

In the **Federal Register** notice of December 5, 2001 (66 FR 63237), EPA requested public comment on the voluntary cancellation and use deletion requests, and provided a 30-day comment period. The registrants requested that the Administrator waive the 180-day comment period provided under FIFRA section 6(f)(1)(C).

No public comments were submitted to the docket in response to EPA's request for comments.

### III. Cancellation Order

Pursuant to section 6(f) of FIFRA, EPA is approving the requested registration cancellations. The Agency orders that the registrations identified in Table 1 are hereby canceled. After January 25, 2002, any distribution, sale, or use of existing stocks of the products identified in Table 1 in a manner inconsistent with the terms of this Order or the Existing Stock Provisions in Unit IV of this **Federal Register** notice will be considered a violation of section 12(a)(2)(K) of FIFRA and/or section 12(a)(1)(A) of FIFRA.

### IV. Existing Stocks Provisions

For purposes of this Order, the term "existing stocks" is defined, pursuant to EPA's existing stocks policy (56 FR 29362, June 26, 1991), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation.

1. *Distribution or sale by registrants.* Except for the purposes of returns for relabeling consistent with the June 7, 2000 Memorandum of Agreement, shipping for export consistent with the requirements of section 17 of FIFRA, or proper disposal, the distribution or sale of existing stocks by registrants of any product identified in Table 1 will not be lawful under FIFRA after January 25, 2002.

2. *Retail and other distribution or sale.* The retail sale of existing stocks of products listed in Table 1 will not be lawful under FIFRA after January 25, 2002. Except as otherwise provided in this order, any other distribution or sale (for example, return to the manufacturer for relabeling) is permitted until stocks are exhausted.

3. *Use of existing stocks.* The use of existing stocks of products listed in Table 1 is permitted until such stocks are exhausted, provided such use is in accordance with the existing labeling of that product.

### List of Subjects

Environmental protection, Memorandum of Agreement, Pesticides and pests.

Dated: January 15, 2002.

**Jack Housenger,**

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

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**BILLING CODE 6560-50-S**

### ENVIRONMENTAL PROTECTION AGENCY

[PF-1066; FRL-6819-2]

#### 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-1066, must be received on or before February 25, 2002.

**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-1066 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Geri McCann, Insecticide/Rodenticide Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8375; e-mail address: mccann.geri@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<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>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-1066. 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-1066 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-1066. 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 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 14, 2002.

**Peter Caulkins,**

*Acting 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 petitioners. 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.

#### PP 1F6301

EPA has received a pesticide petition (PP 1F6301) from E. I. du Pont de Nemours and Company (DuPont), P.O. Box 30, Newark, DE 19714, 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 combined residues of indoxacarb, [(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno [1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate] in a 75:25 mixture (DPX MP062), respectively, in or on the raw agricultural commodities as follows: Alfalfa forage at 12 parts per million (ppm), alfalfa hay at 50 ppm, peanut at 0.01 ppm, peanut hay at 40 ppm, potato at 0.02 ppm, soybean aspirated grain fractions at 70 ppm, soybean hulls at 6.5 ppm, head lettuce at 5 ppm, meat (of cattle, goats, hogs, horses and sheep) at 0.05 ppm, fat (of cattle, goats, hogs, horses and sheep) at 1.5 ppm, meat by-products (of cattle, goats, hogs, horses and sheep) at 0.03 ppm and milk at 0.15 ppm. Two analytical enforcement methods are available for determining these plant and animal residues. They are GC-MSD and HPLC column-switching with UV detection. 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

The active ingredient in the end-use formulations, Steward® and Avaunt™, is a 75:25 mixture of two isomers, indoxacarb (IN-KN128) and IN-KN127. Only one of the isomers, indoxacarb (DPX-KN128), has insecticidal activity. Since the insecticidal efficacy is based

on the concentration of indoxacarb (DPX-KN128), the application rates have been normalized on an indoxacarb (DPX-KN128) basis. The proposed tolerance expression includes both indoxacarb (DPX-KN128) and IN-KN127 and the residue method does not distinguish between the enantiomers, therefore residues are reported as the sum of indoxacarb (DPX-KN128) combined with IN-KN127. Residues of indoxacarb (DPX-KN128) combined with IN-KN127 will be referred to as "KN128/KN127."

