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

COPY

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SUBJECT: PP# 0E2380. BAS 352F (Ronilan(R)) in or on Kiwifruit. Evaluation of Analytical Methodology and Residue Data

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and

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THRU: Richard D. Schmitt, Deputy Branch Chief
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BASF Wyandotte Corporation proposes that a tolerance be established for combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methy]-2,4-oxazolidinedione [aka BAS 352F, vinclozolin (ISO prop.), Ronilan(R)] and its metabolites containing the 3,5-dichloroaniline moiety, in or on the raw agricultural commodity kiwifruit at 10 ppm.

No permanent tolerances for BAS 352F have been established as yet; however, one is pending (PP #9F2205-10ppm strawberries) and awaiting promulgation. There have also been two petitions for temporary tolerances (PP #8G2068-5 ppm strawberries, established 3/2/79; PP #9G2204-lettuce, 10 ppm and various stone fruits, 2.5 to 25 ppm, co-pending in reject status).

The proposed tolerance on kiwifruit is to permit the importation of BAS 352F-treated kiwis from New Zealand. Registration of the use proposed herein in New Zealand is pending the establishment of this tolerance in the USA. New Zealand is currently the major exporter of kiwifruit to the U.S.A.

Conclusions

1a. The nature of the residue in kiwifruit is considered to be sufficiently understood from metabolism data on other crops. Parent BAS 352F and its 3,5-dichloroaniline moiety-containing metabolites are the residues of concern.

1b. A large animal (lactating ruminant) metabolism study is lacking for BAS 352F. In the instant case, this is not a relevant issue since no animal feed use is involved.

2. Adequate analytical methodology is available to enforce the proposed tolerance.

3. Residues in kiwifruit treated in accordance with the proposed use directions are not reasonably expected to exceed the proposed 10 ppm tolerance level.

4. There are no animal feed uses associated with kiwifruit. There is, thus, no reasonable expectation of secondary residues of BAS 352F or its metabolites occurring in meat, milk, poultry, or eggs as a result of the proposed use.

5. The proposed tolerance is to permit the importation of New Zealand kiwifruit which may have been treated with BAS 352F or will be in the future. Registration of the proposed use in New Zealand is awaiting establishment of the U.S.A. tolerance. New Zealand has an adequate regulatory authority to oversee proper pesticide usage.

6. There are no Mexican, Canadian, or Codex tolerances established for BAS 352F. There is, thus, no conflict between the proposed tolerance level and any international residue limit for this chemical.

Recommendation

Toxicological considerations permitting, we recommend that the proposed tolerance be established.

NOTE: TOX's review has not been received in RCB to date.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The schema for the manufacturing process of technical BAS 352F is appended to our (M. Nelson) 7/23/79 review of PP #9F2205 as Attachment 1, which see.

A listing of the impurities in the technical product is also appended thereto as Attachment 2, which see. None of those impurities is expected to present a residue problem at the levels present.

Attachment 3 of the aforecited review, which see, is a copy of the confidential statement of formula for Ronilan Fungicide, a 50% wettable powder manufactured in Germany. This is also the formulated product proposed for use in this present petition for kiwifruit.

All the inerts (including [redacted] requesting its exemption) in Ronilan Fungicide are cleared for use under 40 CFR 180.1001(c) or (d).

Proposed Use

For control of Botrytis disease in kiwifruit grown in New Zealand, a total of 5 separate foliar applications of Ronilan during the growth period is recommended. The timing of these applications is: at 20% blossom; full blossom; petal fall; 21 days before harvest; and lastly, 3 days before harvest. The recommended application rate is 1 lb ai/A (1.1 kg ai/ha) per application, for a total of 5 lb. ai/A/season (5.5 kg. ai/ha/season). Delivery is to be via dilute spray (ca 235 gpa or 2200 l/ha).

[Note: in one place in Section B, it appears that a 7-day PHI rather than a 3-day PHI, is espoused. However, on that same page and in Sections D and F, it is clearly stated that a last application-to-harvest interval of 3 days is being proposed. This apparent discrepancy is being pointed out merely for our records. It is a moot point, actually, since over-tolerance residues would not be anticipated from use of either of those intervals. We shall proceed with our review on the assumption that a 3-day PHI is correct, since it is mentioned throughout the petition; the allusion to a 7-day PHI is most likely a typographical error.]

Nature of the Residue

Reports of studies of the metabolism of BAS 32F using ^{14}C uniformly ring-labeled compound in crops (strawberries, grapes, peaches, lettuce), animals (rats), and soil were previously submitted with PP's #8G2068 and 9G2204, and were extensively discussed in our (G. Makhijani, 1/19/79, and B. Davis, 1/18/80, respectively) reviews thereof, which see. Degradative schemata are appended to the aforecited 1/18/80 review.

No additional metabolism data were submitted with this present petition. Accordingly, our metabolism conclusions are based on translation of the aforecited data from the other crops (grapes being the most relevant since both grapes and kiwi are trellised vine fruit crops).

