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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0116; FRL-9338-2]

Nitric Acid; 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 nitric acid (CAS Reg. No. 7697-37-2) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 1,000 parts per million (ppm). Ecolab 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 nitric acid**.**

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0116, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7894; e-mail address: *austin.lisa@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. Potentially affected entities may include, but are not limited to:

- 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-2012-0116 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0116, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.*

II. Petition for Exemption

In the **Federal Register** of April 7, 2000 (65 FR 18324) (FRL-6499-7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E6029) by Ecolab Inc., 370 N. Wabasha Street, St. Paul, MN 55102. The petition requested that 40 CFR 180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of nitric acid (CAS Reg. No. 7697-37-2) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 1,000 parts per million (ppm). That notice referenced a summary of the petition prepared by Ecolab Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in

establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for nitric acid including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with nitric acid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by nitric acid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Nitric acid is a highly corrosive inorganic acid. In a concentrated form, nitric acid is corrosive at the site of contact and does not elicit systemic toxicity. Acute dermal and eye exposures to concentrated forms of nitric acid can result in skin burns and irreversible eye corrosion. Acute inhalation exposure to nitric acid can result in severe respiratory irritation followed by pulmonary edema. Acute ingestion of nitric acid may result in ulceration, hemorrhage and perforation of the esophagus and stomach.

The U.S. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for nitric acid as well as the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) for nitric acid is 2 ppm (5 milligrams/meter (mg/m^3)).

While there are no data on the toxicity of dilute forms of nitric acid following oral exposure, the toxicity of dilute nitric acid would be expected to be comparable to the toxicity of the NO_3- anion known as nitrate.

Sodium nitrate. Several studies were available for sodium nitrate. These studies included a 6-week oral toxicity range-finding study, chronic/carcinogenicity studies in rodents and a 2-generation toxicity study in rabbits. In a 6-week oral toxicity study in F344 rats, sodium nitrate was administered in the diet. Signs of toxicity were manifested as decreased body weight gain at ≥5% (approximately 2,500 milligrams/kilograms/day (mg/kg/day)). In the International Agency for Research On Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans (Vol 94), the carcinogenic potential of sodium nitrate was evaluated in several studies in rodents. In two studies in mice, no evidence of carcinogenic activity of sodium nitrate alone was observed in the drinking water at concentrations up to approximately 5,000 mg/kg/day. In four studies in rats, no increased incidence of tumors was observed when sodium nitrate alone was administered in the drinking water or in the diet at concentrations up to approximately 2,500 mg/kg/day. Therefore, IARC concluded that there is inadequate evidence in humans for the carcinogenicity of nitrate in food or drinking water.

There were no treatment related effects observed in the 2-generation reproduction study in rabbits. In addition, the Food and Drug Administration (FDA) sponsored several reproductive and developmental studies in rodents, hamsters and rabbits treated with sodium nitrate. No adverse effects were observed in maternal reproductive parameters nor was there fetotoxicity or fetal malformations up to the maximum doses tested in each species (41 mg/kg/day in mice and hamsters and 66 mg/kg/day in rats and rabbits).

Immunotoxicity studies for nitric acid were not available for review. However, there was no evidence of potential immunotoxicity in any of the submitted studies. Therefore, nitric acid is not expected to be immunotoxic.

There were three human epidemiological studies available for review. These epidemiological studies reported that cases of infant methemoglobinemia are associated with exposure to nitrate in drinking water. The American Public Health Association (APHA) conducted a survey to identify clinical cases of infantile methemoglobinemia that were associated with ingestion of nitrate-contaminated water. They concluded that greater incidences of methemoglobinemia were observed in infants consuming >1.8 mg/kg/day of sodium nitrate. Methemoglobinemia was not observed in any of the studies where infants consumed water containing less than 1.6 mg/kg/day of sodium nitrate.

Specific information on the studies received and the nature of the adverse effects caused by nitric acid 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 "Nitric Acid; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pp. 9-26 in docket ID number EPA-HQ-OPP-2012-0116.

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*.

The chronic reference dose (cRfD) of 1.6 mg/kg/day and an uncertainty factor of 1X were established based on the results of the American Public Health Association's epidemiology study in infants. The endpoint was based on the concentration of sodium nitrate (1.6 mg/kg/day) in water at which methemoglobinemia was not observed in infants. Data from this study represented the most sensitive endpoint in the most sensitive population; therefore, the standard uncertainty factors were reduced to 1X.

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

Table —Summary of Toxicological Doses and Endpoints for Nitric Acid for Use in Human 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)	There were no effects that could be attributed to a single dose in the database. Therefore, an acute dietary assessment was not necessary.		
Chronic dietary (All populations)	NOAEL= 1.6 mg/kg/day U F_A = 1x UF_H = 1 x FQPA SF = 1x	Chronic RfD = 1.6 mg/kg/day cPAD = 1.6 mg/kg/day	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3 months old infants.
Incidental oral short-term (1 to 30 days)	NOAEL= 1.6 mg/kg/day UF_A = 1x UF_H = 1 x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3

			months old infants.
Incidental oral intermediate-term (1 to 6 months)	NOAEL= 1.6 mg/kg/day UF_A = 1x UF_H = 1x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3 months old infants.
Dermal short-term (1 to 30 days)	NOAEL= 1.6 mg/kg/day UF_A = 1x UF_H = 1x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3 months old infants.
Dermal intermediate-term (1 to 6 months)	NOAEL= 1.6 mg/kg/day UF_A = 1x UF_H = 1x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in

			excess of 10% in 0-3 months old infants.
Inhalation short-term (1 to 30 days)	NOAEL= 1.6 mg/kg/day (inhalation absorption rate = 100%) UF_A = 1x UF_H = 1x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3 months old infants.
Inhalation (1 to 6 months)	NOAEL= 1.6 mg/kg/day (inhalation absorption rate = 100%) UF_A = 1x UF_H = 1x FQPA SF = 1x	LOC for MOE = 1	APHA Human Epidemiological Survey LOAEL = 1.8-3.2 mg/kg/day based on early clinical signs of methemoglobinemia in excess of 10% in 0-3 months old infants.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic based on the lack of evidence of carcinogenicity in the submitted studies.		

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. UF_S = use of a short-term study for long-term risk

assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

In evaluating dietary exposure to nitric acid, EPA considered exposure under the petitioned-for exemption from the requirement of a tolerance. EPA assessed dietary exposures from nitric acid in food as follows:

The requested exemption from the requirement of a tolerance for the use of nitric acid could allow for uses in food contact surface sanitizing solutions in which residues of nitric acid could migrate to food or otherwise be ingested.

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to nitric acid, EPA considered exposure under the proposed exemption from the requirement of a tolerance. In the absence of actual dietary exposure data resulting from this use, the EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use of nitric acid in food contact sanitizing pesticide products. This same methodology has been utilized by EPA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of nitric acid can be found at *http://www.regulations.gov* in document "Nitric Acid; Human Health Risk Assessment and Ecological Effects

Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pp. 9-26 in docket ID number EPA-HQ-OPP-2012-0116.

EPA assessed dietary exposures from nitric acid in food as follows:

i. *Acute exposure*. No adverse effects attributable to a single exposure of nitric acid were seen in the toxicity databases. Therefore, an acute dietary exposure assessment for nitric acid is not necessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, the Agency believes the assumptions used to estimate chronic dietary exposures lead to an extremely conservative assessment of chronic dietary risk due to a series of compounded conservatisms. First, when a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). In the absence of any other data, EPA has used an estimated worst-case concentration of 1 mg of solution per square centimeter (cm) of treated surface area for this quantity.

Second, the conservatism of this methodology is compounded by EPA's decision to assume a worst case scenario that all food that an individual consumes will come into contact with 4,000 cm^2 of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility. The surface area of counter tops that comes in contact with food is expected to be smaller than the surface area for food utensils. As a conservative estimate, EPA assumed that 2,000 cm^2 of treated counter top surface area, comes into contact with an individual's food per day.

Third, EPA assumes that 100% of the material present on food contact surfaces will migrate to food.

iii. *Cancer*. Sodium nitrate did not cause an increase in tumors in rodents at doses up to 2,500 mg/kg/day. Therefore, based on the weight of evidence, nitric acid is not likely to cause cancer in humans and a cancer dietary exposure assessment is not necessary to assess cancer risk.

2. *Dietary exposure from drinking water***.** The proposed use of nitric acid will not result in its presence in surface water or ground water and therefore not contribute to dietary exposure.

3. *From non-dietary exposure***.** The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Nitric acid is not used as an inert ingredient in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. Therefore, a residential exposure and risk assessment was not conducted for nitric acid.

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 nitric acid to share a common mechanism of toxicity with any other substances, and nitric acid does not appear to produce a toxic metabolite produced

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

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) 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 concern for fetal susceptibility. There were no treatment related effects observed in the 2-generation reproduction study in rabbits. Also, the FDA sponsored several reproductive and developmental studies in rodents, hamsters and rabbits treated with sodium nitrate. No adverse effects were observed in maternal reproductive parameters nor was there fetotoxicity or fetal malformations up to the maximum doses tested in each species (41 mg/kg/day in mice and hamsters and 66 mg/kg/day in rats and rabbits). Fetal susceptibility was not observed

in these any of these studies. Therefore, there are no concerns for residual uncertainties concerning prenatal and postnatal toxicity.

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 nitric acid is adequate as it is based on the use of sodium nitrate data for which there is a robust toxicity database. The NOAEL used for risk assessment was derived from the critical toxic effect in the most sensitive human subpopulation (infants age 8 days to 5 months).

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

iii. There is no indication that nitric acid is a immunotoxic chemical and there is no need additional UFs to account for immunotoxicity.

iv. There is no evidence that nitric acid results in increased susceptibility in *in utero* rodents. Several reproductive and developmental studies in rodents, hamsters and rabbits showed no evidence of increased fetal susceptibility at doses as high as 41 mg/kg/day in mice and hamsters and 66 mg/kg/day in rats and rabbits. Further, although effects in infants were found in an epidemiological study, the cRfD (1.6 mg/kg/day) is based on a clear NOAEL established in that study.

v. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions regarding dietary exposure to nitric acid. This assessment will not underestimate the exposure and risks posed by nitric acid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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, nitric acid 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 nitric acid from dietary exposure will utilize 24% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for nitric acid.

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).

Because no short-term adverse effect was identified, nitric acid is not expected to pose a short-term risk.

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, nitric acid is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in adequate rodent carcinogenicity studies, nitric acid is not expected to pose a cancer risk to humans.

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 nitric acid residues under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180**.** 940(a) for residues of nitric acid when used as an inert ingredient in pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 1,000 ppm, is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. 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 nitric acid.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 940(a) for nitric acid (CAS No. 7697-37-2) when used as an inert ingredient in pesticide formulations applied to food-contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils at a maximum level in the end-use concentration of 1,000 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: August 17, 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. In §180.940(a), the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
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Nitric acid	7697-37-2	When ready for use, the end-use concentration is not to exceed 1,000 ppm.
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