East Niagara River within a 210-foot radius of land position 43°01′17.8″ N, 078°52′40.9″ W in Tonawanda, NY, from 9:15 p.m. through 10:05 p.m. on July 23, 2023.

(2) *Oswego Harborfest, Oswego, NY;* The safety zone listed in (b)(28) will be enforced on all waters within a 600-foot radius of positions 43°28.014′ N, 76°31.174″ W and 43°27.867′ N,76°31.446′ W along with a 350 foot radius of the break wall between positions 43°27′53.0″ N, 076°31′25.3″ W then Northeast to 43°27′58.6″ N, 076°31′12.1″ W, from 9:15 p.m. through 10:15 p.m. on July 29, 2023.

(3) *Thunder on the Niagara Hydroplane Boat Races, North Tonawanda, NY;* The safety zone listed in Table 165.939 (c)(4) as All U.S. waters of the Niagara River near the North Grand Island Bridge, encompassed by a line starting at 43°03′32.9″ N, 078°54′46.9″ W to 43°03′14.6″ N, 078°55′16.0″ W then to 43°02′39.7″ N, 078°54′13.1″ W then to 43°02′59.9″ N, 078°53′42.0″ W and returning to the point of origin will be enforced from 8:30 a.m. through 6:30 p.m. on August 5, 2023, and 8:30 a.m. through 6:30 p.m. on August 6, 2023.

This notice of enforcement is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552(a). Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within these safety zones during an enforcement period is prohibited unless authorized by the Captain of the Port Buffalo or their designated representative; designation need not be in writing. Those seeking permission to enter these safety zones may request permission from the Captain of the Port Buffalo via channel 16, VHF–FM. Vessels and persons granted permission to enter the safety zone shall obey the directions of the Captain of the Port Buffalo or their designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement periods via Broadcast Notice to Mariners or other suitable means. If the Captain of the Port Buffalo determines that the safety zone need not be enforced for the full duration stated in this notice, they may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

This notification is being issued by the Coast Guard Sector Buffalo Prevention Department Head at the direction of the Captain of the Port.

Dated: July 17, 2023.

Jeff B. Bybee,

Commander, U.S. Coast Guard, Sector Buffalo Prevention Department Head.

[FR Doc. 2023–15697 Filed 7–24–23; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0172; FRL–11166–01–OCSPP]

N-(n-Octyl)-2-pyrrolidone in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in pesticide formulations containing prothioconazole as an active ingredient at a maximum concentration of 15% by weight. International Specialty Products submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the exemption. This regulation eliminates the need to establish a maximum permissible level for residues of N-(n-octyl)-2-pyrrolidone, when used in accordance with the terms of the exemption.

DATES: This regulation is effective July 25, 2023. Objections and requests for hearings must be received on or before September 25, 2023 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–2021–0172, 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 and the OPP docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 **Federal Register** Office's e-CFR site at *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180?toc=1.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2021–0172 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 September 25, 2023. 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–2021–0172, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets#express.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of March 22, 2021 (86 FR 15162, FRL–10021–44), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11526) by International Specialty Products, an Ashland Inc. Company, 1005 US 202/206, Bridgewater, NJ 08807. The petition requested that 40 CFR 180.1130 be amended by establishing an exemption from the requirement of a tolerance for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in pesticide formulations containing prothioconazole at a maximum concentration of 15%. That document referenced a summary of the petition prepared by the petitioner, which is available in the docket, *https://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(c)(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. When making a safety determination for an exemption for the requirement of a tolerance FFDCA section 408(c)(2)(B) directs EPA to take into account the considerations in section 408(b)(2)(C) and (D). 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. . . .'' Section 408(b)(2)(D) lists other factors for EPA's consideration in making safety determinations, *e.g.,* the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among other factors.

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 harm 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 N-(n-octyl)-2-pyrrolidone, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with N-(n-octyl)-2-pyrrolidone 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 N-(n-octyl)-2-pyrrolidone 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.

N-(n-octyl)-2-pyrrolidone has low acute toxicity via the oral and dermal routes. N-(n-octyl)-2-pyrrolidone is considered extremely irritating to the eyes and skin and is a dermal sensitizer. No acute inhalation study was available in the database for N-(n-octyl)-2-pyrrolidone alone; however, a product containing N-(n-octyl)-2-pyrrolidone and prothioconazole showed low concern for acute inhalation toxicity.

Clinical signs of neurotoxicity (*e.g.,* increased salivation, hunched posture, abnormal gait, and lethargy) are the most sensitive and common effects observed throughout the database following repeated dosing. These effects were observed in a 28-day study in rats, 13-week study in dogs, and a developmental toxicity study in rats.

