



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2013-0700; FRL-9939-39]**

### **Ammonium Acetate; 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 acetate (CAS No. 631-61-8) when used as an inert ingredient (buffering agent) limited to 15% in pesticide formulations applied to pre-harvested crops. Exponent Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036 on behalf of the Gowan Company LLC., 370 South Main Street, Yuma, AZ 85364 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 acetate.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2013-0700, 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:** Susan Lewis, Registration Division (7505P), 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).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA 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-2013-0700 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2013-0700, 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 December 30, 2013 (78 FR79359) (FRL-9903-69), EPA issued a document pursuant to FFDCa section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10604) by Exponent Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036, on behalf of the Gowan Company LLC., 370 South Main Street, Yuma, AZ 85364. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium acetate (CAS No. 631-61-8) when used as an inert ingredient in pesticide formulations applied to crops pre-harvest and limited to 15% in pesticide formulations. That document referenced a summary of the petition prepared by Exponent Inc., on behalf of the Gowan Company LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. No comments were received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

## **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 FFDCFA 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 FFDCFA 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 FFDCFA 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 ammonium acetate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ammonium acetate 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 acetate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies.

Ammonium acetate is an ammonium salt of acetic acid. In aqueous solutions acetic acid and its salt ammonium acetate dissociate into the acetate anion ( $\text{CH}_3\text{COO}^-$ ) and the respective cations ( $\text{H}^+$  and  $\text{NH}_4^+$ ). The cations and ammonia (also a human metabolite) are physiological components of the human body. The chemical structures, physical-chemical properties, environmental fate behavior, and aquatic and mammalian toxicity of ammonium acetate and acetic acid are similar. Since limited data are available on ammonium acetate, toxicity data on acetic acid were used to represent toxicity due to exposure to ammonium acetate.

Acetic acid is of low acute dermal and inhalation toxicity in rats. It causes dermal irritation in mice and is corrosive in rabbits. It was also irritating in the eyes of rabbits. Although reduced body weight was observed at 390 mg/kg/day in a 90-day oral toxicity study in the rat,

the reduction in weight gain was likely attributed to reduced appetite and food consumption observed in the study. Therefore, this is not considered an adverse effect. Although increased spleen weight was observed at 23-31 ppm (equivalent to 15-19 mg/kg/day) of acetic acid in a toxicity study in rats via the inhalation route of exposure, there is no concern for potential immunotoxicity. The Agency considers that this effect is due to red blood cell destruction rather than an immunotoxic response. Fetal susceptibility was not observed in several developmental studies in rats, mice and rabbits. Neither maternal nor developmental toxicity was not observed up to 1,600 mg/kg/day. It is not mutagenic in an Ames test nor is it clastogenic in a cytogenetic assay with Chinese hamster ovary K1 cells. It is not carcinogenic. In an eight month cancer study, tumors were not observed in rats at 60 mg/kg/day. While evidence of potential neurotoxicity was observed in a literature study in rats conducted by Sapute et.al.<sup>1</sup>, a second study in rats showed no indication of systemic toxicity, neurotoxicity, neuropathological or histological lesions at the same dose that was previously tested, 100 mg/kg/day. Since the second study (MRID 49703201)<sup>2</sup> was conducted according to the Organization for Economic Co-operation and Development (OECD) and good laboratory practice (GLP) guidelines, it was considered to accurately represent the neurotoxic potential for ammonium acetate.

As noted above, acetic acid undergoes dissociation to the acetate anion and the H<sup>+</sup> cations in aqueous media at pHs commonly found in the environment. Also, it is a naturally-occurring substance in plants and animals. In aerobic metabolism, acetic acid (as acetate) is a metabolite that combines with Co-enzyme A to form acetyl Co-A which subsequently enters into

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<sup>1</sup> Satpute, R.M., Lomash, V., Hariharakrishnan, J., Roa, P., Singh, P., Gujar, N., and Bhattacharya, R. (2014). Oxidative Stress and Tissue Pathology Caused By Subacute Exposure To Ammonium Acetate In Rats And Their Response To Treatments With Alpha-Ketoglutarate And N-Acetyl Cysteine. *Toxicology and Industrial Health*: 30(1) 12-14. MRID. 49507001.

