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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0655; FRL-9953-82]

2-Pyrrolidinone, 1-butyl-; 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 2-pyrrolidinone, 1-butyl- (CAS Reg. No. 3470-98-2) when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops only at a concentration not to exceed 30% by weight under EPA regulations. SciReg. Inc. on behalf of Taminco U.S., Inc. a subsidiary of Eastman Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This rule eliminates the need to establish a maximum permissible level for residues of 2-pyrrolidinone, 1-butyl- when used in accordance with the regulations**.**

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-2015-0655, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael 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 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-2015-0655 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of*

publication in the **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0655, 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 October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10854) by SciReg Inc. (12733 Director's Loop, Woodbridge, VA 22192) on behalf of Taminco U.S., Inc. a subsidiary of Eastman Chemical Company (Two Windsor Plaza, Suite 400, 7540 Windsor Drive, Allentown, PA 18195). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-pyrrolidinone, 1-butyl- (CAS Reg. No. 3470-98-2), when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops only. That document referenced a summary of the petition prepared by SciReg. Inc. on behalf of Taminco U.S., Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. No relevant **c**omments were received on the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the concentration of 2-pyrrolidinone, 1-butyl- in final pesticide formulation not to exceed 30% w/w. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov in document* 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.

in docket ID number EPA-HQ-OPP-2015-0655.

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 2-pyrrolidinone, 1-butyl- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-pyrrolidinone, 1-butyl- 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 2-pyrrolidinone, 1-butyl- 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.

The oral LD_{50} for 2-pyrrolidinone, 1-butyl- in the rat is greater than 300 mg/kg. The dermal LD_{50} in the rat is > 2,000 mg/kg. It is moderately irritating to the eye of New Zealand White rabbits. It is slightly irritating to the skin of New Zealand White rabbits. It is not a skin sensitizer in mice in the local lymph node assay.

A 90-day subchronic oral toxicity study was conducted with Wistar rats exposed to 2-pyrrolidinone, 1-butyl- via gavage dose of 0, 10, 100, and 500 mg/kg/day, according to OECD Test Guideline 408. The following effects were considered to be treatment-related and adaptive in nature and, therefore, not adverse:

1. The microscopic liver changes in animals of either sex treated with 500 mg/kg/day and males treated with 100 mg/kg/day; however, these changes were not associated with blood chemistry changes. Therefore they were considered as an adaptive response.

2. The microscopic changes in the adrenals of males treated with 500 and 100 mg/kg/day and the microscopic thymus changes were not associated with any changes in the organ weights, therefore they were not considered as adverse effects. Minor changes in the kidney weights were not associated with any clinical chemistry changes or treatment related histopathological findings; therefore, it was not considered adverse. The NOAEL is 500 mg/kg/day.

A Prenatal development toxicity study was conducted with 2-pyrrolidinone, 1-butyl-, in accordance with OECD Test Guideline 414 using Pregnant Crl:CD(SD) rats exposed to the test item at concentrations of 0, 5, 50, or 500 mg/kg/day by oral gavage. Maternal toxicity was manifested as decreased food consumption and weight loss on days 6 to 19 of gestation at a dose level of 500 mg/kg/day. Developmental toxicity was manifested as decreased fetal weight in female fetuses at the same dose as maternal toxicity, 500 mg/kg/day. There was no evidence of fetal susceptibility. The NOAEL for developmental toxicity of 2-pyrrolidinone, 1-butyl- was determined to be 50 mg/kg/day.

Since there is a wide dose spread in the developmental toxicity study in rats, a benchmark dose (BMD) modeling was conducted using decreased fetal weight as an adverse effect. The BMD value is 306 mg/kg/day and the average BMDL is 201 mg/kg/day for a 5% response in decreased fetal body weight.

Carcinogenicity data are not available for 2-pyrrolidinone, 1-butyl-. In the 90-day toxicity study, the liver, kidney, thymus, and adrenals were target organs, however, they were considered as adaptive response at the dose levels tested. Evaluation of the database for N-methylpyrrolidone (NMP) shows similar target organ toxicity as 2-pyrrolidinone, 1-butyl- (structurally related chemicals differing only in carbon chain length (1 vs 4 carbon chain length)) and 1-ethylpyrrolidin-2-one (NEP) (2 carbon chain length), as both chemicals are considered suitable surrogates for evaluation. Neither 2-pyrrolidinone, 1-butyl-, N-methylpyrrolidone, nor 1-ethylpyrrolidin-2-one was found to be genotoxic or mutagenic in a number of assays. In carcinogenicity studies, N-methylpyrrolidone was not carcinogenic in two-year rat studies by the inhalation and dietary routes of exposure. An increased incidence of liver adenomas and carcinomas was seen in mice exposed to a

dietary level of N-methylpyrrolidone exceeding 1,000 mg/kg/day for 18 months. However, based on the lack of mutagenicity or genotoxicity and the similarity of 2-pyrrolidinone, 1-butyl- to n-methylpyrrolidone, it can be concluded that 2-pyrrolidinone, 1-butyl- should not be considered as potentially carcinogenic at doses below the limit dose of 1,000 mg/kg/day.

The mutagenic potential of 2-pyrrolidinone, 1-butyl- was assessed in the *Salmonella typhimurium* reverse mutation assay, mammalian cell gene mutation and micronucleus tests. 2-Pyrrolidinone, 1-butyl- was negative in all assays. Therefore, 2-pyrrolidinone, 1-butyl- is not considered mutagenic nor clastogenic.

There were no studies/data directly related to the possible neurotoxicity of 2-pyrrolidinone, 1-butyl. However, evidence of potential neurotoxicity was not observed in functional observation battery (FOB) performed in the 90-day oral toxicity study in the rat. Therefore, pyrrolidinone, 1-butyl is not expected to be neurotoxic.

There were no studies/data directly related to the immunotoxicity of 2-pyrrolidinone, 1-butyl. Thymic atrophy was observed at >100 mg/kg/day in rats treated with 2-pyrrolidinone, 1-butyl for 90 days via gavage. However, microscopic changes in thymus were considered as an adaptive response and not as an adverse effect.

There were no studies/data directly related to the metabolism, of 2-pyrrolidinone, 1-butyl.

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*.

For purposes of risk assessment, the Agency utilizes the toxicity point of departure identified in the developmental toxicity study in rats for chronic dietary assessment, residential exposure assessment and all dermal and inhalation exposure durations. Since there was a large dose spread, a benchmark dose modeling (BMD) assessment was conducted. The average benchmark model lower confidence limit (BMDL) is 201 mg/kg/day for a 5 % response which was based on a 5 % decreased fetal body weight. The BMDL of 201 mg/kg/day is used as a point departure for the risk

assessment. An uncertainty factor of 10X is applied for interspecies extrapolation and an uncertainty factor of 10X is applied for intraspecies variation. The Food Quality Protection Act factor is reduced to 1X. Therefore, the Agency's level of concern is for Margins of Exposure (MOE) less than 100. No endpoint of concern was identified for acute dietary assessment in the database. Although there was a decrease in body weights in maternal animals on GD7 in the developmental toxicity study in rats, this effect is not considered relevant for acute dietary exposure assessment since the body weights returned to normal on GD8. A cancer risk assessment was not conducted because the Agency concluded that 2-pyrrolidinone, 1-butyl is unlikely to be carcinogenic at the anticipated dietary exposure levels. Dermal and inhalation absorption is assumed 100% of the oral equivalent dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to 2-pyrrolidinone, 1-butyl-, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-pyrrolidinone, 1-butyl- in food as follows:

Dietary exposure (food and drinking water) to 2-pyrrolidinone, 1-butyl- can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of 2-pyrrolidinone, 1-butyl- are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 3.16, and 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). One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 30% by weight of 2-pyrrolidinone, 1-butyl- in pesticide formulations applied to food.

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 residues of 2-pyrrolidinone, 1-butyl- 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 assessment. This value was 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).

2-Pyrrolidinone, 1-butyl- may be used as an inert ingredient in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted a screening level assessment to represent worst-case residential exposure by assessing 2-pyrrolidinone, 1-butyl- in pesticide formulations (Outdoor Scenarios) and in disinfectant-type uses (Indoor Scenarios).

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 2-pyrrolidinone, 1-butyl- to share a common mechanism of toxicity with any other substances, and 2-pyrrolidinone, 1-butyl do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-pyrrolidinone, 1-butyl- 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 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*. A developmental toxicity study in rats was available with 2-pyrrolidinone, 1-butyl. Fetal susceptibility was not observed. Maternal

and developmental toxicity were observed at the same dose, 500 mg/kg/day, the highest dose tested.

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 2-pyrrolidinone, 1-butyl is adequate for FQPA assessment. It includes a 90-day rat oral toxicity study with FOB measurements, a prenatal developmental study in rats, acute toxicity studies and mutagenicity studies.

ii There is no evidence of increased susceptibility in the database. There are no concerns for the lack of 2-generation reproduction study because the male and female reproductive parameters were evaluated in the 90-day study and no evidence of fetal susceptibility was seen in the rat developmental toxicity study in rats.

iii. There were no studies/data directly related to the possible neurotoxicity of 2-pyrrolidinone, 1-butyl. However, no evidence of potential neurotoxicity was observed in the functional observation battery (FOB) performed in the 90-day oral toxicity study in the rat. Therefore, pyrrolidinone, 1-butyl is not expected to be neurotoxic.

iv. There were no studies/data directly related to the immunotoxic potential of 2-pyrrolidinone, 1-butyl. However, no evidence of potential immunotoxicity was observed in the 90-day oral toxicity study in rats. EPA concluded that the immunotoxicity study is not required at this time.

v. The dietary food exposure assessment utilizes proposed tolerance level or higher residues and 100% crop treated (CT) information for all commodities. In addition, a conservative drinking water concentration value of 100 parts per billion (ppb) was used to assess the contribution to drinking water. By using these screening-level assessments, chronic exposures/risks will not be underestimated.

Taking into consideration the available information, EPA concludes the additional 10X FQPA safety factor be reduced to 1X.

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, 2-pyrrolidinone, 1-butyl- 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, 2-pyrrolidinone, 1-butyl- from food and water will utilize 21.1 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

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

2-Pyrrolidinone, 1-butyl- may be used as inert ingredients in pesticide products that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to 2-pyrrolidinone, 1-butyl-. Using the exposure assumptions described above, EPA has concluded that the combined short-term and intermediate-term aggregated food, water, and residential exposures result in an MOE of 350 for both adult males and females respectively. Adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, wiping with a high-end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined short-term and intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 218 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOEs is not of concern.

4. Aggregate cancer risk for U.S. population. Based on lack of carcinogenicity for N-methyl pyrrolidone (a surrogate chemical of 2-pyrrolidinone, 1-butyl-), 2-pyrrolidinone, 1-butyl- is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-pyrrolidinone, 1-butyl- 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 2-pyrrolidinone, 1-butyl- in or on any food commodities. EPA is establishing a limitation on the amount of 2-pyrrolidinone, 1-butyl- that may be used in pesticide formulations applied to growing crops. That limitation 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 use on growing crops for sale or distribution that exceed 30% of 2-pyrrolidinone, 1-butyl-.

B. Revision to Petitioned-for Tolerances.

The submitter requested an unlimited use of *2*-pyrrolidinone, 1-butyl in pesticide formulations under 180.920. However, MOEs for the aggregate residential exposure exceeded the Agency's level of concern; therefore the refinement was made using 30% maximum concentration in the final formulation. At that concentration level, the Agency is able to support the safety finding for the inert tolerance exemption; therefore, the Agency is limiting the tolerance exemption to cover residues of *2*-pyrrolidinone, 1-butyl only when used at levels not to exceed 30% by weight in pesticide formulations.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for residues of 2-pyrrolidinone, 1-butyl- (CAS Reg. No. 3470-98-2) when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops at a concentration not to exceed 30% by weight in the end-use formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption to the requirement for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption 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: October 20, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In §180.920, add alphabetically the inert ingredient "2-Pyrrolidinone, 1-butyl- (CAS Reg. No. 3470-98-2)" to the table to read as follows:

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

***** ***** ***** ***** *****

Inert ingredients	Limits	Uses
***	*	***
2-Pyrrolidinone, 1-butyl- (CAS Reg. No. 3470-98-2)	Not to exceed 30% by weight of pesticide formulation	Solvent/cosolvent
***	*	***

[FR Doc. 2016-27212 Filed: 11/9/2016 8:45 am; Publication Date: 11/10/2016]