

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.

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### 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:

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#### 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.