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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**.

#### *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 10, 2003.

**Debra Edwards,**

*Acting 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 Syngenta Crop Protection, Inc. 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.

#### **Syngenta Crop Protection, Inc.**

*PP 1F6280*

EPA has received a pesticide petition (1F6280) from Syngenta Crop Protection, Inc., Greensboro, NC 27419 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 trifloxysulfuron-sodium in or on the raw agricultural commodities sugarcane at 0.01 parts per million (ppm), cottonseed at 0.05 ppm, cotton by-products at 1.0 ppm, citrus at 0.01, almond hulls at 0.01 ppm, almond nut meat at 0.01 ppm, and tomatoes at 0.01 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 primary metabolic pathways of trifloxysulfuron-sodium in plants (cotton, sugarcane and citrus) were similar to those described for animals, with certain extensions of the pathway in plants. The metabolism of trifloxysulfuron-sodium is well characterized in plants and animals and the data is adequate for tolerance setting purposes.

The metabolism profile in plants and animals supports the use of an analytical enforcement method that accounts for parent trifloxysulfuron-sodium. The multiple other metabolites formed in plants and animals are considered of equal or lesser toxicity than parent compound.

2. *Analytical method.* Syngenta Crop Protection, Inc. has submitted practical analytical methodology for detecting and measuring levels of trifloxysulfuron-sodium in or on raw agricultural commodities. This method is based on crop specific cleanup procedures and determination by liquid chromatography with a ultraviolet (UV/Vis) detector. The limit of detection (LOD) for each analyte of this method is 2 nanograms of trifloxysulfuron-sodium. The limit of quantitation (LOQ), as demonstrated by acceptable recoveries from fortified control samples, is 0.01 ppm for each substrate.

3. *Magnitude of residues.* A residue program was performed with trifloxysulfuron-sodium on a full geography to support use on cotton, sugarcane, citrus, and almonds. Adequate residue trials were performed to support the proposed use on tomatoes.

#### *B. Toxicological Profile*

1. *Acute toxicity.* Trifloxysulfuron-sodium has low acute toxicity. The oral LD<sub>50</sub> in rats is >5,000 milligrams/kilogram (mg/kg) for males and females combined. The rat dermal LD<sub>50</sub> is >2,000 mg/kg and the rat inhalation LC<sub>50</sub> is >5.03 milligrams/liter (mg/L) air. Trifloxysulfuron-sodium is not a skin sensitizer in guinea pigs and is considered to have slight dermal or eye irritation in rabbits. End-use formulations of Trifloxysulfuron-sodium have similar low acute toxicity profiles.

2. *Genotoxicity.* Trifloxysulfuron-sodium has been tested for its potential to induce gene mutation and chromosomal changes in five different test systems. Trifloxysulfuron-sodium technical did not induce point mutations in bacteria (Ames assay in *Salmonella typhimurium* or *Escherichia coli*) or in cultured mammalian cells (Chinese hamster V79) and was not genotoxic in an *in-vitro* unscheduled DNA synthesis assay in rat hepatocytes. Chromosome aberrations were not observed in an *in-vitro* test using Chinese hamster ovary cells and there were no clastogenic or aneugenic effects on mouse bone marrow cell *in-vivo* in a mouse micronucleus test. These studies show that trifloxysulfuron-sodium is not genotoxic.