PMSD | I&S 0857

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

JUN 20 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4E3043 [RCB #949]. Acephate on Almonds - Evaluation of Amendment Dated May 1, 1986

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

Michael P. Firestone

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

R D Schmitt for

TO: Hoyt L. Jamerson, Minor Uses Officer
Process Coordination Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

IR-4 National Coordinator, George Markle, has submitted this amendment, consisting of revised Sections B (proposed use) and F (proposed tolerances), in response to deficiencies cited in RCB's latest review of the subject petition (see M. Firestone memo of August 29, 1985).

Each deficiency will be restated below followed by IR-4's response and RCB's comments/conclusions.

Deficiency 1b

RCB will require revision of the application rate also in terms of pounds active ingredient per 100 gallons spray solution for dilute spray because of the large variation in the number of pounds per acre needed for small trees versus large trees. In addition, the quantity of pesticide applied per acre for concentrate orchard sprays should also be related to tree size, usually by specifying the same or less active ingredient as that which would be applied using a full coverage spray.

The label could contain a restriction indicating the maximum number of gallons of spray solution to be applied per acre for an established grove of large trees to limit the possibility of excessive treatment. However, the label must also indicate that smaller trees are to be treated with less volume and thus, less ai per acre.

Also, for further consideration with regard to the proposed label, the petitioner should submit to RCB all information concerning the way acephate was applied for the almond field trials including type of equipment used, gallons of spray solution per acre, the size (height, width) and spacing of trees, etc.

IR-4's Response

A revised Section B/label has been submitted in which application rates are expressed as 0.5 lb ai/100 gal and 2.0 lb ai/A (based on a standard of 400 gal of dilute spray per acre to drip, or the equivalent amount of product per acre in concentrate sprays).

RCB's Comments/Conclusions re: Deficiency 1b

The proposed Section B/label has been correctly revised with regard to expressing the application rate in terms of lb ai per 100 gal sprayed to the point of drip as well as lb ai per acre.

However, IR-4 has failed to submit information relating to the generation of residue data vis-a-vis type of equivalent used, gallons of spray solution per acre, the size (height, width) and spacing of trees, etc. This information is needed by RCB to determine the adequacy of the residue data. Thus, Deficiency 1b has not been resolved.

Deficiency 1e

The residue data reflect intervals between the first and second acephate application of 70, 62, 63, 61, and 53 days. Even at 102 days following a single treatment at 2.0 lb ai/A (the maximum proposed use allows 2 treatments at up to 2.0 lb ai/A each), the residue level (acephate plus methamidophos) in/on almond hulls was almost 5 ppm. Thus, the amount of residue depends on both the PHI for the last treatment and the interval between treatments.

The petitioner will either need to impose a minimum 70-day interval between first and second treatment, or submit additional residue data reflective of shorter intervals.

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IR-4's Response

A revised Section B/label now contains a minimum 70-day interval between first and second application.

RCB's Comments/Conclusions re: Deficiency 1e

Deficiency 1e has now been resolved.

Deficiency 5a

RCB concludes that the proposed tolerance of 20 ppm total acephate on almond hulls (a feed item) would result in residue levels exceeding the present tolerance of 0.1 ppm for dairy cattle milk, and meat by-products of cattle, goats, horses and sheep. The established 0.1 ppm acephate tolerances for meat and fat of the preceding animals is adequate.

IR-4's Response

None

RCB's Comments/Conclusions re: Deficiency 5a

This deficiency remains pending at this time.

Deficiency 6 (Originally cited in the Other Considerations section of RCB's August 29, 1985 review)

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 tolerance be expressed in terms of only acephate per se under 40 CFR 180.315 and 21 CFR 561.277. The reason for this is to achieve compatibility with the MRL's of the Codex Alminentarius Commission, if only in terms of residue definition.

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 formulation are not registered for use on these commodities) and where (a) includes tolerances reflecting the situation where methamidophos alone or both acephate and methamidophos are registered on the same crop.

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IR-4's Response

A revised Section F has been submitted in which the following tolerances are proposed:

Acephate per se (40 CFR 180.108):

Almonds ---------- 0.1 ppm

Almond Hulls ---------- 20 ppm

Methamidophos (Monitor®) (40 CFR 180.315):

Almond Hulls ---------- 2 ppm

RCB's Comments/Conclusions re: Deficiency 6

The above tolerances are tentatively considered adequate, pending resolution of Deficiency 1b.

However, IR will need to submit a revised Section F in which a methamidophos tolerance is also proposed for "almonds." This methamidophos tolerance on "almonds" and the above proposed 2 ppm methamidophos tolerances on almond hulls will appear under Section b of 40 CFR 180.315. Thus, Deficiency 6 has not been resolved.

Other Considerations

An International Residue Limit Status sheet is attached.

No Codex or Canadian limits are established covering acephate residues in/on almonds. Mexico has a 0.2 ppm acephate (parent compound only) tolerance established for nuts.

Recommendation

At this time, RCB recommends against establishment of the proposed tolerances covering residues of acephate and its metabolite methamidophos on almonds and almond hulls for the reasons cited under Deficiencies 1b, 5a, and 6 above.

Attachment 1: International Residue Limit Status Sheet

cc:R.F., Circu, Reviewer,TOX, EAB, EEB, PP#4F3043 FDA, PMSD/ISB
RDI:J. Onley:6/16/86:R.D. Schmitt:6/17/86
TS-769:RCB:CM#2:RM810:X1991:M. Firestone:wh:6/18/86

F. Suarez
6/9/86

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: Acephate PETITION NO.: 4E3043

CCPR NO.: 95 REVIEWER: Michael P. Firestone

Codex Status

☐ No Codex Proposal Step 6 or above

Residue (if Step 9): _____

Crop(s)	Limit (mg/kg)
none (on almonds)	

Proposed U.S. Tolerances

Residue: _____

Crop(s)	Tol. (ppm)
① acephate per se on:	
a) almonds	0.1
b) almond hulls	20
② methamidophos on:	
a) almond hulls	2

CANADIAN LIMIT

Residue: _____

Crop(s)	Limit (ppm)
none	

MEXICAN TOLERANCIA

Residue: acephate (presumably)

Crop(s)	Tolerancia (ppm)
nuts	0.2

Notes: