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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0757; FRL-9914-14]

C.I. Pigment Red 112; 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 C.I. Pigment Red 112 (CAS Reg. No. 6535-46-2) when used as an inert ingredient seed treatment pigment not to exceed 10% weight/weight (w/w) in pesticide formulations. Clariant Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of C.I. Pigment Red 112**.**

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-2013-0757, 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: Lois Rossi, 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 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-2013-0757 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-2013-0757, 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 February 21, 2014 (79 FR 9870) (FRL-9904-98), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-10631) by Exponent, 1150 Connecticut Ave, NW., Washington, DC 20036, on behalf of Clariant Corporation, 4000 Monroe Road, Charlotte, NC 28205. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of C.I. Pigment Red 112 (CAS Reg. No. 6535-46-2) when used as an inert ingredient seed treatment pigment not to exceed 10% w/w in pesticide formulations. That document referenced a summary of the petition prepared by Exponent, on behalf of Clariant Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 C.I. Pigment Red 112 including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C.I. Pigment Red 112 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 C.I. Pigment Red 112 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.

Based on the physical and chemical properties of C.I. Pigment Red 112 it is unlikely that C.I. Pigment Red 112 will be absorbed in the body and therefore, it is unlikely that C.I. Pigment Red 112 becomes systemically bioavailable after exposure. It is expected that C.I. Pigment Red 112 will pass though the body and be excreted in the feces.

Acute studies revealed low oral and dermal toxicity. When tested on rabbits, the chemical was shown to be non-irritating to the skin and eyes.

Skin sensitization testing of C.I. Pigment Red 112 (containing 3% Naphtol AS-D, a manufacturing impurity) was performed on guinea pigs according to the Buehler method. The study portion for erythma was performed with a 20% pigment composition (due to the red coloring of the chemical). Based on the results of this study, the chemical and the 20% mixture

were not considered to be a dermal sensitizer.

In addition, two Local Lymph Node Assays were conducted with up to 20% C.I. Pigment Red 112; one study had <0.01% Naphtol AS-D and the other claimed 4.1% Naphtol AS-D. The second test substance containing what the petitioner claimed was 4.1% Naphtol AS-D was positive for skin sensitization whereas the test with 0.01% Naphtol AS-D was not, indicating that skin sensitization is possible when Naphtol AS-D is present at sufficiently high concentrations. The percent of Napthol AS-D in the second study could not be confirmed with the study data available. However, the two negative skin sensitization studies did have documented proof of the Napthol AS-D content at up to 3%. The manufacturing process for C.I. Pigment Red 112 that will be used as a seed treatment inert ingredient is specifically manufactured to contain less than 1% Naphtol AS-D which, based on the study results, would not result in skin sensitization. Therefore, the C.I. Pigment Red 112 manufactured for use as a seed treatment inert ingredient is not considered a skin sensitizer.

In a 28-day oral toxicity study in rats no treatment-related changes were noted in neurological evaluations, body weights, food consumption, hematology or clinical chemistry analyses, or organ weights at the limit dose of 1,000 milligram/kilogram/day (mg/kg/day). Although there were no reproductive or developmental toxicity studies available for C.I. Pigment Red 112, the 28-day oral study in rats included endpoints specific to reproductive toxicity including organ weights, gross pathology and histopathology. No adverse effects were seen at doses up to 1,000 mg/kg/day (highest dose tested). In addition, DEREK modeling was conducted and did not indicate any structural alerts for reproductive toxicity or endocrine-related toxicity. There was also no indication from the blood parameters, organ weights, or histopathology of an immunotoxic effect at 1,000 mg/kg/day.

No neuropathological changes or effects were reported in the 28-day study (i.e., hearing ability, pupillary reflex, static righting reflex, grip strength, and motor activity testing); therefore, the Agency does not believe C.I. Pigment Red 112 will be neurotoxic. Also, there was no evidence of cytotoxicity or mutagenicity in any of the reviewed studies: A reverse gene mutation study, an *in vitro* cell mutagenicity study, and a Chinese hamster cell *in vitro* study.

