

Hwy., 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.

### III. How Can I Respond to this Action?

#### A. 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 OPP-34215A in the subject line on the first page of your response.

1. *By mail.* Submit comments 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.

2. *In person or by courier.* Deliver comments to: Public Information and Records Integrity Branch, Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.* Submit electronic comments by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file, avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by the docket control number OPP-34215A. Electronic comments may also be filed online at many Federal Depository Libraries.

#### B. How Should I Handle CBI Information 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 listed under "FOR FURTHER INFORMATION CONTACT."

### IV. What Action is EPA Taking in this Notice?

EPA is making available for public viewing the revised risk assessments and related documents for one organophosphate pesticide, mevinphos. These documents have been developed as part of the pilot public participation process that EPA and USDA are now using for involving the public in the reassessment of pesticide tolerances under the Food Quality Protection Act (FQPA), and the reregistration of individual organophosphate pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The pilot public participation process was developed as part of the EPA-USDA Tolerance Reassessment Advisory Committee (TRAC), which was established in April 1998, as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology. A goal of the pilot public participation process is to find a more effective way for the public to participate at critical junctures in the Agency's development of organophosphate risk assessments and risk management decisions. EPA and USDA began implementing this pilot process in August 1998, to increase transparency and opportunities for stakeholder consultation. The documents being released to the public through this notice provide information on the revisions that were made to the mevinphos preliminary risk assessments, which was released to the public January 12, 2000 (65 FR 1869) (FRL-6486-9) through a notice in the **Federal Register**.

In addition, this notice starts a 60-day public participation period during which the public is encouraged to submit risk management proposals or otherwise comment on risk management for mevinphos. The Agency is providing an opportunity, through this notice, for interested parties to provide written risk management proposals or ideas to the Agency on the chemical specified in this notice. Such comments and proposals could address ideas about how to manage dietary, occupational, or ecological risks on specific mevinphos

use sites or crops across the United States or in a particular geographic region of the country. To address dietary risk, for example, commenters may choose to discuss the feasibility of lower application rates, increasing the time interval between application and harvest ("pre-harvest intervals"), modifications in use, or suggest alternative measures to reduce residues contributing to dietary exposure. For occupational risks, commenters may suggest personal protective equipment or technologies to reduce exposure to workers and pesticide handlers. For ecological risks, commenters may suggest ways to reduce environmental exposure, e.g., exposure to birds, fish, mammals, and other non-target organisms. EPA will provide other opportunities for public participation and comment on issues associated with the organophosphate tolerance reassessment program. Failure to participate or comment as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments and proposals must be received by EPA on or before August 29, 2000 at the addresses given under the "ADDRESSES" section. Comments and proposals will become part of the Agency record for the organophosphates specified in this notice.

#### List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: June 21, 2000.

**Lois Rossi,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

[FR Doc. 00-16635 Filed 6-29-00; 8:45 am]

**BILLING CODE 6560-50-F**

## ENVIRONMENTAL PROTECTION AGENCY

[PF-951; FRL-6592-6]

### Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filings and amendments of pesticide petitions proposing the establishment/amendments of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-951, must be received on or before July 31, 2000.

**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-951 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Vera Soltero, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9359; and e-mail address: soltero.vera@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:

Cat-egories	NAICS	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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/fedrgrstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-951. 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-951 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](mailto: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-951. 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. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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 supports 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: June 23, 2000.

### James Jones,

Director, Registration Division, Office of Pesticide Programs.

### Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

#### Initial Filings

##### 1. Aventis CropScience USA LP

PP 0E6162

EPA has received a pesticide petition 0E6162 from Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate (CAS No. 163520-33-0) (herbicide safener isoxadifen-ethyl, Company Code AE F122006) in or on the raw agricultural commodities corn grain at 0.1 parts per million (ppm), corn forage at 0.3 ppm, and corn stover at 0.5 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 isoxadifen-ethyl (ethyl 5,5-diphenyl-2-isoxazoline-3-carboxylate) in corn and rice has been investigated and is understood. Total residue levels in corn commodities were very low. The initial metabolic transformation of isoxadifen-ethyl in plants is hydrolysis of the prominent ester function, yielding the carboxylic acid, AE F129431 (4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylic acid), the principal metabolite in forage, grain and stover. The pathway then proceeds via hydroxylation of the phenyl ring to AE F162241 (4,5-dihydro-5-(4-hydroxyphenyl)-5-phenyl-3-isoxazolecarboxylic acid) which was also significant in forage and stover. AE F129431 and AE F162241 were also identified in a rice metabolism and rat metabolism study.

2. *Analytical method.* Based on the results of the metabolism studies, the analytical targets selected were the parent compound, isoxadifen-ethyl, the major metabolite AE F129431 and the minor metabolite AE F162241. A practical method for the determination of these targets is available. Extractable residues of isoxadifen-ethyl and its two metabolites are extracted from crops with blending in a mixture of acidic aqueous acetonitrile. After washing with hexane and treatment with saturated brine, the analytes of interest are partitioned into dichloromethane. Isoxadifen-ethyl is separated from the two acidic metabolites by selective solid phase extraction, concentrated and quantified by capillary gas chromatography with ion-trap mass spectrometric detection. The extract containing the metabolites is divided in two portions. One portion is treated with trimethylsilyl-diazomethane to convert AE F129431 to its methylated derivative then quantified by capillary gas chromatography with ion-trap mass spectrometric detection. AE F162241 is quantified in the second portion by high performance liquid chromatography with ion-trap mass spectrometric detection. The limits of quantification (LOQ) are 0.02 ppm in corn grain and 0.05 ppm in corn forage and stover.

3. *Magnitude of residues.* Residue trials were carried out in a total of 29 field residue trials, in the U.S. and Canada using a water dispersible

granule (WG) formulation containing 50% weight/weight (w/w) isoxadifen-ethyl. The preparation was predominantly applied in a split application of 30 grams/hectares (g/ha) followed by 60 g/ha. In a limited number of Canadian trials the treatments were split as two sequential applications of 45 grams active ingredient/hectare (g ai/ha) each. In the U.S. trials a single application of 160 g ai/ha was also investigated. Pre-harvest intervals were between 37 to 67, 60 to 121 and 79 to 151 days for forage, grain and stover, respectively. No residues of the parent compound were detected in any corn grain stover or forage. Isoxadifen-ethyl derived residues in corn grain were limited to isolated observations of the metabolite AE F129431, to a maximum of 0.06 ppm. Residues in corn stover and forage were only observed in the form of AE F129431 and AE F162241. Following treatment of the corn with two applications totaling 90 g ai/ha, residues of AE F129431 and AE F162241 reached respective maxima of 0.13 ppm and 0.08 ppm in stover but were not detected in forage. Following treatment of the corn with a single application of 160 g ai/ha, residues of AE F129431 reached respective maxima of 0.35 ppm and 0.15 ppm in stover and forage. Following the higher application rate, residues of AE F162241 reached respective maxima of 0.1 ppm and 0.05 ppm in stover and forage. Tolerances are being proposed for the parent compound and AE F129431. Tolerances for the combined residues of isoxadifen-ethyl and AE F129431 are proposed at 0.1 ppm, 0.3 ppm and 0.5 ppm respectively, for grain, forage and stover. Tolerances are not proposed for the more polar metabolite, AE F162241 as it is not found in corn grain. In animal feed items levels are considerably lower than AE F129431 and it does not accumulate in animal tissues.

In a corn processing study, no residues above 0.02 milligrams/kilograms (mg/kg) were observed in corn grain following treatment of the crop at the nominal rate of 150 followed by 300 g ai/ha. This exaggerated rate is approximately five times the maximum proposed label rate. Since no residues were observed in the raw agricultural commodity, 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 for a safener because metabolism studies in cattle and poultry indicated very low residue levels at

dosing rates considerably higher than anticipated from field ingestion.

### B. Toxicological Profile

1. *Acute toxicity.* Isoxadifen-ethyl is slightly toxic following acute oral exposure, no more than slightly toxic following acute dermal exposure and practically non-toxic following acute inhalation exposure. The acute rat oral LD<sub>50</sub> of isoxadifen-ethyl was 1,740 mg/kg. The acute rat dermal LD<sub>50</sub> was greater than 2,000 mg/kg and the 4-hour rat inhalation LC<sub>50</sub> was > 5 milligrams/liter (mg/L). Isoxadifen-ethyl was slightly irritating to rabbit eyes and non-irritating to rabbit skin. Based on these results, isoxadifen-ethyl would be classified as EPA Category III for oral and dermal toxicity and eye irritation, and EPA Category IV for inhalation toxicity and dermal irritation. Technical isoxadifen-ethyl was shown to be a dermal sensitizer in a guinea pig maximization assay, but no evidence of sensitization has been observed in a Buehler assay when formulated into a commercial product.

2. *Genotoxicity.* No evidence of genotoxicity was noted in *Salmonella* and *E. coli* reverse bacterial mutation assays, an *in vitro* mammalian gene mutation assay in Chinese hamster lung (V79) cells, an *in vivo* unscheduled DNA synthesis assay in rat hepatocytes, or a mouse micronucleus assay. An increase in chromosomal aberrations was observed in an *in vitro* assay in Chinese hamster lung (V79) cells, but only at toxic concentrations. Thus, the overall weight of evidence indicates that isoxadifen-ethyl does not possess significant genotoxic activity.

3. *Reproductive and developmental toxicity.* A rat developmental toxicity study was conducted at dose levels of 0, 15, 120, and 1,000 mg/kg/day. Maternal toxicity (including one death) was noted at 1,000 mg/kg/day. Slight developmental toxicity (an increase in resorptions) but no evidence of teratogenicity was also noted at this level. No effects were noted at 120 mg/kg/day, which was considered to be the no observed adverse effect level (NOAEL) for both maternal and developmental toxicity.

A rabbit developmental toxicity study was conducted at dose levels of 0, 5, 50, and 500 mg/kg/day. Maternal effects at 500 mg/kg/day consisted of decreased food consumption, slight weight loss during gestation days 6-8, and one death. In addition, one animal at 500 mg/kg/day had only two empty implantation sites. No evidence of teratogenicity or developmental toxicity was noted. Thus, 50 mg/kg/day was considered to be the NOAEL for

maternal toxicity while 500 mg/kg/day was the NOAEL for developmental effects.

In the 2-generation reproduction study in the rat, administration of isoxadifen-ethyl at 4,000 ppm, resulted in parental toxicity in both sexes from the F<sub>0</sub> and F<sub>1</sub> generation consisting of reduction in body weight gain food intake and an increase in microscopic kidney lesions. The only effect seen in the offspring was lower pup weights of the F<sub>1</sub> generation together with a delay in achievement of vaginal patency and balanopreputial separation (due to the reduced body weight), at 4,000 ppm. The weights of F<sub>0</sub> males were significantly reduced throughout the pre-mating treatment period; those of F<sub>2</sub> females were reduced only during the first week after weaning. The NOAEL for both parental and neonatal toxicity was 200 ppm, equivalent to an overall mean achieved intake of about 16.4 mg/kg body weight/day.

4. *Subchronic toxicity.* In a 90-day rat feeding study, isoxadifen-ethyl was administered at dietary concentrations of 0, 20, 200, 2,000, and 4,000 ppm. The NOAEL for this study was considered to be 200 ppm (approximately 15.3 mg/kg/day) based on decreased weight gain at 2,000 ppm, and decreased weight gain, increased liver weights, and centrilobular hepatocyte enlargement at 4,000 ppm.

In a 90-day feeding study in mice, isoxadifen-ethyl was administered at dietary concentrations of 13, 125, 1,250, and 2,500 ppm. Decreased kidney weights, increased liver weights, and histopathological changes in the liver (centrilobular hepatocyte enlargement and vacuolation) were noted at 1,250 and 2,500 ppm. The NOAEL for this study was 125 ppm (approximately 23 mg/kg/day).

In a 90-day dog feeding study, isoxadifen-ethyl was administered to beagle dogs at dietary concentrations of 0, 25, 125, and 1,000 ppm. Dietary administration of 1,000 ppm isoxadifen-ethyl exceeded the maximum tolerated dose (MTD), and it was concluded that 700 ppm would be a suitable high dose level for a chronic dog study. The NOAEL for this 90-day study was considered to be 25 ppm (approximately 1.3 mg/kg/day) based on slight histopathological effects in the kidneys at 125 ppm, and effects on the kidneys, spleen, liver, heart, and intestines at 1,000 ppm.

5. *Chronic toxicity.* Chronic toxicity has been assessed in both the rat and the dog. In the rat combined chronic toxicity and oncogenicity study, the liver was the target organ as evidenced by increases in liver weight and

centrilobular hepatocyte hypertrophy. The no-effect level was 200 ppm (10 mg/kg/day). Whilst in the dog the kidney was the target organ with vacuolation of the straight tubular cytoplasm occurring at the high dose level. The no-effect level was 3.5 mg/kg/day indicating, as in the subchronic studies, that the dog is the most sensitive species. Based on the dog, Aventis CropScience believes the Reference Dose (RfD) for isoxadifen-ethyl is 0.035 mg/kg/day. No carcinogenic activity was detected in dogs, mice, and rats at the Maximum Tolerated Dose (MTD). Isoxadifen-ethyl is not oncogenic in dogs, rats, or mice and is not likely to be carcinogenic in humans. Aventis CropScience believes isoxadifen-ethyl should be classified as a "Not Likely" carcinogen based on the lack of carcinogenicity in rats and mice.

6. *Animal metabolism.* The metabolism of isoxadifen-ethyl has been determined in the rat and dog. In both species the main metabolic route was hydrolysis of the ester to yield the free acid AE F129431 (5,5-diphenyl-2-isoxazoline-3-carboxylic acid), which is the same as observed in plants. This was the only significant metabolic route in the dog following either gavage or dietary dosing. In the rat there was an additional metabolic route which led to the formation of a hydroxylated free acid, AE F162241 (4,5-dihydro-5-(4-hydroxyphenyl)-5-phenyl-3-isoxazolecarboxylic acid), also a plant metabolite. This was a major metabolic route in male rats, particular at the low-dose, but was only a minor metabolic route in female rats. Unchanged isoxadifen-ethyl was only excreted in trace amounts in the feces. There were a number of minor (< 3%) polar metabolites also excreted, which were not identified. A further plant metabolite AE C637375 (b-hydroxy-b-benzenepropanenitrile) was also shown to be a trace metabolite in the rat.

The metabolism of isoxadifen-ethyl in ruminants is adequately understood. A dairy cow was dosed with the compound at a level equivalent to 11.52 ppm in the diet for 7 days. Total residue levels were very low. Parent compound was seen in fats and milk only. The carboxylic acid, AE F129431, was the major metabolite identified in all of the tissues, with traces also being found in the milk.

The metabolism of isoxadifen-ethyl in poultry is also adequately understood. Laying hens were fed the compound at a level equivalent to 11 ppm in the diet for 14 days. Residue levels were low in all commodities. The vast majority of the dose was excreted as AE F129431, with smaller amounts of AE F162241

and isoxadifen-ethyl. AE F129431 was the major metabolite identified in all of the tissues and yolks. Trace amounts of isoxadifen-ethyl and AE F162241 were detected in liver and eggs with isoxadifen-ethyl also being detected in the muscle. The metabolic profile of isoxadifen-ethyl in the hen was similar to that seen in the cow and rat.

7. *Endocrine disruption.* No special studies have been conducted to investigate the potential of isoxadifen-ethyl 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.* Isoxadifen-ethyl will be used only as a herbicide safener for use on rice and corn. No non-agricultural uses are anticipated. Thus, the only potential sources of non-occupational exposure to isoxadifen-ethyl would consist of any potential residues in food and drinking water. As previously indicated, in the absence of any acute toxicity concerns, only chronic exposures have been evaluated.

i. *Food.* Chronic dietary analysis was conducted to estimate exposure to potential isoxadifen-ethyl derived residues in/on corn. A Tier One analysis was conducted using the Dietary Expected Evaluation Model (DEEM) software and the 1994-1996 CSFII food consumption data. It was assumed that residues were at proposed tolerance levels in rice (0.05 ppm) and corn grain (0.1 ppm) and that 100% of 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 0.035 mg/kg/day is derived from the NOAEL of 3.5 mg/kg/day in the most sensitive species, dog. Using these inputs the chronic dietary exposure estimate from residues of isoxadifen-ethyl for the U.S. population was 0.000173 mg/kg/day or 0.5% of its RfD. For the sub-population with the highest exposure, non-nursing infants, the chronic dietary exposure estimate from residues of isoxadifen-ethyl was 0.000448 mg/kg/day, or 1.3% 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.* 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 drinking water assessment. These tools include water models such as Screening Concentration in Ground Water (SCI-GROW), Generic Expected Environmental Concentration (GENEEC), Pesticide Root Zone Model (PRZMS)/EXAMS, and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface and ground water and the highest is assumed to be the drinking water residue. In the case of isoxadifen-ethyl monitoring data do not exist; therefore, model calculations were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for chronic exposures for all adults and children greatly exceed the drinking water estimated concentrations (DWECC) from the models. The chronic DWLOC for adults is 1,218 parts per billion (ppb). The chronic DWLOC for children/toddlers is 346 ppb. The worst case chronic DWECC is 0.165 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 DWECC represents combined residues of isoxadifen-ethyl and AE F129431, expressed as isoxadifen-ethyl equivalents.

2. *Non-dietary exposure.* Exposure to isoxadifen-ethyl for the mixer/loader/ground boom/aerial applicator was calculated using the Pesticide Handlers Exposure Database (PHED). It was assumed that the product would be applied to a maximum of 50 ha per day (125 acres/day) by ground boom applicator and 140 ha per day (350 acres/day) by aerial applicator at a maximum use rate of 45 g 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 body weight/day from the rat dermal toxicity study and an inhalation NOAEL of 3.5 mg/kg body weight/day based on the dog chronic toxicity study. The combined MOE (inhalation plus dermal) for isoxadifen-ethyl was 28,000 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 17,000 for the mixer/loader and 233,000 for the pilot. The results indicate that large margins

of safety exist for the proposed use of isoxadifen-ethyl.

#### D. Cumulative Effects

There is no information to indicate that isoxadifen-ethyl may share a common mechanism of toxicity with any other chemical. Thus, this assessment was not needed.

#### 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 AE F 122006 will utilize at most 0.5% 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. Drinking water levels of comparison 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 isoxadifen-ethyl.

2. *Infants and children.* No evidence of increased sensitivity to fetuses was noted in 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 RfD that will be used for exposure to residues of isoxadifen-ethyl in food for non-nursing infants (the most highly exposed subgroup) is 1.3%. The children (1-6) exposure is 1.1% of the RfD. As in the adult situation, DWLOCs are much higher than the worst case DWECCs 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 AE F122006.

#### F. International Tolerances

There are no Codex Alimentarius Commission maximum residue levels

established for residues of isoxadifen-ethyl.

## 2. Cabot Corporation

PP 0E6109

EPA has received a pesticide petition (0E6109) from Cabot Corporation, 75 State St., Boston, MA, 02109 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for silicon dioxide, fumed, amorphous when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to animals. Silicon dioxide, fumed, amorphous is already exempted from the requirements of a tolerance when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; 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

No residue chemistry data are presented in the petition as the Agency does not generally require these data to rule on the exemption from the requirement of a tolerance for an inert ingredient.

### B. Toxicological Profile

The Agency has established a set of criteria which identifies categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compounds compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit polymer's ability to cause adverse effects. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Cabot Corporation believes that silicon dioxide, fumed, amorphous conforms to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria used to identify a low risk polymer.

1. Silicon dioxide, fumed, amorphous is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. Silicon dioxide, fumed, amorphous contains as an integral part of its

composition the atomic elements silicon and oxygen.

3. Silicon dioxide, fumed, amorphous does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(iii).

4. Silicon dioxide, fumed, amorphous is not designed, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize prior to, during, or after use.

5. Silicon dioxide, fumed, amorphous is not manufactured or imported from monomers and/or reactants that are not included on the Toxic Substances and Control Act (TSCA) substance inventory or manufactured under an applicable TSCA section 5 exemption.

6. Silicon dioxide, fumed, amorphous is not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000.

7. Silicon dioxide, fumed, amorphous has a minimum-average molecular weight of 645,000 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. Silicon dioxide, fumed, amorphous has a minimum average molecular weight of 645,000 daltons. Silicon dioxide meets the requirements for molecular weight distribution of oligomer contents of less than 5% with molecular weights less than 1,000 and less than 2% with molecular weights less than 500.

Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silicon dioxide, fumed, amorphous. No toxicology data are being submitted as the Agency does not generally require these data to rule on the exemption from the requirement of a tolerance for an inert ingredient. Because silicon dioxide conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with toxicity.

### C. Aggregate Exposure

1. *Dietary exposure.* Silicon dioxide, fumed, amorphous is not absorbed through the intact gastrointestinal tract and is incapable of eliciting a toxic response.

2. *Drinking water.* Silicon dioxide, fumed, amorphous is not soluble in water and therefore there is no reason to

expect human exposure to residues in water.

3. *Non-dietary exposure.* For most uses of silicon dioxide, fumed, amorphous the primary route of exposure is dermal. Silicon dioxide, fumed, amorphous with a molecular weight significantly greater than 400 is not absorbed through the intact skin.

### D. Cumulative Effects

Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silicon dioxide, fumed, amorphous. Because silicon dioxide, fumed, amorphous conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with cumulative effects.

### E. Safety Determination

1. *U.S. population.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silicon dioxide, fumed, amorphous. Because silicon dioxide, fumed, amorphous conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silicon dioxide, fumed, amorphous. Because silicon dioxide, fumed, amorphous conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with exposure to infants and children.

### Amended Petitions

#### 1. Cabot Corporation

9E6017

EPA has received an amendment to a pesticide petition (9E6017) from Cabot Corporation, 75 State St., Boston, MA, 02109 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to amend an exemption from the requirement of a tolerance for dimethyl silicone polymer with silica (TS-720) when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops in or on the raw agricultural commodity after harvest or to animals. The initial notice of filing was published in the **Federal Register** of August 25, 1999 (64 FR 46378) (FRL-

6096-1). 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.

An exemption from the requirement of a tolerance under 40 CFR 180.1001(c) and (e) was established for dimethyl silicone polymer with silica in the **Federal Register** on March 1, 2000 (65 FR 10946) (FRL-6490-9), with the following uses: "moisture barrier, anti-caking agent, anti-settling agent." This amendment to the petition requests that the use "thickening agent" be added so that the uses for dimethyl silicone polymer with silica under 40 CFR 180.1001(c) and (e) will read as follows: "moisture barrier, anti-caking agent, anti-settling agent, thickening agent."

#### A. Residue Chemistry

No residue chemistry data are presented in the petition as the Agency does not generally require these data to rule on the exemption from the requirement of a tolerance for an inert ingredient.

#### B. Toxicological Profile

As discussed in the March 1, 2000 **Federal Register**, dimethyl silicone polymer with silica meets all the criteria for a low risk polymer, as specified in 40 CFR 723.250.

#### C. Aggregate Exposure

1. *Dietary exposure.* Dimethyl silicone polymer with silica is not absorbed through the intact gastrointestinal tract and is incapable of eliciting a toxic response.

2. *Drinking water.* Dimethyl silicone polymer with silica is not soluble in water and therefore there is no reason to expect human exposure to residues in water.

3. *Non-dietary exposure.* For most uses of dimethyl silicone polymer with silica, the primary route of exposure is dermal. Dimethyl silicone polymer with silica with a molecular weight significantly greater than 400 is not absorbed through the intact skin.

#### D. Cumulative Effects

Cabot Corporation believes that sufficient information has been submitted to assess the hazards of dimethyl silicone polymer with silica. Because dimethyl silicone polymer with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot

Corporation believes there are no concerns for risks associated with cumulative effects.

#### E. Safety Determination

1. *U.S. population.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of TS-720. Because TS-720 conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of dimethyl silicone polymer with silica. Because dimethyl silicone polymer with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with exposure to infants and children.

#### 2. Cabot Corporation

##### 9E6018

EPA has received an amendment to a pesticide petition (9E6018) from Cabot Corporation, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to amend an exemption from the requirement of a tolerance for silane, dichloromethyl-, reaction product with silica (TS-610) when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops in or on the raw agricultural commodity after harvest or to animals. The initial notice of filing was published in the **Federal Register** of August 25, 1999 (64 FR 46378) (FRL-6096-1). 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.

An exemption from the requirement of a tolerance under 40 CFR 180.1001(c) and (e) was established for silane, dichloromethyl-, reaction product with silica in the **Federal Register** of March 1, 2000 (65 FR 10946) (FRL-6490-9), with the following uses: "moisture barrier, anti-caking agent, anti-settling agent, anti-thickening agent." This petition amendment requests that "anti-thickening" be revised by deleting "anti," so that the uses for silane,

dichloromethyl-, reaction product with silica under 40 CFR 180.1001(c) and (e) will read as follows: "moisture barrier, anti-caking agent, anti-settling agent, thickening agent."

#### A. Residue Chemistry

No residue chemistry data are presented in the petition as the Agency does not generally require these data to rule on the exemption from the requirement of a tolerance for an inert ingredient.

#### B. Toxicological Profile

As discussed in the March 1, 2000 **Federal Register**, silane, dichloromethyl-, reaction product with silica meets all the criteria for a low risk polymer, as specified in 40 CFR 723.250.

#### C. Aggregate Exposure

1. *Dietary exposure.* Silane, dichloromethyl-, reaction product with silica is not absorbed through the intact gastrointestinal tract and is incapable of eliciting a toxic response.

2. *Drinking water.* Silane, dichloromethyl-, reaction product with silica is not soluble in water and therefore there is no reason to expect human exposure to residues in water.

3. *Non-dietary exposure.* For most uses of silane, dichloromethyl-, reaction product with silica the primary route of exposure is dermal. Silane, dichloromethyl-, reaction product with silica, with a molecular weight significantly greater than 400, is not absorbed through the intact skin.

#### D. Cumulative Effects

Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silane, dichloromethyl-, reaction product with silica. Because silane, dichloromethyl-, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with cumulative effects.

#### E. Safety Determination

1. *U.S. population.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of silane, dichloromethyl-, reaction product with silica. Because silane, dichloromethyl-, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of TS-610. Because silane, dichloromethyl-, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with exposure to infants and children.

### 3. Cabot Corporation

9E6019

EPA has received an amendment to a pesticide petition (9E6019) from Cabot Corporation proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to amend an exemption from the requirement of a tolerance for hexamethyldisilazane, reaction product with silica (TS-530) when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to growing crops in or on the raw agricultural commodity after harvest or to animals. The initial notice of filing was published in the **Federal Register** of August 25, 1999 (64 FR 46378) (FRL-6096-1). 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.

An exemption from the requirement of a tolerance under 40 CFR 180.1001(c) and (e) was established for hexamethyldisilazane, reaction product with silica in the **Federal Register** of March 1, 2000 (65 FR 10946) (FRL-6490-9), with the following uses: "moisture barrier, anti-caking agent, anti-settling agent." This petition amendment requests that the use "thickening agent" be added so that the uses for TS-530 under 40 CFR 180.1001(c) and (e) will read as follows: "moisture barrier, anti-caking agent, anti-settling agent, thickening agent."

#### A. Residue Chemistry

No residue chemistry data are presented in the petition as the Agency does not generally require these data to rule on the exemption from the requirement of a tolerance for an inert ingredient.

#### B. Toxicological Profile

As discussed in the March 1, 2000 **Federal Register**, hexamethyldisilazane, reaction product with silica meets all the criteria for a low risk polymer, as specified in 40 CFR 723.250.

#### C. Aggregate Exposure

##### 1. Dietary exposure.

Hexamethyldisilazane, reaction product with silica is not absorbed through the intact gastrointestinal tract and is incapable of eliciting a toxic response.

##### 2. Drinking water.

Hexamethyldisilazane, reaction product with silica is not soluble in water and therefore there is no reason to expect human exposure to residues in water.

3. *Non-dietary exposure.* For most uses of hexamethyldisilazane, reaction product with silica the primary route of exposure is dermal.

Hexamethyldisilazane, reaction product with silica with a molecular weight significantly greater than 400 is not absorbed through the intact skin.

#### D. Cumulative Effects

Cabot Corporation believes that sufficient information has been submitted to assess the hazards of hexamethyldisilazane, reaction product with silica. Because hexamethyldisilazane, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with cumulative effects.

#### E. Safety Determination

1. *U.S. population.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of hexamethyldisilazane, reaction product with silica. Because hexamethyldisilazane, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children.* Cabot Corporation believes that sufficient information has been submitted to assess the hazards of hexamethyldisilazane, reaction product with silica. Because hexamethyldisilazane, reaction product with silica conforms with the definition of a polymer and meets the criteria of a polymer under 40 CFR 723.250, Cabot Corporation believes there are no concerns for risks associated with exposure to infants and children.

[FR Doc. 00-16633 Filed 6-29-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6727-4]

### Draft EPA Guidance for Community Involvement in Supplemental Environmental Projects

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

**ACTION:** Notice.

**SUMMARY:** The Office of Enforcement and Compliance Assurance (EPA) is noticing a draft document, "Guidance for Community Involvement in Supplemental Environmental Projects," for comment. This document is intended to provide guidance to EPA personnel on how to achieve the community involvement objectives of the 1998 Supplemental Environmental Projects Policy (SEP Policy). EPA is soliciting public comments on this guidance to assist it in addressing issues such as identifying communities affected by enforcement actions, facilitating the outreach process, encouraging realistic community expectations, and using liaisons to facilitate communication.

**DATES:** Comments are due on or before August 29, 2000.

**ADDRESSES:** Mail written comments to the Enforcement and Compliance Docket and Information Center (2201A), Docket Number EC-G-2000-055, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. (Comments may be submitted on disk in WordPerfect 8.0 or earlier versions.) Written comments may be delivered in person to: Enforcement and Compliance Docket and Information Center, U.S. Environmental Protection Agency, Room 4033, Ariel Rios Bldg., 1200 Pennsylvania Avenue, NW., Washington, DC. Submit comments electronically to [doCKET.oeca@epa.gov](mailto:doCKET.oeca@epa.gov). Electronic comments may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** Melissa Raack, 202-564-7039, Office of Regulatory Enforcement, Mail Code 2248-A, United States Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, e-mail: [raack.melissa@epa.gov](mailto:raack.melissa@epa.gov).

**SUPPLEMENTARY INFORMATION:** In its Supplemental Environmental Projects Policy of May 1, 1998, EPA affirmed its commitment to involve communities in the consideration of SEPs in appropriate enforcement cases. Although there is no formula for effective community