

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: February 3, 2003.

**Debra Edwards,**

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

### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was 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.

### Janssen Pharmaceutica Inc.

PP 2F6480

EPA has received a pesticide petition (2F6480) from Janssen Pharmaceutica Inc., Plant and Material Protection Division, 1125 Trenton-Harbourton Road, Titusville, NJ 08560 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 tolerances for residues of the fungicide, pyrimethanil (4,6-dimethyl-N-phenyl-2-pyrimidinamine) in or on the raw agricultural commodities citrus fruits (calamondin, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, sour and sweet oranges, pummelo and Satsuma mandarin) at 6 parts per million (ppm), pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) wet pomace at 12 ppm, and pome fruit (apples, pears, oriental pears, crabapples, loquats, mayhaws, and quince) at 3 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 metabolic profile of pyrimethanil has been investigated following application to five different crops (apple, carrots, grapes, lettuce and tomatoes) and is well understood. In plants, pyrimethanil is the only significant residue ranging from essentially all of the Total Radioactive Residues (TRR) in carrots and tomatoes to 44% in lettuce. Limited metabolism of pyrimethanil occurs with minor amounts (less than 10%) of the phenyl and pyrimidyl hydroxylated metabolites (AE C614276, AE C614277, AE C614278, and AE C621312) being released after acid hydrolysis. Analysis of the foliage from apples and carrots confirmed that the metabolism of pyrimethanil in plants proceeded primarily via hydroxylation of the aromatic ring structures as well as the methyl groups.

2. *Analytical method.* The plant metabolism studies indicated that analysis for the parent compound, pyrimethanil was sufficient to enable the assessment of the relevant residues in crop commodities. For citrus, the pyrimethanil was extracted with acetone, the extract acidified and washed with isohexane and basified to enable solvent partition. After solvent exchange to ethyl acetate, the residue is determined using GC-MS. For pome fruits, the pyrimethanil was extracted directly with ethyl acetate/isohexane (1:1), dried, and analyzed for residues with GC-MS. The limit of quantitation is 0.05 ppm. These methods allow detection and measurement of residues

in or on agricultural commodities at or above the proposed tolerance level.

3. *Magnitude of residues.* Magnitude of residue trials were conducted for pyrimethanil on apples, pears, and citrus (lemons, oranges (navels and valencias), tangerines, tangelos, and grapefruit). Trials were conducted in the major producing states which together represent 97%, 70%, and 75% of the citrus, apple and pear domestic production, respectively. Samples were collected according to good agricultural practices at harvest and/or following a postharvest treatment. The pre-harvest interval (PHI) for pome fruit was 7 days following application of the fungicide at the proposed label rate, to approximate maximum field residues. The proposed PHI for pome fruit is 72 days. Samples were harvested at maturity and analyzed with a method having an level of quantitation (LOQ) of 0.05 ppm pyrimethanil. Residues in the raw agricultural commodity (RAC) samples (range, maximum and average) are discussed per crop grouping below.

i. *Citrus fruits (calamondin, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin, sour and sweet oranges, pummelo and Satsuma mandarin).* Nine trials were conducted on citrus during 2001. An end use formulation containing 400 gram/liter or 3.34 lbs/active ingredient/gallon of pyrimethanil was applied by drench, dip and/or line spray in water, storage wax or shipping wax. Multiple treatments (single, double and triple applications) were investigated. A maximum of ten different multiple treatment scenarios were investigated for lemons, seven for oranges, and five for grapefruit. Fruit were washed between treatments only when this was typical of commercial packinghouse operations. The maximum rates applied were 1,000 ppm in drench and dip tanks, and 2,000 ppm in any type of line spray. The maximum proposed use recommendations are for a 4 minute drench at 500 ppm, 2 minute dip at 1,000 ppm, and/or 2,000 ppm line spray for water or storage and shipping wax, with a maximum of three applications. Whole fruit and edible pulp were analyzed separately for pyrimethanil residues. In the whole fruit samples, maximum residues were 6.0 ppm for the proposed applications, and 0.76 ppm for edible pulp. Mean pyrimethanil residues ranged from 1.1 ppm for an single aqueous line spray applied with a 20,000 ppm treating solution to 5.45 ppm for a triple treatment that included a drench (1,000 ppm), dip (1,000 ppm), and 2,000 ppm wax line spray. A single orange trial was established in Florida as a processing study. Pyrimethanil was