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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2012-0515; FRL-9904-27]**

# Diflubenzuron; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of diflubenzuron (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzimide) in or on fruit, citrus, group 10-10 and citrus, oil. Chemtura Corporation, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**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-2012-0515, 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, 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 EPA's tolerance regulations at 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-2012-0515 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-2012-0515, 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. Summary of Petitioned-For Tolerance**

In the **Federal Register** of September 12, 2013 (78 FR 56185) (FRL-9399-7), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8015) by Chemtura Corporation,199 Benson Road, Middlebury, CT 06749. The petition requested that 40 CFR 180.377 be amended by establishing tolerances for residues of the insecticide diflubenzuron, (DFB) and its metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA), in or on fruit, citrus, group 10-10 at 3.0 parts per million (ppm), and citrus, oil at 32.0 ppm. That document referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In conjunction with this rulemaking, EPA has updated the tolerance expression to be consistent with the FFDCA. See Unit IV.D. EPA is also removing the existing tolerances for grapefruit, orange, pummelo, and tangerine that are made redundant by establishment of the crop group tolerance for citrus.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and 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 action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diflubenzuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with diflubenzuron follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The acute oral, dermal and inhalation toxicity of diflubenzuron is low. It is a mild eye irritant and not a skin irritant in laboratory animals. It is negative for sensitization in

the guinea pig. In subchronic and chronic feeding studies, the primary endpoint of concern was methemoglobinemia and/or sulfhemoglobinemia. These effects were evident in both sexes of mice, rats, and dogs and were produced by more than one route of administration in rats (i.e., oral, dermal and inhalation). The general consequence of methemoglobinemia and/or sulfhemoglobinemia is the impairment of the oxygen transportation capacity of the blood, which is generally known to be caused by aromatic amines in both humans and animals. Degradates of diflubenzuron with aromatic amines, CPU and PCA, are also included in the diflubenzuron non-cancer risk assessment. CPU, an analog of monuron, does not effect methemoglobin formation but does produce tumors in the liver and kidneys of male rats. The toxicity of PCA is well understood with methemoglobin formation the primary systemic effect. PCA is similar in potency to diflubenzuron on methemoglobin formation. Therefore, the non-cancer assessment will include diflubenzuron, CPU and PCA. Since the toxicity of CPU and PCA is well understood, additional toxicity studies are not required.

The toxicity data provide no indication of an increased susceptibility to rats or to rabbits from *in utero* or postnatal exposure to diflubenzuron. Developmental and reproduction studies in rats and rabbits indicate a very low hazard potential for adverse effects. Developmental studies were tested at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) without apparent effects in both dams and the fetuses. The reproduction study indicated that effects in offspring occurred at doses that were higher than the doses producing effects in parents. The requirement for acute and subchronic neurotoxicity studies were recently waived because there are no clear signs of neurotoxicity following subchronic or chronic dosing in multiple species in the

diflubenzuron database. The toxicity profile of diflubenzuron shows that the principal toxic effects are the formation of methemoglobinemia and/or sulfhemoglobinemia in the blood. The immunotoxicity study has been reviewed and immunotoxicity was not observed above the limit dose.

The Agency concluded that diflubenzuron is not carcinogenic in humans based on lack of evidence of carcinogenicity in rats and mice. PCA, a plant metabolite of diflubenzuron, tested positive for splenic tumors in male rats and hepatocellular adenomas/carcinomas in male mice in a National Toxicology Program (NTP) study. Therefore, EPA has treated PCA as a probable human carcinogen. CPU is the major degradate found in water and is a significant metabolite in milk. CPU is structurally related to monuron (*N*,*N*-dimethyl-CPU), a compound producing tumors of the kidney and liver in male rats. EPA has assumed CPU is a probable human carcinogen as well.

Specific information on the studies received and the nature of the adverse effects caused by diflubenzuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http*://*www.regulations.gov* in document, "Diflubenzuron: Human Health Risk Assessment for an Amended Section 3 Registration for the Expanded Citrus Crop Group 10-10." in docket ID number EPA-HQ-OPP-2012-0515.

