## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2007–1065; FRL–8375–4]**

## Forchlorfenuron; Permanent and Time-Limited Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a permanent tolerance for residues of forchlorfenuron in or on bushberry subgroup 13–07B requested by the IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. Time-limited tolerances are also being established under this regulation in support of experimental use permit 71049-EUP-4 for residues of forchlorfenuron in or on almond, cherry, fig, pear, pistachio, plum/prune requested by KIM-C1, LLC c/o Siemer and Associates, Inc. 135 W. Shaw, Suite 102, Fresno, CA 93704. The time-limited tolerances expire on December 31, 2011. IR-4 and KIM-C1, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 15, 2008. Objections and requests for hearings must be received on or before October 14, 2008, 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:** EPA has established dockets for this action under docket identification (ID) numbers EPA–HQ–OPP–2007–0627 and EPA–HQ–OPP–2007–1065. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8050; e-mail address: *maignan.tawanda@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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–2007–1065 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 14, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–1065, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

### II. Petition for Tolerance

In the **Federal Register** of October 24, 2007 (72 FR 205) (FRL–8150–8) and of February 13, 2008 (73 FR 30) (FRL–8351–5), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7228) by the IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540 and pesticide petition (PP 7F7246) by KIM-C1, LLC c/o Siemer and

Associates, Inc. 135 W. Shaw, Suite 102, Fresno, CA 93704, respectively. The petitions requested that 40 CFR 180.569 be amended by establishing permanent tolerances and time-limited tolerances for residues of the plant growth regulator forchlorfenuron, in or on bushberry subgroup 13B at 0.01 parts per million (ppm) (PP 7E8228) and almond, cherry, fig, pear, pistachio, plum/prune at 0.01 ppm (PP 7F7246), respectively. Those notices referenced a summary of the petitions prepared by the registrants, Valent U.S.A. Corporation and KIM-C1, LLC, respectively which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filings.

Based upon review of the data supporting the petitions, EPA has revised certain proposed tolerance levels and corrected commodity definitions as follow:

The Agency determined that adequate data are available to support establishing a tolerance for the bushberry subgroup 13–07B. IR-4 petitioned for a tolerance for bushberry subgroup 13B as well as individual tolerances on aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, honeysuckle, jostaberry, juneberry, lingonberry, native currant, salal, and sea buckthorn (PP 7E7228). In the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8340–6), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised berries group 13. Changes to crop group 13 (berries) included adding new commodities, revising existing subgroups and creating new subgroups (including a bushberry subgroup 13–07B consisting of the commodities requested in PP 7E7228 and cultivars, varieties, and/or hybrids of these).

EPA indicated in the December 7, 2007 final rule as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL–8126–6) that, for existing petitions for which a notice of filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA is establishing a tolerance for the bushberry subgroup 13–07B. Bushberry subgroup 13–07B consists of the berries for which tolerances were requested in PP 7E7228.

EPA concludes it is reasonable to revise the petitioned-for tolerances so that they agree with the recent crop grouping revisions because:

- Although the subgroup includes several new commodities, these commodities were proposed as individual tolerances and are closely related minor crops which contribute little to overall dietary or aggregate exposure and risk.
- Forchlorfenuron exposure from these added commodities was considered when EPA conducted the dietary and aggregate risk assessments supporting this action.
- The representative commodities for the revised subgroup has not changed.

## 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for permanent tolerances for residues of forchlorfenuron on bushberry subgroup 13–07B at 0.01 ppm and time-limited tolerances for residues of forchlorfenuron on almond, cherry, fig, pear, pistachio, plum/prune at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

Forchlorfenuron is not acutely toxic via the oral, dermal, and inhalation routes. Dose-related effects noted in the dog following subchronic and chronic exposure were generally limited to decreased body weight and body-weight gain. In the rat, the only organ that appeared to be affected was the kidney, which showed suppurative inflammation, suppurative pyelonephritis, non-suppurative interstitial nephritis, and cortical cysts following chronic exposure. Developmental toxicity (decreased fetal body weight) was observed in the rat only at a maternally-toxic dose. Forchlorfenuron did not induce any signs of reproductive toxicity or neurotoxic potential. The developmental toxicity studies in rats and rabbits, as well as the reproductive toxicity study in rats, did not demonstrate any prenatal or postnatal sensitivity. There was no evidence of neurotoxicity in any of the submitted studies. Forchlorfenuron is classified as not likely to be a human carcinogen and there is no concern for mutagenicity. There was no evidence of endocrine disruption in the forchlorfenuron database.

