis. It is only after these buffers are exhausted that adverse effects are seen. According to Food and Drug Administration in the "Evaluation of the Health Aspects of Certain Ammonium Salts as Food Ingredients" (1974), "the normal liver so readily detoxifies ammonium ion from alimentary sources that blood concentrations of ammonium salts do not rise to the levels necessary to evoke toxic response." The FDA has designated ammonium chloride as a "Generally Recognized as Safe-GRAS" chemical for use in food products. Many of the studies noted that the effects were reversible.

Although no reproduction studies are available, ammonium chloride has been used medicinally on pregnant women and has been classified in Australia under Pregnancy Category A meaning that it "has been used for many pregnant women and women of conceiving age, and that there is no proof of increase in the frequency of deformation and the frequency of direct or indirect detrimental action to the embryo." Because ammonium chloride is found naturally in the environment and is a normal component of the human diet, the Agency does not feel that there is an increased risk to pregnant woman or woman of childbearing age.

Available studies show that ammonium chloride is of low toxicity for human health endpoints. Although one developmental study did observe 7% ectrodactyly in the offspring of mice that were given 600 mg/kg 4 times a day on day 10 of gestation (2.4 g/kg/day), another study found no teratogencity in the fetuses of rats given almost 4 times that dosage (~8.9 mg/kg/day) during days 7 to 10 of gestation. Effects of treatment were seen in regards to fetal weight; however, no fetal malformations were observed.

Based on available data, the 56–day rat study was selected for establishing the chronic Reference Dose (cRfD). In this study the NOAEL was 580 mg/kg/day (the highest dose tested) where no clinical signs of toxicity or histopathologic changes were attributed to this chemical. With an uncertainty factor of 100X for interspecies and intraspecies extrapolation and the Food Quality Protection Act (FQPA) safety factor (SF) reduced to 1X the cRfD is

equal to the chronic population adjusted Furthermore, the unpalatability of the dose (cPAD). Furthermore, the unpalatability of the amount of ammonium chloride needed

V. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

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

In order to quantify the anticipated dietary exposure, the Agency's Dietary Exposure Evaluation Model (DEEM) was employed. In modeling exposure, EPA made several very conservative assumptions including the assumption that the inert ingredient was used in all food use pesticide products applied to all crops and that 100% of the crop was treated. EPA also assumed that the residues of ammonium chloride would be present in all crops at levels equal to or greater than the highest established tolerance levels for any pesticide active ingredient for pre-harvest use.

ingredient for pre-harvest use.

Although EPA used a default value of 100 parts per billion for the concentration of the inert in all sources of drinking water, the Agency does not anticipate increased exposure to ammonium chloride from drinking water as a result of the use of ammonium chloride as an inert ingredient. This conclusion is based on the fact that excess ammonium chloride is taken up by the plant as a nutrient, the rapid disassociation of ammonium chloride into its anion/cation parts, and the regulation of water treatment plants for nutrients in drinking water.

Furthermore, the unpalatability of the amount of ammonium chloride needed to induce a toxic response would discourage consumption. Due to the nature of the chemical, it is unlikely that ammonium chloride will volatize from water.

This exposure assessment is particularly conservative for several reasons. Given the wide spread use of ammonium chloride in the food supply (both as a direct food additive and fertilizer), the amount of ammonium chloride contributed by its use as an inert ingredient in pesticide products will not significantly increase the overall exposure to infants and children. In addition, based on its high water solubility and the use of this product in the growing phase of plant life, it is expected that the majority of this inert ingredient will be washed from the plant prior to it reaching the consumer market and therefore the residues on the plant will be limited.

VI. Cumulative Effects

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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ammonium chloride and any other substances, and these chemicals do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemicals 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://ww.epa.gov/ pesticides/cumulative/.

VII. Additional Safety Factor for the Protection of Infants and Children

Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 that a different margin of safety will be safe for infants and children. EPA concluded that the FQPA SF for ammonium chloride should be reduced to 1X.

The database for ammonium chloride is adequate to make a determination of safety. Although specific reproduction studies have not been presented, the use of ammonium chloride as a pharmacological agent gives an understanding of how the chemical will behave.