*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 (LOC) 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*.

A summary of the toxicological endpoints for diflubenzuron used for human risk assessment is shown in Table 1 and 2 of this unit.

**Table 1. -- Summary of Toxicological Doses and Endpoints for Diflubenzuron for Use in Dietary Human Health Risk Assessments**

| Exposure/Scenario | POD | Uncertainty/ FQPA Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Acute dietary all populations | N/A | N/A | No appropriate endpoint attributable to single exposure was available. | |
| Chronic dietary all populations | NOAEL = 2 mg/kg/ day | $UF_A$ = 10X $UF_H$ = 10X FQPA SF = 1X | cPAD = chronic RfD FQPA SF = 0.02 mg/kg/day | Chronic dog study 00146174 LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia |
| Cancer (all routes) Diflubenzuron | Classification: “Group E” evidence of non- carcinogenicity for humans | | | |

| | | | |
|---|---|---|---|
| Cancer (oral, dermal, inhalation) | PCA "Group B2" probably human carcinogen $Q_1^*$ $1.12 \times 10^{-1}$ $(mg/kg/day)^{-1}$ | N/A | NTP oral mouse study |
| Cancer (oral, dermal, inhalation) | CPU $Q_1^*$ based on monuron a structural analog and the $Q_1^*$ $1.52 \times 10^{-2}$ | N/A | NTP oral rat study |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable

**Table 2. -- Summary of Toxicological Doses and Endpoints for Diflubenzuron for Use in Residential and Occupational Human Health Risk Assessments**

| **Exposure/Scenario** | **POD** | **Uncertainty/ Factors** | **Level of Concern for Risk Assessment** | **Study and Toxicological Effects** |
|---|---|---|---|---|
| Short- and intermediate-term incidental oral (1 day - 6 months) (residential) | N/A | N/A | N/A | These endpoints were not evaluated. There are no registered uses of diflubenzuron which result in significant residential exposure. |
| Short-term dermal (1 - 30 days) (occupational) | NOAEL = 500 mg/kg/day | $UF_A$ = 10X $UF_H$ =10X | LOC for MOE = 100 | 21-day rat dermal LOAEL = 1,000 mg/kg/day based on methemoglobinemia |
| Dermal intermediate term (1-6 months) | NOAEL = 2 mg/kg/ day | $UF_A$ = 10X $UF_H$ =10X dermal absorption: 0.5% | LOC for MOE = 100 | 13 - week oral dog LOAEL = 6.4 mg/kg/day based on methemoglobinemia |

| | | | | |
|---|---|---|---|---|
| Inhalation short term (1-30 days) | NOAEL = 0.109 mg/L NOAEL = 20.30[1] mg/kg/day | $UF_A$ = 10X $UF_H$ =10X | LOC for MOE = 100 | 28-day Inhalation rat study No effect at HDT[2], 0.109 mg/L |
| Inhalation intermediate term (1-6 months) | NOAEL = 0.109 mg/L NOAEL = 20.30[1] mg/kg/day | $UF_A$ = 10X $UF_H$ =10X | LOC for MOE = 100 | 28-day Inhalation rat study<br><br>No effect at HDT, 0.109 mg/L |
| Inhalation long term (1-6 months) | NOAEL = 2 mg/kg/ day | $UF_A$ = 10X $UF_H$ =10X | LOC for MOE = 100 | Chronic dog study LOAEL = 10 mg/kg/day based on methemoglobinemia and sulfhemoglobinemia |
| Cancer (all routes) | Classification: "Group E" evidence of non- carcinogenicity for humans. | | | |

[1] Conversion from mg/L to oral dose (mg/kg/day) = mg/L x absorption (1.0) x Respiratory Volume (Sprague-Dawley rats) for 6 hours/d x Duration of Exposure (5 d/week)/body weight x 7 d/week = 0.109 mg/L x 1.0 x (0.26(RV) x 6 hrs)x 5 d/wk ÷ 0.236 kg x 7 d/wk = 20.3 mg/kg/day (TXR 0050503).

