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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0536; FRL-9970-38]

Ziram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of ziram in or on hazelnut. United Phosphorus, Inc. requested this tolerance 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-2016-0536, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 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-2016-0536 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-2016-0536, 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 November 30, 2016 (81 FR 86312) (FRL-9954-06), 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 6F8493) by United Phosphorus, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406. The petition requested that 40 CFR 180 be amended by establishing a tolerance for residues of the fungicide ziram, zinc dimethyldithiocarbamate, in or on filbert (hazelnut) at 0.1 parts per million (ppm). That document referenced a summary of the petition prepared by United Phosphorus, Inc., 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 revised the tolerance value to add an additional significant figure and also revised the commodity term from filbert (hazelnut) to hazelnut. 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 ziram including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ziram 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 primary target organs of ziram are the nervous system, liver, and thyroid. A single oral dose causes neurological impairments (ataxia and slight impaired gait) while repeated short-term exposure results in inhibition of brain cholinesterase and brain neurotoxic esterase in rats. Developmental neurotoxic effects were not observed in offspring of the most recent DNT study. Liver histopathology was identified throughout the database at various doses in the rat subchronic and chronic studies and the mouse carcinogenicity study, and at times is accompanied by increases in hepatic serum enzyme levels. Chronic studies also included thyroid effects, specifically follicular cell hypertrophy and c-cell carcinoma. When ziram was administered orally in rats, it was rapidly absorbed, distributed, and excreted via urine, expired air, and excreted feces within 72 hours. Small amounts were widely distributed in the body with the highest tissue concentrations in the liver, fat, kidney, spleen, lung, thyroid, and adrenals. Metabolites were not identified.

There is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits and following pre-/postnatal exposure to rats in the developmental, reproduction, and developmental neurotoxicity studies with ziram. There was an apparent quantitative evidence of increased susceptibility identified in an older unacceptable developmental neurotoxicity study in rats. Increased motor activity was observed in the offspring at the lowest dose tested, while the maternal rats exhibited reduced body weights and/or body weight gains, and decreased food consumption during gestation and lactation at the highest dose tested. However, this study was classified as unacceptable since brain morphometric analysis – a key evaluation in DNTs - was not conducted. A second DNT study was submitted and does not demonstrate quantitative susceptibility. This second DNT identifies a clear NOAEL and includes brain morphometric data on post-natal day 21 and 72 rats with no treatment-related effects.

Based on the occurrence of benign tumors (hemangiomas) in male CD (SD) BR male rats, supported by an increasing trend in preputial gland adenomas in male F344 rats. However, since no hemangiosarcomas or preputial gland carcinomas were observed, no treatment-related increase in tumors was identified in the female CD(SD) BR or female F344/N rat, and because ziram was not carcinogenic to CD-1 mice (both genders), and there is no concern regarding mutagenicity, the EPA has determined that quantification of risk using a non-linear approach (i.e. RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to ziram.

Ziram has low acute toxicity via the dermal and oral routes. However, ziram is classified as Toxicity Category I for eye irritation and a Category II for the acute

inhalation study. Ziram is also a moderate dermal sensitizer. Specific information on the studies received and the nature of the adverse effects caused by ziram 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 "Ziram. Human Health Risk Assessment for Proposed New Use on Hazelnuts (Filberts) in Tree Nuts Crop Group 14-12", pages 12-17, in docket ID number EPA-HQ-OPP-2016-0536.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for ziram used for human risk assessment is shown in the Table of this unit.

Table --Summary of Toxicological Doses and Endpoints for ziram for Use in Human Health Risk Assessment

Exposure/Scenario	**Point of Departure and Uncertainty/Safety Factors**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Acute dietary (All Populations)	LOAEL = 15 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF (UF_L) = 3x	Acute RfD = 0.05 mg/kg/day aPAD = 0.05 mg/kg/day	Acute Neurotoxicity in rat (MRID 43362801 LOAEL = 15 mg/kg/day based on ataxia and slight impairment of gait. NOAEL not established.
Chronic dietary (All populations)	NOAEL = 1.6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.016 mg/kg/day cPAD = 0.016 mg/kg/day	52-Week Oral Toxicity in dog (MRID 42823901) LOAEL = 6.6 mg/kg/day based on liver histopathology (aggregates of Kupffer cells and macrophages, increased foci of degenerate hepatocytes, infiltration of inflammatory cells around central veins,

