

Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by

reference, Ozone, Volatile organic compounds.

Dated: September 1, 2010.

Beverly H. Banister,
Acting Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart S—Kentucky

■ 2. Section 52.920(c) Table 1 is amended by revising the entries for “401 KAR 51:001,” “401 KAR 51:017,” and “401 KAR 51:052” to read as follows:

§ 52.920 Identification of plan.

* * * * *
(c) * * *

TABLE 1—EPA-APPROVED KENTUCKY APPROVED KENTUCKY REGULATIONS

| State citation | Title/subject | State effective date | EPA approval date | Explanation |
|--|--|----------------------|---|--|
| * * * * * | | | | |
| Chapter 51 Attainment and Maintenance of the National Ambient Air Quality Standards | | | | |
| 401 KAR 51:001 | Definitions for 401 KAR Chapter 51. | 2/5/2010 | 9/15/2010 [Insert citation of publication]. | Except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140,” in 401 KAR 51:001 Section 1 (118)(1)(b)(i) and the phrase “except ethanol production facilities producing ethanol by natural fermentation under NAICS codes 325193 or 312140,” in 401 KAR 51:001 Section 1(118) (2)(c)(20). |
| * * * * * | | | | |
| 401 KAR 51:017 | Prevention of significant deterioration of air quality. | 2/5/2010 | 9/15/2010 [Insert citation of publication]. | Except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140;” in 401 KAR 51:017 Section 7(1)(c)20. |
| 401 KAR 51:052 | Review of new sources in or impacting upon non-attainment areas. | 2/5/2010 | 9/15/2010 [Insert citation of publication]. | Except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140,” in 401 KAR 51:052 Section 2 (3)(t). |
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[FR Doc. 2010–22856 Filed 9–14–10; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0121; FRL–8839–3]

Ammonium 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 ammonium formate (CAS Reg. No. 540–69–2) when used as an inert ingredient (complexing or fixing agent with copper compounds) in pesticide formulations for certain pre-harvest uses. Phyton Corporation 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 ammonium formate.

DATES: This regulation is effective September 15, 2010. Objections and requests for hearings must be received on or before November 15, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0121. 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:

Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8353; e-mail address: debesai.alganesh@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

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-2006-121 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 November 15, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0121, by one of the following methods:

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

II. Petition for Exemption

In the **Federal Register** of April 21, 2006 (71 FR 20671) (FRL-8067-3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 6E7028) by Phyton Corporation, 7449 Cahill Rd., Edina, MN 55439. The

petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium formate (CAS Reg. No. 540-69-2) when used as an inert ingredient (complexing or fixing agent) with the active ingredient copper in pesticide formulations applied to growing crops. That notice referenced a summary of the petition which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the exemption requested to not restrict to use with the active ingredient copper. No limitations are necessary because no hazard was identified.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

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

chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ammonium formate including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with ammonium 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. Specific information on the studies received and the nature of the adverse effects caused by ammonium formate are discussed in this unit.

The following provides a brief summary of the risk assessment and conclusions for the Agency’s review of ammonium formate. The Agency’s full decision document for this action can be found at <http://www.regulations.gov> in the document: Ammonium Formate. Human Health Risk Assessment and Ecological Effects Summary to Support

Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations Applied Pre-harvest in docket ID number EPA-HQ-OPP-2006-0121.

Ammonium formate breaks down into ammonium and formate ions. Ammonium ions are a toxic waste product of the metabolism in animals; they are ubiquitous in the natural environment and can be considered as having little toxicity or hazard risk. In fish and aquatic invertebrates, it is excreted directly into the water. In mammals, sharks, and amphibians, it is converted in the urea cycle to urea, because urea is less toxic and can be stored more efficiently. In birds, reptiles, and terrestrial snails, metabolic ammonium is converted into uric acid, which is solid, and can therefore be excreted with minimal water. Formic acid is readily metabolized and eliminated by the body; it slowly decomposes to carbon monoxide and water.

