

CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-30505. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Registration Applications

EPA received applications as follows to register pesticide products containing an active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(4) of FIFRA. Notice of receipt of the application does not imply a decision by the Agency on the applications.

*Products Containing an Active Ingredient Not Included in Any Previously Registered Products*

1. File Symbol: 34704-IEU. Applicant: Platte Chemical Company, 419 18th St., Greeley, CO 80632-0667. Product Name: Smolder G. Product type: Biological herbicide. Active ingredient: *Alternaria destruens* at 4.40%. Proposed classification/Use: Control of dodder (*Cuscuta spp.*).
2. File Symbol: 34704-IEL. Applicant: Platte Chemical Company. Product Name: Smolder WP. Biological herbicide. Active ingredient: *Alternaria destruens* at 4.10%. Proposed classification/Use: Control of dodder (*Cuscuta spp.*).

### List of Subjects

Environmental protection, Pesticides and pest.

Dated: January 5, 2001.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 01-3165 Filed 2-6-01; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[PF-995; FRL-6765-6]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-995, must be received on or before March 9, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as

provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-995 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: tompkins.jim@epa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this Action Apply to Me?

You may be 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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 Industrial 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**.

##### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-995. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-995 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file

format. All comments in electronic form must be identified by docket control number PF-995. Electronic comments may also be filed online at many Federal Depository Libraries.

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5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21

U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### **List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 25, 2001.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### **Aventis CropScience**

*OF6161*

EPA has received a pesticide petition (OF6161) from Aventis CropScience USA LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl] amino] sulfonyl]-4-(formylamino)-N, N-dimethylbenzamide (CAS #173159-57-4) (foramsulfuron, company code AE F130360) in or on the raw agricultural commodities (RAC) corn grain at 0.02 parts per million (ppm), and corn forage and corn stover at 0.1 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### A. Residue Chemistry

1. *Plant metabolism.* The metabolism of foramsulfuron in corn has been investigated and is understood. Two primary routes of degradation occur for foramsulfuron. One pathway involves the hydrolysis of the sulfonylurea bridge, resulting in AE F153745 (4-formylamino-*N,N*-dimethyl-2-sulfamoylbenzamide) and AE F092944 (2-amino-4,6-dimethoxypyrimidine). Foramsulfuron also hydrolyzes at the formamide moiety on the phenyl ring to produce AE F130619 (4-amino-2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-*N,N*-dimethylbenzamide). All these metabolites are subjected to further degradation leading to the formation of highly polar, water soluble components. The two metabolites resulting from cleavage of the sulfonylurea bridge, namely AE F153745 and AE F092944 were found in the extractable residue of the forage and stover. Only traces of AE F130619 (from hydrolysis of the formamide moiety) were found also in the forage and stover. The major metabolite detected in plants (AE F153745) was also identified in the rat and livestock metabolism studies.

2. *Analytical method.* Based on the results of the metabolism studies, the analytical targets selected were parent compound (AE F130360) and the metabolite AE F153745. Extractable residues of foramsulfuron and AE F153745 are removed from the crop matrix by blending with aqueous acetonitrile. After filtration, the extract is rotary evaporated down to a reduced volume. The aqueous/organic extract is transferred to a separatory funnel and washed with hexane. After the hexane wash, the extract is cleaned up via special column chromatography then analyzed by high performance liquid chromatography/mass spectrometry (HPLC/MS).

3. *Magnitude of residues.* The metabolism studies with <sup>14</sup>C-labelled foramsulfuron in corn using exaggerated application rates (over 2.5-fold the normal rate) demonstrated that in general, low residues were detected in the plant samples. These results have been confirmed in a total of 29 North American residue field trials using a water dispersible granule (WG) formulation containing 50% weight/weight (w/w) foramsulfuron. The preparation was applied in split applications. The predominant regimen was 30 gram/health advisories (g/ha) followed by 60 g/ha or alternatively, 2 times 45 g/ha. Pre-harvest intervals (PHI) were between 37 and 67 days, 60 and 121 days or 67 and 151 days

respectively for forage, grain, or stover. Grain, stover, and forage of field corn did not contain residues of foramsulfuron at or above the respective limits of quantification (LOQ) of 0.01, 0.05, and 0.05 milligram/kilogram (mg/kg). Also no residues of the metabolite AE F153745 were found in corn grain, stover, or forage at harvest above the respective LOQ of 0.02, 0.05, and 0.05 mg/kg. Residues trials included testing the effects of adding typical non-ionic surfactants, esterified seed oils, or crop oil concentrates to the spray mix. In no case were residues above the LOQ observed. Although AE F153745 was the major metabolite detected in the corn metabolism study, it did not exceed 10% of the total foramsulfuron-derived residue in grain, stover, or forage at harvest. It is proposed, therefore, that AE F153745 is not included in the tolerance expression as field trials confirmed its lack of formation at levels above the LOQ. Tolerances of foramsulfuron are proposed at twice the LOQ of the analytical method, namely 0.02, 0.1, and 0.1 mg/kg in grain, stover, and forage, respectively. In a corn processing study, no residues of AE F130360 above 0.01 mg/kg or AE F153745 above 0.02 mg/kg were observed in corn grain following treatment of the crop at the nominal rate of 150 followed by 300 g/ha. This exaggerated rate is approximately five times the maximum proposed label rate. Since no residues were observed in the RAC, neither analysis of the processed commodities nor tolerances are required. Although corn grain is fed to cattle, and poultry and cattle may be grazed on forage, or fed stover, tolerances in meat, milk, or eggs are not necessary because none of these commodities contained foramsulfuron or its metabolite.

### B. Toxicological Profile

1. *Acute toxicity.* Foramsulfuron has been shown to have very low acute toxicity to mammals irrespective of the route of exposure. Only non-specific clinical signs were seen after oral administration of 5,000 mg/kg to rats and after inhalation exposure of rats to 5.04 milligram/liter (mg/L). These signs had completely resolved 4 days following oral treatment and by day 1 after inhalation exposure. There was no evidence of systemic toxicity following acute dermal exposure to 2,000 mg/kg foramsulfuron. It was not irritant to rabbit skin and only mildly irritating to rabbit eyes. Foramsulfuron did not induce delayed contact hypersensitivity (skin sensitization) in a Magnusson and Kligman maximization test. Based on these results, foramsulfuron would be

classified as EPA category III for dermal toxicity and eye irritation, and EPA category IV for skin irritation, oral, and inhalation toxicity.

2. *Genotoxicity.* Genotoxic potential was evaluated in a battery of tests which examined gene mutation in bacteria and mammalian cells, chromosome damage *in vitro* and *in vivo* and DNA damage in mammalian cells *in vivo*. The only finding was weak evidence *in vitro* of chromosome aberrations in human lymphocytes in the absence of metabolic activation. The increases in incidences occurred only at the highest dose level tested, 2,400 µg/mL, and were only just outside the historical control range. However, there was no evidence of chromosome damage *in vivo*, no effects in the *in vivo* assay for unscheduled DNA synthesis and no oncogenic activity or developmental toxicity. Thus, the overall weight of evidence indicates that foramsulfuron does not possess significant genotoxic activity.

3. *Reproductive and developmental toxicity.* A 2-generation reproduction study in rats evaluated continuous dietary dose levels of 0, 100, 1,225, and 15,000 ppm of technical foramsulfuron. No treatment-related effects were observed, including no effects on reproductive parameters (fertility, mating, gestation, parturition, litter size sex ratios), parental toxicity, neonatal toxicity, or on markers of endocrine function (oestrous cycling, balanopreputial separation, vaginal opening, spermatogenic function and capacity). Therefore, the no observed adverse effect level (NOAEL) was 15,000 ppm, equivalent to a mean daily intake of 1,038 mg/kg foramsulfuron body weight (bwt) for F<sub>0</sub> and F<sub>1</sub> males and 1,430 mg/kg/day for F<sub>0</sub> and F<sub>1</sub> females combined (about 1,234 mg/kg/day for the study overall).

