EPA-APPROVED GEORGIA NON-REGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approval date	Explanation
Negative Declaration for Control of VOC Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment EPA–450/3–83–006, March 1984.	Atlanta 1997 8-Hour Ozone Nonattainment Area.	10/21/2009	09/28/2013	
Negative Declaration for Control of VOC Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry (SOCMI), EPA–450/3–84–015, December 1984.	Atlanta 1997 8-Hour Ozone Nonattainment Area.	10/21/2009	09/28/2013	
110(a)(1) and (2) Infrastructure Requirements for 1997 Fine Particulate Matter National Ambient Air Quality Standards.	Georgia	7/23/2008	4/12/2013	Addressing element 110(a)(2)(D)(i)(II) prong 3 only
110(a)(1) and (2) Infrastructure Requirements for 2006 Fine Particulate Matter National Ambient Air Quality Standards.	110(a)(1) and (2) Infrastructure Requirements for 1997 Fine Particulate Matter National Ambient Air Quality Standards.	10/21/2009	4/12/2013	Addressing element 110(a)(2)(D)(i)(II) prong 3 only
1997 8-Hour Ozone Reasonable Further Progress Plan for Atlanta Area.	Atlanta 1997 8-Hour Ozone Nonattainment Area.	10/21/2009	5/29/2013	

[FR Doc. 2013–12467 Filed 5–28–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0780; FRL–9387–1]

Triforine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of triforine in or on blueberry and tomato. Summit Agro North America Holding Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 29, 2013. Objections and requests for hearings must be received on or before July 29, 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–2011–0780, 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: Heather Garvie, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–0034; email address: *garvie.heather@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–2011–0780 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 July 29, 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–2001–0780, 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 November 9, 2011 (76 FR 69690) (FRL–9325–1), 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 1E7911) by Summit Agro North America Holding Corporation, 600 Third Avenue, New York, NY 10016–2001. The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the fungicide triforine, piperazine-1,4-diylbis(2,2,2-trichloroethane-1,1-diyl)diformamide [also more commonly known as triforine, (*N,N′*-[1,2-piperazinediylbis(2,2,2-trichloroethylidene)]bis[formamide])], in or on blueberry and tomato at 0.02 and 0.5 parts per million (PPM), respectively. That document referenced a summary of the petition prepared by Landis International, Inc. on behalf of Summit Agro North America Holding Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerance for blueberry from 0.02 ppm to 1.0 ppm. The reasons for this change are explained in Unit IV.D.

There are no registered food uses for triforine in the United States. These tolerances were requested in connection with use of triforine on tomatoes and blueberries grown overseas. These tolerances will allow blueberries and tomatoes containing triforine residues to be imported into the United States.

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 triforine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triforine 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 principal toxic effects of triforine are changes in the liver and hematopoietic system following repeated oral dosing, and the dog is the most sensitive species for the hematopoietic effects. Liver effects include increased liver weights, cholesterol and alkaline phosphatase levels. Toxicity was not observed in a rat 21-day dermal toxicity study at dose levels greater than the limit dose. Triforine is not acutely toxic *via* the oral, dermal, and inhalation routes. No developmental or reproductive toxicity was observed at doses below the limit dose. Triforine does not demonstrate neurotoxic or immunotoxic potential. Although the mouse study showed that triforine was associated with common tumors in the mouse, the EPA has determined that quantification of risk using a non-linear approach; i.e., reference dose (RfD), for triforine will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to triforine. That conclusion is based on the following considerations: (1) No carcinogenic response was seen in either sex in an acceptable rat cancer study; (2) the tumors found in the mouse are commonly seen in the mouse; (3) both tumors types were found only at the high dose, which was above the limit dose (males 1204, females 1507 milligrams/kilogram (mg/kg/day)); (4) triforine is not mutagenic; (5) each tumor type was observed in one sex only; i.e., liver tumors in male mice and lung tumors in female mice.

Specific information on the studies received and the nature of the adverse effects caused by triforine 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 *Triforine. Human Health Risk Assessment to Support Petition for the Establishment of Permanent Tolerances without U.S. Registration for Blueberries and Tomatoes* on pages 8 through 13 in docket ID number EPA–HQ–OPP–2011–0780.

