[FR Doc. 2014–28955 Filed 12–9–14; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0122; FRL–9919–40]

C.I. Pigment Yellow 1; 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 Yellow 1 (butanamide, 2- (4-methyl-2-nitrophenyl) azo -3-oxo-N-phenyl-) when used as an inert ingredient as a colorant in seed treatment formulations not to exceed 10% weight(wt)/wt under 40 CFR 180.920. Exponent Inc. on behalf of 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 Yellow 1.

DATES: This regulation is effective December 10, 2014. Objections and requests for hearings must be received on or before February 9, 2015, 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–2014–0122, 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 T. 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 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–2014–0122 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 February 9, 2015. 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–2014–0122, 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 October 24, 2014 (79 FR 63594) (FRL–9916–03), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10661) by Exponent, Inc. (1150 Connecticut Ave. NW., Suite 1100, 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 Yellow 1 (butanamide, 2- (4-methyl-2-nitrophenyl) azo -3-oxo-N-phenyl-) (CAS Reg. No. 2512–29–0) when used as an inert ingredient as a colorant in pesticide formulations applied as a seed treatment not to exceed 10% wt/wt. That document referenced a summary of the petition prepared by Exponent, Inc., the petitioner, which is available in the docket, *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 C.I. Pigment Yellow 1 including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C.I. Pigment Yellow 1 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 Yellow 1 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 acute oral lethal dose $(LD)_{50}$ of C.I. Pigment Yellow 1 in rat was greater than 10,000 milligram/kilogram (mg/kg). The acute dermal LD_{50} of C.I. Pigment Yellow 1 in rats was greater than 2,000 mg/kg. In a primary skin and eye irritation study in rabbits, C.I. Pigment Yellow 1 was not irritating to the skin or eyes of rabbits. C.I. Pigment Yellow 1 was not a sensitizer as determined by mouse Local Lymph Node Assay (LLNA)/Redfern Contract Consultants (LLNA/RCC) cytotest cell assay.

In a repeated dose toxicity study with a reproduction/developmental toxicity screening test, C.I. Pigment Yellow 1 was administered orally to groups of 11 male and female Wistar rats at dose levels of up to 1,000 mg/kg/day. Parental systemic toxicity, functional observation battery (FOB) parameters, locomotor activity, reproductive function and performance, and offspring viability and growth were assessed in this study. Over the entire treatment period, weight gain was decreased by 11% and 16% in mid- and high-dose group males, respectively, however, the absolute body weights were not affected. The parental systemic toxicity, reproductive toxicity and offspring toxicity NOAEL for C.I. Pigment Yellow 1 was 1,000 mg/kg/day (the limit dose).

C.I. Pigment Yellow 1 was negative for mutagenicity in a reverse gene mutation assay and in an *in vitro* mammalian cell gene mutation assay using Chinese hamster cells.

No studies investigating the carcinogenic potential of C.I. Pigment Yellow 1 are available. A Deductive Estimation of Risk from Existing Knowledge (DEREK) evaluation of the toxicity of C.I. Pigment Yellow 1 indicated structural alerts based on the aromatic nitrogen structure and included plausible outcome for mutagenicity *in vitro* and plausible outcomes for carcinogenicity and hepatoxicity. However, based on the lack of target organ toxicity at the limit dose, lack of mutagenicity, limited solubility and limited bioavailability, C.I. Pigment Yellow 1 is not expected to be carcinogenic.

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 the NOAEL and the LOAEL are identified. 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.*

The available data suggest low acute oral toxicity. There was no evidence systemic toxicity in the reproductive and developmental study at the limit dose. There were no effects on reproductive, developmental and offspring toxicity at the limit dose of 1,000 mg/kg/day. It was negative for mutagenicity in two *in vitro* assays. In addition, based on its limited water solubility of C.I. Pigment Yellow 1 is not expected significantly via oral and dermal routes. Based on above consideration, EPA concluded that it is not necessary to conduct quantitative dietary risk as well as risk from exposure via dermal and inhalation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to C.I. Pigment Yellow 1, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from C.I. Pigment Yellow 1 in food as follows:

Dietary exposure can occur from eating foods containing residues of C.I. Pigment Yellow 1. Because no hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

2. *Dietary exposure from drinking water.* C.I. Pigment Yellow 1 residues may be found in drinking water. However, since an endpoint of concern was not identified for the dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

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). C.I. Pigment Yellow 1 is used as an inert ingredient in pesticide products that could result in short- and intermediate-term residential exposure. However, based on the lack of toxicity, a quantitative exposure assessment from residential exposures was not performed.

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 Yellow 1 to share a common mechanism of toxicity with any other substances, and C.I. Pigment Yellow 1 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 Yellow 1 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

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.

Based on an assessment of C.I. Pigment Yellow 1, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has conducted a qualitative assessment. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

Based on the lack of any endpoints of concern, 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 C.I. Pigment Yellow 1 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 C.I. Pigment Yellow 1.

C. Response to Comments

One comment was received for a notice of filing from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. 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 Federal Food, Drug and Cosmetic Act (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 180.920 for C.I. Pigment Yellow 1 (2512–29–0) when used as an inert ingredient colorant in seed treatment formulations not to exceed 10% wt/wt.

VII. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect

Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 26, 2014.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, add alphabetically the inert ingredient in the table 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 Yellow 1 (CAS Reg. No. 2512–29–0).	Not to exceed 10% (weight/weight) in pesticide formulation	Colorant.
* * * * * * *		

[FR Doc. 2014–28936 Filed 12–9–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 13–39; FCC 14–175]

Rural Call Completion

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document affirms the Commission's commitment to ensuring that high quality telephone service must be available to all Americans. In the underlying Order, the Commission established rules to combat extensive problems with successfully completing calls to rural areas, and created a framework to improve the ability to monitor call problems and take appropriate enforcement action. In the Order on Reconsideration, the Commission denies several petitions for reconsideration that, if granted, would impair the Commission's ability to monitor, and take enforcement action against, call completion problems. The Commission does, however, grant one petition for reconsideration because the Commission finds that modifying its original determination will significantly lower providers' compliance costs and burdens without impairing the Commission's ability to obtain reliable and extensive information about rural call completion problems.

DATES: Effective January 9, 2015, except for amendments to §§ 64.2101, 64.2103, and 64.2105, which contain new or modified information collection requirements that will not be effective until approved by the Office of Management and Budget. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Claude Aiken, Wireline Competition Bureau, Competition Policy Division, (202) 418–1580, or send an email to *claude.aiken@fcc.gov*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration in WC Docket No. 13–39, adopted and released November 13, 2014. The full text of this document is available for public inspection during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the