1. *Plant metabolism* The metabolism of indoxacarb in plants is adequately understood to support these tolerances. Plant metabolism studies in cotton, lettuce, grapes and tomatoes showed no significant metabolites. The only significant residue was parent compound.

2. *Analytical method.* One plant residue enforcement method detects and quantitates indoxacarb in cotton and sweet corn matrices by HPLC with UV detection. The other plant residue enforcement method detects and quantitates indoxacarb in various matrices including lettuce, tomato, pepper, cabbage, broccoli, cauliflower, apple, pear, grape, cottonseed, tomato and apple processed commodity samples by GC-MSD. The analytical method for detecting and quantitating indoxacarb in animal matrices including whole and skim milk, cream, fat, muscle, liver and kidney is an HPLC column-switching method using UV detection. The limit of quantitation in each method allows monitoring of crops and animal matrices with indoxacarb residues at or above the levels proposed in these tolerances.

3. *Magnitude of residues—i. Alfalfa.* Residue studies were conducted at a total of 12 field sites. All studies were done using Steward<sup>®</sup> Insecticide. One broadcast application of Steward<sup>®</sup> Insecticide was made for each alfalfa cutting at each test site. Each application was made at a maximum rate of 0.11 lb. a.i. DPX-KN128/A. After application, the plant was cut at a PHI of 7 days and samples of forage were taken. Additional forage was allowed to dry to proper moisture content to produce hay samples (cutting 1). Plants were allowed to regrow and were retreated with 0.11 lb. a.i. DPX-KN128 seven days prior to the next cutting. Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Maximum residues of KN128/KN127 in individual duplicate forage samples were 9.0 ppm at a PHI of 7 days (range 0.8–9.0 ppm). Maximum residues of KN128/KN127 in

individual duplicate hay samples were 39 ppm at a PHI of 7 days (range 3.2–39 ppm).

ii. *Lettuce.* Residue studies were conducted at a total of 18 field sites. All studies were done using Avaunt<sup>™</sup> Insecticide. Avaunt<sup>™</sup> contains 30% active ingredient (a.i.) (300 g DPX-KN128 per kg, w/w). Four broadcast applications of Avaunt<sup>™</sup> Insecticide were made at each test site. Each application was made at a maximum rate of 0.111 lb. a.i. DPX-KN128/A (maximum seasonal use rate of 0.444 lb. a.i./A). Applications were made approximately 3 days apart. The target PHI was 3 days. Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Maximum residues of KN128/KN127 in individual duplicate head lettuce samples collected from the field with wrapper leaves were 4.4 ppm at a PHI of 3 days (range < 0.40–4.4 ppm). Maximum residues of KN128/KN127 in individual duplicate head lettuce samples without wrapper leaves were 1.1 ppm at a PHI of 3 days (range < 0.02–1.1 ppm). Maximum residues of KN128/KN127 in individual duplicate leaf lettuce samples were 8.7 ppm at a PHI of 3 days (range 2.7–8.7 ppm). Head lettuce and leaf lettuce were each grown at 9 field sites.

iii. *Peanuts.* Residue studies were conducted at a total of 12 field sites. All studies were done using Steward<sup>®</sup> Insecticide. Steward<sup>®</sup> contains 15% a.i. (150 g DPX-KN128 per liter, w/v). Four broadcast applications of Steward<sup>®</sup> Insecticide were made at each test site. Each application was made at a maximum rate of 0.110 lb. a.i. DPX-KN128/A (maximum seasonal use rate of 0.440 lb. a.i./A). Applications were made approximately 5 days apart. The target PHI was 14 days. Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Maximum residues of KN128/KN127 in peanut hay were 32 ppm at a PHI of 14 days (range 2.1–32 ppm). No detectable residues of KN128/KN127 were found in peanut nutmeat at a PHI of 14 days at any of the 12 test sites in the study (residues < 0.003 ppm).

iv. *Peanuts, process fractions.* A processing study was conducted to determine the magnitude of KN128/KN127 residues in peanut nutmeat and their possible concentration in peanut processed fractions (refined oil and meal). Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Peanuts were treated with Steward Insecticide (see

description above). Four broadcast applications were made each at a rate of 0.110 and 0.550 lb. a.i./A (1X and 5X the proposed maximum seasonal use rate of 0.440 lb. a.i./A). The application interval was 5 days and the pre-harvest interval (PHI) was 14 days. At 5X the maximum seasonal use rate, quantifiable residues of KN128/KN127 were found in peanut nutmeat (0.013 ppm). Residues of KN128/KN127 in refined oil were 0.013 ppm. Quantifiable residues were not found in meal (residues < 0.0075 ppm). Residues of KN128/KN127 did not concentrate in refined oil or meal to levels greater than those on the raw agricultural commodity (concentration factors = 1 or < 1, respectively).

v. *Potatoes.* Residue studies were conducted at a total of 16 field sites. All studies were done using Avaunt<sup>™</sup> Insecticide. Avaunt<sup>™</sup> contains 30% a.i. (300 g DPX-KN128 per kg, w/w). Four broadcast applications of Avaunt<sup>™</sup> Insecticide were made at each test site. Each application was made at a maximum rate of 0.065 lb. a.i. DPX-KN128/A (maximum seasonal use rate of 0.26 lb. a.i./A). Applications were made approximately 5 days apart. The target PHI was 7 days. Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). No quantifiable residues of KN128/KN127 were found in potato tubers at a PHI of 7 days at any of the 16 test sites in the study (residues < 0.010 ppm).

vi. *Potatoes, process fractions.* A processing study was conducted state to determine the magnitude of KN128/KN127 residues in unwashed and washed potato tubers and culls and their possible concentration in potato tuber processed fractions (wet peel, chips and flakes). Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Potatoes were treated with Avaunt Insecticide (see description above). Four broadcast applications were made each at a rate of 0.065 and 0.325 lb. a.i./A (1X and 5X the proposed maximum seasonal use rate of 0.26 lb. a.i./A). The application interval was 5 days and the pre-harvest interval (PHI) was 7 days. At 5X, the maximum seasonal use rate, no quantifiable residues of KN128/KN127 were found in unwashed or washed potatoes, culls or in wet peel, chips or flakes (residues < 0.010 ppm). Residues of KN128/KN127 did not concentrate in any potato processed fraction to levels greater than those on the raw agricultural commodity.

vii. *Soybeans.* Residue studies were conducted at a total of 20 field sites. All

studies were done using Steward<sup>®</sup> Insecticide. Steward<sup>®</sup> contains 15% a.i. (150 g DPX-KN128 per liter, w/v). Four broadcast applications of Steward<sup>®</sup> Insecticide were made at each test site. Each application was made at a maximum rate of 0.111 lb. a.i. DPX-KN128/A (maximum seasonal use rate of 0.444 lb. a.i./A). Applications were made approximately 5 days apart. The target PHI was 21 days. Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Maximum residues of KN128/KN127 in soybean seed were 0.59 ppm at a PHI of 21 days (range < 0.010–0.59 ppm). As part of this study, large samples of soybean seed were collected and subsequently processed into aspirated

grain fraction (dust). Analysis of the seed showed a residue of 0.032 ppm. Analysis of the aspirated grain fraction (dust) showed a residue of 2.8 ppm (concentration factor of 88:1).

viii. *Soybean, process fractions.* A processing study was conducted to determine the magnitude of KN128/KN127 residues in soybean seed and their possible concentration in processed fractions (hulls, meal and refined oil). Residues were measured as the combination of DPX-KN128 and IN-KN127 (enantiomers not resolved by the analytical method). Soybeans were treated with Steward<sup>®</sup> Insecticide (see description above). Four broadcast applications were made each at a rate of 0.111 and 0.555 lb. a.i./A (1X and 5X the proposed maximum seasonal use

rate of 0.444-lb. a.i./A). The application interval was 5 days and the pre-harvest interval (PHI) was 21 days. At 5X the maximum seasonal use rate, residues of KN128/KN127 in soybean seed were 0.077 ppm. Quantifiable residues were found in hulls (0.63 ppm) and refined oil (0.049 ppm). Quantifiable residues were not found in meal (residues < 0.010 ppm). Residues of KN128/KN127 concentrated in hulls (concentration factor = 8.12) but did not concentrate in refined oil or meal to levels greater than those on the raw agricultural commodity (concentration factors < 1).

## B. Toxicological Profile

1. *Acute toxicity* Based on EPA criteria, indoxacarb is classified as follows for Toxicity Categories

| Guideline | Title                     | Results  | Category     |
|-----------|---------------------------|--|--------------|
| 81-1      | Acute oral toxicity       | LD <sub>50</sub> 1,730 mg/kg (M Rat)<br>LD <sub>50</sub> 268 mg/kg (F Rat) | Category II  |
| 81-2      | Acute dermal toxicity     | LD <sub>50</sub> > 5,000 mg/kg (Rat)                                       | Category IV  |
| 81-3      | Acute inhalation toxicity | LC <sub>50</sub> > 5.5 mg/L (M Rat) (70% MUP)                              | Category IV  |
| 81-4      | Primary eye irritation    | Effects reversed within 72 hours (Rabbit)                                  | Category III |
| 81-5      | Primary Dermal Irritation | No irritation (Rabbit)   | Category IV  |
| 81-6      | Skin Sensitization        | Sensitizer (Guinea Pig)  | -----        |

Formulated products are slightly less acutely toxic than indoxacarb.

In an acute neurotoxicity study, indoxacarb exhibited decreased forelimb grip strength, decreased foot splay, and some evidence of slightly reduced motor activity, but only at the highest doses tested. The NOAEL was 100 mg/kg for males and 12.5 mg/kg for females based on body weight effects in females 50 mg/kg.

2. *Genotoxicity.* Indoxacarb has shown no genotoxic activity in the following listed *in-vitro* and *in-vivo* tests:

- i. Ames--Negative
- ii. *In-vitro* mammalian gene mutation (CHO/HGPRT)-- Negative
- iii. *In-vitro* unscheduled DNA synthesis-- Negative
- iv. *In-vitro* chromosomal aberration-- Negative
- v. *In-vivo* mouse micronucleus-- Negative

3. *Reproductive and developmental toxicity.* The results of a series of studies indicated that there were no reproductive, developmental or teratogenic hazards associated with the use of indoxacarb. In a 2-generation rat reproduction study, the parental no observed adverse effect level (NOAEL) was 1.5 mg/kg/day. The parental

NOAEL was based on observations of reduced weight gain and food consumption for the higher concentration groups of the F0 generation and potential treatment-related changes in spleen weights for the higher groups of the F1 generation. There was no effect on mating or fertility. The NOAEL for fertility and reproduction was 6.4 mg/kg/day. The offspring NOAEL was 1.5 mg/kg/day, and was based on the reduced mean pup weights noted for the F1 litters of the higher concentration groups. The effects on pup weights occurred only at a maternal effect level and may have been due to altered growth and nutrition in the dams. In studies conducted to evaluate developmental toxicity potential, indoxacarb was neither teratogenic nor uniquely toxic to the conceptus (i.e., not considered a developmental toxin). Developmental studies conducted in rats and rabbits demonstrated that the rat was more susceptible than the rabbit to the maternal and fetal effects of DPX-MP062. Developmental toxicity was observed only in the presence of maternal toxicity. The NOAEL for maternal and fetal effects in rats was 2 mg/kg/day based on body weight effects

and decreased food consumption at 4 mg/kg/day. The NOAEL for developmental effects in fetuses was >4 mg/kg/day. In rabbits, the maternal and fetal NOAELs were 500 mg/kg/day based on body weight effects, decreased food consumption in dams and decreased weight and delayed ossification in fetuses at 1,000 mg/kg/day.

