6-3-83

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

JUN 3 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2837: Bayleton in Almonds. Evaluation of residue data and analytical method.

FROM: Alfred Smith, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: H. M. Jacoby, PM#21
RD (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The Agricultural Chemicals Division of Mobay Chemical Corporation proposes tolerances for residues of the fungicide Bayleton, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone and its metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol in or on almonds (meats) at 0.05 ppm and almond hulls at 0.10 ppm.

The following permanent tolerances for Bayleton and its metabolites have been approved.

PP#1F2474

Apple	1.0 ppm
Grapes	1.0 ppm

FAP#1H5292

Apple pomace (wet and dried)	4.0 ppm
Grape pomace (wet and dried)	3.0 ppm
Raisin waste	7.0 ppm

PP#1E2459

Chick peas	0.1 ppm

PP#2F2665

Wheat grain	1.0 ppm
Wheat green forage	15.0 ppm
Wheat straw	5.0 ppm
Barley grain	1.0 ppm
Barley green forage	15.0 ppm
Barley straw	5.0 ppm
Meat, fat, and meat byproducts of cattle, goats, horses and sheep	1.0 ppm
Eggs; milk; meat, fat, and meat byproducts of poultry and hogs	0.04 ppm

FAP#2H5343

Wheat milled fractions (except flour)	4.0 ppm
Barley milled fractions (except flour)	4.0 ppm

PP#2F2704

Seed grass cleanings, including hulls	145 ppm
Seed grass straw, including chaff	105 ppm
Grass forage	0.2 ppm

Conclusions

1. The nature of the residues in plants and animals is adequately understood. The significant components of plant residues are Bayleton and its metabolite KWG0519 (free and conjugated). The significant components of animal residues are Bayleton and free and conjugated components of its metabolites KWG0519, KWG1323, and KWG1342.

2. Adequate analytical methods are available for enforcement purposes.

3. Residues in or on almond meats or hulls are not likely to exceed the proposed tolerances.

4a. Because almond hulls are not a poultry feed, no residues are likely to occur in eggs, meat, fat, or meat byproducts of poultry due to the proposed uses [§180.6(a)(3)].

4b. Residues could occur in milk, meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep [§180.6(a)(2)]. However, such residues would be adequately covered by the approved tolerances in PP#2F2665.

5. There are no Codex, Mexican or Canadian tolerances for Bayleton on almonds.

Recommendation

TOX and EAB considerations permitting, we recommend for the proposed tolerances.

We suggest the proposed tolerance for almonds (meats) be established in terms of almonds.

Detailed Considerations

Manufacturing Process MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

We have discussed the manufacture of Bayleton in our review of PP#2F2665. Technical grade Bayleton has a typical composition as follows: Bayleton [redacted] were identified, but were not quantitated. The level of each component was estimated at less than 0.01%.

The impurities in technical Bayleton are not likely to be a residue problem.

Formulation

Bayleton is formulated as a wettable powder, containing 50% active ingredient (a.i), for application to almonds.

The formulation's inert ingredients are cleared for use under §180.1001.

Proposed Use

Aerial or ground applications at pink bud and full bloom at 12-16 oz. act/A (3-4 ozs act/100 gal.). Do not apply more than 32 ozs. act/A per crop season.

Nature of the Residue

We have discussed in detail the nature of the residue in previous reviews (cf. PP#'s 2F2665/2F2668/2F2704). Bayleton is absorbed, metabolized, and translocated by plants (wheat, apples, cucumbers, tomatoes). The significant components of plant residues are the parent compound Bayleton and its metabolite KWG0519.

In animals (rats, cows, pigs, hens), Bayleton is metabolized and excreted with some transfer of residues to eggs and milk and deposition in tissues. The residue components in eggs, milk, and meat are 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 Method

The residue method detemrines the free and conjugated forms of the parent compound Bayleton and its metabolites KWG0519, KWG1323, and KWG1342.

A sample is extracted by blending with methanol-water. The mixture is refluxed, cooled, and filtered. The filtrate is evaporated to the aqueous phase.

The aqueous phase is incubated with the enzyme cellulase. (The enzyme frees conjugated residues.) The components are extracted into dichloromethane which is evaporated to dryness.

The residue is taken up with chloroform and cleaned up using gel permeation chromatography followed by Florisil column chromatography. The parent compound Bayleton and the metabolites KWG0519 and traces of KWG1323 are eluted with a solvent mixture of hexane/ethyl acetate. The remaining residues of KWG1323 as well as the metabolite KWG1342 are eluted from the Florisil column with a solvent mixture of ethyl acetate/methanol.

The residues of Bayleton and KWG0519 are determined directly by gas chromatography.

The metabolites KWG1323 and KWG1342 are derivatized with the reagent trifluoroacetic anhydride and determined as such by gas chromatography.

A confirmatory procedure is presented, and it uses a different column in the gas chromatograph.

Nitrogen-containing compounds with registered uses on almonds were tested as possible sources of interferences. Several interferences were noted, but were resolved through the use of a different detector.

Untreated (control) samples of almond meats, shells, and hulls had no detectable (<0.01 ppm) Bayleton-equivalent residues (a single hull example had 0.02 ppm). Control samples of almond meats, shells, and hulls were fortified with Bayleton and its metabolites KWG0519 and KWG1342 at levels of 0.05-1.0 ppm. Recoveries were 70-108%. The validation data are adequate.

A successful method trial with Bayleton and its metabolites (KWG0519, KWG1323, KWG1342) on meat and eggs at levels of 0.005-0.1 ppm has been performed. Overall recoveries were 73-120% (PP#1F2474, memo 12/16/82, A. Smith).

An adequate analytical method is available for enforcement purposes.

Residue Data

Samples of almonds were obtained from crops in California which had received two applications as proposed and at the rate of 20 oz. act/A (1.25X maximum proposed rate). The samples were divided into meats, shells, and hulls, and each was examined for Bayleton and the metabolites KWG0519 and KWG1342. The samples were collected at intervals of 181-209 days after the last treatment (PHI).

The nutmeats had no detectable residues (<0.01 ppm) from any treatment. The shells had residues of <0.01-0.04 ppm, and the hulls had residues of <0.01-0.02 ppm from all treatments.

Residues of Bayleton and its metabolites in or on almond nutmeats or almond hulls are not likely to exceed the proposed tolerances of 0.05 ppm for nutmeats or 0.1 ppm for hulls.

Meat and Milk

Almond hulls may be fed to livestock (except poultry). By using the proposed hull tolerance level of 0.1 ppm and the percentages of hulls in the daily diet, we can estimate the level of residues likely to be ingested. These levels are as follows: Cattle (0.025 ppm); hogs (0.01 ppm); horses (0.02 ppm); and, goats and sheep (0.05 ppm).

Cattle and poultry feeding studies with Bayleton were discussed in PP#2F2665. The studies show that residues could result in milk, meat, fat, and meat byproduct of cattle, hogs, horses, goats, and sheep from the proposed tolerances [§180.6(a)(2)]. Since hulls are not fed to poultry, no residues are expected in eggs, meat, fat, and meat byproducts of poultry [§180.6(a)(3)].

Tolerances have been approved by RCB in PP#2F2665 to cover residues in eggs, milk, and meat of livestock. The residues derive from tolerances on various feed items (cf. wheat and barley forages at 15 ppm; wheat and barley grains at 1.0 ppm; grass cleanings at 145 ppm; grass straw at 105 ppm; wheat and barley milled fractions at 4.0 ppm).

In view of the foregoing, we conclude that any residues in milk, meat, fat, and meat byproducts of livestock would be adequately covered by the tolerances approved in PP#2F2665.

Other Considerations

There are no Codex, Canadian or Mexican tolerances for Bayleton on almonds; thus, there is no problem of compatibility.

cc: R.F.
Circu
Reviewer
FDA
TOX
EEB
EAB
PP# No. 3F2837
Robert E. Thompson (Res. Triangle Park, NC)

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Bayleton (triadimefon) PETITION NO. 3F2837

CCPR NO. 133 Smith, A.

Codex Status	Proposed U.S. Tolerances
/ x / No Codex Proposal Step 6 or above	1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone and its metabolite beta-(4-chloro-phenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol
Residue (if Step 9):	Residue:

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

Crop(s)	Tol. (ppm)
Almond, meats	0.05 ppm
Almond, hulls	0.10 ppm

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
None	

NOTES:

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm
None	