

Concerning the reproduction study in rats, the pup effects shown at the HDT were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants and children.

In addition, the 10X factor to account for enhanced sensitivity of infants and children is not needed because: (1) The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or post-natal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and 2-generation reproduction in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity, (2) no neurotoxic signs have been observed in any of the standard required studies conducted, (3) the toxicology data base is complete and there are no data gaps, and (4) exposure data are complete or are estimated based on data that reasonably account for potential exposure.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on existing crop uses is 84.4% for children 1 to 6 years old, the most sensitive population subgroup from an EPA assessment based on the chronic population adjusted dose (cPAD). The new crop uses proposed in this notice are minor ones and are expected to contribute only a negligible impact to the RfD. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the above proposed uses including existing crop uses.

#### F. International Tolerances

There are no Codex maximum residue levels (MRLs) established for residues of spinosad on grapes, herbs, caneberries, root vegetables, dry bulb onions, or figs. [FR Doc. 02-21281 Filed 8-16-02; 4:19 pm]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0184; FRL-7194-7]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2002-0184, must be received on or before September 20, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0184 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311  32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0184. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

###### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0184 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs

(OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0184. Electronic comments may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 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.

August 12, 2002.

**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 section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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.

### **Magna Bon Corporation**

2E6476

EPA has received a pesticide petition (2E6476) from Magna Bon Corporation,

1531 NW 25th Drive, Okeechobee, FL 34972 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 amending an established exemption from the requirement of a tolerance for sulfuric acid in 40 CFR 180.1001(c). Currently this tolerance exemption allows the use of sulfuric acid as an inert ingredient for pre-harvest and post-harvest uses with a limitation of 0.1% in the pesticide formulation when used as a pH control agent. This petition proposes to increase the limitation to 10% and to include a new use as a chelating agent. This petition also requests the establishment of an exemption from the requirement of a tolerance in plants and plants products, meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use of sulfuric acid as an inert ingredient in a pesticide product used in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated.

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.* Sulfuric acid is used to adjust the pH in water in mix tanks and will be continually used for other purposes, such as chelation, etc. In-can formulations also use sulfuric acid for the same reasons. The metabolism of sulfuric acid is well known in the literature (see Reregistration Eligibility Decision (RED)) FACTS, December 1993 - an EPA RED Fact Sheet which is available through EPA's pesticide website (<http://www.epa.gov/pesticides>). Sulfuric acid is already registered as an active ingredient (10%) on garlic and onion when used as an herbicide and for the purpose of defoliation of crop plants such as potatoes. The metabolism of sulfuric acid was examined at the time of reregistration. Sulfuric acid is also used as a sanitizer for food processing and dairy facilities, and equipment and utensils used in food and feed contact.

The current exemption from the requirement of a tolerance in 40 CFR 180.1001(c) describing the limitation for sulfuric acid as an inert in the "formulated product" should be changed to read 10% rather than the exemption from a tolerance at the level

of 0.1%. Any data in the existing files can be used to support this change in the "formulated" product. The use pattern should be changed from use only as a pH control agent to "a chelating agent." People may be exposed to sulfuric acid in the formulated product. However this exposure involves such dilute solutions when in the "final use dilution" applied that it is believed inconsequential.

The product will also be applied post-harvest and the sulfuric acid in a formulation will not affect the metabolism of harvested products. Sulfuric acid is already used to sanitize milk lines and food processing surfaces by wipe-on and CIP treatments. The use as an inert in formulations in the "final use dilution" will not increase risk when used in formulations applied to growing crops or to raw agricultural commodities after harvest, meat, milk, poultry, eggs, fish, shellfish, and irrigated crops. In addition, sulfuric acid can be used in formulations as an algaecide, herbicide, or fungicide in irrigation conveyance systems and lakes, ponds, reservoirs, or bodies of water which fish or shellfish are cultivated or the bodies of water to be used for drinking water.

2. *Analytical method.* Standard methodology for sulfuric acid is adequate.

3. *Magnitude of residues.* The sulfuric acid will be used in accordance with good agricultural practices and no residues are expected. The history of the compound suggests that the product is safe for use on or in products for uses on/in plants, animals, humans and potable water.

Sulfuric acid will be applied as an inert ingredient according to labels approved by the EPA at rates reflected in a change in the wording of the tolerance exemption that reads 0.1% to 10.0%. The "final use dilution" will contain considerably less sulfuric acid when applied to growing crops, post-harvest produce, drinking water, meat, milk, poultry, eggs, fish, shellfish, irrigated crops, conveyance systems, lakes, ponds, reservoirs, or bodies of water in which fish or shellfish are cultivated or water that is used for drinking water. Since the product is not systemic the product can be washed from the surface of the plant or animal parts before being consumed as the normal practice.

#### B. Toxicological Profile

1. *Acute toxicity.* The toxicology of sulfuric acid is well-known. The toxicology file for registrations which use sulfuric acids as an active ingredient are available through EPA's data bases.

In addition, EPA has issued a RED document: Mineral Acids, in 1994, which includes sulfuric acid. This document explored the toxicology profile of sulfuric acid. The website is: <http://www.epa.gov/pesticides/reregistration/status.htm>.

The literature is full of references on the acute toxic effects of sulfuric acid. The data file for Magna Bon includes a toxicology study performed with sulfuric acid used as an inert at 4%. A material safety data sheet is available upon request.

2. *Genotoxicity.* There is no known genotoxicity. All studies have been negative.

3. *Reproductive and developmental toxicity.* There are no known effects on man or other animals.

4. *Subchronic toxicity.* There are no known effects on man or other animals.

5. *Chronic toxicity.* There are no known effects on man or other animals.

6. *Animal metabolism.* There are no known adverse effects to animals.

7. *Metabolite toxicology.* The metabolism of sulfuric acid is well known.

8. *Endocrine disruption.* There are no known effects on man.

#### C. Aggregate Exposure

1. *Dietary exposure.* Sulfuric acid is present in small amounts in every day living. Sulfur dioxide is present in air as the result of petro-chemical combustion. Sulfuric acid is formed as a result of the combination of water and sulfur dioxide in the air and is common in all metropolitan areas.

Sulfuric acid being used as a crop protector or in a post-harvest application will add little exposure given the current exposure.

Although there are no guideline studies for this data requirement *per se*, there is adequate information in the extensive open literature on sulfuric acid to characterize its toxicity.

In addition, sulfuric acid is Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration.

i. *Food.* The total consumption of agricultural products, fish, shell-fish, and meat treated with sulfuric acid can be calculated as being at or below daily minimums of mineral requirements for humans. In addition, the plant and meat products are washed before cooking.

ii. *Drinking water.* A food additive tolerance is requested in potable water at a level of 0.1 ppm maximum.

2. *Non-dietary exposure.* The population is exposed to sulfuric acid on an almost daily basis. Dermal exposure is the most prevalent.

#### D. Cumulative Effects

There are no cumulative effects. The amount of sulfuric acid used to treat the plants, harvested plant products, fish, shellfish, poultry, and meat would be a way of lowering bacterial, fungi and even-viral organisms from becoming a problem under most circumstances.

#### E. Safety Determination

1. *U.S. population.* Using sulfuric acid will reduce costs of protecting the above-mentioned products and giving adequate protection to such post-harvested crops, fish, shellfish, poultry, and meat products without harm to humans, animals, plants, plant products and the environment.

2. *Infants and children.* Foods are washed and processed. Sulfuric acid food products will be washed. The foods are normally further processed with the result of little or no detectable levels of sulfuric acid.

#### F. International Tolerances

The countries of the world have not restricted sulfuric acid for the purposes requested.

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### ENVIRONMENTAL PROTECTION AGENCY

[FRL-7265-3]

#### Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations; Correction

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability; correction.

**SUMMARY:** On August 14, 2002, the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) of the Office of Research and Development (ORD) published a notice in the **Federal Register** (67 FR 53001) announcing the availability of a final report titled, *Real-Time Monitoring for Toxicity Caused by Harmful Algal Blooms and Other Water Quality Perturbations* (EPA/600/R-01/103). This document corrects a telephone number correction for the National Service Center for Environmental Publications (NSCEP).

**FOR FURTHER INFORMATION CONTACT:** For further information contact the Technical Information Staff, National Center for Environmental Assessment/ Washington Office (8623D), U.S. Environmental Protection Agency, 1200