(b) Section 18 emergency exemptions. [Reserved]
(c) Tolerances with regional registrations. [Reserved]
(d) Indirect or inadvertent residues. [Reserved]

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180
[OPP–2002–0234; FRL–7198–3]

Fluroxypyr 1-methylheptyl ester; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of fluroxypyr [1-methylheptyl ester ([(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate) and its metabolite fluroxypyr [[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate] in or on sorghum, grain, stover at 4.0 ppm; sorghum, forage at 2.0 ppm; and 1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite all expressed as fluroxypyr in these food commodities. The tolerances will expire and are revoked on December 31, 2005.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0234, must be received on or before November 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, you objections and hearing requests must identify docket ID number OPP–2002–0234 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: sec–18–Mailbox@epamail.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 categories and entities may include, but are not limited to:

<table>
<thead>
<tr>
<th>Categories</th>
<th>NAICS Codes</th>
<th>Examples of Potentially Affected Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry 111</td>
<td>112 311 32532</td>
<td>Crop production Animal production Food manufacturing Pesticide manufacturing</td>
</tr>
</tbody>
</table>

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the herbicide fluroxypyr 1-methylheptyl ester, [1-methylheptyl ([(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate) and its metabolite fluroxypyr [[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate], in or on sorghum, grain, stover at 4.0 ppm; sorghum, forage at 2.0 ppm; and sorghum, grain, stover at 4.0 ppm. These tolerances will expire and are revoked on December 31, 2005. EPA will publish a document in the Federal Register to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(l)(2)(A)(I) of the 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) 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) 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 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fluroxypyr on Sorghum and FFDC

Tolerances

Due primarily to unusual drought conditions, registered alternative herbicides have proven ineffective. Drought conditions have resulted in poor activation of preemergence herbicides. Available post-emergence herbicides are proving ineffective due to the drought hardened condition of the kochia infestations. Kansas has declared a crisis exemption under FIFRA section 18 for the use of fluroxypyr on sorghum for control of kochia.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fluroxypyr on sorghum, grain and its associated commodities. In doing so, EPA considered the safety standard in FFDC section 408(b)(2), and EPA decided that the necessary tolerance under FFDC section 408(b)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(b)(6). Although this tolerance will expire and is revoked on December 31, 2005, under FFDC section 408(b)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sorghum, grain and its associated commodities after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether fluroxypyr meets EPA’s registration requirements for use on sorghum or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of fluroxypyr by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Kansas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA’s regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fluroxypyr, contact the Agency’s Registration Division at the address provided under FOR FURTHER INFORMATION CONTACT.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Feciticide Tolerances (62 FR 62961, November 26, 1997) [FRL–5754–7].

Consistent with 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 fluroxypyr and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for combined residues of fluroxypyr 1-methylheptyl ester, [1-methylheptyl ([4-amino-3,5-dichloro-6-fluoro-2-pyridinyl]oxy)acetate] and its metabolite fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr ([4-amino-3,5-dichloro-6-fluoro-2-pyridinyl]oxy)acetate], in or on sorghum, grain at 0.035 ppm; sorghum, forage at 2.0 ppm; and sorghum, grain, stover at 4.0 ppm. The most recent estimated aggregate risks resulting from the use of fluroxypyr 1-methylheptyl ester are discussed in the Federal Register for September 17, 2001 (66 FR 47964) (FRL–6798–5) Final Rule, establishing tolerances for residues of the combined residues of the herbicide fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr, in or on grass, forage at 120 ppm, grass, hay at 160 ppm, and modifying the permanent tolerances for milk from 0.1 ppm to 0.30 ppm and for kidney (cattle, goat, hog, horse, and sheep) from 0.5 ppm to 1.5 ppm because in that prior action, risks were estimated assuming tolerance level residues in all commodities for established tolerances, as well as those for which action was being proposed, such as in this sorghum exemption use. Refer to the September 17, 2001 Federal Register (66 FR 47964) document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the Federal Register document in support of this action. Below is a brief summary of the aggregate risk assessment.

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. A summary of the toxicological dose and endpoints for fluroxypyr for use in human risk assessment is discussed in Unit IV.A. of the Federal Register of September 17, 2001 (66 FR 47964).

EPA assessed risk scenarios for fluroxypyr under acute, chronic, and short- and intermediate-term exposures. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

The following assumptions were made for the acute exposure assessments: Tolerance level residues were assumed and it was also assumed that 100% of the crops and other commodities with proposed or established fluroxypyr tolerances contained fluroxypyr. Anticipated residues, and percent crop treated (PCT) values of less than 100%, were not used.
Using these exposure assessments, EPA concluded that fluroxypyr exposure from food consumption will occupy 1.5% of the acute population adjusted dose (aPAD) for females 13–50 years old, the only population subgroup of concern. A dose and endpoint were not selected for the U.S. population, including infants and children because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose). Therefore, a risk assessment is not required for this population subgroup.

In addition, despite the potential for acute dietary exposure to fluroxypyr in drinking water, after calculating drinking water levels of concern (DWLOCs) and comparing them to conservative model estimated environmental concentrations (EECs) of fluroxypyr in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 1.

**TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUROXYPYR**

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>aPAD (mg/kg)</th>
<th>% aPAD (Food)</th>
<th>Surface Water EEC (ppb)</th>
<th>Ground Water EEC (ppb)</th>
<th>Acute DWLOC (ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (13 to 50 years)</td>
<td>0.33</td>
<td>1.5</td>
<td>7.6</td>
<td>0.017</td>
<td>9,700</td>
</tr>
</tbody>
</table>

The following assumptions were made for the chronic exposure assessments: Tolerance level residues were assumed and it was also assumed that 100% of the crops and other commodities with proposed or established fluroxypyr tolerances contained those residues. Anticipated residues, and PCT values of less than 100%, were not used.

Using these exposure assumptions EPA concluded that exposure to fluroxypyr from food will utilize 0.6% of the chronic population adjusted dose (cPAD) for the U.S. population, 0.4% of the cPAD for females 13 to 50 years and 2.1% of the cPAD for children 1 to 6 years, the subpopulation at greatest exposure. Based on the use pattern, chronic residential exposure to residues of fluroxypyr is not expected. In addition, there is potential for chronic dietary exposure to fluroxypyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

**TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUROXYPYR**

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>cPAD mg/kg/day</th>
<th>%cPAD (Food)</th>
<th>Surface Water EEC (ppb)</th>
<th>Ground Water EEC (ppb)</th>
<th>Chronic DWLOC (ppb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population</td>
<td>0.50</td>
<td>0.6</td>
<td>1.6</td>
<td>0.017</td>
<td>17,000</td>
</tr>
<tr>
<td>Females (13 to 50 years)</td>
<td>0.50</td>
<td>0.4</td>
<td>1.6</td>
<td>0.017</td>
<td>15,000</td>
</tr>
<tr>
<td>Children (1 to 6 years)</td>
<td>0.50</td>
<td>2.1</td>
<td>1.6</td>
<td>0.017</td>
<td>4,900</td>
</tr>
<tr>
<td>Seniors 55+</td>
<td>0.50</td>
<td>0.4</td>
<td>1.6</td>
<td>0.017</td>
<td>17,000</td>
</tr>
</tbody>
</table>

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluroxypyr is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluroxypyr is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

The Agency has classified fluroxypyr as “not likely” to be a human carcinogen, therefore this risk assessment is not required.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fluroxypyr residues.

**V. Other Considerations**

**A. Analytical Enforcement Methodology**

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

**B. International Residue Limits**

No Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established for residues of fluroxypyr in or on these commodities. Therefore, no tolerance discrepancies exist between countries for this chemical.

**VI. Conclusion**

Therefore, the tolerance is established for combined residues of fluroxypyr 1-methylheptyl ester, [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite furoxypyr ([4-amino-3,5-dichloro-6-fluoro-2-pyridinyl]oxy) acetic acid), in or on sorghum, grain, stover at 4.0 ppm; sorghum, forage at 2.0 ppm; and sorghum, grain, stover at 4.0 ppm.

**VII. Objections and Hearing Requests**

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may...
file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0210 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 on or before November 25, 2002.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor’s contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it “Tolerance Petition Fees.”

EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket ID number OPP–2002–0210, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). 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., or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the tolerances in...
SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of certain sucrose octanoate esters on all food commodities when applied/used in accordance with good agricultural practices. AVA Chemical Ventures, L.L.C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sucrose octanoate esters.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket identification (ID) number OPP–2002–0016, must be received on or before November 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0016 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. By facsimile: (202) 566-0490. By telephone: (202) 566-0544.