2-25-85

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 25 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3013/FAP#4H5421, (RCB#390, 391) Thiodicarb on Tomatoes - A Written Rationale on "Acetamide as a Potential Metabolite of Thiodicarb in Plants." Evaluation of Amendment dated November 26, 1984, and a Protocol for a study of C^{14}-acetontrile in tomato fruit.

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THRU: Philip V. Errico. Acting Section Head
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TO: Jay Ellenberger, PM-12
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and

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Background

Union Carbide Agricultural Products Company, Inc. has submitted an amendment, consisting of a cover letter dated 11/26/84 from J. S. Lovell of Union Carbide to Jay S. Ellenberger of EPA submitting a rationale entitled "Acetamide as a Potential Metabolite of Thiodicarb in Plants," and a protocol entitled "Disposition of C^{14}-Acetonitrile in Tomato Fruit," dated October 5, 1984.

The RCB review of July 26, 1984, concluded that residue levels for acetamide in tomatoes would be needed. At a follow-up Conference (Memo of Conference, 10/18/84) on 10/2/84, a mathematical rationale was presented by the petitioner concerning the levels of acetamide that could be formed in tomatoes. It was suggested by the EPA reviewer that the petitioner present this rationale as an amendment, but that some quantitative data would probably be required.

This presentation is a review of the rationale, plus a review of the protocol for a two-part study designed to generate quantitative residue data for acetamide in tomatoes.

The mathematical rationale is based on several unproved assumptions:

(1) Acetamide is shown to be present in animals, but is only assumed to be produced in plants.

(2) Acetonitrile and acetamide are produced, only, from anti-methomyl and not syn methomyl in plants, because that has been shown in animals.

(3) Because acetonitrile is volatile and can be vaporized from leaf surfaces, it is assumed that only a small amount of endogenous compound is present in tomato fruit for producing acetamide.

(4) Similarly a large percent of the volatile acetonitrile will be respired in animals, and this is assumed to be true for plants.

Such assumptions are necessary to mathematically determine the maximum acetamide (0.27 ppb) expected from thiodicarb as a residue in plants (tolerance proposed at 3.0 ppm). The assumptions are logical and the mathematical evaluation is reasonable, but without some quantitative data it is not possible to refer a hypothetical value to TOX, for an assessment of safety. A quantitative value needs to be obtained for acetamide in tomatoes.

The protocol entitled, "Disposition of C^{14}-Acetonitrile in Tomato Fruit" will allow such a quantifiable determination. The protocol proposed two studies:

(a) One study to determine the disappearance of C^{14}-acetonitrile as a volatile providing for a 1/2 - life determination and radiolabeled balance determination.

(b) A second study would determine the nature of C^{14}-acetonitrile residues in the fruit, providing for characterization, quantifications and rate of formation of C^{14}-acetamide. Both studies are to be performed by injection of the C^{14}-acetonitrile dose into the tomato.

Several suggestions are appropriate, regarding the protocol:

(1) Dosing (injection) of tomatoes should be performed while fruit are on the vine.

(2) To assure an adequate exaggeration level the dose of C^{14}-acetonitrile should be 1.0 ppm or higher.

(3) If C^{14}-acetamide is not formed or found in tomatoes, some provision should be made to prove that the methodology would find acetamide if it had been there.

(4) These studies should afford an excellent opportunity to provide a method of analysis for residues of acetamide in tomatoes.

Recommendation

The mathematical rationale is logical to the reviewer, but insufficient for establishing a numerical residues for acetamide in tomatoes.

Per the above comments we can concur with the submitted protocol for purposes of determining measurable quantities of acetamide.

TS-769:RCB:F.Boyd:vg:CM#2:Rm810:X77484:2/22/85
cc: R.F., Circu., Reviewer, TOX, EEB, EAB, FDA, Thompson
RDI: Schmitt, 2/15/85