The toxicological database for ammonium formate is limited. There is available data on formic acid and related formate compounds (such as calcium and sodium formate), which can serve as suitable surrogates for ammonium formate. Studies conducted with methanol are also applicable to formate compounds, since methanol is metabolized into formic acid.

Acute oral toxicity of ammonium formate in mice is reported to be moderate via oral route (LD₅₀ 2,250 milligrams/kilogram (mg/kg)). Acute oral toxicity studies have been performed with formic acid, calcium formate and sodium formate; they all have relatively low toxicity via this route of exposure.

A subchronic inhalation (13-week) study was performed by the NTP with formic acid in mice and rats at concentrations of 0.015, 0.030, 0.061, 0.122, or 0.244 milligrams/liter (mg/L) equal to (8, 16, 32, 64, or 128 parts per million (ppm)) for 13 weeks. Body weight gains were significantly decreased in mice exposed to 64 and 128 ppm formic acid. Changes in organ weights in mice were limited largely to increases in relative weights in animals in the 128 ppm groups. This was primarily a reflection of the lower body weights of these animals compared to controls, and of the greater relative weight of organs in smaller animals. In mice, there were no exposure-related gross lesions; microscopic changes attributed to toxicity of formic acid were limited to degeneration of the olfactory epithelium of the nose in a few mice from the 64 and 128 ppm exposure

groups. In rats, hematologic changes observed were all minimal and, generally, were consistent with hemoconcentration. Therefore, they were not considered as toxicologically relevant. Few and slight changes of the biochemical serum parameters were observed but not considered as adverse. No unusual gross lesions were observed. In rats, absolute liver weights were increased in the males of all test groups while the relative liver weights were increased in the three highest dose groups. Absolute and relative lung weights were reduced in female rats in all dose groups; in males, the relative lung weights were reduced in all exposure groups and absolute lung weights were reduced in the two highest dose groups. However, these changes in liver weights and lungs were not considered as adverse because they seem without histopathological correlation. Histopathological changes at the respiratory and olfactory nasal epithelia were restricted to the highest dose groups. The no observed adverse effect level (NOAEL) is 0.061 mg/L (32 ppm) in mice based on a decrease in body weight gains seen at the lowest observed adverse effect level (LOAEL) of 0.122 mg/L (64 ppm). The NOAEL in rats is 0.122 mg/L equal to (64 ppm) based on a decrease in body weight gains in mice and histopathological changes seen in the respiratory and olfactory epithelia at the LOAEL of 0.244 mg/L (124 ppm). Lifetime and repeat dose drinking water studies were conducted in rats with calcium formate and sodium formate, respectively. Toxicity was not observed during either study at doses up to 200 mg/kg/day and 100 mg/kg/day for calcium formate and sodium formate, respectively.

In a reproduction study in rats and mice with formic acid via inhalation route, no effects on sperm motility, sperm concentration, testicular and epididymal weight or on the duration of estrous cycles were observed. In mice, formic acid showed no effects on the testicular and epididymal weight or on the duration of the estrous cycles. In a three generation reproduction study in rats via drinking water, no treatment related effects were observed in the parental animals and off springs at doses up to 200 mg/kg/day.

In an *in vitro* incubation in whole embryo culture study in rats with formic acid, incubations showed significant and concentration-dependent reduction of yolk sac diameter, crown-rump length, head length, somite number, and developmental score after 24-hours and of crown-rump length, head length, somite number and developmental score after 48-hours. Embryo lethality was

significantly increased in the highest concentration after 24–hours and in the two highest concentrations after 48–hours. Protein and DNA concentrations showed significant and concentration dependent decreased in both cases. The number of anomalies (open anterior and posterior neuropores, rotatory defects and enlarged maxillary process) showed a significant increase only at the highest doses after 48–hours. Considering the results of *in vivo* reproduction study in mice and rats with formic acid and 3–generation reproduction study in rats via drinking water at doses up to and including 200 mg/kg/day, there is less confidence in the results of *in vitro* study. In addition, no developmental toxicity was seen in several developmental toxicity studies in mice and rats with calcium and sodium formate described below.

