RIN-2884-86

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

AUG 1 1984

MEMORANDUM

862AA

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCE

SUBJECT: PP#4E3088, Bayleton on caneberries. Evaluation of analytical methods and residue data. (Accession No. 072644).

FROM: Linda L. Kutney, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Linda L. Kutney

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

TO: Hoyt L. Jamerson
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The IR-4 and the Agricultural Experiment Station of California propose a tolerance of 1.0 ppm for residues of the fungicide 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2 butanone, (Bayleton), and its alcohol metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on caneberries (blackberries, boysenberries, dewberries, loganberries, raspberries and youngberries).

Bayleton tolerances are established for a variety of agricultural commodities ranging from 0.04 ppm to 145 pm (See 40 CFR 180.410). Several tolerances are pending.

A letter of authorization has been submitted from G.E. Brussell of the Mobay Chemical Corporation to H. Jamerson, Registration Division, Office of Pesticide Programs (dated May 1, 1984) for the use of Bayleton data in support of this tolerance petition.

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Conclusions

1. The residue in caneberries is expected to be comprised of Bayleton and its free and conjugated alcohol metabolite, beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol.

2a. Adequate analytical methods are available for the determination of Bayleton and its alcohol metabolite in caneberries.

2b. A storage stability study has been previously submitted to support the residue data reported in the petition.

3. The Directions for use submitted in Section B of this petition should be revised to include the proposed method(s) of application. We recommend that the proposed label be submitted to clarify the intended use pattern(s). If the proposed method of application is to include both aerial and ground applications this should be specified on the proposed label and in Section B.

4a. The crop grouping "caneberries" is not listed in §180.34(f) of the 40 Code of Federal Regulations and is therefore not an authorized, official crop grouping. The petitioners should submit a revised Section F which lists the berries to be included in the caneberry grouping. The tolerance proposed should read, "tolerances are proposed for combined residues of the fungicide 1-(4-chlorphenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone and its metabolites beta-(4-chlorphenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the raw agricultural commodities blackberries, boysenberries, dewberries, loganberries, raspberries and youngberries at 1.0 part per million."

4b. One study on one commodity from one state is insufficient residue data to recommend for the requested tolerances. Additional residue data on blackberries and raspberries should be submitted from the major producing states of Oregon and Washington. These residue studies should be conducted at the maximum proposed use and minimum PHI.

These residue studies should include the maximum application rates proposed as well as pre-harvest intervals (PHI's) which are less than or equal to the proposed three day PHI.

We can draw no conclusion concerning the expected residue levels of Bayleton and its alcohol metabolite until additional residue studies are submitted.

5. Because caneberries are not a feed item, there will be no problem of secondary residues of Bayleton or its alcohol metabolite in milk, meat, poultry and eggs as a result of the proposed use.

6. An International Residue Limit Status sheet is attached. Codex tolerances for Bayleton and its alcohol metabolite have been established on raspberries at 0.2 ppm. We can draw no conclusion as to whether this tolerance level is appropriate until further residue data is submitted (See appropriate Conclusions above).

Recommendations

We recommend against the proposed tolerance for the reason stated in conclusion 3,4a and 4b.

Requirements for resolutions of these deficiencies are discussed in the appropriate conclusions above.

We will reevaluate Codex tolerance compatibility when the above deficiencies are satisfied.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacture of Bayleton was discussed in the review of PP#2F2665, by A. Smith, 9/9/82. [redacted]

Bayleton is formulated as a wettable powder containing 50% active ingredient (a.i.), for applications to caneberries. The inerts used in the formulation have cleared for use under §180.1001.

Proposed Use

Apply 2 oz. a.i. (equivalent to 4 oz. product) of Bayleton 50 WP (wettable powder) in no less than 20 gallons of water per acre to control powdery mildew.

Apply when powdery mildew first appears and at 4 to 6 weeks intervals, as needed. A maximum of four total applications may be made in one year. No more than two applications may be made within the same thirty day period. Do not harvest within three days of application.

The proposed use submitted in Section B of this petition should be revised to include the method(s) of application. If the proposed method of application is to include both aerial and ground applications, this should specified on the proposed label and in Section B.

Nature of the Residue

No new metabolism studies have been submitted in conjuction with this this petition. The nature of residue has been discussed in previous reviews (2F2665/2F2668/2F2704, by A Smith). Bayleton is absorbed, metabolized, and translocated by plants (wheat, apples, cucumbers, tomatoes). The significant components of plant residues are the parent compound and its free and conjugated alcohol metabolite, beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol.

In animals (rats, cows, pigs, hens), Bayleton has been shown to be metabolized and excreted with same transfer of residues to eggs and milk and deposition in tissues (See PP#3F2887, 9/12/83, A. Smith). The residues in eggs, milk and meat include the parent compound, Bayleton, and its metabolites containing the chlorophenoxy and triazole moieties (i.e., KWG0519, KWG1323, KWG1342).

The nature of the residue in plants and animals is adequately understood.