Specific information on the studies received and the nature of the adverse effects caused by forchlorfenuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document Forchlorfenuron: *Human Health Risk Assessment for Proposed Uses on the Bushberry Subgroup 13 B and to Support a Requested Experimental Use Permit on almonds, sweet cherries, figs, pears, pistachios and plums/prunes*, in docket ID number EPA–HQ–OPP–2007–1065.

### *B. Toxicological Endpoints*

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account

uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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*.

A summary of the toxicological endpoints for forchlorfenuron used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FORCHLORFENURON FOR USE IN HUMAN RISK ASSESSMENT

| Exposure/Scenario | Point of Departure and Uncertainty/ Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute dietary (all populations) | No appropriate endpoint attributable to a single exposure (dose) was identified from oral toxicity studies, including the developmental studies. | | |
| Chronic dietary (All populations) | NOAEL= 7 mg/kg/day<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | Chronic RfD = 0.07 mg/kg/day | Chronic oral toxicity study- rat<br>LOAEL = 93 mg/kg/day based on decreased body weight/body-weight gain/food consumption, and kidney toxicity (suppurative inflammation in males; nonsuppurative interstitial nephritis in females) |
| Dermal short-term (1 to 30 days) | (oral) NOAEL = 100 mg/kg/day<br>(Dermal absorption rate = 100%<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Developmental toxicity study - rabbit<br>LOAEL = 125 mg/kg/day based on body-weight loss during dosing period in the range-finding study |
| Dermal intermediate-term (1 to 6 months) | (Oral) NOAEL= 87 mg/kg/day<br>(Dermal absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic oral toxicity study - dog<br>LOAEL = 195 mg/kg/day based on decreased body weight/body-weight gain/food consumption |
| Dermal long-term (>6 months) | (Oral) NOAEL = 7 mg/kg/day<br>(Dermal absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic oral toxicity study - rat<br>LOAEL = 93 mg/kg/day based on decreased body weight/body-weight gain/food consumption, and kidney toxicity (suppurative inflammation in males; nonsuppurative interstitial nephritis in females) |
| Inhalation short-term (1 to 30 days) | (oral)NOAEL= 100 mg/kg/day<br>(Inhalation absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Developmental toxicity study - rabbit<br>LOAEL = 125 mg/kg/day based on body-weight loss during dosing period in the range-finding study |
| Inhalation intermediate-term (1 to 6 months) | (Oral) study<br>NOAEL = 87 mg/kg/day<br>(inhalation absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic oral toxicity study - dog<br>LOAEL = 195 mg/kg/day based on decreased body weight/body-weight gain/food consumption |
| Inhalation long-term (>6 months) | (Oral) NOAEL = 7 mg/kg/day<br>(inhalation absorption rate = 100%)<br>$UF_A$ = 10x<br>$UF_H$ = 10x<br>FQPA SF = 1x | LOC for MOE = 100 | Chronic oral toxicity study - rat<br>LOAEL = 93 mg/kg/day based on decreased body weight/body-weight gain/food consumption, and kidney toxicity (suppurative inflammation in males; nonsuppurative interstitial nephritis in females) |

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FORCHLORFENURON FOR USE IN HUMAN RISK ASSESSMENT—Continued

| Exposure/Scenario | Point of Departure and Uncertainty/ Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Cancer (Oral, dermal, inhalation) | Classification: Not likely to be a human carcinogen, based on two adequate rodent carcinogenicity studies. | | |