<sup>2</sup> Barnett, Jr., John F. (2015). A 28-Day Oral (Gavage) Repeated Dose Study of Ammonium Acetate in Adult Rats. Laboratory Project ID 20073669. Unpublished study prepared by Charles River Laboratories. MRID 49703201.

the Citric Acid Cycle, a common metabolic pathway in which food molecules are broken down to form energy. A major function of the Citric Acid Cycle is the oxidation of acetate. In animals, acetate is obtained from the breakdown of glucose molecules.

Specific information on the studies received and the nature of the adverse effects caused by acetic acid as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document "Ammonium Acetate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2013-0700.

*B. Toxicological Points of Departure/Levels of Concern*

In an aqueous environment, ammonium acetate dissociates to acetic acid and its salt. Therefore, it is appropriate to expect toxicity due to exposure to ammonium acetate to be similar to that of acetic acid. Therefore, based on the absence of a toxicological endpoint of concern via dietary route of exposure for acetic acid, its regulatory history, and no new toxicological data to indicate concern regarding previous decisions, a qualitative assessment was appropriate for ammonium acetate for all pathways of human exposure (food, drinking water, and residential). A potential endpoint of concern for the inhalation route of exposure was identified in a toxicity study. Increased spleen weight due to red blood cell destruction was observed at 23-31 ppm (equivalent to 15-19 mg/kg/day) of acetic acid in rats. However, according to the American Conference of Governmental Industrial Hygienists, Inc. (ACGIH), the threshold limit value (TLV) for occupational exposure to acetic acid is 10 ppm via inhalation. Residential exposure to the proposed use of ammonium acetate via inhalation is not expected to exceed the TLV limit of 10 ppm because the residential use pattern would result in drastically

lower opportunities for inhalation exposure than allowed occupational use patterns, which are limited to 10 ppm. In addition, residential exposure will be much lower because exposure is expected to occur for shorter periods to diluted acetic acid as compared to workers who are exposed for 8 hours continuously, to more concentrated acetic acid. Therefore, a qualitative assessment was conducted with regard to inhalation exposure.

### *C. Exposure Assessment*

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

Under this exemption from the requirement of a tolerance, residues of this ammonium acetate may be found on foods from crops that were treated with pesticide formulations containing ammonium acetate. However, a quantitative dietary exposure assessment was not conducted since an endpoint for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops.

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).

Ammonium acetate may be used in pesticide products and non-pesticide products that may be used around the home. Based on the discussion in Unit IV.B., a quantitative residential exposure assessment for ammonium acetate was not conducted.

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 acetate to share a common mechanism of toxicity with any other substances, and ammonium acetate 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 acetate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of ammonium acetate and its chemical properties, EPA has concluded that

there are no toxicological endpoints of concern for the U.S. population, including infants and children.

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

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of ammonium acetate will not pose a risk to the U.S. population, including infants and children, and 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 acetate 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. EPA is establishing a limitation on the amount of ammonium acetate that may be used in pesticide formulations. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any pesticide formulation used on crops for sale or distribution containing ammonium acetate at ready for use end-use concentrations exceeding 15%.

#### **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for ammonium acetate (CAS No. 631-61-8) when used as an inert ingredient (buffering agent) in pesticide formulations applied to crops pre-harvest and limited to 15% in the end use formulation.

#### **VII. Statutory and Executive Order Reviews**

This action establishes a tolerance exemption 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). 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 tolerance 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: December 11, 2015.

Susan Lewis,  
*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 following 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            |
|--|-----------|-----------------|
| * * * * *                              | * * * * * | * * *           |
| Ammonium acetate<br>(CAS No. 631-61-8) | 15%       | Buffering Agent |
| * * * * *                              | * * * * * | * * *           |

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