Analytical Methodology

The residue method use is Mobay method #54166 entitled, "A Gas Chromatography Method for Bayleton® and its metabolites in Apples." The method has been previously described in PP#3F2887, by A. Smith. Briefly, extraction is accomplished by blending the ground sample with acetone and then with dichloromethane. The extract is then filtered and washed with water. The water is discarded and the remaining organic phase is evaporated to dryness.

The remaining residue is cleaned-up using a florisil column and hexane/ethyl acetate eluant. The eluant is evaporated to dryness, re-dissolved in acetone, and analyzed using gas chromatography equipped with a flame detector.

Validation data for Bayleton was submitted for one raspberry control sample fortified with 0.1 ppm Bayleton and 0.1 ppm of its alcohol metabolite. The reported recovery was 76% for Bayleton and 75% for its alcohol metabolite; both control samples showed no detectable (<0.01 ppm) levels of Bayleton and its alcohol metabolite were present.

Mobay Method #54166 was also used previously in conjunction with PP#3F2887 (See A. Smith memo dated 9/12/83). In this earlier petition, the method was reported to yield recoveries of 74-100% at the 0.05 ppm and 0.10 ppm levels of fortification of Bayleton and metabolites respectively, on peaches, apricots and plums, as well as equally good recoveries on various cucurbits.

A previous storage stability study has been submitted for Bayleton and its alcohol metabolite in apple peel which had been frozen for 132-420 days (See study #54192 in PP#0G2300). Only 5% decomposition was observed over that time period. Based on this frozen storage stability study, we conclude that no additional data is required to demonstrate the stability of caneberries stored frozen for less than 420 days.

We conclude that adequate analytical methods are available for the determination of Bayleton and its alcohol metabolite in caneberries.

Residue Data

A residue study, consisting of three replicates, was submitted on raspberries grown in California at the 1 X (2 oz a.i./A) and 1 1/2 X (3 oz. a.i./A) application rates. Two applications were made, although the directions for use in Section B state that a maximum of four applications may be made per year. The pre-harvest interval (PHI) was 0,7 and 16 days (a PHI of 3 days was proposed). The fungicide was applied when powdery mildew appeared, but the specific details of how this was done was not explained.

Data for residues of Bayleton ranged from 0.01 ppm to 0.46 ppm, with PHI's ranging from 0 to 16 days. The limit of detection was reported to be 0.01 ppm for Bayleton.

Data for residues of the Bayleton alcohol metabolite ranged from 0.09 to o.17 ppm, with PHI's ranging from 0 to 16 days. The limit of detection was reported to be 0.01 ppm for the alcohol metabolite, also.

Additional data are needed to reflect the shortest PHI's likely under the conditions of the proposed use and the period between harvest and analysis should remain as short as possible. This data should reflect the maximum proposed use and minimum PHI requested.

Residue studies should also be included on blackberries and raspberries from Washington and Oregon to ensure an adequate geographical representation. These studies should include the maximum proposed application rates and minimum PHI.

We can draw no conclusion concerning the expected residue levels of Bayleton and its alcohol metabolite until additional residue studies requested above are submitted.

Residues in Meat, Milk, Poultry and Eggs

Caneberries are not a feed item, therefore there will be no problem of secondary residues of Bayleton or its alcohol metabolite in milk, meat, poultry and eggs as a result of the proposed use.

Other Considerations

An International Residue Limit Status sheet is attached. Codex tolerances for Bayleton and its alcohol metabolites have been established on raspberries at 0.2 ppm. We can draw no conclusion as to whether this tolerance level is appropriate until further residue data is submitted.

The crop grouping "caneberries" is not listed in §180.34(f) of the 40 Code of Federal Regulations, and is therefore not an authorized, official crop grouping. The petitioners should submit a revised Section F which lists the berries to be included in the caneberry grouping. The tolerance proposal should read, "tolerances are proposed for combined residues of the fungicide 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone and its metabolites beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol in or on the raw agricultural commodities blackberries, boysenberries, dewberries, loganberries, raspberries and youngberries at 1.0 part per million."

TS-769:RCB:L.Kutney:vg:CM#2:Rm810:X77484:7/27/84
cc: RF, Circu., Thompson, FDA, TOX, EEB, EFB, PP#4E3088
RDI: Quick, 7/23/84; Schmitt, 7/23/84

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Bayleton (Triadimefon) PETITION NO [illegible]

CCPR NO. 133

T. Sue 6/28/88

Codex Status

☐ No Codex Proposal Step 6 or above

Proposed U. S. Tolerances

Caneberries 1.0 ppm

Residue (if Step 9): sum of triadimefon and 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1,2,4-triazol-1-yl) butan-ol ("triadimenol")

| Crop(s) | Limit (mg/kg) |
|---|---|
| raspberries | 0.2 |

Residue: 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone metabolite beta-(4-chloro-alpha-(1,1-dimethylethyl)-1H-1,2,4-tria- etl

| Crop(s) | Tol. (ppm) |
|---|---|
| Caneberries | 1.0 ppm |

CANADIAN LIMIT

Residue: _____

| Crop | Limit (ppm) |
|---|---|
| none | |

MEXICAN TOLERANCIA

Residue: _____

| Crop | Tolerancia (ppm) |
|---|---|
| none | |

Notes: