

respectively, of the DWLOC. Therefore, the exposures to drinking water from imazethapyr use are negligible.

2. *Non-dietary exposure.* Imazethapyr products are not currently registered or requested to be registered for residential use; therefore the estimate of residential exposure is not relevant to this tolerance petition.

#### D. Cumulative Effects

Imazethapyr is a member of the imidazolinone class of herbicides. Other compounds of this class are registered for use in the United States. However, the herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxyacid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the low toxicity of the imidazolinone compounds in animals. We are aware of no information to indicate or suggest that imazethapyr has any toxic effects on mammals that would be cumulative with those of any other chemical. Therefore, for the purposes of this tolerance petition no assumption has been made with regard to cumulative exposure with other compounds having a common mode of action.

#### E. Safety Determination

1. *U.S. population.* The RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. In 1990, the EPA set the RfD for imazethapyr at 0.25 mg/kg bwt/day, based on the NOAEL from the 1-year dietary toxicity study in dogs of 25 mg/kg bwt/day and a 100-fold uncertainty factor. The chronic dietary exposure of 0.000419 mg/kg bwt/day for the general U.S. population will utilize only 0.2% of the RfD of 0.25 mg/kg bwt/day. EPA generally has no concern for exposures below 100% of the RfD. Due to the low toxicity of imazethapyr, an acute exposure dietary risk assessment is not warranted. The complete and reliable toxicity data base, the low toxicity of the active ingredient, and the results of the chronic dietary exposure risk assessment, support the conclusion that there is a "reasonable certainty of no harm" from the proposed use of imazethapyr on imidazolinone tolerant rice. Furthermore, these factors support the proposed tolerance on rice.

2. *Infants and children.* The conservative dietary exposure estimates of all registered uses including the proposed tolerance for rice show exposures of 0.001104, 0.000440,

0.000870, and 0.000610 mg/kg bwt/day which will utilize 0.4, 0.2, 0.3, and 0.2% of the RfD for all infants (<1 year), nursing infants, children 1-6 years, and children 7-12 years, respectively. The chronic dietary exposures for non-nursing infants, the most highly exposed subgroup, will utilize only 0.5% of the RfD. Results from the 2-generation reproduction study in rats and the developmental toxicity studies in rabbits and rats indicate no increased sensitivity to developing offspring when compared to parental toxicity. These results also indicate that imazethapyr is neither a developmental toxicant nor a teratogen in either the rat or rabbit. Therefore, an additional safety factor is not warranted, and the RfD of 0.25 mg/kg bwt/day, which utilizes a 100-fold safety factor is appropriate to ensure a reasonable certainty of no harm to infants and children.

#### F. International Tolerances

There are no Codex maximum residue levels established or proposed for residues of imazethapyr on rice.

[FR Doc. 00-24680 Filed 9-26-00; 8:45 am]

BILLING CODE 6560-50-S

### ENVIRONMENTAL PROTECTION AGENCY

[PF-972; FRL-6742-4]

#### 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-972, must be received on or before October 27, 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-972 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@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                      | 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," "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/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-972. 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-972 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-972. 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: September 15, 2000.

**James Jones,**

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

## **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the Federal Food Drug and Cosmetic Act (FFDCA). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announce 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.

## **DuPont Company**

*PP 6E4785*

EPA has received a pesticide petition (PP 6E4785) from the DuPont Company, DuPont Fluoroproducts, Chestnut Run Plaza, P.O. Box 80711, Wilmington, DE, 19880-0711 proposing, pursuant to section 408(d) of the (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of dimethylether (CAS Reg. No. 115-10-6) when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities (RAC) after harvest, and including area application in and around commercial and residential food handling facilities and establishments by certified applicators only. 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*

*Analytical method.* DME is used as a propellant in pesticide formulations and exists as a gas at ambient conditions. Upon release from the container, it vaporizes completely with essentially no residue; consequently, no analytical method for residue measurement is needed.

### B. Toxicological Profile

Since dimethylether (DME) exists as a gas at room temperature and any exposure to humans would occur via inhalation, all toxicity testing conducted with DME was done via inhalation or in the vapor phase.

1. *Acute toxicity.* An acute inhalation toxicity study was conducted in rats. The 4-hr LC<sub>50</sub> was determined to be 164,000 parts per million (ppm), EPA category IV.

2. *Genotoxicity*—i. An *in vitro* Ames/*Salmonella* mutagenicity assay in five commonly used strains was negative for mutagenic potential.

ii. An *in vitro* chromosomal aberration test in cultured human lymphocytes was negative for chromosomal aberrations.