In developmental toxicity studies with calcium and sodium formate in rats and mice, respectively, there were no statistical differences in organ and bone abnormalities and growth of treated offspring to controls were similar. There was no reduction of fertility, maternal toxicity, embryotoxic or teratogenic effects observed. The NOAEL for the maternal and developmental toxicity in rats with calcium formate via drinking water was 200 mg/kg/day (the highest dose tested; HDT). The NOAEL for the maternal and developmental toxicity in mice with sodium formate via gavage was 750 mg/kg/day (HDT).

In mutagenicity studies with calcium, sodium and methyl formate, results of the test were negative for all chemicals. The weight-of-evidence suggested that inorganic formates are not mutagenic.

In a non-Good Laboratory Practice (GLP) lifelong (2–3 years) drinking water study with Wistar rats, test animals were exposed to calcium formate at concentrations of 0.2% and 0.4% (150–200 mg/kg/day). No neoplasias were observed. In a separate non-GLP study with Wistar rats, test animals were exposed to sodium formate at a concentration of 1% (274 mg/kg/day) for 18 months. No neoplasias were observed. Based on lack of mutagenicity and no evidence of carcinogenicity on surrogate chemicals, EPA concluded that the ammonium formate is not expected to be carcinogenic.

Ammonium formate breaks down into ammonium and formate ions. Ammonium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard risk. Formate, as noted in the above toxicity discussion, is not excessively toxic. Formate ions are

readily converted to carbon dioxide in the environment by biodegradation or photo oxidation.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoints of concern were identified based on available toxicity studies on surrogate chemicals. Most of these studies 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. 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) is equal to chronic Population Adjusted Dose (cPAD). A 100% dermal absorption is assumed for converting oral to dermal equivalent dose 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 (32 ppm) was observed in a 90–day inhalation toxicity study in rats. The uncertainty factor is 100X (10X for interspecies variability and 10X for interspecies extrapolation). The FQPA factor of 10X was reduced to 1X.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effect attributable to a single exposure of ammonium formate was seen in the toxicity databases. Therefore, no acute risk from exposure to ammonium formate is expected and an acute exposure assessment is not needed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) (1994–1996 and 1998) Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for ammonium formate. 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.” (DP Barcode: 361707, S. Piper, 2/25/2009) and can be found at <http://www.regulations.gov> in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA’s decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA’s assumption that all foods contain the inert ingredient at

the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, 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 show that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer.* Ammonium formate is not expected to be carcinogenic, since there was no evidence of carcinogenicity in the available studies. The Persistent, Bioaccumulative, and Toxic (PBT) profiler, a component of the Agency's P2 Framework did not raise any cancer concerns. Since the Agency has not identified any concerns for carcinogenicity relating to ammonium formate, a cancer dietary exposure assessment is not necessary to assess cancer risk.

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 ammonium 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. The Agency considers the value of 100 ppb to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

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 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 ammonium formate to share a common mechanism of toxicity with any other substances, and ammonium 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 ammonium 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 available to EPA support the choice of a different factor.

EPA concluded that the FQPA safety factor could be removed for ammonium formate for the following reasons:

i. No toxicological studies were identified for ammonium formate in the publically available databases. However, ammonium formate breaks down into ammonium and formate ions. Ammonium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard risk. There is available data on formic acid and related formate compounds (such as calcium, sodium and methyl formate), which can serve as suitable surrogates for ammonium 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.

ii. 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 multi-generation reproduction study (3 to 5 generations), no parental, reproductive or offspring toxicity was observed at doses up to 200 mg/kg/day.

iii. 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.

iv. 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.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and

residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute aggregate (food and drinking water) risk.* No adverse effect attributable to a single exposure of ammonium formate was seen in the toxicity databases. Therefore, ammonium formate is not expected to pose an acute risk.

2. *Chronic aggregate (food and drinking water) risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure, the chronic dietary exposure from food and water to ammonium formate is 9.6% of the cPAD for the U.S. population and 31.2% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. The chronic dietary exposure estimates for food and drinking water are below the Agency's level of concern (<100% cPAD) for the U.S. population and all population subgroups. There are no residential uses known or proposed, and therefore, no residential exposure is expected.

