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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0048; and EPA-HQ-OPP-2019-0327; FRL-10009-36]

Formic Acid and Sodium Formate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of formic acid when used as an inert ingredient limited to 25% in pesticide formulations applied to growing crops pre- and post-harvest (adjuvant, pH buffering agent, or pH adjuster) and applied in/on animals (pH adjuster). In addition, this rule establishes an exemption from the requirement of a tolerance for residues of sodium formate when used as an inert ingredient (adjuvant, pH buffering agent) in pesticide formulations applied to growing crops pre- and post-harvest. The Monsanto Company and the Spring Trading Company on behalf of Stoller Enterprises, Inc., submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of these exemptions. This regulation eliminates the need to establish a maximum permissible level for residues of formic acid and sodium formate when used in accordance with the terms of these exemptions.

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 dockets for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0048 and EPA-HQ-OPP-2019-0327 are 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 note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://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 40 CFR part 180 through the Government Publishing 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 numbers EPA-HQ-OPP-2019-0048 and/or EPA-HQ-OPP-2019-0327 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 numbers EPA-HQ-OPP-2019-0048 and/or EPA-HQ-OPP-2019-0327, 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. Petition for Exemption

In the **Federal Register** of May 13, 2019 (84 FR 20843) (FRL-9991-91), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11136) by Monsanto Company (1300 I Street, NW, Suite 450 East, Washington, DC 20005). The petition requested that 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of formic acid (CAS Reg No. 64-18-6) and sodium formate (CAS Reg No. 141-53-7) when used as inert ingredients (adjuvants, pH buffering agents) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910. In addition, in the **Federal Register** of August 2, 2019 (84 FR 37818) (FRL-9996-78), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11264) by the Spring Trading

Company (203 Dogwood Trail, Magnolia, TX 77354) on behalf of Stoller Enterprises, Inc. (9090 Katy Freeway, Suite 400, Houston, TX 77024). The petition requested that 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of formic acid (CAS Reg No. 64-18-6) when used as an inert ingredient (pH adjuster) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and applied in/on animals under 40 CFR 180.930. The documents referenced summaries of petitions prepared by Monsanto Company, LLC (docket EPA-HQ-OPP-2019-0048) and Spring Trading Company on behalf of Stoller Enterprises, Inc. (docket EPA-HQ-OPP-2019-0327). The documents are available in the aforementioned dockets, *http://www.regulations.gov*. No substantive, relevant comments were received on the notices 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 FFDCA section 408(c)(2)(A), 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 formic acid and sodium formate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with formic acid and sodium formate 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 formic acid and sodium formate 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 the document Formic Acid and Sodium Formate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations at page 7 in docket ID number EPA-HQ-OPP-2019-0048 and Formic Acid; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations at page 7 in docket ID number EPA-HQ-OPP-2019-0327.

Formic acid and sodium formate exist in an equilibrium in aqueous solutions and the toxicological profiles of formic acid and its salts are expected to be similar. Therefore, data on dissociative salts, such as sodium formate and potassium diformate are used to bridge data gaps for formic acid.

Formic acid and sodium formate are of low acute toxicity via oral, dermal and inhalation routes of exposure. They are not dermal or eye irritants in rabbits. They are not dermal sensitizers in the guinea pig .

Repeated dose oral toxicity studies, developmental, and 2-generation reproduction toxicity studies show that formic acid and sodium formate are not toxic at doses less than 1,000 mg/kg/day, the limit dose, in rats, mice and rabbits. Portal of entry effects are observed in toxicity studies via the inhalation route of exposure. Systemic effects are seen at a high dose in chronic oral toxicity and carcinogenicity studies in rats and mice. However, no cancers or tumors were observed; therefore, formic acid and sodium formate are not expected to be carcinogenic. Formic acid and sodium formate are not considered mutagenic based on negative results in the bacterial reverse mutation assay, mammalian cell gene mutation assay, mammalian cell cytogenetics assays.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

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*.

An acute toxicity endpoint was not identified for formic acid and sodium formate; therefore, an acute dietary assessment was not performed. The 52-, 80- and 104-week chronic/carcinogenicity toxicity studies in rats and mice are considered co-critical studies and are selected for the chronic dietary exposure scenario. The NOAELs are 400 mg/kg/day (142 mg/kg/day formic acid), and the lowest observed adverse effect levels (LOAELs) are 2,000 mg/kg/day (708 mg/kg/day formic acid) based on decreased reduced bodyweight gain and body weight. This represents the lowest NOAEL in the database in the most sensitive species. The developmental toxicity study in rats was selected for short-term incidental oral and dermal exposure scenarios. The NOAEL is 945 mg/kg/day, the highest dose tested. The LOAEL is not established. The 90-day oral toxicity in rats is selected for intermediate-term incidental oral and dermal exposure scenarios. The NOAEL is 3,000 mg/kg/day, the highest dose tested. The LOAEL is not established. The 2-week toxicity study via inhalation is selected for short-term inhalation exposure scenarios. The NOAEC is 31 ppm (18.36 mg/kg/day). The LOAEC is 64 ppm (36.72 mg/kg/day) based on squamous metaplasia, necrosis, and inflammation in the upper respiratory tract. The 90-day toxicity study via inhalation in mice is selected for intermediate-

and long-term inhalation exposure scenarios. The NOAEC is 32 ppm. The LOAEC is 64 based on degeneration of olfactory epithelia. The Food Quality Protection Act (FQPA) safety factor of 10x is applied to the inhalation exposure scenario only to account for the extrapolation from subchronic to chronic inhalation exposure scenarios. The standard inter- and intra-species uncertainty factors of 10x are applied. The default factor of 100% is applied for dermal and inhalation absorption rates.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to formic acid and sodium formate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from formic acid and sodium formate in food as follows:

No adverse effects attributable to a single exposure of endpoint was identified for formic acid and sodium formate; therefore, an acute dietary exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM-FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for formic acid and sodium formate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl

Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts," (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA-HQ-OPP-2008-0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of any active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product; however, formic acid is assessed at 25%. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally,

a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

In the dietary assessment, EPA also considered exposures due the use of formic acid as a miticide, as a direct and indirect food additive and its natural occurrence in some foods; and sodium formate as an indirect food substance. Based on information on the typical concentrations of and use patterns as a miticide, direct and indirect food additive, the Agency believes that exposures to formic acid and sodium formate that might result from these uses would be markedly less than the conservatively-estimated exposures resulting from pesticide use and would not meaningfully contribute to aggregate exposures.

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for formic acid and sodium formate, a conservative drinking water concentration value of 100 ppb

based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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).

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). Formic acid and sodium formate may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure. A conservative residential exposure and risk assessments were completed for pesticide products containing formic acid and sodium formate as inert ingredients. The Agency assessed pesticide products containing formic acid and sodium formate using exposure scenarios used by OPP's Antimicrobials Division to represent conservative residential handler exposure. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled: "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA-HQ-OPP-2008-0710).

Formic acid and sodium formate may be also be used in laundry detergents, rust remover, household cleaners, personal care products, and cosmetics. The Agency does not have sufficient data to quantitatively assess exposures to formic acid and sodium formate that might result from

these uses. However, based on the typical concentrations of and use patterns of formic acid and sodium formate, the Agency believes that exposures that might result from these uses would be markedly less than the conservatively estimated exposures resulting from pesticide use and would not meaningfully contribute to aggregate exposures.

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

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*. The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x for the assessment of all exposure scenarios except for the long-term inhalation exposure scenario for the following reasons. The toxicity database for formic acid and sodium formate contains subchronic, developmental, reproduction, chronic/carcinogenicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. No fetal susceptibility is observed in developmental toxicity studies in the rat and rabbit or the 2-generation reproduction toxicity study. Neither maternal, offspring nor reproduction toxicity is observed in any of the studies. The FQPA 10x safety factor is retained for the long-term inhalation exposure scenario to account for the extrapolation from the use of a subchronic inhalation toxicity study to chronic inhalation exposure scenarios. Therefore, based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x all exposure scenarios, except for long-term inhalation exposure scenarios in which the 10x is retained.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, formic acid and sodium formate are 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 formic acid and sodium formate from food and water will utilize 25% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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).

Formic acid and sodium formate are currently used as inert ingredients in pesticide products that are registered for uses that could result in short-term residential exposures; however, the Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with short-term residential exposures to formic acid and sodium formate. The mode of action of the toxicological effect must be the same across routes of exposure in order to aggregate the exposures; in this case, the toxic effects differ by route and duration. Therefore, to produce an aggregate risk estimate in situations in which it is not appropriate to aggregate exposures due to differing toxicological effects, risk measures are calculated separately for each route and duration for a given toxic effect for each hypothetical “individual.”

