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

MAY 16 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4E3106 [RCB #961]. Acephate on Sugarcane
Grown in Puerto Rico Only. Evaluation of Amendment
Dated April 19, 1985 (No Accession Number).

FROM: Michael P. Firestone, Ph.D., Chemist *Michael P. Firestone*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Hoyt L. Jamerson, Minor Uses Officer
Registration Support and Emergency Response Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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Note: The Residue and Product Chemistry chapters of the Acephate Registration Standard were transmitted January 28, 1982, and subsequently updated by RCB on March 9, 1982, April 4, 1982, and October 5, 1984.

IR-4 has submitted this amendment, consisting of a cover letter from Dr. M. E. Burt of IR-4 to H. L. Jamerson of EPA and a revised Section B (proposed use), in response to several deficiencies cited in RCB's review of the original submission (see M. Firestone memo of September 26, 1984).

The revised Section B/label proposes the following use:

For control of rootstock borer weevil, apply acephate, if necessary, twice per year, once in spring and again in the fall at the rate of 1 lb ai/A when adult weevils are present. Do not harvest within 90 days of application. Do not graze or feed sugarcane forage or fodder within 90 days of application. Apply by ground equipment only. Based upon available residue data, the use of acephate in sugarcane production is limited to Puerto Rico only.

The deficiencies in RCB's September 26, 1984, review will be restated below followed by the petitioner's response and RCB's comments/conclusions:

Deficiency 1

Due to the large variation in sugarcane cultural practices, the proposed timing restrictions for acephate application are inadequate. The petitioner should submit a revised Section B/label in which the proposed acephate use on sugarcane reflects common agricultural practice for each of the principal growing regions (i.e., Florida, Hawaii, Louisiana, Puerto Rico, and Texas).

Petitioner's Response

Section B/label has been revised so that the use of acephate is restricted to Puerto Rico only.

RCB's Comments/Conclusions re: Deficiency 1

With submission of a revised Section B restricting use to Puerto Rico only, RCB considers Deficiency 1 resolved.

Deficiencies 4a through 4d

- 4a. Although the limited amount of residue data generated from two Puerto Rican field trials support the proposed 0.05 ppm tolerance (acephate plus methamidophos) on sugarcane, the petitioner should supply additional residue data from the other principal growing regions including Florida, Louisiana, Hawaii, and Texas.
- 4b. The mode of application (i.e., aerial vs. ground) used in the 1981 Puerto Rico field trial should be specified in a future amendment.

2

- 4c. If the petitioner requires treatment by aerial and ground equipment, the additional residue data requested in conclusion 4a above should reflect such use. Otherwise, Section B/label should be revised to allow application by ground equipment only.
- 4d. The petitioner should supply residue data for sugarcane forage and fodder, and, if needed, propose an appropriate tolerance on these two r.a.c.'s.

Petitioner's Response

A revised Section B/label now limits acephate application to include only treatment by ground equipment in Puerto Rico, with a restriction against grazing or feeding sugarcane forage and fodder.

RCB's Comments/Conclusions re: Deficiencies 4a through 4d

With submission of the revised Section B, RCB considers these deficiencies resolved.

Deficiency 4e

The petitioner should conduct a sugarcane processing study which must simulate commercial practices as closely as possible. Sugarcane samples used in the processing study should contain field-treated detectable residues so that concentration factors for the various by-products (i.e., molasses, refined sugar, and bagasse) can be determined. This may require field treatment at exaggerated application rates to obtain sufficient residue levels for the processing study. If the sugarcane processing study indicates that residues concentrate in any fraction(s) upon processing, then a food additive petition, including food additive tolerance proposal(s) will be required.

Petitioner's Response

"The proposed label rate is 1.0 lb. a.i./A. Residues were not detected in the RAC at 2x the proposed label rate. Because of this, a processing study for sugarcane is not necessary."

RCB's Comments/Conclusions re: Deficiency 4e

Based on pesticide tolerances established under 40 CFR 180 and food/feed additive tolerances established under 21 CFR 193/561, it is evident that pesticide residues could concentrate as high as 20 fold upon processing of sugarcane into sugarcane molasses or bagasse. Thus, the petitioner will need to conduct a field trial in which acephate is applied at the exaggeated rate of 10x (i.e., 10 lb ai/A), and sugarcane is harvested at a 90-day PHI. If no detectable residues of acephate and methamidophos are found, no food/feed additive tolerances will be required. If detectable residues are found in the r.a.c., a sugarcane processing study will need to be conducted to determine if acephate and methamidophos residues concentrate upon processing, and thus, a food/feed additive petition including food/feed additive tolerance proposals are required.

At this time, RCB concludes that Deficiency 4e has not been resolved.

Deficiency 5

RCB cannot adequately evaluate the levels of secondary residues in meat, fat, milk, poultry, and eggs until such time as the deficiency associated with the lack of a sugarcane processing study is resolved (see Deficiency 4e).

Petitioner's Response

None

RCB's Comments/Conclusions re: Deficiency 5

This deficiency remains outstanding at this time pending resolution of Deficiency 4e.

Other Considerations

In accordance with conclusions reached in RCB's third addendum to the Acephate Registration Standard (see C. Trichilo memo of October 5, 1984), it is now recommended that all acephate tolerances be expressed in terms of only acephate per se under 40 CFR 180.108 and 21 CFR 561.20. Residues of methamidophos resulting from the metabolism of acephate are most appropriately placed under the tolerance regulations for methamidophos as a pesticide (40 CFR 180.315 and 21 CFR 561.277). The reason for this is to achieve compatibility with the MRLs of the Codex Alimentarius Commission, if only in terms of residue definition.

4

Such a change in the residue definition would require deletion of paragraph (d)(8) of 40 CFR 180.3 which states that methamidophos residues may not exceed the higher of the two tolerances established for the use of acephate or methamidophos as a pesticide. A statement should be added to 40 CFR 180.108 explaining that residues of the acephate metabolite methamidophos are regulated under 40 CFR 180.315, the methamidophos section. Also, 40 CFR 180.315 should be subdivided into parts (a) and (b) where (b) includes tolerances reflecting registration of acephate formulations alone (i.e., methamidophos formulations are not registered for use on these commodities) and where (a) includes tolerances reflecting the situation where both acephate and methamidophos are registered on the same crop.

Based on the results of two Puerto Rican field trials (no detectable residues, <0.05 ppm acephate and <0.025 ppm methamidophos, in/on sugarcane resulting from 2x acephate treatments), the petitioner will need to submit a revised Section F in which separate tolerances are proposed for acephate at 0.05 ppm and methamidophos at 0.05 ppm in/on the raw agricultural commodity sugarcane. The need for separate acephate and methamidophos tolerances for sugarcane processed fractions can only be evaluated pending resolution of Deficiency 4e. The need for a revised Section F will be designated Deficiency 7 (a new issue).

Finally, an International Residue Limit Status sheet is attached to this review. No Codex, Canadian or Mexican tolerances/limits have been established for acephate on sugarcane. Thus, there are no compatibility problems at this time.

Recommendation

At this time, RCB recommends against establishment of the proposed acephate on sugarcane tolerance for the reason cited under Deficiencies 4e, 5 and 7 (see Other Considerations) above.

Should RD ultimately approve the proposed "Tolerances With Regional Registration" (i.e., Puerto Rico only), RCB recommends that the tolerances for methamidophos and acephate on sugarcane be included in separate subsections under 40 CFR 180.315 and 180.108, respectively, to avoid confusion regarding future 24(c) registrations and crop-grouping eligibility. The "tolerances with regional registration" would be referenced along with future regional registration tolerances in a new subsection (n) under 40 CFR 180.1 which would define the Agency's interpretation of "tolerances with regional registration." An appropriate interpretation for 40 CFR 180.1, subsection "n," would be:

5

Certain tolerances are based on geographically limited residue data. These "tolerances with regional registration" are included in separate subsections under 40 CFR 180.101 through 180.999. In order to expand the area of usage on these crops, additional residue data generated in these areas will be required. Persons seeking geographically broader registration on these crops should contact the appropriate EPA product manager concerning whether additional residue data are required.

cc:R.F., Circu, Reviewer, TOX, EAB, PP#4E3106, FDA,
Robert Thompson, W. Hazel, PMSD-ISB
RDI:JHOnley-5/9/85:RDSchmitt-5/9/85
TS-769:CM#2:RCB:X7484:MPFirestone:Kendrick-5/10/85:
edited by MPF-5/14/85

6

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: acephate

PETITION NO.: 4E 3106

CCPR NO.: 95

REVIEWER: Michael P. Firestone

Codex Status

☐ No Codex Proposal Step
6 or above

Residue (if Step 9):

parent

Proposed U.S. Tolerances

Residue: acephate plus its
metabolite methamidophos

Crop(s) Limit (mg/kg)

none (on sugarcane)

Crop(s) Tol. (ppm)

sugarcane 0.05

CANADIAN LIMIT

Residue:

MEXICAN TOLERANCIA

Residue:

Crop(s) Limit (ppm)

none

Crop(s) Tolerancia (ppm)

none (on sugarcane)

Notes:

^{Codex}
" separate limits are set for methamidophos on commodity
for which there are acephate limits.

p. 1 of 1

7