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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP#3F2887: Bayleton in Stone Fruits, Sugar Beets, and Cucurbits. Evaluation of residue data and analytical method.

FROM: Alfred Smith^{U.S.}, Chemist
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THRU: Charles L. Trichilo, Chief
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TO: Henry M. Jacoby, PM#21
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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-(1-H-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 as follows.

Apricots, Peaches, Nectarines, Plums (fresh prunes)	4.0 ppm
Cucurbits	0.3 ppm
Sugar Beets	1.0 ppm
Sugar Beet Tops	3.0 ppm

Temporary tolerances for Bayleton on apricots, peaches, and nectarines at 10 ppm have been approved (PP#2G2638).

The following permanent tolerances for Bayleton have been approved.

<u>PP#1F2474</u>	
Apples	1.0 ppm
Grapes	1.0 ppm
<u>FAP#1H5292</u>	
Apple pomace (wet and dried)	4.0 ppm
Grape pomace (wet and dried)	3.0 ppm

Y/10

Raisin waste	7.0 ppm
<u>PP#1E2459</u>	
Chick Peas	0.1 ppm
<u>PP#2F2665</u>	
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
<u>FAP#2H5343</u>	
Wheat milled fractions (except flour)	4.0 ppm
Barley milled fractions (except flour)	4.0 ppm
<u>PP#2F2704</u>	
Seed grass cleanings, including hulls	145 ppm
Seed grass straw, including chaff	105 ppm
Grass forage	0.2 ppm
<u>PP#3F2837</u>	
Almonds	0.05 ppm
Almond hulls	0.10 ppm

Conclusions

1. The nature of the residues in plants and animals is adequately understood. The significant components of the residues are the parent compound and its components containing the chlorophenoxy and triazole moieties.
2. Adequate analytical methods are available for enforcement purposes.
- 3(a). Residues in or on apricots, peaches, nectarines, plums (fresh prunes), and cucurbits are not likely to exceed the proposed tolerances.
- 3(b). Residues in or on sugar beet tops, roots, and root byproducts are not likely to exceed the proposed tolerances. However, the tolerance for roots is excessive. A level of 0.5 ppm is appropriate and should be proposed.

4. Residues could result in eggs, milk, meat, fat, and meat byproducts of livestock [§180.6 (a)(2)]. However, such residues would be adequately covered by the tolerances approved in PP#2F2665.
5. There are codex proposals for cucumbers at 0.2 ppm, sugar beets at 0.1 ppm, and sugar beet leaves at 0.1 ppm; however, there are no Canadian or Mexican tolerances on the crops of this petition. The proposed tolerances reflect the residue levels expected for the proposed uses. As a result, no changes are recommended.

Recommendation

We recommend against the proposed tolerances. A favorable recommendation is contingent upon resolution of the question raised in conclusion 3(b).

Recent residue data for sugar beet tops indicate that all tolerances (established and pending) are more appropriately expressed in terms of Bayleton and its metabolites containing the chlorophenoxy and triazole moieties. The appropriate CFR section should be revised to reflect this change. The residue levels of established tolerances will not be significantly affected by this change.

Detailed Considerations

Manufacturing Process

We have discussed the manufacture of Bayleton in our review of PP#2F2665. Technical grade Bayleton has a typical composition as follows: Bayleton

[REDACTED], 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 wettable powder, containing 50% active ingredient (a.i.), for application to stone fruits, sugar beets, and cucurbits.

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

Proposed Use

Apricots, nectarines, peaches, plums (fresh prunes); ground or aerial applications at pink bud and full bloom at rate of 2 oz act/100 gal (6 oz. act/A). For California only, apply at rates of 3-4 oz act/100 gal (12-16 oz act/A). Additional applications may occur as needed up to

day of harvest. In California, do not apply more than 64 oz act/A/crop season. In other areas, do not apply more than 36 oz act/A/season.

Cucurbits: Make foliar applications by ground or aerial equipment when disease symptoms first appear at 1-2 oz act/A and repeat at 10-14 day intervals or as needed up to day of harvest. A maximum of 8 oz act/A per season is permitted.

Sugar beets: make broadcast application by ground or aerial equipment when disease symptoms appear at 4-8 oz act/A. Repeat application permitted at 4 oz act/A, and do not apply more than 8 oz act/A (season). Applications may be made up to 15 days of harvest (15-day PHI). A band application is permitted at 8 oz act/A with a 30-day PHI.

Nature of the Residue

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

The plant metabolism studies have generally shown the presence of the parent compound and its metabolites KWG0519, KWG1342, and KWG1323. However, the metabolites KWG1342 and KWG1323, when present, were at very low levels (much less than 10% of total residues). As a result, the significant components of plant residues have been considered to be the parent compound and its metabolite KWG0519. However, field residue data for sugar beet tops have altered this position.

Sugar beet tops represent the case in which another component, KWG1342, is present in field residues at significant levels (greater than 10%). The sugar beet roots, however, show no such pattern. This pattern may be indicative of residue components likely to occur in leafy vegetables. (Bayleton has not yet been proposed for use on leafy vegetables.) In anticipation of uses for commodities which may contain additional metabolic components and to ensure that the tolerance expression for residues of Bayleton is consistent with the residue data, we believe all tolerances (established and proposed) should be expressed in terms of the parent compound and its metabolites containing the chlorophenoxy and triazole moieties (expressed as Bayleton).

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 Methods

Stone fruits; cucurbits: the method (Report No. 54166) determines the parent compound Bayleton and its metabolite KWG0519. A ground sample is extracted by successively blending with acetone and dichloromethane. The filtered extracts are combined and washed with water. The water washes are discarded. The organic phase is evaporated to dryness.

The residue is cleaned up on a florisil column, and the components are eluted with an hexane/ethyl acetate solvent mixture which is evaporated to dryness.

The residue is taken up in acetone and examined by gas chromatography.

Untreated (control) stone fruit samples (peaches, apricots plums) had equivalent residues of Bayleton and KWG0519 of <0.01-0.06 ppm. Control samples were fortified with Bayleton and KWG0519 at levels of 0.05 ppm and 0.10 ppm. Recoveries were 74-100%.

Control cucurbit samples (squash, cantaloupes, honeydew melons, cucumbers) had equivalent residues of Bayleton and KWG0519 of <0.01-0.02 ppm. Control samples were fortified with Bayleton and KWG0519 at levels of 0.02-0.50 ppm. Recoveries were 70-112%. The validation data are adequate.

Sugar Beets and sugar beets byproducts

The residue method determines the free and conjugated forms of the parent compound Bayleton and its metabolites KWG0519, KWG1323, and KWG1342. (Report #80488).

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 the subject crops were tested as possible sources of interferences. Several interferences were noted, but were resolved through the use of a different detector.

Control samples of sugar beet tops, roots, and byproducts (juice, molasses, sugar, pulp) had total Bayleton-equivalent residues of <0.01-0.04 ppm. Control samples were fortified with Bayleton and its metabolites (KWG0519, KWG1342) at levels of 0.05 ppm and 0.10 ppm. Recoveries were 72-110%. 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).

We believe the method trials can be extended to include the crops of this petition.

An adequate analytical method is available for enforcement of the proposed tolerances.

Residue Data

Cucurbits

Samples were obtained from crops grown in Arizona, Virginia, Texas, California, Mississippi, Indiana, Georgia, Florida, Illinois, North Carolina, Michigan, and Oklahoma. The crops had received ground and aerial foliar application at intervals of 6-20 days between applications. (Proposed rates: 1-2 oz act/A with maximum of 8.0 oz act per season and 10-14 days between applications. A 0-day PHI is proposed.) The representative crops are discussed below.

Squash: 4 applications of 2.0 oz act/A yielded residue levels of <0.01-0.11 ppm (0-day), <0.01-0.08 ppm (1-day), <0.01-0.05 ppm (3 days), and <0.01 ppm (4 days).

Cucumbers: 4 applications of 2.0 oz act/A had residue levels of <0.01-0.16 ppm (0-day), <0.01-0.15 ppm (1-day), 0.01-0.13 ppm (3 days), and <0.01-0.04 ppm at 4-5 days after the last treatment.

Melons: the pulp and peel of cantaloupe and honeydew melons were analyzed separately, and the residues were expressed on the pulp, peel, and whole melon. The cantaloupes were treated with 4-5 applications at 2.0 oz act/A and harvested at intervals of 0-7 days after the last application. At the proposed 0-day PHI, residues were 0.06-0.19 ppm (peel), <0.01-0.03 ppm (pulp), and 0.02-0.09 ppm on the whole melon. At 1-day, residues were 0.03-0.17 ppm (peel), <0.01-0.02 ppm (pulp), and 0.02-0.06 ppm on the whole melon. At day 7, residues were 0.07 ppm (peel), <0.01 ppm (pulp), and 0.02 ppm (whole melon).

Honeydew melons had <0.01-0.11 ppm (peel at 0-day), <0.01-0.03 ppm (pulp at 0-day), and <0.01-0.05 ppm on the whole melon at 0-day. At 1-day, residues were <0.01-0.07 ppm (peel), <0.01 ppm (pulp), and < 0.01ppm on the whole melon.

The various crops are sufficient to represent the crop group, cucurbits, and the residue data adequately reflect the proposed use. We therefore conclude that residues of Bayleton and its metabolite KWG0519 in cucurbits are not likely to exceed the proposed tolerance (0.3 ppm).

Apricots, Peaches, Nectarines, Plums (Fresh Prunes)

Samples were obtained from crops in Pennsylvania, Virginia, Texas, Georgia, North Carolina, Michigan, Oregon, and California. (Proposed uses: in California, 3-4 oz act/100 gal. - equivalent to 12-16 oz act/A-with a maximum of 64 oz act/A/season; in other areas, 2 oz act/100 gal.-equivalent to 6 oz act/A-with a maximum of 36 oz act/A/season; 0-day PHI proposed). The samples had been treated as proposed and at slightly exaggerated rates.

California

Peaches: samples received 4 applications at 4 oz act/100 gal (16 oz act/A). Residues were 1.63-2.12 ppm (0-day), 0.88-1.72 ppm (7 days), and 0.55-0.95 ppm at 14 days after the last treatment.

Apricots: samples received 4 applications at 4 oz act/100 gal. (16 oz act/A). Residues were 1.42 ppm (0-day), 0.91 ppm (9 days), and 0.39 ppm at 14 days.

Plums: samples received 4 and 5 (1.25X) applications at 4 oz act/100 gal (16 oz act/A). Residues in fresh plums were 0.85-2.82 ppm (0-day), 0.88-0.95 ppm (7 days), and 0.76-0.79 ppm at 11-14 days. Residues in the dried fruit were 0.56 ppm, at 0-day and 0.78 ppm at 11 days. Residues in the fresh fruit from which these dried fruit were processed were 2.82 and 0.79 ppm respectively. Since residues do not appear to be concentrated upon drying, then residue levels in dried prunes made from fresh fruits are not likely to exceed the levels in the fresh fruit. As a result, a food additive tolerance will not be needed.

Other Geographical Areas

Peaches: samples were treated with 5-7 applications at 2 oz act/100 gal (24-42 oz act/A/season). Residues were 0.11-1.04 ppm (0-day), 0.07-0.82 ppm (7 days), and 0.05-0.28 ppm at 14-15 days.

Plums: samples were treated with 4 applications at 3-4 oz act/100 gal (36-48 oz act/A per season). Residues were 0.53-1.52 ppm (0-day), 0.52-1.32 ppm (7 days), and 0.31-0.82 ppm at 14 days.

Nectarines: no data are submitted for nectarines. However, the data for the other stone fruits are sufficient to reflect residues likely to occur in nectarines from the proposed uses.

