MEMORANDUM


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

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

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

IR-4 Project National Coordinator, George Markle has submitted this amendment, consisting of a cover letter, a revised Section B (proposed label), and a letter from R. Huntoon of Chevron Chemical Company (manufacturer of acetate) to M. Burt of IR-4, in response to several deficiencies noted in RCB's review of the original petition (see M. Firestone memo of April 11, 1984).

Each deficiency will be restated below, followed by the petitioner's response and RCB's comments/conclusions.

Deficiency 1a

The petitioner will need to submit a revised Section B in which the label will not allow livestock to graze on treated areas and will not allow the feeding of cover crops.
Petitioner's Response

The revised proposed label now includes the following restriction:

Do not graze livestock on treated areas or feed treated cover crops.

RCB's Comments/Conclusions re: Deficiency 1a

This deficiency is now considered resolved.

Deficiency 1b

The petitioner will need to express the dosage on the proposed label as pounds active ingredient per 100 gallons spray solution to runoff. This would be in agreement with the following passage from the EPA Guidelines [§171-3 (a) Subdivision O Residue Chemistry]:

"...In the case of full coverage sprays, as for orchards, the dosage should also be expressed as pounds active ingredient per 100 gallons spray solution to runoff, because of the large variation in the number of pounds per acre needed for small trees versus large trees. 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. ..."

Petitioner's Response

"It is requested that the application rate in the original Section B be retained. We are concerned about the possibility of an overtreatment if the a.i./100 gallons was specified. A grower could apply 100, 300 or more gallons per acre. It is more reasonable to state maximum pounds of a.i./A. By stating rate only in pounds a.i./A, there would be no confusion on the part of the applicator; gallons/A could be adjusted while the amount of a.i./A would remain the same."

RCB's Comments/Conclusions re: Deficiency 1b

RCB will still 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 over 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 (weight, width) and spacing of trees, etc.

At this time, Deficiency 1b has not been resolved.

**Deficiency 1c**

Since the Navel Orangeworn Egg Trap Method measures the timing rather than the level of insect infestation, the petitioner will need to revise the statement concerning spring application of acephate in the Section B/label to read: "Apply in spring according to the navel orangeworn egg trap method if pest populations warrant."

**Petitioner's Response**

The proposed label has been revised accordingly.

**RCB's Comments/Conclusions re: Deficiency 1c**

Deficiency 1c is now considered resolved.

**Deficiency 1d**

Since most of the residue data were generated from trials in which the summer application occurred at hull split, the petitioner will need to revise the Section B/label to read: "In the summer, apply only until the first sign of hull split (when nuts in the tree tops show any sign of splitting), and do not apply within 40 days of harvest."

**Petitioner's Response**

The proposed label has been revised accordingly.

**RCB's Comments/Conclusions re: Deficiency 1d**

This deficiency has now been resolved.
Deficiency le

The petitioner will need to state on the proposed label submitted in a revised Section B, that an interval of at least 70 days must occur between the first and second applications.

Petitioner's Response

"The interval between the spring application and the summer application will normally be about 45 days, therefore, the suggested 70 day interval between the first and second application is not appropriate. Additionally, the important limitations are the up-to-hull split and the 40 days PHI restrictions."

RCB's comments/Conclusions re: Deficiency le

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.

Deficiency le has not 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.
Petitioner's Response

IR-4 has submitted a copy of a letter dated 6/5/85 from R. Huntoon of Chevron to M. Burt of IR-4, in which the following was stated:

E.P.A.'s comments and calculations in their letter to you on August 16, 1984 was based upon a theoretical diet for cattle consisting of 25% almond hulls and 60% grass. This is not a typical feeder cattler ration within California where over 95% of all almonds hulls are consumed.

Upon consultation with Dr. R. A. Zinn - Professor of Animal Science, University of California - Imperial Valley Field Station, El Centro, CA. (619) 352-0111, a more typical diet containing almond hulls was obtained and is outline in Table I. As Dr. Zinn pointed out, variations in percentage of composition will be dictated by price of each ingredient thus keeping almond hulls (ruffage) at not more than 10% of the total diet.

Table I

Typical California Feeder Cattle Ration

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hay (Alfalfa, Oat, Sudan)</td>
<td>10%</td>
</tr>
<tr>
<td>Almond Hulls</td>
<td>10%</td>
</tr>
<tr>
<td>Fats</td>
<td>4%</td>
</tr>
<tr>
<td>Molasses</td>
<td>8-10%</td>
</tr>
<tr>
<td>Minerals</td>
<td>1.5%</td>
</tr>
<tr>
<td>Grains (Barley, Wheat, Oats)</td>
<td>60-65%</td>
</tr>
</tbody>
</table>

Based upon this more realistic diet and proposed almond hull tolerance of 20 ppm, we will not exceed our current established meat and milk tolerances for acephate.

RCB's Comments/Conclusions re: Deficiency 5a

RCB bases its conclusion re: likely maximum level of secondary residues (acephate plus methamidophos) in animal commodities on worst case situations, not on typical diets. Thus, the percentages used in RCB's calculations (found in the Pesticide Assessment Guidelines - Residue Chemistry - Sub-division O) are in agreement with those obtained from the Harris Guide.

Deficiency 5a has not been resolved at this time.
Other Considerations

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.

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 Alimentarius 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 both acephate and methamidophos are registered on the same crop.

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, 1e, and 5a.

RCB suggests that IR-4 come in for a meeting with regard to Deficiency #1b above.

Attachment 1 - International Residue Limit Status sheet

cc:R.F., Circu, Reviewer, TOX, EAB, EEB, PP#4E3043, PMSD/ISB
FDA
RDI:JHOnley:8/19/85:RDSchmitt:8/19/85
TS-769:RM810:CM#2:X7484:MPFirestone:wh:8/26/85
INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: acephate

CCPR NO.: 95

PETITION NO.: 4E3043

REVIEWER: Michael P. Firestone

Codex Status

☐ No Codex Proposal Step 6 or above

Residue (if Step 9):

Proposed U.S. Tolerances

Residue: acephate + methamidophos

Crop(s) Limit (mg/kg)

none (on almonds)

Crop(s) Tol. (ppm)

almonds 0.1

almond hulls 20.0 (of which methamidophos ≤ 20 ppm)

CANADIAN LIMIT

Residue:

Crop(s) Limit (ppm)

none

MEXICAN TOLERANCIA

Residue: parent

Crop(s) Tolerancia (ppm)

none

nots 0.2

Notes:

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