On that basis, we conclude that the nature of the residue in kiwifruit is adequately understood; parent BAS 352F and its 3,5-dichloroaniline moiety-containing metabolites are the residues of concern.

A large animal (lactating ruminant) metabolism study is lacking for BAS 352F and will be needed in the future if tolerance(s) for crops with animal feed uses are ever proposed. In the instant case, this is not a relevant issue.

Analytical Methodology

The residue method of analysis was reportedly the same as that previously submitted with PP #9F2205 (BAS 352F/strawberries); i.e., petitioner's Analytical Method No. 25, 11/21/77, which determines residues of BAS 352F and its 3,5-dichloroaniline containing metabolites.

Briefly, the method entails subjecting the crop macerate to alkaline hydrolysis to degrade BAS 352F and metabolites residues to form free 3,5-dichloroaniline, which is quantitatively isolated by steam distillation.

Following clean-up by liquid-liquid partitioning and derivatization, final determination is based on EC-GLC detection of the acylated 3,5-dichloroaniline. The total residue found is expressed in terms of BAS 352F equivalents. The method is sensitive to 0.05 ppm.

A successful method trial for this analytical procedure using strawberries as substrate was run (0, 10, 20 ppm BAS 352F fortification levels) in re PP# 9F2205 (see G. Makhijani memo of 9/7/79). Recoveries ranged 74.0-99.6%; controls were <0.05 ppm.

Confirmatory procedures to ensure specificity are available in the form of an alternate GLC column and/or use of a N-specific electrolytic conductivity detector, if needed.

Validation data for kiwifruit appears to be quite limited; 80% recovery was reported following fortification with BAS 352F at 1.2 ppm. A few representative gas chromatograms were submitted; based on them, the control(s) contained ≤ 0.1 ppm apparent BAS 352F equivalents. We consider these data adequate to support the type use involved (i.e., imported minor specialty crop). Validation data on a number of other crops (strawberries, lettuce, stone fruits) is available via this same methodology in other petitions (PP's #9F2205 and 9G2204), if needed; recoveries therein averaged ca 90% or better.

We conclude that adequate analytical methodology is available to enforce the proposed tolerance.

Residue Data

Storage stability data for kiwifruit per se were not submitted. However, available data on other fruits (strawberries, stone fruits; see PP's #9F2205 and 9G2204, respectively) indicate stability during frozen storage for prolonged lengths of time (>19 months in ongoing studies).

Residue data were submitted from various field trials (9) conducted in New Zealand during the 1978-9 growing season on the only commercial variety of kiwifruit grown for export, the Hayward. A total of 5 applications were made as per the proposed use directions (3 during blossom plus 2 preharvest) in the majority of the studies, each at the rate of 50 gm ai/100l. (equals 1 lb ai/A based on a spray volume of 2200 l/ha) which is the proposed use rate. For each application, the spray solution was applied to the point of run-off. In the remainder of the trials, only the 2 preharvest applications were made (same rate as above).

Samples of whole kiwifruit were taken 1, 3, 7, 14, and 21 days after the last application to provide residue decline data. All results reported were corrected for method recovery (80%). One sample with a 1-day PHI (10.72 ppm residue) exceeded the proposed tolerance level of 10 ppm; otherwise, all samples--regardless of PHI--were within the proposed 10 ppm tolerance level. At the 3-day PHI (the proposed use PHI), the range of residues was 1.97-8.40 ppm. Significant (up to 8.97 ppm) residues were also present in the 7-day PHI

samples exceeding, in some cases, the 3-day PHI residue values reported. Based on all the submitted data on kiwifruit, however, there is no reasonable expectation that over-tolerance (i.e., 10 ppm) residues would result from adherence to the proposed use pattern (i.e., 3-day PHI).

Residues in Meat, Milk, Poultry, and Eggs

There are no animal feed items associated with kiwifruit. Accordingly, there is no reasonable expectation of secondary residues of BAS 352F or its metabolites occurring in meat, milk, poultry, or eggs as a result of the proposed use.

Other Considerations

The proposed tolerance is to permit the importation of New Zealand kiwifruit which may have been treated with BAS 352F or will be in the future. Registration of the proposed use in New Zealand is awaiting establishment of the USA tolerance. New Zealand has an adequate regulatory authority (Agricultural Chemicals Act, 1959) to oversee proper pesticide usage.

There are no Mexican, Canadian, or Codex tolerances established for BAS 352F. There is thus no conflict between the proposed tolerance level and any international residue limit for this chemical.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Vinclozolin

PETITION NO OE2380

CCPR NO none

Codex Status

[X] No Codex Proposal Step 6 or above

Residue (if Step 9):

none

Crop(s)	Limit (mg/kg)
none	

Proposed U. S. Tolerances

3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidenedione and its metabolites containing the 3,5-dichloroaniline moiety

Residue:

Crop(s)	Tol. (ppm)
Kiwifruit (imported)	10

CANADIAN LIMIT

Residue:

none

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

Residue:

none

Crop	Tolerancia (ppm)
none	

Notes: Vinclozolin (150 prop.)