Available studies show that ammonium chloride is of low toxicity for human health endpoints. Although one developmental study did observe 7% ectrodactyly in the offspring of mice that were given 600 mg/kg 4 times a day (2.4 g/kg/day) on day 10 of gestation, another study found no teratogencity in the fetuses of rats given almost 4 times that dosage (~8.9 mg/kg/day) during days 7 to 10 of gestation. Effects of treatment were seen in regards to fetal weight; however, no fetal malformations were observed. Similar results were seen when rats were given 0.9% (0.17mol/L) ammonium chloride in drinking water. The effects seen in these studies are believed to be a result of maternal acidosis.

Many of the repeat dose studies and human case studies show that the effects of ammonium chloride were reversible once the exposure was removed (in some cases sodium bicarbonate was given to reverse the acidosis). It was inferred in many of the studies that the toxicity was secondary to acidosis.

No clinical signs of neurotoxicity were seen in any of the repeat dose studies. Although evidence of neurotoxicity was observed in two specialized studies at high doses, the scenarios presented are not likely to occur in a natural setting (i.e., the chemical injected directly into the brain) and do not include the oral, dermal, or inhalation routes of exposure. After evaluating the available data and the expected exposure from the intended use pattern of this inert ingredient, the Agency does not feel that a developmental neurotoxicity study is needed.

Ammonium chloride is a natural part of the metabolic process and therefore, the body has buffers in place to bring the system back to homeostasis when levels of ammonium or chloride exceed normal values. Because of the low toxicity of the chemical, the body's ability to achieve homeostasis, the conservative approach taken for

estimating exposure, the Agency concludes there are reliable data showing that a reduction of childrens' safety factor from 10X to 1X is safe.

VIII. Determination of Safety for U.S. Population

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate uncertainty/safety factors. EPA calculates the aPAD and cPAD by dividing the point of departure by all applicable uncertainty/safety factors.

As noted in Unit IV., ammonium chloride is not expected to pose an acute risk. To evaluate chronic risk, EPA compared estimated chronic exposure to the cPAD of 5.8 mg/kg/day. Utilizing a highly conservative aggregate exposure assessment, the resulting chronic exposure estimates do not exceed the Agency's level of concern (<100% cPAD). Children 1 to 2 years old were the most highly exposed population with the chronic exposure estimate occupying 10.8% of the cPAD. In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to ammonium chloride as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by EPA.

Taking into consideration all available information on ammonium chloride, it has been determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to this chemical. Therefore, the exemption from the requirement of a tolerance for residues of ammonium chloride (CAS Reg. No. 12125–02–9), when used as inert ingredient in preharvest applications, under 40 CFR 180.920 can be considered safe under section 408(q) of the FFDCA.

IX. Other Considerations

A. Analytical Method

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

B. Existing Exemptions

Ammonium chloride has exemptions under 40 CFR 180.910 when used as an intensifier with ammonium nitrate as a dessicant or defoliant or as a fire suppressant in aluminum phosphide and magnesium phosphide formulations and under 40 CFR 180.940(a) as an ingredient in antimicrobial pesticide formulation where the end-use concentration cannot exceed 48 parts per million.

C. International Tolerances

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

X. Conclusions

Therefore, a tolerance exemption is established for ammonium chloride (CAS Reg. No. 12125–02–9) when used as an inert ingredient in pesticide formulations applied to growing crops only.

XI. 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).

XII. 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: September 29, 2009.

G. Jeffrey Herndon,

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, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.920 Inert ingredients used preharvest; exemptions from the requirement of a tolerance.

[FR Doc. E9–24161 Filed 10–6–09; 8:45 am] BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0518; FRL-8434-3]

Quinclorac; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA). **ACTION:** Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of quinclorac in or on cranberry. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cranberries. This regulation establishes a maximum permissible level for residues of quinclorac in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2012.

DATES: This regulation is effective October 7, 2009. Objections and requests for hearings must be received on or before December 7, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0518. All documents in the docket are listed in the docket index available in 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:

Marcel Howard, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6784; e-mail address: Howard.Marcel@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at http://www.regulations.gov, you may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at http://www.epa.gov/fedrgstr. You may also access a frequently updated electronic version of 40 CFR part 180