

■ 10. Effective April 1, 2010 through October 3, 2011, amend 40 CFR 52.21 to add (i)(1)(vii) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

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(i) * * *

(1) * * *

(vii) The source or modification would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and the source does not belong to any of the following categories:

(a) Coal cleaning plants (with thermal dryers);

(b) Kraft pulp mills;

(c) Portland cement plants;

(d) Primary zinc smelters;

(e) Iron and steel mills;

(f) Primary aluminum ore reduction plants;

(g) Primary copper smelters;

(h) Municipal incinerators capable of charging more than 250 tons of refuse per day;

(i) Hydrofluoric, sulfuric, or nitric acid plants;

(j) Petroleum refineries;

(k) Lime plants;

(l) Phosphate rock processing plants;

(m) Coke oven batteries;

(n) Sulfur recovery plants;

(o) Carbon black plants (furnace process);

(p) Primary lead smelters;

(q) Fuel conversion plants;

(r) Sintering plants;

(s) Secondary metal production plants;

(t) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

(u) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;

(v) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;

(w) Taconite ore processing plants;

(x) Glass fiber processing plants;

(y) Charcoal production plants;

(z) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;

(aa) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act; or

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0714; FRL-8816-3]

Cloquintocet-mexyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending 40 CFR 180.560 to add a reference to the active ingredient flucarbazone-sodium (wheat only) to the tolerance for the inert ingredient cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607-70-2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) on wheat forage, wheat grain, wheat hay, and wheat straw. Arysta LifeScience North America, LLC requested this tolerance amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 31, 2010. Objections and requests for hearings must be received on or before June 1, 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-2009-0714. 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: Karen Samek, Registration division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 347-8825; e-mail address: samek.karen@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 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. 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-2009-0714 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 1, 2010.

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 this copy, identified by docket ID number EPA-HQ-OPP-2009-0714, 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 Tolerance

EPA has received a petition from Arysta LifeScience North America, LLC, 15401 Weston Parkway, Cary, NC 27513, requesting an amendment to the existing tolerances for the inert ingredient (safener) (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607-70-2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid). For ease of reading this document, acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester will be referred to as cloquintocet-mexyl. EPA published two final rules to establish tolerances for the safener under 40 CFR 180.560 in the **Federal Register** of June 22, 2000 (65 FR 38757) (FRL-6592-4) and the **Federal Register** of December 16, 2005 (70 FR 74679) (FRL-7753-4). These tolerances establish tolerances for cloquintocet-mexyl when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley) or clodinafop-propargyl (wheat only). In addition, a final rule that established tolerances for this safener was published in the **Federal Register** of March 5, 2008 (73 FR 11816) (FRL-8350-8). That final rule amended 40 CFR 180.560 by adding a reference to the active ingredient pyroxsulam (wheat only), and increased the existing tolerances for residues of cloquintocet-mexyl in or on wheat, forage and wheat, hay, and removed the specification of a 1:4 ratio inert ingredient safener to

active ingredient from the tolerance expression.

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL-8792-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of the above-referenced pesticide petition (PP 9E7592) by Arysta LifeScience North America, LLC. The petition requested that 40 CFR 180.560 be amended by expanding the tolerance to cover cloquintocet-mexyl residues when used in formulation with the active ingredient flucarbazone-sodium on wheat. No numerical change to the tolerances for the specific wheat commodities was sought. That notice referenced a summary of the petition prepared by Arysta LifeScience North America, LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the chemical. The Agency's decision document for this action is available on EPA's Electronic Docket at <http://www.regulations.gov>/ under docket ID number EPA-HQ-OPP-2009-0714. For the full toxicity data and information on which this risk assessment is based, the

reader is referred to the final rules establishing tolerances for cloquintocet-mexyl that published in in the **Federal Register** of March 5, 2008, December 16, 2005, and June 22, 2000.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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 cloquintocet-mexyl 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 the final rules published on March 5, 2008, December 16, 2005, and June 22, 2000. In these final rules, the Agency reviewed the available information on cloquintocet-mexyl submitted by the petitioners as well as additional information available to EPA. The toxicity database is sufficient for cloquintocet-mexyl and has not changed since the time of those publications. Therefore, only a brief summary is provided here.

Cloquintocet-mexyl has a low order of acute oral, dermal, and inhalation toxicity. It is slightly irritating to the eyes and non-irritating to the skin. Cloquintocet-mexyl is a skin sensitizer. The chemical is not genotoxic and is not a reproductive and developmental toxicant. There is no evidence of neurotoxicity in the available studies. Cloquintocet-mexyl is classified as "not likely to be a human carcinogen." The main metabolite for cloquintocet-mexyl is 5-chloro-8-quinolinoxyacetic acid, and testing on the metabolite is part of the toxicology database for cloquintocet-mexyl. For additional information on the human health toxicity data for cloquintocet-mexyl and its metabolite, see EPA's Electronic Docket at <http://www.regulations.gov> and the **Federal Register** of March 5, 2008, December 16, 2005, and June 22, 2000.

B. Exposure Assessment

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

uses). In the 2008 rulemaking, EPA assessed human exposure to cloquintocet-mexyl from use on wheat and barley. EPA assumed that 100% of the wheat and barley crops were treated with cloquintocet-mexyl and that residues on all wheat and barley commodities were at the tolerance level. The Agency has determined that this assessment is sufficient for the current amendment to the cloquintocet-mexyl tolerance expression because no new crops are being added and the label requirements limit the total number of applications from all of the various cloquintocet-mexyl safener products to one application from this group of pesticides on a crop per growing season. For additional information on the exposure assessment for cloquintocet-mexyl, see the docket and the **Federal Register** of March 5, 2008.

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

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility of *in utero* or post-natal exposure to rats or rabbits in the prenatal developmental studies or in rats in the 2-generation reproduction study. NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cloquintocet-mexyl is complete, except for immunotoxicity and neurotoxicity studies. EPA began requiring these studies on December 26, 2009. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for cloquintocet-mexyl and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. EPA's determination is based on the following considerations.

There was some indication of possible immunotoxicity in the form of lymphoid hyperplasia of the thymus in male rats (without any histopathology changes in the study) at the LOAEL of 73.5 milligrams/kilogram/day (mg/kg/day) in the combined chronic/ oncogenicity study in rats (with a NOAEL of 36.4 mg/kg/day). This effect was observed only in males. No blood parameters were affected. In addition, cloquintocet-mexyl does not belong to a class of chemicals that would be expected to be immunotoxic. A clear NOAEL was established for these effects (36.4 mg/kg/day), and the regulatory endpoint of 4.3 mg/kg/day (the NOAEL from the combined chronic/ oncogenicity study) is nearly 10X below the NOAEL for the possible immunotoxic effect. Therefore, based on the considerations in this unit, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL significantly less than the NOAEL of 4.3 mg/kg/day already established for cloquintocet-mexyl, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity. A confirmatory immunotoxicity study will be required as a condition of the registration.

No acute and subchronic neurotoxicity studies are available, however, there is no evidence of neurotoxicity in the toxicology database on cloquintocet-mexyl. Therefore, based

on the considerations in this unit, the Agency does not believe that conducting acute and subchronic neurotoxicity studies will result in a NOAEL less than the NOAEL of 4.3 mg/kg/day. Therefore, there is no need for additional uncertainty factors (UF). Confirmatory acute and subchronic neurotoxicity studies will be required as a condition of registration.

ii. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to cloquintocet-mexyl in the available toxicity database.

iii. There is no indication that cloquintocet-mexyl is a neurotoxic chemical and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children from the use of cloquintocet-mexyl (currently there are no proposed residential uses and therefore non-occupational exposure is not expected).

For additional information on the Safety Factor determination for infants and children for cloquintocet-mexyl, see the docket and the **Federal Register** of March 5, 2008.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate safety factors (SFs). EPA calculates the aPAD and cPAD by dividing the point of departure (POD) by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

In the 2005 and 2008 rulemakings for cloquintocet-mexyl, EPA concluded that aggregate risks from exposure to cloquintocet-mexyl did not exceed 1% of the aPAD or cPAD for the most exposed population groups. (73 FR 11819); (70 FR 74685). These findings are applicable to this tolerance amendment.

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 cloquintocet-mexyl and its acid metabolite (5-chloro-8-quinolinoxyacetic acid).

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; e-mail address: residuemethods@epa.gov. For the complete description of Analytical Methods for cloquintocet-mexyl, see the docket and the **Federal Register** of December 16, 2005.

B. International Residue Limits

There are no Codex tolerances for cloquintocet-mexyl.

V. Conclusions

Therefore, 40 CFR 180.560 is amended by establishing a tolerance for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607-70-2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients flucarbazone-sodium (wheat only), pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on barley, grain at 0.1 ppm; barley, hay at 0.1 ppm; barley, straw at 0.1 ppm; wheat, forage at 0.2 ppm; wheat, grain at 0.1 ppm; wheat, hay at 0.5 ppm; and wheat, straw at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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).

VII. 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: March 22, 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. Section 180.560, revise paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607-70-2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients, flucarbazone-sodium (wheat only), pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on the following food commodities:

| Commodity | Parts per million |
|---------------------|-------------------|
| Barley, grain | 0.1 |
| Barley, hay | 0.1 |
| Barley, straw | 0.1 |
| Wheat, forage | 0.2 |
| Wheat, grain | 0.1 |
| Wheat, hay | 0.5 |
| Wheat, straw | 0.1 |

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