

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 pesticide petitions as follow 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 these petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 24, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by the petitioner and

represents the view of the petitioner. The petitions 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)

PP 2E6419, 1E6306, 1E6270, 1E6337, 9E5082, 0E6199, and 1E6292

EPA has received pesticide petitions (2E6419, 1E6306, 1E6270, 1E6337, 9E5082, 0E6199, 1E6292) from the IR-4 Project, Center for Minor Crop Pest Management, Rutgers, The State University of New Jersey, 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 180.284 by establishing tolerances for residues of the rodenticide zinc phosphide in or on the following raw agricultural commodities:

- PP 2E6419 proposes to establish a tolerance in or on alfalfa, forage and alfalfa, hay at 0.1 parts per million (ppm).
- PP 1E6306 proposes a tolerance in or on barley, grain and barley, hay at 0.05 ppm, and barley, straw at 0.2 ppm.
- PP 1E6270 proposes a tolerance in or on bean, dry, seed at 0.05 ppm.
- PP 1E6337 proposes tolerances in or on beet, sugar, roots at 0.05 ppm and beet, sugar, tops at 0.2 ppm.
- PP 9E5082 proposes a tolerance in or on potato at 0.05 ppm.
- PP 0E6199 proposes a tolerance in or on timothy hay and timothy forage at 0.05 ppm.
- PP 1E6292 proposes a tolerance in or on wheat grain; wheat, hay; and wheat, straw at 0.05 ppm.

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

A. Toxicological Profile

1. *Acute toxicity.* The rat acute oral lethal dose (LD)₅₀ values for zinc phosphide technical (89% active ingredient (a.i.)) ranged from 13-35 milligrams/kilogram (mg/kg) body weight (bw) and averaged 21 mg/kg. The acute dermal LD₅₀ was greater than 2,000 mg/kg for zinc phosphide

technical (94% a.i.) in rabbits. The 4-hour inhalation lethal concentration (LC)₅₀ on end-use product was less than 69 mg/cubic meter(m³) air (aerosol). Zinc phosphide was not irritating dermally to rabbit skin (94% a.i.) and caused only slight conjunctival redness, chemosis, and discharge in the rabbit's eyes. Zinc phosphide end-use product did not cause skin sensitization in guinea pigs. No toxicology studies were identified by EPA which demonstrated the need for an acute dietary risk assessment (65 FR 49936).

2. *Genotoxicity.* Salmonella TA-strains of bacteria were exposed to zinc phosphide (97% a.i.) suspended in dimethyl sulfoxide (DMSO), at doses up to 5,000 µg/plate, with and without metabolic activation (S9). Zinc phosphide was negative for gene mutation in the Ames test. Mouse lymphoma cells were exposed to zinc phosphide (97% a.i.) with and without mammalian metabolic activation (S9). Increased mutants at the thymidine kinase locus (TK) were induced in a dose-dependent manner at doses of 10 through 80 µg/mL (+/- S9). Zinc phosphide was positive for gene mutation in this mouse lymphoma assay. Mice were treated with zinc phosphide (97% a.i.) suspended in corn oil up to severely toxic levels (150 mg/kg). No increased aberrations (micronuclei) were induced. Zinc phosphide was negative for mutagenicity in this micronucleus test.

3. *Reproductive and developmental toxicity.* The requirements for a two-generation reproductive toxicity study in rats and a developmental study on a non-rodent species were waived in the Reregistration Eligibility Decision (RED Zinc Phosphide, EPA 738-R-98-006, July 1998). In a developmental toxicity study, the maternal no observed adverse effect level (NOAEL) was determined to be 2.0 mg/kg and the lowest effect level (LEL) was 4.0 mg/kg based on mortality. The developmental NOAEL was at or above 4.0 mg/kg, which was the highest dose tested.

4. *Short- and intermediate-term toxicity.* Based on the acute dermal LD₅₀ study in rabbits, no appropriate toxic effects were identified for risk assessment. In that study no mortalities were observed at 5,000 mg/kg. At the lowest observed adverse effect level (LOAEL) of 2,000 mg/kg, there was a decrease in body weight. Based on the physical properties of the chemical, dermal absorption is expected to be very low, since zinc phosphide reacts with water and stomach acid to produce the toxic gas phosphine from oral, but not dermal exposure. As no endpoint of toxicological concern for dermal