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 an 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 triforine used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFORINE 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) ..	No hazard or appropriate acute endpoint was identified in the database.		
Chronic dietary (All populations)	NOAEL= 22 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.22 mg/kg/day. cPAD = 0.22 mg/kg/day	Subchronic/Chronic oral toxicity (dog) LOAEL = 120 mg/kg/day, based on decreased RBC, hematocrit, hemoglobin values and siderosis in the liver, spleen, and bone marrow.
Incidental oral short-term (1 to 30 days).	NOAEL= 22 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100.	Subchronic/chronic oral toxicity (dog) LOAEL = 120 mg/kg, based on decreased RBC, hematocrit, and hemoglobin values, increased spleen weight, and siderosis in the liver, spleen, and bone marrow.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 22 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100.	Subchronic/chronic oral toxicity (dog) LOAEL = 120 mg/kg, based on decreased RBC, hematocrit, and hemoglobin values, increased spleen weight, and siderosis in the liver, spleen, and bone marrow.
Dermal short-term (all durations).	No potential hazard *via* the dermal route based on the lack of systemic effects following repeat dermal exposure of rats at dose levels up to 1100 mg/kg/day which is greater than the limit dose. The endpoints of concern were all assessed in this study, and there is no developmental or reproductive concern at dose levels below the limit dose.		
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study. NOAEL= 22 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100.	Subchronic/chronic oral toxicity (dog) LOAEL = 120 mg/kg, based on decreased RBC, hematocrit, and hemoglobin values, increased spleen weight, and siderosis in the liver, spleen, and bone marrow.
Inhalation intermediate-term (1 to 6 months).	Inhalation (or oral) study. NOAEL = 22 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100.	Subchronic/chronic oral toxicity (dog) LOAEL = 120 mg/kg, based on decreased RBC, hematocrit, and hemoglobin values, increased spleen weight, and siderosis in the liver, spleen, and bone marrow.
Cancer (Oral, dermal, inhalation).	EPA has determined that quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity.		

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).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to triforine, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from triforine 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 triforine; therefore, a quantitative acute dietary exposure assessment was unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residues levels in food, EPA assumed tolerance level residues in the chronic

dietary assessment for these raw agricultural commodities (RACs). A processing study for tomatoes was submitted that showed no concentration of triforine residues in tomato paste and puree; therefore the RAC tolerance was used and the concentration factor were set to a value of ''1'' for all processed tomato products, with the exception of dried tomatoes. Empirical data are not available for this processed commodity, so the DEEM 7.81 default processing factor for dried tomatoes of 14.3 was included in the dietary risk assessment. In addition, the dietary assessment assumes that 100% of the blueberry, tomato, and tomato processed commodities consumed in the U.S. are imported, and further that all of the imports have been treated with triforine, effectively assuming 100 percent crop treated (PCT) for the two crops that are included in the dietary risk assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has determined that although the mouse study showed that triforine was associated with common tumors in the mouse, quantification of risk using a non-linear approach for triforine would adequately account for all chronic effects, including potential carcinogenicity that could result from exposure to triforine.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for triforine. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Since this petition requests tolerances without U.S. registration, establishing the requested tolerances will have no impact on domestic drinking water. However, for the purpose of this risk assessment, the most recent drinking water assessment dated March 5, 2008, which estimated residues resulting from the residential uses of triforine, was consulted. Along with the other risk assessments supporting this action, the drinking water assessment (DP 339605; K. Moore, 3/5/08) can be found in the triforine docket, EPA–HQ–OPP–2011–0780. Modeled estimated drinking water concentrations from those uses are included in this risk assessment. Surface water estimated drinking water concentrations (EDWCs) are based on first index reservoir screening tool (FIRST) modeling and represent untreated surface water concentrations. For surface water, the modeled EDWC for annual average exposure was 0.84 parts per billion (PPB). The one-in-10-year annual average concentration is used for chronic exposure assessments. Groundwater EDWCs are based on Screening Concentration in Ground Water (SCIGROW) modeling and represent the concentration that might be expected in shallow unconfined aquifers under sandy soils. For groundwater, the average exposure estimate is 0.43 ppb. The drinking water models and their descriptions are available at the EPA Internet site: *http://www.epa.gov/oppefed1/models/water/*. The highest annual average EDWC from the surface water model of 0.84 ppb was included in the chronic dietary risk assessment.