$UF_A$ = extrapolation from animal to human (interspecies). $UF_H$ = potential variation in sensitivity among members of the human population (intraspecies). $UF_L$ = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to forchlorfenuron EPA considered exposure under the petitioned-for tolerances as well as all existing forchlorfenuron tolerances in (40 CFR 180.569). EPA assessed dietary exposures from forchlorfenuron 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 forchlorfenuron; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Departmemt of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted a highly conservative chronic dietary exposure and risk assessment to support the new uses of forchlorfenuron. Tolerance level residues and 100 percent crop treated (PCT) information was incorporated into the assessment. Dietary Exposure Evaluation Model (DEEM version 7.81) default processing factors were used for apple juice, dried apples, dried pears, prune juice, cranberry juice, and grape juice. A processing factor was not used for raisins because a separate tolerance (resulting from an empirical processing study) is being recommended for this commodity. Additionally, the default processing factor was not used for prunes (dried plums) since data indicated that residues in prunes would not exceed the recommended plum tolerance.

iii. *Cancer*. Forchlorfenuron has been classified as not likely to be carcinogenic based on carcinogenicity studies in the rat and mouse which showed no evidence of an increase in the incidence of tumors therefore a cancer dietary exposure and risk assessment is not required.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for forchlorfenuron. Tolerance level residues and/or 100 PCT were assumed for all existing and new food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for forchlorfenuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of forchlorfenuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Forchlorfenuron is persistent and moderately mobile in soils. Forchlorfenuron is also a substituted urea plant growth regulator that is essentially stable to all routes of dissipation except sensitized photodegradation in water. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the Estimated Environmental Concentrations (EECs) of forchlorfenuron from the newly proposed use on bushberries and the uses on almonds, sweet cherries, figs, pears, plums and pistachios under the EUP will not exceed the EECs from the grape and kiwi uses previously assessed by the Agency in document titled *Drinking Water Assessment for Forchlorfenuron for Grape and Kiwi Uses.* Therefore, the Agency has incorporated the drinking water EEC from the grape and kiwi analysis directly into this dietary assessment.

For chronic dietary risk assessment, the water concentration of value 0.003 ppb 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).

Forchlorfenuron is not 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.''

EPA has not made a common mechanism of toxicity finding asto forchlorfenuron and any other substances and forchlorfenuron 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 forchlorfenuron 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 *http://www.epa.gov/pesticides/cumulative*.

*D. Safety Factor for Infants and Children*

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity studies showed no evidence of increased sensitivity or susceptibility of young rats or rabbits following pre- and/or postnatal exposure to forchlorfenuron.

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 forchlorfenuron is complete.

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

iii. There is no evidence that forchlorfenuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to forchlorfenuron in drinking water. EPA used similarly conservative assumptions to assess exposure to forchlorfenuron residues in food. These assessments will not underestimate the exposure and risks posed by forchlorfenuron.

*E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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, forchlorfenuron 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 forchlorfenuron from food and water will utilize <1% of the cPAD for the general U.S. population and all subpopulations. There are no residential uses for forchlorfenuron.

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).

Forchlorfenuron is not registered for any use patterns that would result in short-term and intermediate-term residential exposure. Therefore, the short-term and intermediate-term aggregate risk, individually is the sum of the risk from exposure to forchlorfenuron through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Since forchlorfenuron has been classified as not likely to be carcinogenic, aggregate cancer risk is not a concern.

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 forchlorfenuron residues.

## IV. Other Considerations

*A. Analytical Enforcement Methodology*

An adequate high performance liquid chromatography/ultraviolet (HPLC/UV) method (Method # CCRL-MTH-029) is available for enforcing tolerances of forchlorfenuron in/on members of the Bushberry Subgroup 13–07B and the commodities that are the subject of the proposed EUP. For this method, residues are extracted with methanol or acetone, diluted with water, and partitioned against hexane. Residues remaining in the aqueous fraction are then partitioned into dichloromethane (DCM) and if necessary further purified using a silica SPE cartridge. Residues are determined by HPLC/UV using external standards and residues are confirmed by liquid chromatography (LC) mass spectrometry (MS/MS) analysis. The validated limit of quantitation (LOQ) is 0.01 ppm for fruit and nut crops.