A rat developmental toxicity (teratogenicity) study was conducted with dose levels of 0, 5, 71, and 1,000 mg/kg foramsulfuron bwt/day. There was no evidence of any maternal or embryo foetal toxicity up to and including the 1,000 mg/kg dose level, the international limit dose for this type of study. Therefore the NOAEL for both maternal and embryofetal toxicity was 1,000 mg/kg. Foramsulfuron was not teratogenic in rats.

The rabbit developmental toxicity (teratogenicity) study was conducted with dose levels of 0, 5, 50, and 500 mg/kg foramsulfuron bwt/day. Maternal toxicity was seen at the high dose of 500 mg/kg/day, as evidenced by reduced body weight gain and slightly decreased food consumption during the treatment period. There was no embryofetal toxicity at any dose level. The NOAEL

for maternal toxicity was 50 mg/kg and 500 mg/kg for developmental toxicity (teratogenicity). Foramsulfuron was not teratogenic in the rabbit.

Results of the 2-generation and the developmental toxicity (teratogenicity) studies, show that foramsulfuron gives no evidence of reproductive, embryofetal, or neonatal toxicity. Parental (maternal) toxicity was only seen in the rabbit at 1,000 mg/kg, the international limit dose.

Therefore, foramsulfuron was of very low reproductive toxicity.

4. *Subchronic toxicity.* In a 90-day rat feeding study, groups of 10 male, and 10 female Sprague Dawley rats were fed diets containing either 0, 20, 200, 500, or 20,000 ppm of foramsulfuron. There was no treatment-related mortalities or effects seen at any dose level. The NOAEL for this study was considered to be 20,000 ppm (approximately 1,677 mg/kg/day which is in excess of the 1,000 mg/kg/day international limit dose).

In a 90-day feeding study in mice, foramsulfuron was administered at dietary concentrations of 64, 3,200, and 6,400 ppm. There was no treatment-related deaths or effects found in mice at any dose level. The NOAEL for this study was 6,400 ppm (equivalent to 1,002 mg/kg/day for males and 1,178 mg/kg/day for females).

Groups of 4 males and 4 females Beagle dogs were administered foramsulfuron at dietary concentrations of 0, 10, 250, and 1,000 mg/kg/ bwt/day for 13 consecutive weeks. There were no mortalities, and no clinical signs directly related to treatment at any dose level. The NOAEL for both sexes was 1,000 mg/kg/day, the international limit dose.

5. *Chronic toxicity.* The oncogenic potential of foramsulfuron was examined in bioassays with rats and mice with dietary exposure periods of 2 years and 18 months, respectively.

In rats, dietary administration of up to 20,000 ppm of foramsulfuron for 2 years, equivalent to achieved intakes of 849 and 1,135 mg/kg/day for males and females, respectively, did not yield any evidence of toxicity or oncogenicity. The mean daily intakes over the 1-year period were 976 and 1,305 mg/kg/day for males and females, respectively. Thus this dose level approximated to the international regulatory limit dose of 1,000 mg/kg/day.

Similarly in mice, no oncogenic activity was found after dietary treatment with up to 8,000 ppm (equating to 1,115 and 1,358 mg/kg/day in males and females, respectively) for 18 months, which was slightly in excess of the international limit dose.

Based on the achieved intakes, the rat is the most sensitive species in these long-term studies and the overall lowest NOAEL was 849 mg/kg foramsulfuron body weight/day. Given the absence of any carcinogenicity, significant genotoxicity, reproduction toxicity, developmental toxicity or any other special hazard potential, and taking into consideration the low toxicity profile, poor absorption and rapid excretion (predominantly of parent compound), a safety factor of 100 is considered appropriate. Therefore the proposed reference dose (RfD) is 8.5 mg/kg bwt/day.