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). Triforine is currently registered for the following uses that could result in residential exposures: ornamentals including roses, trees, herbaceous plants, and woody shrubs and vines. There are no new residential uses with this petition; however, in order to complete the aggregate risk assessment, the Agency updated the residential exposure assessment. Because triforine does not pose a hazard by the dermal route of exposure, the residential handler assessment includes only inhalation exposure. The residential handler exposure assessment does not identify any residential handler risk concerns, in spite of representing worst case inhalation exposures. For post-application exposures, although a quantitative residential post-application exposure assessment was not performed, the Agency concluded that there is no concern for post-application exposures to triforine for the following reasons:

i. Since no dermal endpoints of concern were identified, there is also no concern for post-application dermal exposures.

ii. While the mouthing behaviors of children are also commonly addressed in post-application assessments, the Agency does not expect, based on the primary use pattern of triforine to control diseases on roses and other ornamental plants, children to routinely contact treated plants and engage in mouthing behaviors.

iii. Triforine is relatively non-volatile which, coupled with the dilution expected outdoors and the small amounts of active ingredient used diminish the possibility of post-application inhalation exposure. Moreover, the residential handler inhalation exposure assessment, which represents worst case inhalation exposures, and is considered protective of most post-application inhalation exposure scenarios. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

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 triforine to share a common mechanism of toxicity with any other substances, and triforine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triforine 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 of increased susceptibility following *in utero* exposure to triforine in either the rat or rabbit developmental toxicity study at dose levels up to the limit dose, and there is no evidence of increased susceptibility following *in utero* and/or pre-/post-natal exposure in the 2-generation reproduction study in rats at any dose levels, even those greater than the limit dose.

Triforine has been evaluated for potential developmental effects in the rat and rabbit (gavage administration). Maternal toxicity included decreased body weight and food consumption in rabbits at the limit dose, and maternal toxicity was not observed in rats at dose levels up to the limit dose. Decreased fetal body weight was observed in the rabbit at the limit dose, whereas there were no developmental effects in the rat at the limit dose (actual 840 mg/kg/day). Decreased fertility index and decreased testes weight was observed in F1 males in the 2-generation reproduction study only at a dose level greater than the limit dose.

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 toxicity database for triforine is complete.

ii. There is no indication that triforine is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. As indicated in Unit III.D.2., there is no evidence that triforine 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. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to triforine in drinking water. No risk is expected from the dermal route of exposure for children's postapplication exposure. Because of the use pattern, no incidental oral exposure is expected for children and no quantitative exposure assessment was conducted. These assessments will not underestimate the exposure and risks posed by triforine.

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-term, intermediate-term, 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, triforine 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 triforine from food and water will utilize <1% of the cPAD for the general U.S. population and all population subgroups. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of triforine is not expected; therefore the chronic aggregate risk includes food and drinking water only.

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). Triforine 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 triforine. The Agency conducted short-term aggregate risk assessments only for adult males and adult females since there are no short-term residential exposures for children. There are no oral residential exposures for adults and triforine does not pose a dermal hazard, so only residential inhalation exposure is included in the aggregate assessment. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential inhalation exposures result in aggregate MOEs of 46,000. Because EPA's level of concern for triforine is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Residential intermediate-term exposure is not anticipated; therefore an intermediate-term aggregate risk assessment is not necessary.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has determined that quantification of risk using a non-linear approach for triforine will be protective of all chronic effects including potential carcinogenicity. There are no chronic aggregate risks of concern and, therefore, there are no cancer aggregate risks of concern.

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 triforine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron capture detection) 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 triforine in or on blueberry and tomato at 1.0 and 0.5 ppm, respectively. These MRLs are the same as the tolerances being established for triforine in the United States.

C. Response to Comments

One comment was received in response to the notice filing. The commenter asked the Agency to deny the petition stating that * * * *''toxic effects to red blood cells and iron deposition in the wrong places is enough reason to deny this product.''* The comment also requested that all studies be verified by an independent lab. The Agency responds to this comment by stating that all toxicity studies required in accordance with new 40 CFR part 158 data requirements have been submitted. The studies available for consideration of triforine toxicity provide a comprehensive and complete database. The Agency has conducted a human health risk assessment with this database and has concluded that there are no risks of concern to human health from the requested use of triforine as demonstrated by the risk assessment. Only dietary exposure is expected for

the establishment of a tolerance on imported blueberries and tomatoes and adequate studies are available for consideration of this potential exposure scenario. All studies conducted on pesticide products to support applications for research or marketing should follow the Good Laboratory Practice (GLP) standards as stipulated in 40 CFR part 160 under FIFRA. When a registrant utilizes the service of a laboratory to conduct a study, they must notify the laboratory that the study should be conducted in accordance with this part (§ 160.10). Every study that is submitted to the Agency must include a statement that the study was conducted in accordance with this part (§ 160.12). Submission of a false statement may for the basis for cancellations, suspension, etc. EPA may refuse to consider reliable any data from a study which was not conducted in accordance with this part (§ 160.17). The Agency's Office of Enforcement and Compliance (OECA) conducts inspections of laboratory facilities for the purpose of compliance review to determine that the GLP regulations of FIFRA are being observed. This compliance review includes inspection of all raw data records, specimens and other entities as needed as stipulated in this part (§ 160.15). The toxicity studies used to assess the potential risks associated with exposure to triforine were conducted in compliance with 40 CR part 160, and included submission of all raw data as well as required GLP compliance statements. Further, Agency scientists conducted a thorough and independent review of these data during the registration process. The Agency has no objection to the establishment of tolerances without U.S. registrations for residues of triforine in or on blueberry and tomato.

D. Revisions to Petitioned-for Tolerances

The tolerance level for blueberry being established by the EPA differs from that proposed in the tolerance petition submitted by Summit Agro North America Holding Corporation. The Agency determined that the tolerance level of 1.0 ppm instead of 0.02 ppm for blueberry is needed so as to harmonize with the established Codex Maximum Residue Limits (MRL). This tolerance level will allow for full harmonization of both the residue definition and the tolerance level between the United States and Codex.

V. Conclusion

Therefore, tolerances are established for residues of triforine, (*N,N*′-[1,2-piperazinediylbis(2,2,2-trichloroethylidene)]bis[formamide]), including its metabolites and degradates, in or on tomato and blueberry at 0.5 and 1.0 ppm, respectively.

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: May 20, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Add § 180.1321 to read as follows:

§ 180.1321 Triforine; tolerances for residues.

(a) *General.* Tolerances are established for residues of triforine, including its metabolites and degradates. Compliance with the tolerance levels specified in the following table is to be determined by measuring only triforine (*N,N*′-[1,2-piperazinediylbis(2,2,2-trichloroehylidene)]bis[formamide]), in or on the following commodities.

Commodity	Parts per million
Blueberry [1]	1.0
Tomato [1]	0.5

[1] There are no U.S. registrations for blueberry and tomato.

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

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

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

[FR Doc. 2013–12461 Filed 5–28–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0558; FRL–9387–2]

Guar Hydroxypropyltrimethylammonium Chloride; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of guar hydroxypropyltrimethylammonium chloride (CAS Reg. No. 71329–50–5) when used as an inert ingredient (thickener/drift reduction agent) in pesticide formulations applied to growing crops. SciReg. Inc., on behalf of Rhodia Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of guar hydroxypropyltrimethylammonium chloride.

DATES: This regulation is effective May 29, 2013. Objections and requests for hearings must be received on or before July 29, 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–2012–0558, 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: William Cutchin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7099; email address: *cutchin.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://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–2012–0558 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 July 29, 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–2012–0558, 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. Petition for Exemption

In the **Federal Register** of September 28, 2012 (77 FR 59581) (FRL–9364–6), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8017) by SciReg. Inc., 12733 Director's Loop, Woodbridge, VA 22192 on behalf of Rhodia Inc. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of guar hydroxypropyltrimethylammonium chloride (CAS No. 71329–50–5) when used as an inert ingredient (thickener/drift reduction agent) in pesticide formulations applied to growing crops under 40 CFR 180.920. That notice referenced a summary of the petition prepared by Rhodia, Inc. the petitioner, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as