*B. International Residue Limits*

There is no established or proposed Canadian, Mexican or Codex MRLs for residues of forchlorfenuron in plant commodities.

*C. Revisions to Petitioned-For Tolerances*

The data submitted also supports a temporary tolerance of 0.15 parts per million (ppm) for almond, hulls. Therefore, a tolerance for residues of forchlorfenuron on almond, hulls at 0.15 ppm is established.

## V. Conclusion

Therefore, a permanent tolerance is established for residues of forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N'*-phenyl urea, in or on bushberry subgroup 13–07B at tolerance level 0.01.

Also, time-limited tolerances are established for residues of forchlorfenuron, *N*-(2-chloro-4-pyridinyl)-*N'*-phenyl urea, in or on almond at 0.01 ppm, almond, hulls at 0.15 ppm, cherry, sweet at 0.01 ppm, fig at 0.01 ppm, pear at 0.01 ppm, pistachio at 0.01 ppm and plum, prune, fresh at 0.01 ppm. A time limitation has been imposed because KIM-C1, LLC has submitted an application for an Experimental Use Permit and Temporary Tolerance for plant growth regulator Forchlorfenuron (CPPU), on six crops (almonds, cherry, fig, pear, pistachio, and plum/prune) to permit experimental use under semi-commercial conditions, which will include collection of additional residue data where necessary to support permanent tolerances.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et*

*seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

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

Dated: August 8, 2008.

**Daniel J. Rosenblatt,**

*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. Section 180.569 is amended by adding bushberry subgroup 13–07B in the table to paragraph (a)(1); and revising the table in paragraph (a)(2) to read as follows:

### § 180.569 Forchlorfenuron; tolerances for residues.

(a) *General* (1) * * *

| Commodity | Parts per million |
|---|---|
| Bushberry subgroup 13–07B | 0.01 |
| * * * * * | |

(2)* * *

| Commodity | Parts per million | Expiration/revocation date |
|---|---|---|
| Almond | 0.01 | 12/31/2011 |
| Almond, hulls | 0.15 | 12/31/2011 |
| Cherry, sweet | 0.01 | 12/31/2011 |
| Fig | 0.01 | 12/31/2011 |
| Pear | 0.01 | 12/31/2011 |
| Pistachio | 0.01 | 12/31/2011 |
| Plum, prune, fresh | 0.01 | 12/31/2011 |

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## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### 49 CFR Part 541

**[Docket No. NHTSA–2008–0049]**

**RIN 2127–AK31**

## Federal Motor Vehicle Theft Prevention Standard; Final Listing of 2009 Light Duty Truck Lines Subject to the Requirements of This Standard and Exempted Vehicle Lines for Model Year 2009

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

**ACTION:** Final rule.

**SUMMARY:** This final rule announces NHTSA's determination that there are no new model year (MY) 2009 light duty truck lines subject to the parts-marking requirements of the Federal motor vehicle theft prevention standard because they have been determined by the agency to be high-theft or because they have a majority of interchangeable parts with those of a passenger motor vehicle line. This final rule also identifies those vehicle lines that have been granted an exemption from the parts-marking requirements because the vehicles are equipped with antitheft devices determined to meet certain statutory criteria.

**DATES:** *Effective Date:* The amendment made by this final rule is effective August 15, 2008.

**FOR FURTHER INFORMATION CONTACT:** Ms. Rosalind Proctor, Consumer Standards Division, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, West Building, 1200 New Jersey Avenue, SE., (NVS–131, Room W43–302), Washington, DC 20590. Ms. Proctor's telephone number is (202) 366–0846. Her fax number is (202) 493–0073.