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

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to ammonium formate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

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

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for ammonium formate (CAS Reg. No. 540–69–2) when

used as an inert ingredient (complexing or fixing agent) in pesticide formulations applied to growing crops.

VII. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175,

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 7, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

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

* * * * *

| Inert ingredients | Limits | Uses |
|--|--------|----------------------------|
| Ammonium formate (CAS Reg. No. 540-69-2) | | Complexing or fixing agent |

[FR Doc. 2010-22976 Filed 9-14-10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2008-0347; FRL-8843-7]

40 CFR Part 180

Carbaryl; Order Denying NRDC's Objections and Requests for Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In this order, the Environmental Protection Agency (EPA) denies objections, and requests for hearing on those objections, to a prior order denying a petition requesting that EPA revoke all pesticide tolerances for carbaryl under section 408(d) of the Federal Food, Drug, and Cosmetic Act. The objections and hearing requests were filed on December 29, 2008, by the Natural Resources Defense Council (NRDC). The original petition was also filed by NRDC.

FOR FURTHER INFORMATION CONTACT: Jacqueline Guerry, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (215) 814-2184; e-mail address: guerry.jacqueline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

In this document, EPA denies objections, and requests for hearing on those objections, submitted by NRDC in response to a prior order denying NRDC's petition requesting that EPA revoke all pesticide tolerances for carbaryl. In addition to NRDC, and others interested in food safety issues generally, this action may be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse,

nursery, and floriculture workers; farmers.

- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0347. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

II. Introduction

A. What Action Is the Agency Taking?

In this order, EPA denies objections, and requests for a hearing on those objections, to an earlier EPA Order, (73 FR 64229), denying a petition to revoke all tolerances established for the pesticide, carbaryl, under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, (Refs. 1 and 2). Both the objections and hearing requests, as well

as the petition, were filed with EPA by NRDC.

NRDC's original petition, dated January 10, 2005, submitted to the carbaryl public docket during the public comment period for the 2004 Amended Interim Reregistration Eligibility Decision (IRED) for Carbaryl, and filed pursuant to FFDCA section 408(d)(1), asserted a number of grounds why carbaryl tolerances allegedly fail to meet the FFDCA's safety standard. The main arguments raised in the petition concerned EPA's drinking water assessment and EPA's decision on the statutory safety factor to protect infants and children that supported the 2004 IRED decision. NRDC also petitioned the Agency to cancel all carbaryl uses pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 7 U.S.C. 136(bb) and 136a, and argued unreasonable risks on the environment. Subsequently, on November 26, 2007, NRDC petitioned EPA to cancel all carbaryl pet collar uses under FIFRA. (Ref. 3). EPA consolidated this latter petition with the 2005 FFDCA petition because NRDC argued in it that exposure to carbaryl pet collars make the risks presented by carbaryl unsafe within the meaning of FFDCA section 408.

On October 29, 2008, EPA responded to both the 2005 petition to revoke all carbaryl tolerances and the 2007 petition to cancel all pet collar uses, denying them in their entirety. (73 FR 64229, October 29, 2008) (Ref. 4).

NRDC then filed objections to EPA's denial of NRDC's petition to revoke all carbaryl tolerances and requested a hearing on its objections. These objections and hearing requests were filed pursuant to the procedures in the FFDCA, section 408(g)(2). (21 U.S.C. 346a(g)(2)). The objections narrowed NRDC's claims to two main topics - that EPA lacks reliable data to reduce the Food Quality Protection Act (FQPA) Children's Safety Factor and that EPA's exposure assessment for carbaryl is flawed and underestimates the exposure to children from pet collar uses. After carefully reviewing the objections and hearing requests, EPA has determined that NRDC's hearing requests do not satisfy the regulatory requirements for such requests and that its substantive objections are without merit. Therefore, EPA, in this final order, denies NRDC's