We conclude that residues of Bayleton and its metabolite KWG0519 in or on apricots, peaches, nectarines, and plums (fresh prunes) are not likely to exceed the proposed tolerance (4.0 ppm).

Sugar Beets

Samples were obtained from crops grown in Minnesota, North Dakota, Colorado, Texas, California, Idaho, and Michigan. The crops had been treated once as proposed and at the maximum proposed rate (8.0 oz act/A). Samples were collected at intervals of 14-61 days after treatment (proposed PHIs: band, 30 days; broadcast, 15 days).

The tops had residues of 0.13-2.20 ppm at PHIs of 14-17 days; 0.02-1.89 ppm at 27-32 days; and 0.01 ppm at 61 days.

The roots had residues of < 0.01-0.08 ppm at 14-17 days; <0.01-0.18 ppm at 27-32 days; and, <0.01 ppm at 61 days. Processing fractions- sugar beet roots which had residues of 0.06 ppm were processed under simulated commercial conditions. The fractions (juice, wet pulp, dried pulp, sugar, molasses, and lime cake) were examined for residues. No detectable residues (<0.01 ppm) were noted in any fraction. Therefore, residues are not likely to be concentrated in the sugar beet byproducts (sugar, wet or dried pulp, molasses).

Residues in or on sugar beet tops, roots, or its byproducts are not likely to exceed the proposed tolerances for tops (3.0 ppm) and roots (1.0 ppm). However, the level for roots is excessive. A level of 0.5 ppm is appropriate and should be proposed.

Aerial and ground applications are permitted under the proposed uses for all crops. Both aerial and ground applications are submitted for sugar beets only. A comparison of air and ground residue data for sugar beet tops show no significant difference in residue levels. It is reasonable to assume that residue levels on the other crops, due to ground and aerial treatments, are not likely to be significantly different. Therefore, the absence of aerial applications for stone fruits and cucurbits are not likely to present a residue problem.

Meat and Milk

Sugar beet tops, dried pulp, and molasses may be used as livestock feeds. We have indicated that residues, if any, in the pulp and molasses would not exceed the level in the roots. (We have indicated a level of 0.5 ppm to be appropriate for roots.)

Tolerances for residues of Bayleton in milk, eggs, and meat of livestock have been approved (PP#2F2665). The residues derive from tolerances on various feed items (for example: wheat and barley forages at 15 ppm; wheat and barley grain 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 residues could result in eggs, milk, meat, fat, and meat byproducts of livestock [§180.6 (a)(2)]. However, such residues would be adequately covered by the tolerances approved in PP#2F2665.

TS-769:RCB:A.Smith:cdw:CM#2:Rm810:X7377:9/8/83

cc: R.F., Circu, Reviewer, TOX, EEB, EAB, Petition No PP#3F2887

FDA, Robert Thompson

RDI: R.S. Quick, 9/8/83; R. Schmitt, 9/8/83

INTERNATIONAL RESIDUE LIMIT STATUS

10

CHEMICAL Bayleton (Triadimefon)

PETITION NO. 3F2887

CCPR NO. 133

CODEX STATUS

PROPOSED U.S. TOLERANCES

/X/ No Codex Proposal Step 6 or above 1/

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

RESIDUE (If Step 9): Sum of triadimefon and 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1,2,4-triazol-1-yl)butan-2-.01 (triadimenol) 1/

RESIDUE:

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

Cucumbers 0.2 1/ Sugarbeets 0.1 1/, 2/ Sugarbeet leaves 0.1 2/

Apricot, Peaches, Nectarines, Plums (fresh prunes) 4.0 ppm Cucurbits 0.3 ppm Sugar Beets 1.0 ppm Sugar Beet Tops 3.0 ppm

CANADIAN LIMIT

MEXICAN TOLERANCIA

RESIDUE:

RESIDUE:

None

None

Crop Limit (ppm)

Crop Tolerancia (ppm)

None

None

1/ Step 3 in Codex Procedure 2/ At or about limit of determination

NOTES: