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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2008-0039; FRL-9344-2]

#### Acetone; 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 acetone (67-64-1) when used as an inert ingredient as a solvent or co-solvent, 40 CFR 180.930, in pesticides products applied to animals. Whitmire Micro-Gen (now affiliated with BASF Corp.; 3568 Tree Court Industrial Blvd., St. Louis, MO 63112) 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 acetone.

**DATES:** This regulation is effective May 14, 2012. Objections and requests for hearings must be received on or before July 13, 2012, 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-2008-0039. 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:** Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-5533; email address: [dow.mark@epa.gov](mailto:dow.mark@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 site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure

proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2008-0039 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 July 13, 2012. 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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2008-0039, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online 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 February 6, 2008 (73 FR 6966) (FRL-8350-9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 7E7239) by Whitmire Micro-Gen (now affiliated with BASF Corp.; 3568 Tree Court Industrial Blvd., St. Louis, MO 63112). The petition requested that 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of acetone (Cas Reg. No. 67-64-1) when used as an inert ingredient as a solvent or co-solvent in pesticide formulations applied to animals. That notice referenced a summary of the petition prepared by Whitmire Micro-Gen (now affiliated with BASF Corp.; 3568 Tree Court Industrial Blvd., St. Louis, MO 63112), the petitioner, which is available in the docket, <http://>

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the

toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetone including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with acetone 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 acetone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicity data base for acetone includes data relative to acetone per se as well as to isopropanol. Since isopropanol readily metabolizes to acetone in the body, the Agency has concluded that the data regarding isopropanol may be used in conjunction with the data regarding acetone to characterize the toxicity of acetone.

Acetone has low acute toxicity. It is not a skin irritant or sensitizer but is a defatting agent to the skin. Acetone is an eye irritant.

The toxicity of acetone was evaluated in several subchronic toxicity studies in mice and rats via drinking water, gavage and inhalation. The most notable findings in subchronic studies were increased liver and kidney weights, and decreased spleen weights. In mice administered acetone via drinking water, adverse effects (liver and kidney toxicity) were observed at doses  $\geq 1,600$  milligrams/kilogram/bodyweight/day

(mg/kg/bw/day). Rats treated with acetone via gavage for 90 days exhibited decreased body weight and increased relative kidney and liver weights, hemosiderosis of the spleen and an increased incidence and severity of nephropathy at 1,700 mg/kg/day. The NOAEL in rats was 900 mg/kg/day. In a subchronic toxicity study in rats via gavage, acetone resulted in kidney weight changes and lesions at 500 mg/kg/day. The NOAEL in this study was 100 mg/kg/day. Male Sprague-Dawley rats were exposed to acetone via inhalation at a concentration of 19,000 ppm (45,106 mg/m<sup>3</sup>) for 3 hours/day, 5 days/week, for 8 weeks. Groups were sacrificed after 2, 4, and 8 weeks and 2 weeks post-exposure. No treatment related effects were observed in this study at exposure concentrations of 19,000 ppm (equal to 11,703 mg/kg/day). No dermal toxicity studies were available.

Acetone was evaluated in a reproduction screening test with mice via gavage at a dose of 3,500 mg/kg/day and controls receiving no test compound. Toxicity was manifested as decreased reproductive index, increased gestation length, reduced birth weights, decreased neonatal survival and increased neonatal weight gain at 3,500 mg/kg/day. In a 2-generation reproduction study conducted in rats with isopropanol, the maternal NOAEL was 500 mg/kg/day based on increased in liver and kidney weights (absolute and relative) seen at the LOAEL of 1,000 mg/kg/day. The offspring toxicity NOAEL was 500 mg/kg/day based on reduced pup body weights and a slight increase in pup mortality seen at the LOAEL of 1,000 mg/kg/day. No reproductive parameters were altered at doses up to 1,000 mg/kg/day. Two developmental toxicity studies in rodents exposed to acetone via the inhalation route of exposure were also available for review. In mice, maternal (increased incidence of late resorptions) and fetal (reduced weight) toxicities were observed at the same dose, 6,600 ppm (approximately 4,066 mg/kg/day). No teratogenic effects were observed in mice. The NOAEL was 2,200 ppm (equivalent to 1,348 mg/kg/day). In rats, maternal (reduction in body weight, uterine weight and extra-gestational weight gain) and fetal (malformations) toxicities were observed at the same dose, 11,000 ppm (approximately 6,773 mg/kg/day). The NOAEL was 2,200 ppm (equivalent to 1,348 mg/kg/day). In a developmental toxicity study in rats via gavage with isopropanol, the NOAELs for maternal and developmental toxicities were 400 mg/kg/day based on

slightly increased mortality at 800 mg/kg/day and reduced gestational body weight and reduced gravid uterine weights at 1,200 mg/kg/day. Reduced fetal body weights were observed at 800 and 1,200 mg/kg/day. There was also a developmental toxicity study in rabbits treated with isopropanol via gavage. Maternal toxicity was manifested as reduced body weight and food consumption at 480 mg/kg/day. The NOAEL was 240 mg/kg/day. There were no treatment related effects observed in fetuses up to the highest dose tested (480 mg/kg/day). In a developmental neurotoxicity study in rats with isopropanol, no developmental neurotoxicity was observed at doses up to 1,200 mg/kg/day.

Subchronic neurotoxicity studies were available in rats administered acetone via the inhalation or dietary routes of exposure. Repeated daily exposures up to 14,240 mg/m<sup>3</sup> of acetone produced an inhibition of avoidance behavior but did not produce any signs of motor imbalance. Following acetone administered via inhalation, rats exhibited transient ataxia at >28,480 ppm (approximately 17,544 mg/kg/day). When acetone was administered in the diet for 14 weeks, neurotoxicity was not observed at concentrations up to 1.0% (approximately 5,000 mg/kg/day).

Information on the carcinogenicity of acetone is available from dermal studies performed with acetone used as a vehicle. An increased incidence of tumor formation was not observed up to 0.2 milliliter (ml) of acetone in mice. Carcinogenicity studies in rodents administered isopropanol via inhalation, did not exhibit an increased incidence of tumor formation up to 5,000 ppm (approximately 3,086 mg/kg/day).

Acetone is normally eliminated mainly by enzymatic metabolism (70–80% of the total body burden) or excreted via urine or exhaled following inhalation exposure (human volunteer study). The first step includes the oxidation to acetol by acetone monooxygenase, associated with cytochrome P4501IE1. This step is followed by two different pathways that both lead to the formation of pyruvate which—as a key product of intermediary metabolism—can enter various pathways, e.g. gluconeogenesis or the citric acid cycle. Acetone is excreted mainly via the lung both unchanged and, following metabolism, as carbon dioxide.

Specific information on the studies received and the nature of the adverse effects caused by acetone as well as the NOAEL and the LOAEL from the toxicity studies can be found at [http://](http://www.regulations.gov)

[www.regulations.gov](http://www.regulations.gov) in the document “Acetone—Decision Document for Pesticide Petition 7E7239, Acetone, CAS No. 67–64–1; PC Code 844101”, in docket ID number EPA–HQ–OPP–2008–0039.

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

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

Acetone is currently permitted for use as an inert ingredient in pesticide formulations applied pre and post harvest under 40 CFR 180.910. Acetone occurs or is found in a variety of foods and consumer products. Acetone has been approved by FDA as a secondary direct food additive (21 CFR 173.210). The available toxicity studies indicate that acetone has very low toxicity. The NOAELs were 900 mg/kg/day and above except one 90-day toxicity study in rats via gavage in which the NOAEL of 100 mg/kg/day was based on kidney toxicity seen at the LOAEL of 500 mg/kg/day. Differences in the observed effect level between the drinking water/dietary study and the gavage study may relate to the metabolism of acetone. EPA's Integrated Risk Information System (IRIS) concluded that the drinking water route is considered to more closely mimic potential long-term human exposure scenarios. For this reason, EPA concluded that the results of gavage

study in the case of acetone may not be appropriate for the long term risk assessments. As indicated in this Unit, the lowest NOAEL identified in the database is 900 mg/kg/bw/day. For all practical purposes, that is the Agency's identified limit dose. For materials that show no signs of toxicity at or above the limit dose, quantitative risk assessment is not necessary. Since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, a quantitative risk assessment for acetone is not necessary.

#### *C. Exposure Assessment*

No hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), or for the short, intermediate, and long term dermal and inhalation residential assessments, therefore, acute and chronic dietary and short-, intermediate-, and long-term dermal and inhalation residential exposure assessments are not necessary.

*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 acetone to share a common mechanism of toxicity with any other substances, and acetone does not appear to produce a toxic metabolite produced by other substances, however, isopropanol is readily metabolized to acetone in humans. For both isopropanol and its metabolite, acetone, no endpoint of concerns were identified for various dietary and non-dietary exposure scenarios. For the purposes of this tolerance action, therefore, EPA has assumed that acetone 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 Web site at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

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.

The toxicity database is sufficient for acetone and potential exposure is adequately characterized given the low toxicity of the chemical. In terms of hazard, there are no concerns and no residual uncertainties regarding prenatal and/or postnatal toxicity. The lowest NOAEL identified in the database for risk assessment is 900 mg/kg/day. No evidence of increased susceptibility was observed in the available reproduction studies, developmental studies and developmental neurotoxicity study (isopropanol). In these studies developmental toxicity was observed in the presence maternal toxicity and at or above the limit dose of 1,000 mg/kg/day. Therefore, a safety factor analysis has not been used to assess risk. Accordingly, there is no reason to apply an additional safety factor to protect infants and children.

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

Given the lack of concern for hazard posed by acetone, EPA concludes that there are no dietary or aggregate dietary/non-dietary risks of concern as a result of exposure to acetone in food and water or from residential exposure. As discussed in this unit, EPA expects aggregate exposure to acetone to pose no appreciable dietary risk given that the data show a lack of systemic toxicity at doses  $\geq 900$  mg/kg/day and a lack of any increased susceptibility of infants and children. Taking into consideration of all available information on acetone, 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 acetone 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*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with

international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acetone.

#### *C. Response to Comments*

The Agency received one comment from a private citizen who opposed the proposed exemption. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

#### **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.930 for acetone (67–64–1) when used as an inert ingredient (as solvent or co-solvent) in pesticide formulations applied to animals.

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

This final rule establishes an exemption from the requirements of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045,

entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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: May 2, 2012.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

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

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

■ 2. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

**§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * * * *	* * * * *	* * * * *
Acetone (Cas Reg. No. 67–64–1) .....	.....	solvent or cosolvent.
* * * * *	* * * * *	* * * * *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2010–0421; FRL–9346–7]

**Fluxapyroxad; Pesticide Tolerances**

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

**ACTION:** Final rule.

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

**DATES:** This regulation is effective May 14, 2012. Objections and requests for hearings must be received on or before July 13, 2012, 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–2010–0421. 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:** Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9369; email address: [odiott.olga@epa.gov](mailto:odiott.olga@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 those engaged in the following activities:

- 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 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 electronic access to other related information?*

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0421 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 July 13, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).