[2] Highest Dose Tested.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to diflubenzuron, EPA considered exposure under the petitioned-for tolerances as well as all existing diflubenzuron tolerances in 40 CFR 180.377. EPA assessed dietary exposures from diflubenzuron in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for diflubenzuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic non-cancer dietary exposure assessment, EPA used the food consumption data from the United States Department of

Agriculture (USDA) National Health and Nutrition Examination Survey, "What We Eat in America" (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA used the assumption that diflubenzuron residues are present in most commodities at tolerance levels (including tolerances previously established as well as those established in this action) and that 100% of all crops are treated. Average field trial residues were assumed for grapefruit, lemon, and orange. Tolerances include residues of diflubenzuron, PCA, and CPU.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that diflubenzuron does not pose a cancer risk to humans. However, metabolites CPU and PCA are considered probable carcinogens and have Q*s assigned to them. Individual cancer dietary exposure analyses were conducted for each metabolite. For PCA, average percent crop treated (PCT) was used for some commodities. One-half the Limit of Quantitation (LOQ) was used for estimating PCA residues on the majority of crops because most crops did not contain detectable residues of PCA. Average field trial residue was used for mushrooms. The CPU cancer dietary analysis focused on CPU residues in milk because metabolism studies indicate that diflubenzuron metabolizes to CPU in milk. EPA assumed that 100% of milk commodities contained CPU at ½ the LOQ. One-half the LOQ was used since detectable residues of CPU were not found in the feeding study.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to

FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Almond (10%), apricot (10%), artichoke (50%), cotton (1%), grapefruit (15%), oranges (5%), peach (5%), peanut (5%), pear (5%), pecan (2.5%), peppers (1%), rice (1%), soybeans (1%), tangerines (5%), and wheat (1%).

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations, including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA

does not have available reliable information on the regional consumption of food to which diflubenzuron may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for diflubenzuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of diflubenzuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the Estimated Drinking Water Concentrations (EDWC) of 12.8 microgram/Liter (µg /L) (including diflubenzuron and CPU) was used to assess chronic non-cancer dietary risk. CPU cancer risk was assessed using the EDWC of 8.81 µg /L.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Although there are no registered homeowner uses, there are registered uses for professional applications to outdoor trees and ornamentals in residential areas. However, given the effects in the 21-day dermal toxicity study were only observed at the limit dose (1,000 mg/kg/day) and the dermal absorption is extremely low (0.5%) as well as the intermittent potential for post-application residential exposure to ornamentals (i.e.,

contact with ornamentals every day is not likely), a residential post-application assessment is not required at this time.

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 diflubenzuron to share a common mechanism of toxicity with any other substances, and diflubenzuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that diflubenzuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

*D. Safety Factor for Infants and Children*

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Based on the available developmental toxicity studies in rats and rabbits and the reproduction study, there is no increased susceptibility to fetuses exposed *in utero*.

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

i. The toxicological database for diflubenzuron is complete. The toxicity of CPU and PCA is well understood. CPU is less toxic and does not affect methemoglobin. PCA does cause methemoglobin formation but is similar in potency to diflubenzuron. Therefore, assuming equal toxicity of CPU and PCA to diflubenzuron is health protective, additional toxicity studies are not required.

ii. There are no clear signs of neurotoxicity following subchronic or chronic dosing in multiple species in the diflubenzuron database; therefore, there is no need for any neurotoxicity studies.

iii. There is no evidence that diflubenzuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. The dietary exposure assessment uses conservative assumptions which will not underestimate dietary exposure and EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to diflubenzuron in drinking water. These assessments will not underestimate the exposure and risks posed by diflubenzuron.