Short-term aggregated residential pesticidal dermal exposures can occur and result in an MOE of 1,184 for adults. Adult residential dermal exposure combines high-end handler dermal exposure from indoor aerosol spray/trigger pump and post-application dermal exposure to treated lawns. EPA has concluded the short-term aggregated residential pesticide dermal exposure results in an MOE of 1,184 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Short-term aggregated residential pesticidal inhalation exposures result in an MOE of 3,500 for adults. Adult residential inhalation exposure is based on high-end handler inhalation exposure from indoor aerosol spray/trigger pump. Post-application inhalation exposure is considered negligible. As the level of concern is for MOEs that are lower than 100, 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).

For reasons stated above, intermediate-term aggregated residential aggregated risks were calculated for each route of exposure. Intermediate-term pesticidal dermal exposures result in MOEs of 23,000 for adults. Adult residential dermal exposure is based on post-application exposure to treated lawns. Short-term aggregated residential pesticidal inhalation exposures result in an MOE of 3,500 for adults. Adult residential inhalation exposure is based on high-end handler inhalation exposure from indoor aerosol spray/trigger pump. Post-application inhalation exposure is considered negligible. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

5. *Long-term risks*. Long-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background

exposure level).

Long-term residential pesticidal uses of formic acid and sodium formate are not expected. However, long-term residential exposure is possible due to their use in household products, personal care products, and cosmetics. The Agency does not have sufficient data to quantitatively assess exposures to formic acid and sodium formate that might result from these uses. In the absence of actual residential exposure data resulting from such uses, the Agency considered information on the typical concentrations of and use patterns of household cleaning products, personal care products, and cosmetics containing formic acid and sodium formate. The available data indicate that exposures to formic acid and sodium formate that might result from these uses would be markedly less than the conservatively estimated exposures resulting from pesticide use. Therefore, the Agency believes that any contribution to aggregate exposure is negligible.

6. *Aggregate cancer risk for U.S. population*. Based on the lack of tumors in the carcinogenicity studies in rats and mice and the lack of mutagenicity, formic acid and sodium formate are not expected to be carcinogenic. Therefore, formic acid and sodium formate are not expected to pose a cancer risk to humans.

7. *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 formic acid and sodium formate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of formic acid and sodium formate in or on any

food commodities. EPA is establishing limitations on the amount of formic acid and sodium formate that may be used in pesticide formulations applied pre- and post-harvest. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq*. EPA will not register any pesticide formulation for food use that exceeds 25% of formic acid and sodium formate in the final pesticide formulation.

B. Revisions to Petitioned-for Tolerances

In concentrations above 25% of the formulation, formic acid has miticidal activity. Therefore, EPA is limiting the use of formic acid in pesticide formulations to 25% by weight to ensure that it is functioning as an adjuvant and pH buffering agent and not acting as a pesticide active ingredient.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of formic acid (CAS Reg No. 64-18-6), when used as an inert ingredient (adjuvant, pH buffering agent, or pH adjuster) limited to 25% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and when used as an inert ingredient (pH adjuster) applied in/on animals under 40 CFR 180.930. In addition, an exemption from the requirement of a tolerance is established for residues of sodium formate (CAS Reg No. 141-53-7) when used as an inert ingredient (adjuvant, pH buffering agent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest (under 40 CFR 180.910).

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA

section 408(d) in response to petitions 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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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 exemptions 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).

VIII. 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 29, 2020.

Michael Goodis,

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 §180.910, add alphabetically the inert ingredients "Formic Acid (CAS Reg. No. 64-18-6)"; and "Sodium Formate (CAS Reg No. 141-53-7)" to table 1 to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	*	* * *
Formic Acid (CAS Reg. No. 64-18-6)	25%	adjuvant, pH buffering agent, pH adjuster
* * *	*	* * *
Sodium Formate (CAS Reg No. 141-53-7)		adjuvant, pH buffering agent
* * *	*	* * *

2. In §180.930, add alphabetically the inert ingredient "Formic Acid (CAS Reg. No. 64-18-6)" to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Formic Acid (CAS Reg. No. 64-18-6)	25%	pH adjuster
* * *	* * *	*

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