4. *Subchronic toxicity.* Subchronic (90-day) feeding studies were conducted with rats, mice, and dogs. In a 90-day feeding study in rats, the NOAEL was 3.1 and 2.1 mg/kg/day for males and females, respectively. In male rats, the NOAEL was based on decreased body weight and nutritional parameters, mild hemolytic anemia and decreased total protein and globulin concentration. In female rats, the NOAEL was based on decreased body weight and food efficiency. In a subchronic neurotoxicity study in rats, there was no evidence of neurotoxicity at 11.9 and 6.09 mg/kg/day, the highest dose tested for males and females, respectively. The subchronic NOAEL in dogs (5.0 mg/kg/day, M/F) was based on hemolytic anemia. Erythrocyte values for most dogs were within a range that would be considered normal for dogs in

a clinical setting. Mice were less sensitive to indoxacarb than the rats or dogs. NOAELs (23 mg/kg/day, males, 16 mg/kg/day, females) were based on mortality (males only); increased reticulocytes and Heinz bodies and decreased body weight, weight gain, food consumption, food efficiency; and increased clinical signs (leaning to one side and/or with abnormal gait or mobility) (females only). In a 28-day repeated dose dermal study, the NOAEL was 50 mg/kg/day based on decreased body weights, body weight gains, food consumption, and food efficiency in females, and changes in hematology parameters, the spleen and clinical signs of toxicity in both sexes in rats.

5. *Chronic toxicity.* Chronic studies with indoxacarb were conducted on rats, mice, and dogs to determine oncogenic potential and/or chronic toxicity of the compound. Effects generally similar to those observed in the 90-day studies were seen in the chronic studies. Indoxacarb was not oncogenic in rats or mice. The chronic NOAEL in male rats was 5 mg/kg/day based on body weight and nutritional effects. In females, the NOAEL of 2.1 mg/kg/day was based on body weight and nutritional changes, as well as biologically significant hematologic changes at 3.6 mg/kg/day and above. Hemolytic effects were present only through the 6-month evaluation and only in females. The regenerative nature of indoxacarb-induced hemolytic anemia was demonstrated by the absence of significant changes in indicators of circulating erythrocyte mass at later evaluations. In mice, the chronic NOAEL of 2.6 mg/kg/day for males was based on decreased body weight and weight gain effects and food efficiency at 13.8 mg/kg/day and above. The NOAEL for females was 4.0 mg/kg/day based on body weight nutritional effects, neurotoxicity, and clinical signs at 20 mg/kg/day. In dogs, the chronic NOAEL was about 2.3 and 2.4 mg/kg/day in males and females, respectively based on hemolytic effects similar to those seen in the subchronic dog study.

6. *Animal metabolism.*—i. *Livestock animal metabolism.* Animal metabolism has been studied in the rat, hen, and cow and is well understood. In contrast to crops, indoxacarb is extensively metabolized in animals.

ii. *Poultry.* In poultry, hens were fed at 10 ppm/day for 5 days, 87–88% of the total administered dose was excreted; parent comprised 51–54% of the total dose in excreta. Concentration of residues in eggs were low, 0.3–0.4 of the total dose, as was the concentration of residues in muscle, 0.2% of the total dose. Parent and metabolite IN-JT333

were not detected in egg whites; only insecticidally inactive metabolites were identified. Parent and IN-JT333 were found in egg yolks; however, their concentrations were very low—0.01–0.02 ppm. Concentrations of parent and IN-JT333 in muscle were at or below the limit of quantitation, (LOQ) (0.01 ppm).

iii. *Cattle.* For the cow study, the cattle were fed at 10 ppm/day for 5-days; approximately 20% of the total administered dose was excreted in urine and 53–60% was excreted in feces in 5-days. Four-tenths to 1.2% of the total dose in urine was parent indicating extensive metabolism; parent represented 46–68% of the fecal activity. Thus, most residues were not absorbed; those residues that were absorbed were extensively metabolized. Less than 1% of the total administered dose was in milk, most of which was parent compound. The insecticidally active metabolite IN-JT333 was not found in milk. Residues in muscle represented less than 0.01% of the total administered dose most of which was parent. IN-JT333 was not detected in muscle. No other metabolites were seen above 10% of the dose, thus only parent and IN-JT333 were monitored in the cattle feeding study.

iv. *Cattle feeding study.* A cattle feeding study was conducted with indoxacarb at doses of 7.5 ppm, 22.5 and 75 ppm. KN128/KN127 concentrations at the 22.5 ppm feeding level were 0.053 ppm for whole milk, 0.018 ppm for skim milk and 0.58 ppm for cream. The mean KN128/KN127 concentrations were proportional to the dosing level in whole milk, skim milk and cream. IN-JT333 concentrations at the 22.5 ppm feeding level were below the LOQ for whole milk and skim milk. The concentration of IN-JT333 in cream was 0.022 ppm. The mean IN-JT333 concentrations were proportional to the dosing level in cream. KN128/KN127 and IN-JT333 concentrations at the 22.5 ppm feeding level were below the level of LOQ for all tissues, except fat (0.45 ppm, KN128/KN127 and 0.03 ppm IN-JT333) and kidney (0.017 ppm KN128/KN127), throughout 28 days of dosing. The mean KN128/KN127 residues in muscle, fat, liver, and kidney samples were proportional to the dosing level. The mean IN-JT333 residues in fat were proportional to the dosing level. Tolerances have been established at 0.75 ppm in fat (cattle, goat, horse, sheep and hog), 0.03 ppm in meat, 0.02 ppm in meat by-products, 0.10 ppm in milk and 3.0 ppm in milk fat.

7. *Metabolite toxicology.* In rats, indoxacarb was readily absorbed at low dose (5 mg/kg), but saturated at the high dose (150 mg/kg). Indoxacarb was

metabolized extensively, based on very low excretion of parent compound in bile and extensive excretion of metabolized dose in the urine and feces. Some parent compound remained unabsorbed and was excreted in the feces. No parent compound was excreted in the urine. The retention and elimination of the metabolite IN-JT333 from fat appeared to be the overall rate determining process for elimination of radioactive residues from the body. Metabolites in urine were cleaved products (containing only one radiolabel), while the major metabolites in the feces retained both radiolabels. Major metabolic reactions included hydroxylation of the indanone ring, hydrolysis of the carboxymethyl group from the amino nitrogen and the opening of the oxadiazine ring, which gave rise to cleaved products. Metabolites were identified by mass spectral analysis, NMR, UV and/or by comparison to standards chemically synthesized or produced by microsomal enzymes.

8. *Endocrine disruption.* Lifespan, and multigenerational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal endocrine effects. Any endocrine related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of indoxacarb is negligible.

### C. Aggregate Exposure

Tolerances for indoxacarb are proposed to support agricultural uses on alfalfa, lettuce, peanuts, potatoes and soybean. There are no residential uses of indoxacarb.

1. *Dietary exposure.* The chronic RfD of 0.02 mg/kg bw/day is based on a NOAEL of 2.0 mg/kg bw/day from the subchronic rat feeding study, the subchronic rat neurotoxicity study, and the chronic/carcinogenicity study, using an uncertainty factor of 100. The acute RfD for the general population is 0.12 mg/kg/day, based on the NOAEL of 12.5 mg/kg in the acute neurotoxicity study and an uncertainty factor of 100. The acute RfD for females 13–50 years of age is 0.02 mg/kg/day, based on the NOAEL of 2 mg/kg/day observed in the developmental rat toxicity study and using an uncertainty factor of 100.

*Food.* Chronic dietary exposure assessment. Chronic dietary exposure resulting from the currently approved use of indoxacarb on apples, broccoli, cabbage, cauliflower, cotton, pears, peppers, sweet corn, tomatoes and the proposed uses on alfalfa, lettuce, peanuts, potatoes and soybeans are well within acceptable limits for all sectors

of the population. The Chronic Module of the Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1997 Version 7.075) was used to conduct the assessment with the reference dose (RfD) of 0.02 mg/kg/day. The analysis used overall mean field trial values and conservatively assumed

that 100% of the crops on the proposed label would be treated with indoxacarb. The chronic dietary exposure to indoxacarb is 0.001428 mg/kg/day, and utilizes 7.1% of the RfD for the overall U.S. population. The exposure of the most highly exposed subgroup in the population, children age 1–6 years, is

