



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2020-0225; FRL-8572-01-OCSP]

### Ipflufenquin; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of ipflufenquin in or on almond, almond, hulls, and fruit, pome, group 11-10. Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**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-2020-0225, 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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, 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](mailto: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-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *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-2020-0225 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).

Despite the regulatory instructions to submit objections or hearing requests via U.S. Mail or hand delivery, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), [https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10\\_-\\_order\\_urging\\_electronic\\_service\\_and\\_filing.pdf](https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf). At this time, because of the COVID-19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system, at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_upload.nsf](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

Although EPA's regulations require submission via U.S. Mail or hand deliver, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.*, the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564-6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania

Ave., NW, Washington, DC 20460.

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-2020-0225, 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/contacts.html>.

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

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of May 29, 2020 (85 FR 32338) (FRL-10009-84), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8801) by Nippon Soda Co., Ltd., Shin-Ohtemachi Bldg. 2-1, 2-Chome Ohtemachi Chiyoda-ku, Tokyo 100-8165, Japan. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide ipflufenquin, 2-[2-(7,8-difluoro-2-methylquinolin-3-yloxy)-6-fluorophenyl]propan-2-ol, in or on almond at 0.10 ppm; almond hulls at 3.0 ppm; and pome fruit (Crop Group 11-10) at 0.15 ppm; and tolerances for residues for ipflufenquin, QP-1-14, QP-1-10, QP-1-11, and QP-1-15 (in terms of ipflufenquin) on cattle, fat at 0.010 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.010 ppm; dairy

cattle milk at 0.01 ppm; goat, fat at 0.010 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.010 ppm; horse, fat at 0.010 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.010 ppm; sheep, fat at 0.010 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.010 ppm. That document referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has concluded that tolerances for residues of ipflufenquin in livestock commodities are not needed and is establishing the tolerances for almond, almond hulls, and pome fruit with several minor adjustments. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

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

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

with ipflufenquin follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary targets of ipflufenquin in rodents are teeth, the liver, thyroid, hematological system, and intestines. Tooth effects included discoloration, enamel hypoplasia, dysplasia and abrasion of the incisors. Liver effects included changes in liver weight and histopathological changes (increased single cell necrosis, bile duct hyperplasia, and hepatocellular mitotic figures). Thyroid effects were limited to follicular cell hypertrophy. Effects in the hematological system included decrease in red blood cells, hemoglobin and hematocrits, and increases in spleen weight, prothrombin time and erythropoiesis of the spleen. However, these hematological effects were considered mild and occurred at the same or higher doses than the tooth effects. Intestinal findings included black content, minimal cellular infiltration in the lamina propria of the colon, minimal hyperplasia epithelium and minimal regeneration of the surface epithelium in the colon. Intestinal and thyroid effects occurred at the same doses where tooth effects were observed only in the subchronic studies in rats. Tooth effects including discoloration, enamel hypoplasia, dysplasia and abrasion of the incisors were observed throughout the ipflufenquin database in rodents only. The toxicology database showed no adverse toxicological effects were observed in dogs.

Potential signs of neurotoxicity were observed in the acute neurotoxicity (ACN) study, but only in one sex at the highest doses. No changes in motor activity were observed in a 13-week oral study in rats. No developmental or maternal effects were reported in the developmental studies in rats and rabbits. No treatment-related reproductive effects were reported in the reproductive toxicity study in rats. Decreased pup body weight was observed at

the same doses where parental toxicity was observed.

Although no immunotoxicity study is available for ipflufenquin, no evidence of immunotoxicity was observed in other submitted studies. No systemic toxicity was observed in a dermal study in rats up to the limit dose. Ipflufenquin is classified as “Not likely to be carcinogenic to humans”.

Specific information on the studies received and the nature of the adverse effects caused by ipflufenquin 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 <https://www.regulations.gov> in document “Ipflufenquin. Human Health Risk Assessment for Proposed Section 3 Registration of the New Active Ingredient for Uses on Pome Fruit (Crop Group 11-10) and Almond.” (hereinafter “Ipflufenquin Human Health Risk Assessment”) at page 37 in docket ID number EPA-HQ-OPP-2020-0225.

#### *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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

A summary of the toxicological endpoints for ipflufenquin used for human risk assessment can be found in the Ipflufenquin Human Health Risk Assessment.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ipflufenquin, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from ipflufenquin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for ipflufenquin; therefore, a quantitative acute dietary exposure assessment is unnecessary. An acute dietary exposure assessment was not required because no endpoint attributable to a single dose was identified in the ipflufenquin database.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003-2008 food consumption data from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America. EPA conducted an unrefined chronic dietary exposure assessment using tolerance-level residues, 100% crop treated assumptions, the Agency's 2018 default processing factors, and empirical processing factors where available.

iii. *Cancer.* Based on its review of available data, EPA has concluded that ipflufenquin is not likely to be carcinogenic. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for ipflufenquin.



