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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0253; FRL-9919-59]

Clothianidin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of clothianidin, (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-*N''*-nitroguanidine, in or on fruit, citrus, group 10-10. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on citrus. This regulation establishes a maximum permissible level for residues of clothianidin in or on citrus. The time-limited tolerance expires on December 31, 2017.

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-2014-0253, 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), 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.

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.

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

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (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-2014-0253 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-2014-0253, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing a time-limited tolerance for residues of clothianidin, (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N*'-methyl-*N*''-nitroguanidine, in or on fruit, citrus, group 10-10 at 0.07 parts per million (ppm). This time-limited tolerance expires on December 31, 2017.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in food

that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCa section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCa allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Clothianidin in or on Immature Citrus Trees and FFDCA Tolerances

The Florida Department of Agriculture and Consumer Services requested the EPA Administrator to issue a specific exemption for the use of clothianidin as a soil drench application on immature citrus trees to control the transmission of Huanglongbing (HLB) disease vectored by the Asian Citrus Psyllid (ACP). The applicant asserts that clothianidin is needed to control HLB disease due to the lack of effective available alternatives for season long control practices, and that significant economic losses will occur if this urgent, non-routine disease is not controlled.

Further, the Applicant asserts that an emergency condition exists in accordance with the criteria for approval of an emergency exemption, and issued a crisis exemption under FIFRA section 18 to allow the use of clothianidin on immature citrus trees for control of the transmission of HLB disease vectored by the ACP in Florida. After having reviewed the submission, EPA concurred that an emergency condition exists for Florida citrus growers and authorized a specific emergency exemption under FIFRA section 18 for control of clothianidin on immature citrus trees to control the transmission of HLB disease vectored by the ACP.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of clothianidin in or on citrus. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety

standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCFA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2017, under FFDCFA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on fruit, citrus, group 10-10 after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by the time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether clothianidin meets FIFRA's registration requirements for use on fruit, citrus, group 10-10 or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of clothianidin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Florida to use this pesticide on the applicable crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for clothianidin contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. 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....”

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of clothianidin in or on citrus. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2) and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this emergency action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption

and the time-limited tolerance for residues of clothianidin in or on fruit, citrus, group 10-10 at 0.07 ppm.

EPA recently evaluated the currently approved uses of clothianidin when establishing tolerances for residues of clothianidin in three non-citrus commodity groups in the March 29, 2013 **Federal Register** (78 FR 19130) (FRL-9378-6). A summary of the human risk assessment toxicological endpoints is discussed in Units 111.A. and B. of the March 29, 2013 Final Rule.

EPA has also recently evaluated the dietary exposure that would result from a similar use of clothianidin on citrus that would result in clothianidin residues of 0.60 ppm. This is significantly higher than the 0.07 ppm time-limited tolerance level established in today's final rule. In order to expedite this time-limited tolerance rule, EPA has relied on its previous dietary risk assessment assuming clothianidin residues of 0.60 ppm on citrus. The higher application rates and concentrations assure that exposure and risk resulting from the emergency use are not underestimated. In addition, the estimated drinking water concentrations based on the clothianidin use on citrus resulted in higher acute drinking water estimates than those previously assessed. The chronic analysis drinking water estimate remains the same as it was in the previous dietary assessment. Even with these conservative assumptions, the revised acute dietary risk estimates from exposure to clothianidin through food and water are below the Agency's level of concern for all population subgroups.

In its aggregate assessment of exposures and risk associated with clothianidin, including use on citrus which was assessed at a significantly higher use rate, EPA

concluded that the acute dietary exposure from food and water to clothianidin would occupy 28% of the acute population adjusted dose (aPAD) for children 1-2 years old, the population subgroup receiving the greatest exposure; and that chronic exposure to clothianidin from food and water would utilize 28% of the chronic population adjusted dose (cPAD) for children 1-2 years old, the population subgroup receiving the greatest exposure. These population adjusted doses represent the levels below which exposure is not of health concern. Because these levels of dietary exposures for the most exposed subpopulations would be well below the aPAD and cPAD, the expected lower levels of dietary exposures are not of concern.

There are no new residential uses of clothianidin at this time. However, existing uses of clothianidin on turf, ornamental plants, and/or indoor surfaces for bed bug control may result in human exposure in a residential setting. Such exposures may occur during application of products containing clothianidin (handler exposure) as well as following application (post-application exposure) and are expected to be of short-term (1-30 days) duration.

For clothianidin, residential handler and post-application risk estimates are considered to be of potential concern when the dermal margin of exposure (MOE) is less than 100, the inhalation MOE is less than 1,000, and/or the aggregate risk index (ARI), reflecting combined dermal and inhalation exposure, is less than one. The residential handler and post-application risk estimates are not of concern (ARIs range from 1.9 to 990). The aggregate ARIs, which combine residential and dietary exposure, ranged from 1.2 to 6.5, which are not of concern (i.e. when the ARI is greater 1).

Therefore, EPA concluded there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to clothianidin residues as a result of existing uses and the proposed section 18 use pattern.

Refer to the March 29, 2013 final rule, available at <http://regulations.gov>, for a summary of the aggregate risk assessment and determination of safety. Detailed discussion of the aggregate risk assessments and the determinations of safety relied upon in this action may be found in the Agency reviews and human health risk assessments provided as supporting documents in the docket for this action under docket ID number EPA-HQ-OPP-2014-0253.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology, based on solvent extraction and liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) separation, identification, and quantification, is available for plant (Morse Method#Meth-164-modified, RM-39C-1, or Bayer Method 00552) matrices to enforce the tolerance expression. The limit of quantitation (LOQ) for clothianidin in plant commodities is 0.01 ppm. Clothianidin and its major metabolites are not adequately recovered using any of the United States Food and Drug Administration (FDA) multi-residue methods.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

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 Nations 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 established MRLs for clothianidin in or on citrus fruits at 0.07 ppm, the same level the U.S. is establishing for the time-limited-tolerance.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of clothianidin, in or on fruit, citrus, group 10-10 at 0.07 ppm. This tolerance expires on December 31, 2017.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances 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) (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 of 1995 (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: February 13, 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 § 180.586, revise paragraph (b) to read as follows:

§180.586 Clothianidin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance specified in the following table is established for residues of clothianidin, (*E*)-*N*-[(2-chloro-5-thiazolyl)methyl]-*N'*-methyl-*N''*-nitroguanidine, in or on the specified agricultural commodity, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. This tolerance expires on the date specified in the table.

Commodity	Parts per million	Expiration date
Fruit, citrus, group 10-10	0.07	12/31/17

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[FR Doc. 2015-03928 Filed 02/24/2015 at 8:45 am; Publication Date: 02/25/2015]