0.003929 mg/kg/day, and utilizes 19.6% of the RfD. The table below lists the results of this analysis, which indicate large margins of safety for each population subgroup and very low probability of effects resulting from chronic exposure to indoxacarb.

| Subgroup                            | Maximum Dietary Exposure (mg/kg/day) | %RfD |
|-------------------------------------|--------------------------------------|------|
| U.S. population                     | 0.001428                             | 7.1  |
| Non-nursing infants (< 1 year old)  | 0.001707                             | 8.5  |
| Children (1–6 years)                | 0.003929                             | 19.6 |
| Children (7–12 years)               | 0.002233                             | 11.2 |
| Females (13+, pregnant/not nursing) | 0.001353                             | 6.8  |

2. *Acute dietary exposure.* Acute dietary exposure resulting from the currently approved use of indoxacarb on apples, broccoli, cabbage, cauliflower, cotton, pears, peppers, sweet corn, tomatoes and the proposed uses on alfalfa, lettuce, peanuts, and soybeans are well within acceptable limits for all sectors of the population. The Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1997 Version 7.075) was used to conduct the

assessment. Margins of exposure (MOE) were calculated based on an acute NOAEL of 2 mg/kg/day for women of childbearing age and a NOAEL of 12 mg/kg/day for children and the general population (Pesticide Fact Sheet for Indoxacarb). The Tier 2 analysis used anticipated residues and conservatively assumed that 100% of the crops on the proposed label would be treated with indoxacarb. The results of this analysis are given in the table below. The

percent of the acute population adjusted dose (a PAD) for all population subgroups shows that an adequate margin of safety exists in each case. Thus, the acute dietary safety of indoxacarb for established and follow-on uses clearly meets the FQPA standard of reasonable certainty of no harm and presents much lower acute dietary risk than many of its competitors.

| Subgroup                            | 95 <sup>th</sup> Percentile of Exposure |   |
|-------------------------------------|---|---|
|                                     | Exposure (mg/kg/day)                    | % Acute Population Adjusted Dose (aPAD) |
| U.S. population                     | 0.009013                                | 7.5                                     |
| Non-Nursing (< 1 year)              | 0.013429                                | 11.9                                    |
| Children (1–6 years)                | 0.018211                                | 15.8                                    |
| Children (7–12 years)               | 0.010682                                | 8.9                                     |
| Females (13+, pregnant/not nursing) | 0.006256                                | 31.3                                    |

*Drinking water.* Indoxacarb is highly unlikely to contaminate ground water resources due to its immobility in soil, low water solubility, high soil sorption, and moderate soil half-life. Based on the PRZM/EXAMS and SCI-GROW models the highly conservative, estimated environmental concentrations (EECs) of indoxacarb and its R-enantiomer for acute exposures are estimated to be 3.81 parts per billion (ppb) for surface water and 0.02 ppb for ground water (Indoxacarb Final Rule, 65 FR 58421). The EECs for chronic exposures are estimated to be 0.56 ppb for surface water and 0.02 ppb for ground water. Drinking water levels of comparison (DWLOCs), theoretical upper limits on the pesticides concentration in drinking water, were calculated to be much higher than the EEC's. Thus, exposures to drinking water are expected to be negligible.

3. *Non-dietary exposure.* Indoxacarb products are not labeled for residential non-food uses, thereby eliminating the potential for residential exposure. Non-

occupational, non-dietary exposure for DPX-MP062 has not been estimated because the proposed products are limited to commercial crop production. Therefore, the potential for non-occupational exposure is insignificant.

#### D. Cumulative Effects

EPA's consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of indoxacarb would be cumulative with those of any other chemical compounds. Oxadiazine chemistry is new, and indoxacarb has a novel mode of action compared to currently registered active ingredients.

#### E. Safety Determination

1. *U.S. population.* Dietary and occupational exposure will be the major routes of exposure to the U.S. population, and ample margins of safety have been demonstrated for both situations. The chronic dietary exposure to indoxacarb is 0.001428 mg/kg/day,

which utilizes 7.1% of the RfD for the overall U.S. population, assuming 100% of the crops are treated and residues equivalent to overall mean field trial values. The percent of the acute population adjusted dose (7.5% aPAD) for all population subgroups shows that an adequate margin of safety exists. Using only PHED data levels A and B (those with a high level of confidence, MOEs for occupational exposure are 600 for mixer/loaders and 2,500 for applicators. Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is a reasonable certainty that no harm will result from the aggregate exposure of residues of indoxacarb including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* Chronic dietary exposure of the most highly exposed subgroup in the population, children age 1–6 years, is 0.003929 mg/kg/day or 19.6% of the RfD. For infants (non-nursing, >1 year), the exposure

accounts for 8.5% of the RfD. For acute exposure at the 95<sup>th</sup> percentile (based on a conservative Tier 2 assessment) the exposure was 0.018211 mg/kg/day (15.8% aPAD), for children 1–6 and 0.013429 mg/kg/day (11.9% aPAD) for non-nursing infants. There are no residential uses of indoxacarb and contamination of drinking water is extremely unlikely. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to indoxacarb, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of indoxacarb, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.

#### F. International Tolerances

To date, no international tolerances exist for indoxacarb.

[FR Doc. 02–1763 Filed 1–24–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP–50892; FRL–6815–4]

### Issuance of an Experimental Use Permit

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

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

**FOR FURTHER INFORMATION CONTACT:** By mail: Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Hwy., Rm. 220, Crystal Mall #2, Arlington, VA; (703) 305–6502; e-mail address: sibold.ann@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on

pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

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

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,” “Regulations and Proposed Rules,” 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/>.

#### II. EUP

EPA has issued the following EUP: 241–EUP–141. Extension. BASF Corporation, P.O. Box 400, Princeton, NJ 08543–0400. This EUP allows the use of 289.27 pounds of the termiticide chlorfenapyr (4–bromo–2–(4–chlorophenyl)–1–(ethoxymethyl)–5–(trifluoromethyl)–1H–pyrrole–3–carbonitrile) on less than 22 acres of residential/commercial structures to evaluate the control of termites. The program is authorized only in the States of Alabama, Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Virginia, and Washington. The EUP extension is effective from November 26, 2001 to December 31, 2002.

Persons wishing to review this EUP are referred to the designated contact person. Inquiries concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**Authority:** 7 U.S.C. 136.

#### List of Subjects

Environmental protection, Experimental use permits.

Dated: January 7, 2002.

**Peter Caulkins,**

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 02–1765 Filed 1–24–02; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

[FRL–7132–9]

### Proposed Agreement and Covenant Not To Sue Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, As Amended by the Superfund Amendments and Reauthorization Act of 1986; In Re: Pittsfield Economic Development Authority (“PEDA”), Related to CERCLA Site Known as the GE-Pittsfield/Housatonic River Site, Located in Pittsfield, MA

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed prospective purchaser agreement; request for public comment.

**SUMMARY:** In accordance with the Comprehensive Environmental Response Compensation, and Liability Act, as amended (“CERCLA”), 42 U.S.C. 9601, *et seq.*, notice is hereby given of a Prospective Purchaser Agreement and Covenant Not to Sue between the United States, on behalf of the U.S. Environmental Protection Agency (“EPA” or the “Agency”), and the Pittsfield Economic Development Authority (PEDA) (“Purchaser”). The Purchaser plans to acquire 52 acres of the GE-Pittsfield/Housatonic River Site for the purpose of redeveloping for the economic benefit of the City of Pittsfield. Pursuant to a Definitive Economic Development Agreement entered into by PEDA, the City, and the General Electric Company (“GE”), approximately 52 acres of the GE-Pittsfield/Housatonic River Site will be transferred to PEDA after the completion of removal actions pursuant to a CERCLA consent decree entered by the United States District Court in the matter of *United States v. General Electric Company*, Civil Docket No. 99–30225-MAP. PEDA will be the fee owner of property transferred to it by GE and will be responsible for managing future land uses thereon. Under the Proposed Agreement, the United States grants a Covenant Not to Sue to the Purchaser under provisions of CERCLA, the Resource Conservation and Recovery Act, the Oil Pollution Act, the Clean