

information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI 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: August 6, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Valent U.S.A. Corporation 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.

Valent U.S.A. Corporation

PP 2F6420

EPA has received a pesticide petition (2F6420) from Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, Walnut Creek, CA 94596 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 a tolerance for residues of etoxazole in or on the raw agricultural commodity pome fruit (Crop Group 11) at 0.2 parts per million (ppm), apple wet pomace at 1.0 ppm, strawberry at 0.5 ppm, cottonseed at 0.05 ppm, cotton, gin byproducts (gin trash) at 1.0 ppm, and oranges at 0.10 ppm (to support the importation of mandarin oranges into the U.S.). As residues in processed commodities fed to animals may be transferred to milk and edible tissue of ruminants, tolerances are also proposed for animal fat at 0.03 ppm and milk fat at 0.04 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Metabolism of ¹⁴C-etoxazole labeled in the t-butylphenyl, difluorophenyl, or oxazole rings has been studied in apples, cotton, oranges, and eggplants. Etoxazole was rapidly and extensively metabolized to many metabolites in all plants. Even with exaggerated treatment, individual metabolites and parent were only found at very low concentrations. Comparisons of metabolites detected and quantified from plants and animals show that there are no significant aglycones in plants which are not also present in the excreta or tissues of animals. The residue of concern is best defined as the parent etoxazole.

2. *Analytical method.* Practical analytical methods for detecting and measuring levels of etoxazole have been developed and validated in/on all appropriate agricultural commodities and respective processing fractions. The extraction methodology has been validated using aged radiochemical residue samples from ¹⁴C-metabolism studies. The enforcement methods have been validated in cottonseed, cotton gin trash, and in fresh mandarin oranges at independent laboratories. The LOQ of etoxazole in these methods is 0.01 ppm in mandarin oranges and cottonseed and 0.2 ppm in cotton gin trash, which will allow monitoring of food with residues at the levels proposed for the tolerances. Methods have also been developed and validated for determining etoxazole in animal samples. The LOQ of etoxazole in these methods is 0.02 ppm in milk fat and beef fat.

3. *Magnitude of residues.* An extensive crop residue program has been conducted for etoxazole in all major growing regions of the United States for the following crops: apples and pears (representing pome fruits), strawberries, and cotton. Residue trials have also been conducted for etoxazole in Europe to support the importation of mandarin oranges into the U.S. The results of these studies can be summarized as follows:

- For pome fruit, the maximum etoxazole residues from two applications at 0.135 lbs. active ingredient/acre/treatment, are 0.07 ppm for apples and 0.11 for pears harvested 28 days after application.
- The results of an apple processing study indicate that etoxazole residues do not concentrate in apple juice, but do concentrate in wet apple pomace with an average concentration factor of 5.7x.
- The maximum etoxazole residue in strawberries harvested one day following the last of two treatments at