Although no carcinogenicity studies are available for C.I. Pigment Red 112, C.I. Pigment Red 112 is unlikely to be carcinogenic. This conclusion is based on the lack of any evidence of mutagenicity in the available mutagenicity studies and the physical/chemical properties of the substance (e.g., high molecular weight making absorption unlikely and low water solubility).

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

No endpoint of concern was identified for any of the acute studies conducted. In addition, no endpoint of concern was determined in the 28-day study up to the limit dose of 1,000 mg/kg/day (highest dose tested).

C. Exposure Assessment

Since no endpoint of concern was identified in acute and subchronic studies a quantitative exposure assessment for C.I. Pigment Red 112 was not conducted.

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to C.I. Pigment Red 112, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from C.I. Pigment Red 112 in food as follows:

Although there is potential dietary exposure from consuming foods grown from the seeds that were treated with pesticide products containing the inert ingredient, the potential is very low because C.I. Pigment Red 112 will be used on treated seeds only and any pigment that is released into the soil is expected to be tightly bound to the soil and therefore, not expected to

be taken up by the plant. There will not be dietary exposure from the treated seeds themselves since seeds that have been chemically treated may not be used for food, feed, or oil processing. Even if any chemical residue was accessible to the plant a quantitative dietary risk assessment would not be necessary because no endpoint of concern was identified in the available data.

2. *Dietary exposure from drinking water*. Dietary exposure from drinking water is unlikely because C.I. Pigment Red 112 has low water solubility and therefore, runoff from pesticides containing the inert ingredient is not likely to occur.

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). The proposed use of C.I. Pigment Red 112 as a seed treatment/dye under 40 CFR 180.920 is not expected to result in residential exposure to this chemical. Although there are no reliable data to quantify non-pesticidal exposure, it could occur due to the use of C.I. Pigment Red 112 as an industrial colorant in paints, plastics, and inks. However, there is no safety concern because of the low toxicity of the chemical and the lack of an endpoint of concern in the database.

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 C.I. Pigment Red 112 to share a common mechanism of toxicity with any other substances, and C.I. Pigment Red 112 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that C.I. Pigment Red 112 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

No endpoint of concern was identified for any of the acute studies conducted. In addition, no endpoint of concern was determined in the 28-day study up to the limit dose of 1,000 mg/kg/day (highest dose tested). The toxicity database does not contain a carcinogenicity study or an immunotoxicity study but for the reasons stated in Unit IV.A., the Agency has concluded that there are no concerns for carcinogenicity, immunotoxicity, or neurotoxicity for this chemical. No developmental or reproductive effects were seen in the available studies and DEREK modeling did not indicate any structural alerts for reproductive toxicity or endocrine-related toxicity. Since no endpoint of concern was identified in acute and subchronic studies and because C.I. Pigment Red 112 is not expected to be absorbed by the body, a qualitative risk assessment for C.I. Pigment Red 112 was performed. Due to the lack of toxicity of C.I. Pigment Red 112, the Agency determined that a quantitative risk assessment using safety factors was not necessary for assessing risk. For the same reason, no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on C.I. Pigment Red 112 when used as an inert ingredient in seed treatment pesticide formulations at not more that 10% w/w, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to C.I. Pigment Red 112 under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR

180.920 for residues of C.I. Pigment Red 112 when used as an inert ingredient in pesticide formulations as a seed treatment pigment at 10% w/w is safe under FFDCA section 408.

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 without any numerical limitation. EPA is establishing a limitation on the amount of C.I. Pigment Red 112 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 seed treatment, use pesticide for sale or distribution with concentrations of C.I. Pigment Red 112 exceeding 10% by weight of the formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for C.I. Pigment Red 112 (CAS Reg. No. 6535-46-2) when used as an inert ingredient seed treatment pigment not to exceed 10% w/w in pesticide formulations.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement 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 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 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: August 14, 2014.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In §180.920, the table is amended by alphabetically adding an entry for "C.I. Pigment Red 112" after the entry for "C.I. Pigment Green #7" to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
	* * * * * * *	
C.I. Pigment Red 112 (CAS Reg. No. 6535-46-2)	Seed treatment use only. Limited to 10% w/w of pesticide formulation.	Coloring agent
	* * * * * * *	

[FR Doc. 2014-19742 Filed 08/19/2014 at 8:45 am; Publication Date: 08/20/2014]