Aventis CropScience believes foramsulfuron should be classified as a "not likely" carcinogen based on the lack of carcinogenicity in rats and mice.

6. *Animal metabolism.* Following a single oral administration of either 10 or 1,000 mg/kg to rats, 91.5% of the dose was found in the excreta between 0 and 24 hours post-dosing. There were no sex-specific differences in the route of excretion, and tissue residues were generally low. The metabolism of foramsulfuron showed that at both dose rates the main excretion product was unchanged foramsulfuron, excreted mainly in the faeces. Two metabolic routes were identified leading to the formation of metabolites also detected in plants: AE F130619, an amine formed via hydrolysis at the formamide moiety on the phenyl and the cleavage product AE F153745, as minor metabolites. A number of unidentified, minor (<4%), polar metabolites formed from both the phenyl or pyrimidyl ring-labelled compound were also excreted.

Six laying hens were orally dosed with (U-<sup>14</sup>C-phenyl)-foramsulfuron for 14 consecutive days with a mean daily dose of 1.50 mg per bird per day, equivalent to approximately 10 ppm in the diet. The levels of radioactive residues in the hen tissues at necropsy were low, with the highest concentration being found in the liver (0.023 µg equivalents/g). The residues in the muscle, fat, and skin were all found to be 0.003 µg equivalents/g or less, which is below the concentration requiring further analysis. The unchanged parent compound and the cleavage product AE F153745 were the only metabolites identified in the edible tissues, eggs and excreta, which are also significant in the cow and rat.

A dairy cow was orally dosed with (U-<sup>14</sup>C-phenyl)-foramsulfuron for 7 consecutive days with a mean daily dose of 187.4 mg, equivalent to 16 ppm in the diet. Radioactive residues were detectable in all edible tissues at very low levels between 0.004 and 0.036 µg equivalents/g tissue at necropsy. The

major metabolites identified in all tissues were unchanged foramsulfuron and AE F153745. Some very minor metabolites were also seen in the liver and fat but were not identified. The results show that foramsulfuron is poorly absorbed and is excreted mainly in the faeces. The only identifiable metabolic product of foramsulfuron detected in the tissues and excreta of the dairy cow was AE F153745, which is also the principal metabolite identified in the hen, rat, and corn.

7. *Endocrine disruption.* No special studies have been conducted to investigate the potential of foramsulfuron to induce estrogenic or other endocrine effects. However, no evidence of estrogenic or other endocrine effects have been noted in any of the standard toxicology studies that have been conducted with this product and there is no reason to suspect that any such effects would be likely.

#### C. Aggregate Exposure

1. *Dietary exposure.* Foramsulfuron is proposed for use as an herbicide on corn. No non-agricultural uses are anticipated. The potential sources of exposure would consist of any potential residues in food and drinking water. As indicated above, there are no acute toxicity concerns and thus only chronic exposure has been evaluated.

i. *Food.* Chronic dietary analysis was conducted to estimate exposure to potential foramsulfuron residues in/on corn. A Tier 1 analysis was conducted using the dietary exposure evaluation system (DEEM<sup>™</sup>) software and the 1994–1996 CSFII food consumption data. It was assumed that residues were at tolerance levels of 0.02 ppm (twice the LOQ) in grain and that 100% of the crop was treated. Additionally, based on the results from appropriate studies, it was assumed that there was no concentration into processed commodities and that contributions from residues in meat, milk, or eggs are not required. A chronic RfD of 8.5 mg/kg/day is derived from the male rat NOAEL of 849 mg/kg/day. Using these inputs the chronic dietary exposure estimate from residues of foramsulfuron for the U.S. population was 0.000032 mg/kg/day or <0.001% of its RfD. For the sub-population with the highest exposure, non-nursing infants, the chronic dietary exposure estimate from residues of foramsulfuron was 0.000080 mg/kg/day, again <0.001% of its RfD. These values are highly conservative, having been based on worst case assumptions of tolerance level residues and 100% of the crop treated.

ii. *Drinking water.* Unites States EPA's standard operating procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct a screening level drinking water assessment. These tools include water models such as screening concentration ground water (SCI-GROW), generic expected environmental concentration (GENEEC), EPA's pesticide root zone model (PRZMS)/EXAMS, and monitoring data. If monitoring data is not available then the models are used to predict potential residues in surface and ground water and the highest value is assumed to be the potential drinking water residue. In the case of foramsulfuron monitoring data do not exist therefore model calculations were used to estimate a water residue. The calculated drinking water levels of concern (DWLOC) for chronic exposures for adults is 297,498 (ppb) parts per billion (297 ppm). The chronic DWLOC for children/toddlers is 84,999 ppb (84 ppm). The worst case chronic drinking water estimated concentration (DWECC) is 0.225 ppb based on a PRZM/EXAMS simulation of runoff into surface water in a standard EPA exposure assessment scenario for corn (MLRA 111, Ohio). The calculated DWLOCs for chronic exposures for all adults and children therefore greatly exceed the DWECCs from the models.

2. *Non-dietary exposure.* Exposure to foramsulfuron for the mixer/loader/ground boom/aerial applicator was calculated using the pesticide handlers exposure data base (PHED). It was assumed that the product would be applied to a maximum of 50 hectares per day (125 A/day) by ground boom applicator and 140 hectares per day (350 A/day) by aerial applicator at a maximum use rate of 45 grams a.i./ha. Normal work attire consisting of long-sleeved shirt, long pants, and protective gloves was assumed in the PHED assessment. Margins of exposure (MOEs) for a 70 kg operator were calculated utilizing a dermal NOAEL of 1,000 mg/kg bwt/day from the rat dermal toxicity study and an inhalation NOAEL of 50 mg/kg bwt/day based on an oral administration, developmental toxicity study in the rabbit. There were no signs of developmental toxicity in the rabbit developmental toxicity study. The combined MOE (inhalation plus dermal) for foramsulfuron was 126,000 for a ground operator undertaking mixing, loading, and spraying. For aerial application where the mixer/loader was assumed to be a different operator from the pilot combined MOEs were 60,400

for the mixer/loader and 1,425,000 for the pilot. The results indicate that large margins of safety exist for the proposed use of foramsulfuron.

The timing of foramsulfuron application to corn is such that field reentry shortly after spraying is atypical. Therefore estimations of worker reentry exposure were not considered necessary.

#### D. Cumulative Effects

There is no available data at this time to determine whether foramsulfuron has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Therefore a cumulative assessment was not done for this chemical.

#### E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure, in this case food only, to the proposed uses of foramsulfuron will utilize <0.001% of the reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. DWLOC based on the dietary exposure are much greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to foramsulfuron.

2. *Infants and children.* No evidence of increased sensitivity to fetuses was noted in developmental toxicity studies in rats or rabbits. There has been no indication of reproductive effects or indication of increased sensitivity to the offspring in the 2-generation rat reproduction study. No additional safety factor to protect infants and children is necessary as there is no evidence of increased sensitivity in infants and children.

Using the conservative assumptions described in the exposure section above, the percent of the reference dose that will be used for exposure to residues of foramsulfuron in food for non-nursing infants (the most highly exposed sub group) is <0.001%. The children (1-6) exposure uses are also <0.001% of the reference dose. As in the adult situation,

DWLOC are much higher than the worst case DWECC and are expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of foramsulfuron.

#### F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of foramsulfuron.

[FR Doc. 01-3093 Filed 2-6-01; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-994; FRL-6764-8]

### Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-994, must be received on or before March 9, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-994 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7740; e-mail address: giles-parker.cynthia@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be 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: