

on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or 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: March 4, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by Interregional Research Project Number 4 (IR-4), 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 (IR-4)

PP 2E6397 and 2E6413

EPA has received pesticide petitions (2E6397 and 2E6413) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway, #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of tebufenozide in or on the raw agricultural commodities vegetable, tuberous and corn, except potato, subgroup at 0.01 parts per million (ppm) (2E6397) and grape at 3.0 ppm (2E6413). 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. Rohm and Haas company was acquired by Dow Agro Sciences LLC, Indianapolis, IN 46268-1054).

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residue in plants is adequately understood based upon acceptable apple, sugar beet, and rice metabolism studies. The Agency has concluded that the residue of regulatory concern is tebufenozide *per se*.

2. *Analytical method.* High performance liquid chromatographic

(HPLC) analytical methods using ultraviolet (UV) detection have been validated for grape and sweet potato. The methods involve extraction by blending with solvents, purification of the extracts by liquid-liquid partitions, and final purification of the residues using solid phase extraction column chromatography.

3. *Magnitude of residues.* Complete residue data for tebufenozide on grape and sweet potato have been submitted. The requested tolerances are adequately supported.

B. Toxicological Profile

1. *Acute toxicity.* Acute toxicity studies with technical grade: Oral lethal dose LD₅₀ in the rat is >5 grams for males and females - Toxicity Category IV; dermal LD₅₀ in the rat is equal to 5,000 milligrams/kilogram (mg/kg) for males and females - Toxicity Category III; inhalation LD₅₀ in the rat is >4.5 milligram/liter (mg/l) - Toxicity Category III; primary eye irritation study in the rabbit is a non-irritant; primary skin irritation in the rabbit >5 mg - Toxicity Category IV. Tebufenozide is not a sensitizer.

2. *Genotoxicity.* Several mutagenicity tests were all negative. These include an Ames assay with and without metabolic activation, an *in vivo* cytogenetic assay in rat bone marrow cells, and *in vitro* chromosome aberration assay in Chinese hamster ovary (CHO) cells, a CHO/HGPRT assay, a reverse mutation assay with *E. Coli*, and an unscheduled DNA synthesis assay (UDS) in rat hepatocytes.

3. *Reproductive and developmental toxicity.* In a prenatal developmental toxicity study in Sprague-Dawley rats 25/group, tebufenozide was administered on gestation days 6-15 by gavage in aqueous methyl cellulose at dose levels of 50, 250, or 1,000 mg/kg/day and a dose volume of 10 milliliter/kilogram (ml/kg). There was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity no observed adverse effect level (NOAEL) was 1,000 mg/kg/day.

In a prenatal developmental toxicity study conducted in New Zealand white rabbits 20/group, tebufenozide was administered in 5 ml/kg of aqueous methyl cellulose at gavage doses of 50, 250, or 1,000 mg/kg/day on gestation days 7-19. No evidence of maternal or developmental toxicity was observed; the maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

4. *Subchronic toxicity.* A 1-year dog feeding study with a lowest observed adverse effect level (LOAEL) of 250 ppm, 9 mg/kg/day for male and female