ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0051; FRL–7294–3]

Ammonium Thiosulfate; 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–2003–0051, must be received on or before April 4, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: tompkins.jim]@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Industry (NAICS 111)
- Crop production (NAICS 112)
- Animal production (NAICS 311)
- Food manufacturing, and

Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket (ID) number OPP–2003–0051. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search'' and then key in docket ID number OPP–2003–0051. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2003–0051. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2003–0051.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0051. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim 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: February 20, 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 Siemer and Associates 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.

Siemer and Associates, Inc.

PP 6F4789

EPA has received a pesticide petition (PP 6F4789) from Siemer and Associates, Inc. on behalf of National Chelating, 4672 West Jennifer, Suite 103, Fresno, CA 93722, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirements for a tolerance for ammonium thiosulfate when used for blossom thinning on apples.

Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Siemer and Associates, Inc., on behalf of National Chelating has submitted the following

summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Siemer and Associates, Inc., and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

On August 30, 1996 Siemer and Associates on behalf of National Chelating petitioned EPA, under pesticide petition 6F4789, for a permanent exemption from the requirements of a tolerance for ammonium thiosulfate on apples.

Section 408(b)(2)(A) of the amended Federal Food, Drug, and Cosmetic Act allows the EPA to establish an exemption from the requirements for a tolerance only if the Administrator determines that there is a ''reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.''

The available information indicates that there is a reasonable certainty that no harm will result from various types of exposure. Requests for waivers from the requirements of performing studies for known chemistry are presented and substantiated. The following is a summary of the information submitted to EPA, to support the establishment, under Section 408(b)(2)(D) of the amended FFDCA, of a tolerance for ammonium thiosulfate on apples.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of ammonium thiosulfate in apple is adequately understood. The requirement for residue studies was waived by EPA based on the knowledge that ammonium thiosulfate has been used as a soil applied and foliar applied fertilizer for many years. Prior experience and numerous publications teach that ammonium thiosulfate ionizes when placed into water, forming an ammonium ion and a thiosulfate ion which further degrades to form elemental sulfur and a sulfate ion. The sulfur is further oxidized to form a sulfate ion. The ammonium and sulfate ions thus formed are absorbed into the growing plant and moved into the naturally occurring nitrogen and sulfate pools that occur naturally in growing plants. Once applied to the plant, without isotope identification, it is not possible to separate the ammonium and sulfate ions that will occur from those that already occur naturally in the plant. On this basis, an exemption from the requirements of a tolerance is justified. There is no analytical method needed since there is no practical way to separate the ammonium and sulfate ions from those that naturally occur.

2. *Analytical method.* The need for an analytical method is waived on the basis that there is no need for analyzing for the component of ammonium and sulfate ion applied for blossom thinning purposes.

3. *Magnitude of residues.* No residues of ammonium thiosulfate will be identified separately from those ammonium and sulfate ions naturally occurring. This result supports the proposed exemption from the requirements for a tolerance.

B. Toxicological Profile

A request to waive the battery of mammalian toxicity studies for ammonium thiosulfate is based on and justified by the following:

1. *Acute toxicity.* Based on EPA criteria, ammonium thiosulfate previously registered for a non-food use as an ornamental herbicide has been shown to be relatively non-toxic and has been registered for non-food use purposes as a Category III herbicide. These data have previously been supplied to the agency.

2. *Genotoxicity.* A request for a waiver from the following requirements is made on the basis that sodium thiosulfate is on the Food and Drug Administration's Generally Recognized as Safe (GRAS) list at 21 CFR 184.1807, and ammonium thiosulfate is already exempted from the requirements of a tolerance when used in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (at 40 CFR 180.1001(c)). Ammonium thiosulfate ionizes to form ammonium ion and thiosulfate ion in water with neither of these ions being mutagenic or genotoxic. On that basis the following tests are requested to be waived.

i. Gene Mutation - Ames.

ii. *In vitro* Structural chromosomal aberration assay.

iii. *In vitro* CHO/HGPRT assay.

iv. *In vivo* micronucleus aberration assay.

3. *Reproductive and developmental toxicity.* A request for waiving the data requirements for the following is made on the basis of the discussion in paragraph B. above. In addition, all of the tests listed below rely on feeding the test substance, to animals that have acidic stomachs. Placing ammonium thiosulfate into an acidic environment will cause near instantaneous ion formation giving rise to ammonium and thiosulfate ions, which ultimately breaks down to elemental sulfur and sulfite. These sulfur forms will be quickly oxidized under acidic conditions to sulfate, which will be incorporated into the normal sulfate pool that exists within the metabolic system of the various animal test systems. The ammonium ion will react with the acidic component, most likely forming ammonium chloride which will be metabolized in a well understood pathway in the systems of the various animal test systems. The new moiety formed in this acidic medium is the sulfite ion which also is well understood and is quickly oxidized to sulfate. The FDA instituted studies in 1975 and 1985 on the GRAS status of sulfite and, as a result of these studies, has substantiated the GRAS status except for a few individuals that might be allergic to sulfite. In this proposed usage, however, the sulfite will not reach the possibly allergic people, since the sulfite will be metabolized to sulfate in the plant system before reaching any sensitive people who may consume the treated tissue. The data waivers requested are as follows:

i. Teratology in rats.

ii. Teratology in rabbits.

iii. 2-Generation reproduction in rats.