			and increased centrilobular fibrocytes) in males.
Short term oral (Adult only)	NOAEL= 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Prenatal Oral Developmental in rabbit (MRID 00161316) LOAEL = 15 mg/kg/day based on increased incidence of resorptions and post implantation loss.
Dermal Short and Intermediate term (Adult only)	Oral study NOAEL= 7.5 mg/kg/day (dermal absorption rate = 1.0%*) UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential and Occupational LOC for MOE = 100	Prenatal Oral Developmental in rabbit (MRID 00161316) LOAEL = 15 mg/kg/day based on increased incidence of resorptions and post implantation loss.
Inhalation Short and Intermediate term	Oral study NOAEL= 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential and Occupational LOC for MOE = 100	Prenatal Oral Developmental in rabbit (MRID 00161316) LOAEL = 15 mg/kg/day based on increased incidence of resorptions and post implantation loss.
Cancer (Oral, dermal, inhalation)	EPA has determined that a nonlinear approach is appropriate and that the cRfD will be protective of cancer effects.		

FQPA SF = Food Quality Protection Act Safety Factor. 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 = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

*The dermal absorption rate of 1.0% was derived from the ratio of LOAELs in the rabbit oral developmental study and the 21-day dermal rabbit study (RED, 2003).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to ziram, EPA considered exposure under the petitioned-for tolerances as well as all existing ziram tolerances in 40 CFR 180.116. EPA assessed dietary exposures from ziram 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.

Such effects were identified for ziram. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM-FCID; version 3.16). The assessment is based on the maximum percent crop treated estimates for some commodities and assumed

100% crop treated for all others. The analyses also assumed a distribution of residues based on field trial data or the Food and Drug Administration (FDA) monitoring data.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003-2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM-FCID; version 3.16). The assessment is based on the average percent crop treated estimates for some commodities and assumed 100% crop treated for all others. The analyses also assumed a distribution of residues based on field trial data or the FDA monitoring data.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to ziram. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and percent crop treated (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 maximum PCT for existing uses as follows in the acute dietary risk assessment: almonds: 35%; apples: 20%; apricots: 70%; blueberries: 40%; cherries: 15%; grapes: 10%; nectarines: 65%; peaches: 40%; pears: 35%; pecans: 2.5%; and tomatoes: 6%.

The following average percent crop treated estimates were used in the chronic dietary risk assessments for the following crops that are currently registered for ziram:

almonds: 15%; apples: 15%; apricots: 35%; blueberries: 30%; cherries: 5%; grapes: 5%; nectarines: 45%; peaches: 25%; pears: 15%; pecans: 2.5%; and tomatoes: 6%.

For strawberries, the Agency calculated percent detectable residue values from the FDA samples and used that number (4.5%) in the acute and chronic evaluations.

In most cases, EPA uses available data from United States 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 5%. In those cases, EPA rounds to either 2.5% or 1%, whichever is appropriate. 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%, except when the maximum PCT is less than 5%; then EPA uses 2.5%.

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 ziram 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 ziram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ziram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Water Calculator (PWC 1.52) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of ziram for acute exposures are estimated to be 103.7 parts per billion (ppb) for surface water and <0.001 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 2.74 ppb for surface water and <0.001 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 103.7 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 2.74 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).

There are no conventional residential uses of ziram. However, there is a registered use of exterior latex paint, an antimicrobial use, for ziram which could result in residential exposures. The registered antimicrobial use in exterior latex paint (in-can-preservative) may be used by a homeowner and applied either by airless sprayer or by brush. Short-term aggregate risk assessments were previously conducted for adults only; the sole registered scenario resulting in residential exposures. Residential handler risks are not of concern for the loading/application of exterior latex paints either by airless spray or brush (i.e., the combined dermal and inhalation MOE is > 100). Residential post-application inhalation exposures are expected to be negligible due to the low vapor pressure of ziram (1.4E-7 mmHg at 25° C) and low dermal contact potential to treated surfaces.

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."

The Agency reevaluated the existing data suggesting that the dithiocarbamates can be grouped based on a common mechanism of toxicity. The dithiocarbamates included were mancozeb, maneb, metiram, Na-dimethyldithiocarbamate, ziram, thiram, ferbam, and metam sodium. EPA concluded that the available evidence shows that the neuropathology induced by treatment of rats with the dithiocarbamates cannot be linked with the formation of carbon disulfide because: a) the neuropathology induced by the dithiocarbamates is not consistent with the neuropathology induced by exposure to carbon disulfide, b) there is a lack of concordance between doses of the dithiocarbamates that induce neuropathology and the amounts of carbon disulfide formed during metabolism and c) there is evidence that more than one mechanism of toxicity could be operative that accounts for dithiocarbamate induced neuropathology because there is no consistent pattern of neuropathology reported in studies with this subgroup of carbamates. Accordingly, the available evidence does not support grouping the dithiocarbamates based on a common mechanism for neuropathology. For the purposes of this tolerance action, therefore, EPA has assumed that ziram 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

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 quantitative or qualitative evidence of increase in susceptibility following *in utero* exposure to rats and rabbits and following pre-/postnatal exposure to rats in the developmental, the reproduction, and the acceptable DNT studies with ziram.

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 for all scenarios except acute dietary, for which the FQPA SF is being reduced to 3X. That decision is based on the following findings:

i. The toxicity database for ziram is adequate for evaluating and characterizing its toxicity, except for where a NOAEL is extrapolated from a LOAEL in the acute neurotoxicity study used as the endpoint for assessing acute dietary exposure. EPA has determined that a 3x FQPA SF to account for the extrapolation is sufficient to protect infants and children because of the impacts observed at the LOAEL were minimal and other studies did not show effects occurring at similar doses.

ii. There is indication that ziram is a neurotoxic chemical and an acceptable developmental neurotoxicity study has been submitted. A single oral dose resulted in ataxia in both sexes and slight impaired gait in males. Repeated short term oral exposure resulted in inhibition of brain cholinesterase in both sexes and brain neurotoxic esterase activity in male rats. Developmental neurotoxic effects were not observed in offspring of the most recent DNT study. Chronic dietary exposure in adult rats resulted in atrophy and reductions in crural muscle weights. Crural muscles function in the motion of the rodent's grasping foot claw.

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary and non-dietary exposure estimates were based on several conservative assumptions and will not underestimate the exposure and risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ziram in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ziram.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ziram will occupy 26% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ziram from food and water will utilize 1.4 % of the cPAD for Children 1-2, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of ziram is not expected.

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).

Ziram is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to ziram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result

in aggregate MOEs of 170 for adults. Because EPA's level of concern for ziram is a MOE of 100 or below, these MOEs are not of concern.

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). Because no intermediate-term adverse effect was identified, ziram is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. As discussed in Unit III.A., the Agency has determined that quantification of risk using a non-linear approach (*i.e.*, RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to ziram. Because the Agency's assessment indicates that aggregate exposure will be below the Agency's level of concern for chronic risk, the Agency concludes such exposure will not pose an aggregate cancer risk.

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 ziram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (colorimetric method, Method I) 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 a MRL for ziram.

C. Revisions to Petitioned-For Tolerances

EPA revised the 0.1 ppm value to 0.10 ppm based on the practice to add the additional significant figure to provide clarity about permissible residues. In addition, the commodity term for the tolerance was revised from filbert (hazelnut) to hazelnut to be consistent with the general food and feed commodity vocabulary EPA uses for tolerances and exemptions.

V. Conclusion

Therefore, tolerance is established for residues of ziram, zinc dimethyldithiocarbamate, in or on hazelnut at 0.10 ppm.

In addition, EPA is making a number of housekeeping adjustments to this rule. First, consistent with the Agency's policy for drafting the tolerance expression, EPA is

revising the tolerance expression to clarify that the tolerance covers residues of the parent as well as metabolites and degradates of the pesticide chemical in accordance with section 408(a)(3) of the FFDCA, and to clarify how residues of the chemical are to be measured to determine compliance with the tolerance levels. Second, because the tolerance for blackberries has expired by its terms, EPA is removing that tolerance from section 180.116. Finally, because no current tolerances have an expiration date, the third column is not necessary, so EPA is removing that column.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

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

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 9, 2017.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.116, revise paragraph (a) to read as follows:

§ 180.116 Ziram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide ziram (zinc dimethyldithiocarbamate), including its metabolites and degradates, in or on the commodities in the table below as a result of the application of ziram. Compliance with the tolerance levels specified below is to be determined by measuring total dithiocarbamates, determined as CS2, evolved during acid digestion and expressed as zinc ethylenebisdithiocarbamate.

Commodity	Parts per million
Almond	[1]0.10
Apple	[1]7.0
Apricot	[1]7.0
Blueberry	[1]7.0
Cherry, sweet	[1]7.0
Cherry, tart	[1]7.0
Grape	7.0
Hazelnut	0.10
Huckleberry	7.0
Peach	7.0

Pear	[1]7.0
Pecan	0.10
Quince	[1]7.0
Strawberry	7.0
Tomato	[1]7.0

[1]Some of these tolerances were established on the basis of data acquired at the public hearings held in 1950 (formerly §180.101) and the remainder were established on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Public Law 518, 83d Congress (68 Stat. 511).

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