**SUPPLEMENTARY INFORMATION:** On April 6, 2004, the agency published in the **Federal Register** (69 FR 17960) a final rule extending the parts-marking requirements to certain vehicle lines that were not previously subject to these requirements, specifically (1) all low-theft passenger car lines; (2) all low-theft multipurpose passenger vehicle (MPV) lines with a gross vehicle weight rating (GVWR) of 6,000 pounds or less; and (3) low-theft light-duty truck (LDT) lines with a GVWR of 6,000 pounds or less that have major parts that are interchangeable with a majority of the covered major parts of passenger cars or MPVs. The high-theft vehicle lines that were previously exempted under 49 CFR part 543 on the grounds that they were equipped with an antitheft device as standard equipment were unaffected by the April 2004 final rule. The agency also stated that it would continue to grant exemptions for one vehicle line per manufacturer per model year. The final rule was effective September 1, 2006. The final rule included a phase-in provision which required at least 50 percent of the production volume not subject to the current parts marking requirements (excluding light duty trucks) to have been marked by September 1, 2006. The remaining production volume not subject to the current parts marking requirements must have been marked by September 1, 2007 (see 70 FR 28843, May 19, 2005).

The purpose of the theft prevention standard (49 CFR part 541) is to reduce the incidence of motor vehicle theft by facilitating the tracing and recovery of parts from stolen vehicles. The standard seeks to facilitate such tracing by requiring that vehicle identification numbers (VINs), VIN derivative numbers, or other symbols be placed on major component vehicle parts. The theft prevention standard requires motor vehicle manufacturers to inscribe or affix VINs onto covered original equipment major component parts, and to inscribe or affix a symbol identifying the manufacturer and a common symbol identifying the replacement component parts for those original equipment parts, on all vehicle lines subject to the requirements of the standard.

Section 33104(d) provides that once a line has become subject to the theft prevention standard, the line remains subject to the requirements of the standard unless it is exempted under § 33106. Section 33106 provides that a manufacturer may petition to have a line exempted from the requirements of § 33104, if the line is equipped with an antitheft device as standard equipment. The exemption is granted if NHTSA determines that the antitheft device is likely to be as effective as compliance with the theft prevention standard in reducing and deterring motor vehicle thefts.

The agency annually publishes the names of those vehicle lines that have been determined to be high theft pursuant to 49 CFR part 541 and those that are exempted from the theft prevention standard under section 33104. Appendix A to Part 541 identifies those new light-duty truck lines listed for the first time that will be subject to the theft prevention standard beginning in a given model year. Appendix A–I to Part 541 identifies those vehicle lines that are or have been exempted from the theft prevention standard.

On September 26, 2007, the final listing of MY 2008 high-theft vehicle lines was published in the **Federal Register** (72 FR 54600). The final listing identified that there again were no new vehicle lines that became subject to the theft prevention standard beginning with the 2008 model year. For MY 2009, there were no new light-duty truck lines identified that became subject to the theft prevention standard in accordance with the procedures published in 49 CFR part 542.

For MY 2009, the list of lines that have been exempted by the agency from the parts-marking requirements of Part 541 includes nine vehicle lines newly exempted in full. The nine exempted vehicle lines are the Hyundai Genesis, Mazda 5, Subaru Forester, Jeep Wrangler, Chevrolet Equinox, Daimler smart USA fortwo, Nissan Rogue, Ford Escape, and Audi Q5.

We note that the agency removes from the list being published in the **Federal Register** each year certain vehicles lines that have been discontinued more than 5 years ago. Therefore, the Chevrolet Lumina/Monte Carlo (1996–1999) and the Chevrolet Malibu (2001–2003) have been removed from the Appendix A–I listing. The agency will continue to maintain a comprehensive database of all exemptions on our Web site. However, we believe that re-publishing a list containing vehicle lines that have not been in production for a considerable period of time is unnecessary.

The vehicle lines listed as being exempt from the standard have previously been exempted in accordance with the procedures of 49 CFR part 543 and 49 U.S.C., 33106. Therefore, NHTSA finds for good cause that notice and opportunity for comment on these listings are unnecessary. Further, public comment on the listing of selections and exemptions is not contemplated by 49 U.S.C. Chapter 331. For the same reasons, since this revised listing only informs the public of previous agency actions and does not impose additional obligations on any party, NHTSA finds for good cause that the amendment made by this notice should be effective as soon as it is published in the **Federal Register**.