4. *Subchronic toxicity.* The data requirements listed below are requested to be waived on the basis illustrated above at paragraph B. 3.

i. 28–Day dermal in rats.

ii. 13–Week oral feeding in rats.

iii. 90–Day oral feeding in dogs.

5. *Chronic toxicity.* The data requirements listed below are requested to be waived for reasons listed above at paragraph B. 3.

i. 1–Year chronic toxicity in dogs.

ii. 18–month chronic toxicity and carcinogenicity in mice.

iii. 24–month chronic toxicity and carcinogenicity in rats.

6. *Animal metabolism.* The metabolism of ammonium thiosulfate is well understood in animals. As listed above, this substance rapidly ionizes in the acidic portion of the animal gut, giving rise to ammonium ion and sulfate ion. Both of these substances are required and occur in the metabolism of animals.

7. *Metabolite toxicology.* No toxicologically significant metabolites will be detected in plant or animal metabolism studies using ammonium thiosulfate. Therefore, no metabolites are required to be regulated.

8. *Endocrine effects.* There is no information available that suggest that

ammonium thiosulfate would be associated with endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i *Food.* There will be no residues of ammonium thiosulfate that will reach any portion of the U.S. population as a result of using ammonium thiosulfate as a blossom thinner on apples. The ammonium and sulfate ions that will arise will not be different from the naturally occurring forms of the ions, which exceed by far the amount that will be applied as a result of the use of the ammonium thiosulfate.

ii. *Drinking water.* Ammonium and sulfate ions that arise from ammonium thiosulfate use will add no additional burden to the drinking water. The end points of the two ions formed as a result of ammonium thiosulfate use will both be used in plant nutrition. The ammonium form of nitrogen resists leaching by binding to the colloid fraction in the soil to resist ground water contamination. The amount of sulfate added as a result of the described use will add an imperceptible amount to the sulfate level already in existence in the soil.

There is a reasonable certainty that no harm will result from dietary exposure to ammonium thiosulfate, because dietary exposures to residues on food cannot be differentiated from those that will occur naturally in food, and exposure through drinking water is expected to be insignificant.

2. *Non-dietary exposure.* There is no non-dietary exposure expected, since any ammonium thiosulfate finding its way onto the plants or around any plants will be absorbed and metabolized into naturally occurring plant constituents.

D. Cumulative Effects

There are no cumulative effects expected since the ammonium thiosulfate metabolites are all incorporated into naturally occurring constituents found in all plant systems.

E. Safety Determination

1. *U.S. population.* The natural occurrence of the metabolites of the ammonium and sulfate ions in all plants and in humans is the basis for the Generally Recognized As Safe characterization of the thiosulfate ion and the use of the ammonium ion as a component in nearly all fertilizers, supports the conclusion that there is a ''reasonable certainty of no harm'' from aggregate exposure to ammonium thiosulfate.

2. *Infants and children.* No developmental, reproductive or fetotoxic effects have been associated with ammonium thiosulfate and its use as a fertilizer. The calculation of safety margins with respect to ammonium thiosulfate is unnecessary since the ammonium and sulfate ions that will arise from the use of ammonium thiosulfate will add only slightly to the already naturally occurring nitrogen and sulfur pools in existence in various plants. Since there will be no residues of toxicological significance resulting from ammonium thiosulfate, calculations of safety margins are not necessary based on the lack of any unnatural residues.

F. International Tolerances

There is no codex maximum residue level established for ammonium thiosulfate on apple. However, ammonium thiosulfate is widely used as a nutrient in many parts of the world.

[FR Doc. 03–5036 Filed 3–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0305; FRL–7281–6]

Pesticides; Final Guidance for Pesticide Registrants on Labeling of Pesticide Products Under the National Organic Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The Agency is announcing the availability of a pesticide registration notice (PR Notice) titled ''Labeling of Pesticide Products Under the National Organic Program.'' This PR Notice was issued by the Agency on January 31, 2003 and is identified as PR Notice 2003–1. PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This particular final PR Notice provides guidance to the registrant concerning obtaining EPA approval of pesticide product label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide product meet the criteria defined in the National Organic Program Rule. This notice is being issued because of registrant requests to be able to identify, on pesticide product labels, pesticide products that are allowable under the National Organic Program.

FOR FURTHER INFORMATION CONTACT: Robert Torla, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8098; fax number: (703) 308–7026; e-mail address: *torla.robert@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who wish to consider including language on their pesticide labeling identifying their pesticide product as allowable under the National Organic Program. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What Guidance Does this PR Notice Provide?

This PR Notice provides guidance to the registrant concerning how registrants may obtain EPA approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that product meet the criteria defined in the National Organic Program Rule (7 CFR part 205). This notice provides information on:

1. The conditions which must be met for approval of the label language.
2. An example of acceptable label language.
3. Guidance on materials to be submitted for Agency review.
4. Guidance for inserting label language on pesticide products exempted from FIFRA regulation under 40 CFR 152.25.

III. Do PR Notices Contain Binding Requirements?

The PR Notice discussed in this notice is intended to provide guidance to EPA personnel and decision makers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.