| Commodity | Parts per million |
|---|---|
| Goat, meat byproducts | 0.01 |
| Grain, aspirated grain fractions | 10 |
| Grain, cereal, forage, fodder, and straw, group 16, forage | 15 |
| Grain, cereal, forage, fodder, and straw, group 16, hay | 5 |
| Grain, cereal, forage, fodder, and straw, group 16, stover | 10 |
| Grain, cereal, forage, fodder, and straw, group 16, straw | 2 |
| Grain, cereal, group 15, except rice and barley | 0.04 |
| Hog, fat | 0.01 |
| Hog, meat | 0.01 |
| Hog, meat byproducts | 0.01 |
| Horse, fat | 0.01 |
| Horse, meat | 0.01 |
| Horse, meat byproducts | 0.01 |
| Milk | 0.01 |
| Pea and bean, dried shelled, except soybean, subgroup 6C | 0.06 |
| Poultry, fat | 0.01 |
| Poultry, meat | 0.01 |
| Poultry, meat byproducts | 0.01 |
| Rapeseed subgroup 20A | 0.08 |
| Sheep, fat | 0.01 |
| Sheep, meat | 0.01 |
| Sheep, meat byproducts | 0.01 |
| Soybean, forage | 1 |
| Soybean, hay | 3 |
| Soybean, hulls | 0.2 |
| Soybean, seed | 0.05 |
| Vegetable, foliage of legume, except soybean, subgroup 7A | 40 |
| Wheat, bran | 0.06 |
| Wheat, germ | 0.09 |

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012–29250 Filed 12–4–12; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2011–0743; FRL–9364–7]**

### Dodine; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of dodine, (*N*-dodecyl guanidine acetate) in or on multiple commodities and also removes multiple, previously established tolerances which are identified and discussed later in this document. Agriphar S.A., c/o Ceres International LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 5, 2012. Objections and requests for hearings must be received on or before February 4, 2013, 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–2011–0743, 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:** Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–9096; email address: *gibson.tamue@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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0743 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 4, 2013. 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–2011–0743, 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.htm.* 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 August 22, 2012 (77 FR 50661) (FRL–9358–9), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7872) by Agriphar S.A.,

c/o Ceres International LLC, 1087 Heartsease Drive, West Chester, PA 19382. The petition requested that 40 CFR 180.172 be amended by establishing tolerances for residues of the fungicide dodine, (*N*-dodecyl guanidine acetate), in or on stone fruits (group 12) at 5 parts per million (ppm); tree nuts (group 14) at 0.3 ppm; and almond, hulls at 20 ppm. The petitioner also requested that the tolerances in 40 CFR 180.172 be amended by removing established tolerances for residues of dodine as follows: Cherry, sweet at 3 ppm; cherry, tart at 3 ppm; peach at 5 ppm; pecan at 0.3 ppm; and walnut at 0.3 ppm. These tolerances would be redundant if the crop group tolerances for stone fruits (group 12) and tree nuts (group 14) are established. That notice referenced a summary of the petition prepared by Agriphar S.A., c/o Ceres International LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has raised the requested tolerance level for almond, hull. The reason for this change is explained in Unit IV.C.

## 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 dodine, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dodine 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.

Dodine is moderately toxic via the acute oral, dermal and inhalation routes of exposure. It is a severe eye irritant and causes severe dermal irritation; it is not a skin sensitizer. A definitive target organ has not been identified for dodine. The most common effects observed in sub-chronic and chronic studies were decreases in food consumption, body weight and/or body weight gain. Possible neurological clinical signs (excessive salivation and hunched posture/hypoactivity) were observed in chronic studies in rats and mice but were not dose-related or statistically significant. Excessive salivation in the chronic study in dogs was not consistent with a neurological adverse effect since it was seen prior to dosing and was a persistent finding throughout the study. Therefore, there is no evidence of neurotoxicity and the acute and subchronic neurotoxicity studies are not required (HASPOC, October 25, 2012). The current database does not indicate concerns for immunotoxicity and the registrant has agreed to perform an immunotoxicity study (OCSPP Guideline 870.7800). Therefore, the Food Quality Protection Act (FQPA) safety factor is reduced to 1X.