No carcinogenicity studies were available in the database for N-(n-octyl)-2-pyrrolidone. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential carcinogenicity for N-(n-octyl)-2-pyrrolidone. No structural alerts for carcinogenicity were identified for N-(n-octyl)-2-pyrrolidone. In the

absence of any structural alerts and lack of mutagenicity in available mutagenicity and genotoxicity studies, N-(n-octyl)-2-pyrrolidone is not expected to be carcinogenic. The is no evidence of offspring susceptibility, reproduction toxicity, or teratogenicity in the available developmental toxicity study in rats and the 1-generation reproduction toxicity study in rats.

No immunotoxicity or neurotoxicity studies were available in the database for N-(n-octyl)-2-pyrrolidone. However, no evidence of immunotoxicity was observed in the available database, and the selected endpoints are protective of the neurotoxicity effects observed in the database.

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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.*

A summary of the toxicological endpoints for N-(n-octyl)-2-pyrrolidone used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR N-(N-OCTYL)-2-PYRROLIDONE 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 (General population including infants and children).	An acute effect was not found in the database; therefore, an acute dietary assessment is not necessary.		
Chronic dietary (All populations).	NOAEL= 90 mg/kg/day UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	Chronic RfD = 90 mg/kg/day. cPAD = 0.9 mg/kg/day.	[13-week oral Toxicity-dog] LOAEL = 240 mg/kg/day based on neurological effects.
Incidental oral short-term (1 to 30 days).	NOAEL= 90 mg/kg/day UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	LOC for MOE <100	[13-week oral Toxicity-dog] LOAEL = 240 mg/kg/day based on neurological effects.
Dermal short-term (1 to 30 days) and Dermal intermediate-term (1 to 6 months).	Dermal (or oral) study NOAEL = 90 mg/kg/day (dermal absorption rate = 100%). UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	LOC for MOE <100	[13-week oral Toxicity-dog] LOAEL = 240 mg/kg/day based on neurological effects.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Inhalation (or oral) study NOAEL = 90 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10 × UF_H = 10 × FQPA SF = 1 ×	LOC for MOE <100	[13-week oral Toxicity-dog] LOAEL = 240 mg/kg/day based on neurological effects.
Cancer (Oral, dermal, inhalation).	Based on the lack of mutagenicity in N-(n-octyl)-2-pyrrolidone and the absence of structural alerts in the DEREK analysis for N-(n-octyl)-2-pyrrolidone, there is low concern for carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to N-(n-octyl)-2-pyrrolidone, EPA considered exposure under the proposed exemption from the requirement of a tolerance and existing food uses. Dietary exposure may also occur from non-pesticidal uses but no reliable information is available for non-pesticidal exposures. Therefore, EPA assessed dietary exposures from pesticidal uses of N-(n-octyl)-2-pyrrolidone only. EPA assessed dietary exposures from N-(n-octyl)-2-pyrrolidone in food as follows:

i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were not identified for N-(n-octyl)-2-pyrrolidone.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment using DEEM–FCID, Version 4.02, EPA used food consumption information from USDA's 2005–2010 NHANES/WWEIA. As to residue levels in food, no residue data were submitted for N-(n-octyl)-2-pyrrolidone. 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 ''Update to D361707: Dietary Exposure and Risk Assessments for the Inerts.'' (12/21/2021), which can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2018–0090.

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 the active ingredient. While the current request is for use of N-(n-octyl)-2-pyrrolidone with the active ingredient prothioconazole at a limit of 15% in pesticide formulations, there are already existing food uses with other active ingredients up to 20% in pesticide formulations. In order to cover all possible exposure, the dietary exposure assessment utilized the 20% limitation in pesticide formulations except for all commodities except cotton, for which the assessment utilized a default 50% concentration.

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 and often can be much higher. 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.

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 N-(n-octyl)-2-pyrrolidone, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for N-(n-octyl)-2-pyrrolidone. 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).

N-(n-octyl)-2-pyrrolidone may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure (*e.g.,* products used in and around the home). Although there are non-pesticidal uses for N-(n-octyl)-2-pyrrolidone, no reliable exposure information is available for those uses. Therefore, a conservative residential exposure and risk assessment was completed for uses of N-(n-octyl)-2-pyrrolidone as a pesticide inert ingredient only. The Agency assessed pesticide products containing N-(n-octyl)-2-pyrrolidone using exposure scenarios that represent conservative residential handler exposure.