*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 aPAD and 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.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, diflubenzuron is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to diflubenzuron from food and water will utilize 37% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for diflubenzuron.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, diflubenzuron is not registered for any use patterns that would result in short-term residential exposure; therefore, no further assessment of short-term risk is necessary.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, diflubenzuron is not registered for any use patterns that would result

in intermediate-term residential exposure; therefore, no further assessment of intermediate-term risk is necessary.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, diflubenzuron is not expected to pose a cancer risk to humans. However, metabolites CPU and PCA are considered probable carcinogens and have Q*s assigned to them. Individual cancer dietary exposure analyses were conducted for each metabolite. The cancer assessment for PCA includes food only (not present in drinking water). The cancer assessment for CPU includes milk and water only. For PCA, the cancer dietary exposure estimate for the U.S. population is $1 \times 10^{-6}$. For CPU, the cancer dietary exposure estimate for the U.S. population is $3 \times 10^{-6}$.

EPA generally considers cancer risks in the range of $10^{-6}$ or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between $3 \times 10^{-7}$ and $3 \times 10^{-6}$ are expressed as risks in the range of $10^{-6}$. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of $10^{-6}$ until the calculated risk exceeds approximately $3 \times 10^{-6}$. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the PCA and CPU exposure risk assessment are refined, they retain significant conservatism in that residues in food were estimated at ½ LOQ even though no residues were detected in field trials and feeding studies, and for some

commodities EPA assumed 100 PCT. Accordingly, EPA has concluded the cancer risk for all existing diflubenzuron uses, and the uses associated with the tolerances established in this action fall within the range of $1 \times 10^{-6}$ and are thus negligible**.**

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to diflubenzuron residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography/electron capture detection (ECD) and high-performance liquid chromatography/ultraviolet (HPLC/UV)) is available to enforce the tolerance expression.

### *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 diflubenzuron, expressed in terms of diflubenzuron *per se*, for many including: Citrus, fruits 0.5 ppm. This MRL is different than the citrus crop group tolerance being established for diflubenzuron in this action.

Numerical compatibility with Codex is not possible as the good agricultural practices used for the Codex MRL are different from the proposed use pattern in the U.S. Additionally, the tolerance expression for the Codex MRL and the U.S. tolerance are not the same, only the U.S. tolerance contains the CPU and PCA metabolites. EPA is re-examining whether it can harmonize the U.S. tolerance expression with the Codex MRL, but making this change alone would not harmonize the numerical difference.

*C. Revisions to Petitioned-For Tolerances*

EPA is revising the tolerance expression to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of diflubenzuron not specifically mentioned; and that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. Therefore, the tolerance expression for diflubenzuron will be revised under 40 CFR 180.377 (a)(1), (a)(2), and (b) (see the regulatory text of this document).

## V. Conclusion

Therefore, tolerances are established for residues of diflubenzuron, (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzimide) in or on fruit, citrus, group 10-10 at 3.0 ppm; and citrus, oil at 32 ppm. The Agency is removing the currently established tolerances for grapefruit, orange, pummel, and tangerine from 40 CFR 180.377. These tolerances are being replaced by the tolerance for fruit, citrus, group 10-10.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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).

**VII. 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: January 17, 2014

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 § 180.377:

a. Revise the introductory text in paragraph (a)(1).

b. Remove “Grapefruit”, “Orange sweet”, and “Tangerine” from the table in paragraph (a)(1).

c. Revise the introductory text in paragraph (a)(2).

d. Remove “Pummelo”, from the table in paragraph (a)(2).

e. Add Citrus, oil, and Fruit, citrus, group 10-10 to the table in paragraph (a)(2).

f. Revise the introductory text in paragraph (b).

The amendments read as follows:

**§ 180.377 Diflubenzuron; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of diflubenzuron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only diflubenzuron (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide).

* * * * *

(2) Tolerances are established for residues of the insecticide diflubenzuron (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide), in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be

determined by measuring only the sum of diflubenzuron (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide), 4-chlorophenylyurea and 4-chloroaniline, calculated as the stoichiometric equivalent of diflubenzuron, in or on the commodity.

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Citrus, oil | 32 |
| * * * * * | |
| Fruit, citrus, group 10-10 | 3.0 |
| * * * * * | |

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide diflubenzuron (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of diflubenzuron (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide), 4-chlorophenylyurea and 4-chloroaniline, calculated as the stoichiometric equivalent of diflubenzuron, in or on the commodity. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

* * * * *

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