There is no evidence of increased susceptibility (quantitative or qualitative) in pups versus adults based on rat and rabbit developmental studies and the rat multi-generation reproduction study. In rat and rabbit prenatal developmental studies, there was no toxicity identified in the fetuses up to the highest dose tested (HDT). In the 2-generation reproduction study, decreases in body weight gain and food consumption were seen in pups at the same dose at which maternal toxicity (decreased body weight, body weight gain and food consumption) was observed.

There was equivocal evidence of carcinogenicity in animal carcinogenicity studies; however, a weight-of-evidence evaluation of the carcinogenic potential of dodine was performed, and based on the results it was concluded that dodine should be classified as Not Likely to be Carcinogenic to Humans based on the following:

(1) There was no evidence of tumors in male mice or in rats of either sex;

(2) In female mice, the increase in incidence of combined tumors is marginal (8.3%) compared to historical controls (8%), and there were no pre-neoplastic lesions that can be associated with the tumor response, and therefore no evidence that the high dose was associated with further progression to carcinoma;

(3) There was no evidence of genotoxicity, and therefore no mutagenicity concern; and

(4) The Structure Activity Relationship (SAR) assessment does not indicate probable carcinogenicity. Factors bearing on this weight of the evidence determination are described in ''Dodine: Human Health Risk Assessment for Proposed Use Bananas and Peanuts,'' pages 20–21 in docket ID number EPA–HQ–OPP–2007–0221, at *http://www.regulations.gov.* In the absence of carcinogenicity concern, risk assessment using the chronic population adjusted dose will be protective for any chronic toxicity.

Specific information on the studies received and the nature of the adverse effects caused by dodine 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 ''Dodine. Amended Human Health Risk Assessment to Support Use on Stone Fruit and Tree Nut Crops,'' pages 14 and 42 in docket ID number EPA–HQ–OPP–2011–0743.

### *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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). 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 dodine used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DODINE FOR USE IN DIETARY AND NON-OCCUPATIONAL HUMAN HEALTH RISK ASSESSMENTS

| Exposure/scenario | Point of departure and uncertainty/safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|---|
| Acute dietary (Females 13–50 years of age). | N/A | N/A | No appropriate endpoint for females age 13–49. |
| Acute dietary (General population including infants and children). | N/A | N/A | No appropriate endpoint identified. |
| Chronic dietary (All populations) | NOAEL = 2 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | cRfD=0.02 mg/kg/day<br>cPAD = 0.02 mg/kg/day. | Chronic toxicity-dog LOAEL = 10 mg/kg/day based on body weight loss in females. |
| Incidental oral short-term (1 to 30 days).<br>Incidental oral intermediate-term (1 to 6 months). | NOAEL = 26 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x | Residential MOE = 100 | 2-Generation Reproduction-rat Offspring LOAEL = 53 mg/kg/day based on decreased body weight. |
| Dermal short-term (1 to 30 days).<br>Dermal intermediate-term (1 to 6 months). | NOAEL = 200 mg/kg/day (HDT)<br>$UF_A$ = 10x$UF_H$ = 10x. | Residential MOE = 100 | 28-Day Dermal Toxicity-rat LOAEL = not identified. |
| Inhalation short-term(1 to 30 days). | Developmental Study Maternal NOAEL = 10 mg/kg/day.<br>IAF = 100% | Residential MOE = 100 | Developmental Toxicity Study-rat Maternal LOAEL = 45 mg/kg/day based on decreased body weight gain and food consumption. |
| Inhalation (1 to 6 months) | $UF_A$ = 10x<br>$UF_H$ = 10x. | | |
| Cancer (oral, dermal, inhalation) | Not likely to be carcinogenic to humans. | | |

FQPA SF = Food Quality Protection Act Safety Factor. HDT= Highest Dose Tested. IAF = inhalation absorption rate. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. $UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dodine, EPA considered exposure under the petitioned-for tolerances as well as all existing dodine tolerances in 40 CFR 180.172. EPA assessed dietary exposures from dodine 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 dodine; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance level residues for all treated crops. In terms of extent of usage, percent crop treated (PCT) information was used for apples, cherries, peaches, pears, peanuts, pecans, and strawberries. One hundred PCT was assumed for the remainder of crops.

iii. *Cancer.* Based on the data discussed in Unit III.A., EPA determined that dodine did not pose a carcinogenicity concern and that risk assessment using the chronic population adjusted dose will be protective for any chronic toxicity. Accordingly, no exposure assessment, separate from the chronic assessment, was conducted with regard to cancer risk.

iv. *PCT information.* 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:

The Agency used the following PCT information for the currently registered uses of dodine: 10% PCT for pecans, 5% PCT for cherries and pears, 2.5% PCT

for apples and peanuts along with 1% PCT for peaches and strawberries.

In most cases, EPA uses available data from U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 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 1. 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 sub-populations 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 dodine 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 dodine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dodine. 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.*

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of dodine for chronic exposures for non-cancer assessments are estimated to be 1.79 parts per billion (ppb) for surface water and <0.05 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 1.79 ppb was used to assess the contribution to drinking water.

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).

Dodine is not registered for any specific use patterns that would result in residential exposure. However, a closely related chemical, dodecylguanidine hydrochloride (DGH) is used as an antimicrobial in household, industrial, and commercial products having residential and occupational exposure potential. DGH is used as a bacteriostat in paints and in absorbent material in disposal diapers. Dodine and DGH have similar chemical compositions and properties and are therefore considered bio-equivalents.

Residential painters may have short term dermal and inhalation exposure as a result of using DGH treated paint. Infants and small children may have short-, intermediate-, and long-term dermal exposure as a result of wearing DGH impregnated diapers. The Agency believes that a transfer factor of 30% does not underestimate exposure in determining the amount of DGH transferred to infants from diapers based on a transfer study using dodine-treated paper exposed to extreme conditions. Inhalation exposure of infants and children is expected to be negligible. Although small children may have short-term post application oral exposure as a result of accidental ingestion of paint chips which contain DGH, the Agency does not believe that this would occur on a regular basis.

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

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 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.

2. *Prenatal and postnatal sensitivity.* There is no evidence (quantitative or qualitative) of increased susceptibility and no residual uncertainties with regard to prenatal and/or postnatal toxicity following *in utero* exposure to rats or rabbits. In rat and rabbit prenatal developmental studies, there was no toxicity identified in the fetuses up to the HDT. In the 2-generation reproduction study, decreases in body weight gain and food consumption were seen in pups at the same dose at which maternal toxicity (decreased body weight, body weight gain and food consumption) was observed.

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:

The toxicity database for dodine is mostly complete. The database contains the following toxicity studies:

i. A sub-chronic mouse toxicity study.

ii. Chronic rat, mouse, and dog toxicity studies.

iii. A 28-day dermal and dermal penetration studies (rats.

iv. Prenatal developmental studies (rats and rabbits).

v. A reproduction study in rats.

There are also acute $LD_{50}$ studies via the oral, dermal and inhalation routes, a metabolism study, and a complete mutagenicity battery. The current database does not indicate neurotoxicity or immunotoxicity concerns. Thus, EPA has waived the acute and subchronic neurotoxicity studies. An immunotoxicity study is required pursuant to the recent amendment of EPA's data regulations to evaluate the potential of a repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. However, because no immunotoxicity was observed in available toxicity studies, EPA has confidence that this study is unlikely to change the POD in assessing risk to infants and children.

a. There is no evidence that dodine 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.

b. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on Agency recommended tolerance-level residues and health protective modeling assumptions. Although PCT estimates were used for crops with existing tolerances, the use of tolerance values for residue levels will likely overestimate actual exposures. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dodine in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children, as well as incidental oral exposure of children and incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dodine.

*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.