Short-term and intermediate-term residential exposure for adults combines high-end dermal and inhalation handler exposure from indoor hard surface, aerosol sprays and results in a margin of exposure (MOE) of 210. Short-term and intermediate-term high-end post-application dermal exposure from contact with mopping/wiping results in an MOE of 520. Short-term residential exposure for children includes total exposures associated with contact with indoor hard surface, aerosol sprays result in an MOE of 250. Because EPA's level of concern (LOC) for N-(n-octyl)-2-pyrrolidone is an MOE below 100, these MOEs are not of concern.

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 N-(n-octyl)-2-pyrrolidone to share a common mechanism of toxicity with any other substances, and N-(n-octyl)-2-pyrrolidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that N-(n-octyl)-2-pyrrolidone 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act safety factor. 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.

The Agency has concluded that the FQPA safety factor can be reduced to 1x for N-(n-octyl)-2-pyrrolidone for all exposure scenarios for the following reasons:

i. The toxicity database for N-(n-octyl)-2-pyrrolidone consists of a developmental toxicity study and 1-generation reproduction study. There is no evidence of effects on reproductive parameters in the 1-generation reproduction study, and the offspring effects observed in the database occurred at the same or higher doses than parental effects. Therefore, there is no evidence of increased susceptibility in the database.

ii. Additionally, the most sensitive endpoint selected, seen in the 13-week oral toxicity study on dogs, is protective of neurotoxic and all other effects observed in the database.

iii. There are no residual uncertainties identified in the exposure databases. As described earlier, EPA used worst case assumptions for the dietary food exposure assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to N-(n-octyl)-2-pyrrolidone in drinking water. EPA used similarly conservative assumptions to assess residential post application exposure of children as well as incidental oral exposure of children 1–2. These assessments will not underestimate the exposure and risks posed by N-(n-octyl)-2-pyrrolidone.

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, N-(n-octyl)-2-pyrrolidone is not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account chronic exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to N-(n-octyl)-2-pyrrolidone from food and water will utilize 45.9% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

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

N-(n-octyl)-2-pyrrolidone is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short- and intermediate term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate term residential exposures to N-(n-octyl)-2-pyrrolidone.

Using the exposure assumptions described in this unit for short- and intermediate term exposures, EPA has concluded that the combined short- and intermediate term food, water, and residential exposures result in an aggregate MOE of 126 for adults. Adult residential pesticide exposure combines high-end dermal and inhalation handler exposure from indoor hard surface aerosol spray with high end post-application dermal exposure from indoor mopping/wiping. EPA has concluded that the combined short- and intermediate term food, water, and residential exposures result in an aggregate MOE of 121 for children. Children's residential pesticide exposure includes total exposures associated with contact with treated indoor surfaces (mopping/wiping; dermal and hand-to-mouth exposures). Because EPA's level of concern for N-(n-octyl)-2-pyrrolidone is an MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the absence of structural alerts for potential carcinogenicity in the database and the lack of mutagenicity concerns, N-(n-octyl)-2-pyrrolidone 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 N-(n-octyl)-2-pyrrolidone residues. More detailed information on this action can be found in the document titled ''IN–11526; N-(n-octyl)-2-pyrrolidone: Human Health Risk and Ecological Effects Assessment of a Food Use Pesticide Inert Ingredient'' in docket ID EPA–HQ–OPP–2021–0172.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of N-(n-octyl)-2-pyrrolidone in or on any food commodities. EPA is establishing a limitation on the amount of N-(n-octyl)-2-pyrrolidone that may be used in pesticide formulations. This 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 prothioconazole pesticide formulation for food use that exceeds 15% N-(n-octyl)-2-pyrrolidone in the final pesticide formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of N-(n-octyl)-2-pyrrolidone (CAS Reg. No. 2687–94–7) when used as an inert ingredient (solvent) in pesticide formulations containing prothioconazole at a maximum concentration of 15% under 40 CFR 180.1130.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of 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 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: July 19, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Amend § 180.1130 by adding paragraph (c) to read as follows:

§ 180.1130 N-(n-Octyl)-2-pyrrolidone and N-(n-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.

* * * * *

(c) *N*-(n-Octyl)-2-pyrrolidone is exempt from the requirement of a tolerance when used as a solvent in formulations containing prothioconazole as an active ingredient at a concentration not to exceed 15% by weight.

[FR Doc. 2023–15679 Filed 7–24–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0479; FRL–11131–01–OCSPP]

Indaziflam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indaziflam in or on multiple commodities discussed later in this document. Bayer CropScience has requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 25, 2023. Objections and requests for hearings must be received on or before September 25, 2023, 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–2022–0479, is available at *https://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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-