



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

EPA-HQ-OPP-2012-0568; FRL-9396-1]

FD&C Blue No. 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 FD&C Blue No. 1 (CAS Reg. No. 3844-45-9) when used as an inert ingredient (dye) in pesticides formulation applied to growing crops (seed treatment).

Exponent on behalf of Sensient Colors, LLC 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 FD&C Blue No. 1.

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-2012-0568, 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), EPA West 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; 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 FFDCFA 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-2012-0568 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-2012-0568, 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 August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8004) by Exponent (1150 Connecticut Ave., NW., Suite 1100; Washington, DC 20036) on behalf of Sensient Colors, LLC (2515 N. Jefferson Ave., St. Louis, MO 63106). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of FD&C Blue No. 1 (CAS Reg. No. 3844-45-9) when used as an inert ingredient (dye) in pesticide formulations applied to growing crops (seed treatment). That document referenced a summary of the petition prepared by Exponent on behalf of Sensient Colors, LLC, 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 FD&C Blue No. 1 including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with FD&C Blue No. 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 FD&C Blue No. 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 chemical is also referred to as Brilliant Blue FCF in this document, as this name is synonymous with FD&C Blue No. 1.

FD&C Blue No. 1 is not acutely toxic via the oral route in rats and via subcutaneous injection in mice. Long-term studies of the effects of the color administered in the diet to dogs, rats and mice did not indicate any significant toxic effects. In a chronic dog study, treatment at doses up to 200 milligrams/kilogram bodyweight/day (mg/kg bw/day) for a time period of 1 year did not show any treatment related signs of toxicity or histological abnormalities. In a 2-year study, rats fed a diet containing up to 2,000 mg/kg bw/day Brilliant Blue FCF showed no evidence of treatment related effects. In a second long term study in rats, Brilliant Blue FCF was fed as part of the diet for 75 weeks. No treatment related effects were found at 1,500 mg/kg bw/day, the highest dose tested.

Lifetime exposure of mice to Brilliant Blue FCF as part of the diet did not result in consistent biologically significant, compound related adverse effects on behavior, morbidity, mortality, hematology, general physical observations or tumor incidence. The NOAEL for this study was determined to be 7,354 mg/kg bw/day for male and 8,966 mg/kg bw/day for female, the highest doses tested.

Rats were treated with Brilliant Blue FCF in a chronic toxicity study coupled with a reproductive study. The NOAEL was 1,072 mg/kg bw/day for male rats and 631 mg/kg bw/day for females, based on a 15% decrease in terminal mean body weight and decreased survival in high dose females. In the reproductive portion of the study, there were no compound related effects on fertility, gestation, parturition, lactation, pup

survival through weaning, or on number of live and stillborn pups. The NOAEL was 1,073 mg/kg bw/day male rats and 1,318 mg/kg bw/day for females.

Brilliant Blue FCF was fed to three successive generations of male and female rats at dose levels up to 1,000 mg/kg bw/day. There were no treatment related effects on adult mortality, mating, pregnancy and fertility rates, lengths of gestation period, offspring survival or sex, litter survival or necropsy findings. The NOAEL for this study was 1,000 mg/kg bw/day, the highest dose tested. Two additional reproductive studies in rats and rabbits did not result fetal toxicity or anomalies at doses up to 2,000 mg/kg bw/day and 200 mg/kg bw day, respectively.

Based on the results of the available genotoxicity studies, it was concluded that Brilliant Blue FCF is not of concern with respect to genotoxicity. A developmental neurotoxicity study also indicates that there were no toxicological effects of concern. Immunotoxicity studies were not available for review. However, signs of immunotoxicity were not observed in any of the available studies conducted at doses above the limit dose of 1,000 mg/kg/day. The metabolism of Brilliant Blue FCF was determined in multiple studies. In three studies with rats that were given Brilliant Blue FCF either via gavage or in the diet, the major route of excretion was through the feces with total recoveries at a minimum of 92% indicating very limited absorption via oral route of exposure. The lack of gastrointestinal absorption and metabolism was confirmed by studies in guinea pigs and mice.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that FD&C Blue No. 1 has a very low overall toxicity. A NOAEL of 1,072 mg/kg bw/day for male rats and 631 mg/kg bw/day

for females can be derived from a chronic toxicity study coupled with a reproductive study based on a 15% decrease in terminal mean body weight and decreased survival in high dose females. However, these results were not reproducible in several other chronic longer duration studies at higher doses. Several long-term studies indicate a higher NOAEL above the limit dose. Therefore, EPA concludes that the existing database does not show a toxic endpoint of concern for acute, chronic, and short- and intermediate-term risks, and, accordingly, a quantitative risk assessment for FD&C Blue No. 1 is not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to FD&C Blue No. 1, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from FD&C Blue No. 1 in food as follows: Dietary exposure to FD&C Blue No. 1 can occur from eating food treated with pesticide formulations containing this inert ingredient. Dietary exposure can also occur from eating foods which contain FD&C Blue No. 1 as an ingredient. It is widely used as an ingredient in food products such as ice cream, bottled food coloring, icings, ice pops, dairy products, sweets and drinks. However, since an endpoint of concern for risk assessment was not identified, a quantitative dietary exposure assessment for FD&C Blue No. 1 was not conducted.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to FD&C Blue No. 1 can occur by drinking water that has been contaminated by run-off from a pesticide treated area. Since an endpoint for risk assessment was not identified, a

quantitative dietary exposure assessment from drinking water for FD&C Blue No. 1 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., lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The proposed use of FD&C Blue No. 1 as a seed treatment/dye under 40 CFR 180.920 is not expected to result in residential exposure to this chemical. Residential exposure is possible based on other currently approved inert uses of this chemical. However, since there are no toxicological effects of concern identified, it is not necessary to conduct assessments of residential (non-occupational) exposures and risks. There are no dermal or inhalation toxicological endpoints of concern to the Agency therefore quantitative assessments have not been conducted.

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 FD&C Blue No. 1 to share a common mechanism of toxicity with any other substances, and FD&C Blue No. 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 FD&C Blue No. 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 website 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.

The available toxicity studies suggest low toxicity of FD&C Blue No. 1. The toxicity database for FD&C Blue No. 1 contains an acute oral toxicity study, sub-chronic and chronic toxicity studies, including carcinogenicity, reproductive and developmental toxicity studies. No reproductive or developmental toxicity was observed in the modified reproduction study, 3-generation reproduction study and developmental toxicity studies in rats and rabbits. The database also contains mutagenicity studies, neurotoxicity data and metabolism data. There is no indication, based upon the available data, that FD&C Blue No. 1 is a neurotoxic or immunotoxic chemical or results in increased qualitative or quantitative susceptibility in infants or children. Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to this chemical when used as inert ingredient in pesticides formulations. Due to the lack of toxicity of FD&C No. 1, EPA did not use safety factors in qualitatively assessing its risk, and, 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 FD&C Blue No. 1, EPA has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to FD&C Blue No. 1 residues under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of FD&C Blue No. 1 when used as an inert ingredient (dye) in pesticide formulations applied to growing crops (seed treatment) is safe under FFDCa section 408.

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 FD&C Blue No. 1.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for FD&C Blue No. 1 (CAS Reg. No. 3844-45-9) when used as an inert ingredient (dye) in pesticide formulations applied to growing crops (seed treatment).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: September 17, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In §180.920, alphabetically add the following inert ingredient to the table, after the entry for Europic chloride and before the entry for FD&C Blue No. 1, methyl-polyethylene glycol derivative (CAS Reg. No. 9079-34-9), to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	*	* * *
FD&C Blue No. 1 (CAS Reg. No. 3844-45-9)	For seed treatment use only	Dye, coloring agent
* * *	*	* * *