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, dodine 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 dodine from food and water will utilize 21% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. Further, EPA has concluded that the combined long-term food, water, and dermal exposure for infants wearing diapers containing DGH treated material results in an aggregate MOE greater than 100. Because EPA's level of concern for dodine is for MOEs below 100, this MOE does not raise a risk concern.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term combined food, water, and residential exposures aggregated result in aggregate MOEs of 4,200 for adult males handling paint and 4,500 for adult females handling paint. The exposures do not exceed the Agency's level of concern. EPA has concluded that the combined intermediate-term food, water, and dermal exposure for infants wearing diapers containing DGH treated material results in aggregate MOEs of 120 when using a 30% transfer factor. Because EPA's level of concern for dodine is for MOEs below 100, this MOE does not raise a risk concern.

4. *Aggregate cancer risk for U.S. population.* Based on the data discussed in Unit III.A., EPA concluded that dodine is not expected to pose a cancer risk to humans.

5. *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 dodine residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (colormetric method with spectrometric detection and various modifications is listed in FDA's Pesticide Analytical Manual (PAM), Volume II as Methods I, I(a), I(b), and I(d)) 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 not established MRLs for dodine on the tree nut crop group. The Codex has established MRLs for dodine in or on cherries, sweet and cherries, tart at 3 ppm and on peaches and nectarines at 5 ppm. The Codex MRL for cherries is not harmonized with the stone fruit crop group tolerance of 5 ppm.

Harmonization with the Codex MRL for cherries is not possible because the cherry field trial data shows that residues from the domestic, labeled use may exceed the 3 ppm Codex MRL making it impractical for limits to be harmonized based on the proposed domestic use pattern. However, the cherry data when considered as part of the data set to support a stone fruit crop group tolerance, indicate that a 5 ppm crop group tolerance would be appropriate. To harmonize to the best extent possible with Codex, the crop group tolerance will be set at 5 ppm, This at least harmonizes the Codex and U.S. tolerances for peaches and nectarines.

*C. Revisions to Petitioned-for Tolerances*

Based on the analysis of the residue trial data using the Organization for

Economic Cooperation and Development (OECD) tolerance

calculation procedures, tolerances for almond hulls were increased.

**V. Conclusion**

Therefore, tolerances are established for residues of dodine, *N*-dodecylguanidine acetate, including its metabolites and degradates, in or on almond, hulls at 30 ppm; fruit, stone, crop group 12 at 5.0 ppm; and nuts, tree, crop group 14 at 0.3 ppm. This final rule removes established tolerances for cherry, sweet; cherry, tart; peach; pecan; and walnut.

**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: November 21, 2012.

**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. Amend § 180.172 as follows:

■ i. Revise the introductory text in paragraph (a).

■ ii. Remove the entries for cherry, sweet; cherry, tart; peach, pecan and walnut from the table in paragraph (a).

■ iii. Add alphabetically the entries for almond, hull; fruit, stone, crop group 12; and nuts, tree, crop group 14.

The additions and revision read as follows:

**§ 180.172 Dodine; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the fungicide dodine, including its metabolites and degradates, in or on the commodities listed in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only dodine, *N*-dodecylguanidine acetate; in or on the following commodities.

| Commodity | Parts per million |
|---|---|
| Almond, hull | 30.0 |
| * * * * * | |
| Fruit, stone, crop group 12 | 5.0 |
| Nuts, tree, crop group 14 | 0.3 |
| * * * * * | |

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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[MB Docket No. 09–52; FCC 12–127]**

### Policies To Promote Rural Radio Service and To Streamline Allotment and Assignment Procedures

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; petitions for reconsideration and clarification.

**SUMMARY:** In this document, the Commission denied four of six Petitions for Reconsideration, Petitions for Partial Reconsideration, and Petitions for Clarification of the Second Report and Order (Second R&O) in this proceeding, granting in part and denying in part two of the petitions. The Commission clarified some of the methodology to be used in applying the new rules and procedures in the Second R&O, in particular the method of counting reception services in service gain and loss areas, to assist applicants and allotment proponents in accurately applying the new rules and procedures. The Commission also further restricted the categories of applicants and allotment proponents to whom the new rules and procedures apply, finding that equitable considerations supported such restrictions. In addition to restrictions set forth in the Second R&O, the new rules will not apply to applications and allotment proposals filed before the new rules were proposed, or to those applications and proposals that have