2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for ipflufenquin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of ipflufenquin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier II Exposure Model Pesticide in Water Calculator (PWC) (v1.52, Feb. 23, 2016), the estimated drinking water concentrations (EDWCs) of ipflufenquin for acute exposures are estimated to be 3.71 parts per billion (ppb) for surface water and 53.6 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 1.28 ppb for surface water and 49.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 49.1ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Ipflufenquin is not being registered for any specific use patterns that would result in residential exposure.

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.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding

as to ipflufenquin and any other substances, and ipflufenquin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ipflufenquin has 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://www2.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 (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.* No evidence of increased quantitative or qualitative susceptibility was seen in rat and rabbit developmental toxicity studies. Decreased pup body weight was observed in the reproduction study only in the presence of parental toxicity. Subchronic oral toxicity studies indicate tooth discoloration and enamel hypoplasia in rats exposed to ipflufenquin. Children are considered the most susceptible population to the tooth effects since dental enamel development and formation occurs during childhood.

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 ipflufenquin is adequate to characterize the pre- and

postnatal risk for infants and children.

ii. There is evidence of potential neurotoxicity (decreased motor activity) in the ipflufenquin database in the ACN study. However, concern is low because: the observed effects are well characterized, with clear NOAELs; they occur only at the highest doses tested; and the PODs are based on the most sensitive effects and are protective of any potential neurotoxicity.

iii. In the 2-generation reproduction study in rats, there were no reproductive effects observed, and offspring toxicity was observed only in the presence of parental toxicity. Although potential signs of neurotoxicity were observed in the ACN study, clear NOAELs/LOAELs are established, and effects occurred at high doses that are not relevant for risk assessment purposes. Moreover, although children are more susceptible to the tooth effects seen in the database, the PODs selected for risk assessment purposes are protective of the offspring and potential effects seen in the database.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ipflufenquin in drinking water. These assessments will not underestimate the exposure and risks posed by ipflufenquin.

#### *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, ipflufenquin 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 ipflufenquin from food and water will utilize less than 1% of the cPAD for the general U.S. population and all population subgroups. There are no residential uses for ipflufenquin.

3. *Short- and intermediate-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). Short- and intermediate-term adverse effects were identified; however, ipflufenquin is not being proposed to be registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for ipflufenquin.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, ipflufenquin 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 ipflufenquin residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

The petitioner has proposed an adequate analytical method, Method No. P 3996 G,

adapted from the multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; Method No. EN 15662:2009-02) for the determination of ipflufenquin in plant commodities. For livestock commodities, adequate enforcement methodology, Method No. NCAS 18-290 (adapted from QuEChERS multi-residue enforcement method EN 15662), using high-performance liquid chromatography with tandem mass detection (HPLC/MS-MS) is available for determination of residues of ipflufenquin.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

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

The Codex has not established any MRLs for ipflufenquin.

#### *C. Revisions to Petitioned-For Tolerances*

Based on the feeding study and the dietary burden estimates, EPA concludes that there is no reasonable expectation of finite residues in livestock commodities as a result of eating treated feedstuff (40 CFR 180.6(a)(3)). Therefore, tolerances for residues of ipflufenquin in livestock commodities are not needed. Additionally, EPA corrected the pome fruit crop group commodity definition and is establishing the tolerance level for “almond, hulls” at 3 ppm instead of 3.0 ppm to be consistent with OECD’s rounding class practices.

Although the summary of the petition cited in Unit II of this preamble indicated a request for a tolerance on almond at 0.10 ppm (and EPA’s notice of filing published in the *Federal Register* indicated the request for a tolerance at 0.10 ppm), the actual petition sought a tolerance

at 0.01 ppm. Based on its review of the underlying residue data, EPA has determined that it is appropriate to set the tolerance for almond at 0.01 ppm.

## **V. Conclusion**

Therefore, tolerances are established for residues of ipflufenquin, 2-[2-(7,8-difluoro-2-methylquinolin-3-yloxy)-6-fluorophenyl]propan-2-ol, in or on almond at 0.01 ppm; almond, hulls at 3 ppm; and fruit, pome, group 11-10 at 0.15 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this 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 tolerances 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).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 23, 2022.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 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. Add § 180.719 to subpart C to read as follows:

**§ 180.719 Ipflufenquin; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the fungicide ipflufenquin, including its metabolites and degradates, in or on the commodities to Table 1 of this section.

Compliance with the tolerance levels specified in Table 1 is to be determined by measuring only ipflufenquin, 2-[(7,8-difluoro-2-methyl-3-quinolinyl)oxy]-6-fluoro- $\alpha,\alpha$ -dimethylbenzenemethanol, in or on the commodities.

**Table 1 to Paragraph (a)**

<b>Commodity</b>	<b>Parts per million</b>
Almond	0.01
Almond, hulls	3
Fruit, pome, group 11-10	0.15

(b) – (d) [Reserved]