3. *Reproductive and developmental toxicity*—i. Reproductive organs in male and female rats were examined histopathologically following inhalation of 0, 2,000, 10,000, or 25,000 ppm DME for 6, 12, 16, and 24 months. The no observed adverse effect level (NOAEL) in this study was 25,000 ppm as no compound-related effects on the reproductive organs of either male or female rats were observed.

ii. Developmental toxicity testing was conducted in rats exposed via inhalation to DME during days 6–15 of gestation. Fetal body weight (bwt) was decreased at the 20,000 and 40,000 ppm levels (of borderline statistical significance in the 20,000 ppm group) and there was an increased incidence of several skeletal variations (partial rib development in the lumbar region and partial or complete doubling of one or more vertebral centra). The NOAEL for the conceptus was 1,250 ppm. In comparison to maternal effect levels, DME was not demonstrated to represent a unique hazard to the rat conceptus.

4. *Subchronic toxicity.* Male and female Wistar rats were exposed to 0, 200, 2,000, or 20,000 ppm DME via inhalation for 30 weeks. At the 20,000 ppm level, male rats showed a significant reduction in liver weight accompanied by raised serum glutamic pyruvic transaminase (SGPT) levels. In the 20,000 ppm females, there was no significant effect on liver weight but SGPT levels were raised. The NOAEL in this study was 2,000 ppm.

5. *Chronic toxicity.* A 2-year DME inhalation study was conducted in rats for 6 hours/day, 5 days/week at concentrations of 0, 2,000, 10,000, or 25,000 ppm. The NOAEL was 2,000 ppm based on an increase in bwt and a decrease in survival in male rats exposed to 10,000 or 25,000 ppm DME vapors and on hemolytic effects noted

in male rats exposed to 25,000 ppm DME vapors for 6 months. No neoplastic lesions were observed that could be attributable to DME exposure. DME was not carcinogenic.

6. *Animal metabolism.* Dimethylether is a volatile, stable compound. While no metabolism studies were identified, the primary route of DME elimination from the body is likely to be exhalation of parent compound.

7. *Endocrine disruption.* No adverse endocrine effects have been suggested or reported in any toxicity tests conducted with DME.

### C. Aggregate Exposure

1. *Dietary exposure.* Dimethylether exists as a vapor at atmospheric pressure and ambient temperatures. It is handled and contained in aerosol products as a liquefied gas under its own vapor pressure which is 63 psig at 70°F. Upon release from container pressure, as when product is dispensed, dimethylether vaporizes completely with essentially no residue. Dimethylether is intended as an inert ingredient and propellant for pesticide formulations applied in food handling areas and establishments; these products are not intended for direct application to foods. Dietary exposure from use of dimethylether in these types of products is believed to be minimal, as discussed in food and drinking water below.

i. *Food.* Based on its physical properties, when dimethylether is used as a propellant in pesticide formulations applied in food handling areas and establishments, no residue is expected on or in food. Upon dispensing the insect control product, the dimethylether will vaporize and dissipate quickly, affording no residue or accumulation.

ii. *Drinking water.* Similarly, since dimethylether will vaporize completely at ambient conditions, no accumulation is expected in drinking water. There would be no liquid dimethylether to migrate to groundwater aquifers or surface water bodies that may serve as suitable drinking water sources.

2. *Non-dietary exposure.* The greatest potential for residential exposure to dimethylether would be via inhalation routes. However, even when these pesticide products are used in small areas, estimated dimethylether levels will be lower and of much shorter duration than recognized and accepted levels that are considered safe for chronic lifetime exposures. Additionally, tests have shown that such aerosol propellants dissipate within minutes of use.

### D. Cumulative Effects

There is no reliable information that would indicate or suggest that dimethylether has any toxic effect on mammals that would be cumulative with those of any other chemical.

### E. Safety Determination

1. *U.S. population.* Since potential dietary exposures are expected to be minimal, if any, and since potential inhalation exposures are estimated much lower than recognized and accepted levels considered safe for chronic lifetime exposures, dimethylether is not likely to pose any significant risk to the general U.S. population.

2. *Infants and children.* To the best of our knowledge, there is no information that suggests infants and children are more susceptible to exposure to or effects of dimethylether. The lack of significant toxicity in reproductive/developmental studies on dimethylether suggests that growing organisms are not at increased risks. Since potential dietary exposures to infants and children are minimal, if any, based on anticipated use, it is unlikely that any significant risks exist. Direct exposures to infants and children via inhalation are not anticipated for the intended use of dimethylether.

### F. International Tolerances

DuPont is not aware of any tolerances for dimethylether outside the United States.

[FR Doc. 00-24438 Filed 9-26-00; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-977; FRL-6746-4]

### 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 filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-977, must be received on or before October 27, 2000.

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