

CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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**.

#### *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 ID 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 FFDCA 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: June 26, 2003.

**Debra Edwards,**

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

#### **Summary of Petitions**

The petitioner summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions were prepared by the petitioner and represents the view of the petitioner. 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.

#### **Interregional Research Project Number 4 (IR-4)**

*0E6068, 1E6226, 1E6303, 2E6457, and 2E6460*

EPA has received pesticide petitions (0E6068, 1E6226, 1E6303, 2E6457, and 2E6460) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 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 180.494 by establishing tolerances for combined residues of pyridaben, 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one in or on the following raw agricultural commodities: strawberry at 2.5 parts per million (ppm) (PP 0E6068); hop, dried cones at 10.0 ppm (PP 1E6226); tomato at 0.2 ppm (PP 1E6303); fruit, stone, group at 2.5 ppm (PP 2E6457), papaya, black sapote, canistel, mamey sapote, mango, sapodilla, and star apple at 0.1 ppm (PP 2E6460). Registration for tomato will be limited to greenhouse grown tomato based on the available residue data. The petitioner also proposes that established tolerances for nectarine, peach, plum, and prune at 2.5 ppm be deleted since they will be superceded by the tolerance for fruit, stone, group at 2.5 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the

petitions. This summary has been prepared by the BASF Corporation.

#### *A. Residue Chemistry*

1. *Plant metabolism.* The nature of the residue in plants is adequately understood. The residue of concern is pyridaben per se as specified in 40 CFR 180.494.

2. *Analytical method.* The proposed analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd).

3. *Magnitude of residues.* Field trials were carried out in order to determine the magnitude of the residue in the following crops: Strawberries, hops, cherries (to satisfy the requirements for a stone fruits group), and papaya. Two greenhouse tomato residue trials were conducted in Canada. Residue trials were carried out using the maximum label rate, the maximum number of applications, and the minimum pre-harvest interval for each crop or crop group.

#### *B. Toxicological Profile*

1. *Acute.* In general, the acute toxicology studies conducted on technical grade pyridaben demonstrate that it has moderate to mild toxic effects. It was classified as Toxicity Category III based upon the acute oral lethal dose (LD)<sub>50</sub> of 1,100 mg/kg in male rats and 570 mg/kg in female rats. The dermal LD<sub>50</sub> in rabbits was greater than or equal to 2,000 mg/kg (Tox. Cat. III) and the inhalation lethal concentrations (LC)<sub>50</sub> were 0.66 and 0.64 mg/kg in male and female rats, respectively (Tox Cat. III). The eye irritation study (rabbits) produced slight ocular irritation (Tox. Cat. III). Pyridaben was not a dermal irritant (Tox. Cat. IV) or sensitizer.

2. *Genotoxicity.* Genotoxicity studies including Ames testing, *in vitro* cytogenicity (chinese hamster lung cell), *in vivo* micronucleus assay (mouse) and DNA damage/repair (*E. coli*) showed no genotoxic activity associated with pyridaben.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, Sprague-Dawley rats (22/group) from Charles River, U.K., received Pyridaben (98.0% pure) via gavage at dose levels of 0, 2.5, 5.7, 13.0, or 30.0 milligram kilogram day (mg/kg/day) from gestation day 6 through 15, inclusive. Maternal toxicity, observed at 13.0 and 30.0 mg/kg/day, consisted of decreased body weight/weight gain and food consumption during the dosing period. Based on these effects, the maternal toxicity lowest observed adverse effect level (LOAEL) is 13.0 mg/