4 14 80

14 APR 1980

PP#9G2204. BAS352F in or on lettuce and stone fruits (peaches, apricots, cherries, nectarines, and plums). Amendment of 2/5/80.

B. D. Davis, Ph. D, Chemist, RCB, HED (TS-769)

PM# 21 (M. Jacoby) and TOX, HED (TS-769)

11/8/80

THRU: Richard D. Schmitt, Acting Chief, RCB, HED (TS-769)

This amendment is in response to our memo of 1/8/80 in which a number of deficiencies in the subject petition were noted. These deficiencies and the petitioner's response to them will be discussed in the same order as they appeared in our memo cited above.

Deficiency 1:

The inert [redacted] does not appear to be cleared under 180.1001. The petitioner will need to obtain clearance for this inert or substitute a suitable alternate.

Response to 1:

The petitioner states that [redacted] submitted 3/15/79 which is currently being prepared for publication by PM 25. The petition for exemption [redacted] from requirement of a tolerance is currently in reject status.

This deficiency has not been resolved. The petitioner will need to obtain clearance for the inert [redacted] or substitute a suitable alternate.

Deficiency 2a:

The label restrictions for lettuce which state, "Do not apply more than 6 lb of Ronilan in one season" are inappropriate and should be deleted or revised to specify the maximum amount applied per acre in one season.

Response to 2a:

The petitioner has submitted a revised label on which these restrictions have been deleted.

We consider this deficiency resolved.

Deficiency 2b:

The label restrictions for stone fruit which state, "Do not apply more than 14 lb of Ronilan in one season" are inappropriate and should be deleted or revised to indicate the maximum number of applications permitted per season.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Response to 2b:

These restrictions have been deleted on the revised label submitted by the petitioner.

We consider this deficiency resolved. We note that the revised label contains an error. For treatment of high disease pressure of brown fruit rot, 1 lb. product per 100 gal would correspond to application of 2 lb product per acre rather than 1½ lb product per acre as listed on the label.

Deficiency 4:

No gas chromatograms were included to support the petitioner's claim that BAS 35F and its metabolite (determined as acylated 3,5-dichloroaniline) could be distinguished by GC analysis from the pesticides registered for use on stone fruits and lettuce. We will require raw data, including chromatograms, in order to determine whether the analytical method is adequate for enforcement purposes.

Response to 4:

(+)

The petitioner has submitted raw data, including chromatograms, to support the claim that the method distinguishes BAS 352F and its metabolite DCAD from other compounds currently registered for use on lettuce and stone fruits. The groups of pesticides were screened at the 0.05 ppm level, and the detector was sensitive to 0.02 ppm. No peaks within 10% of the DCAD peak were found.

Reservations?

The petitioner has also submitted a confirmatory HPLC method including chromatograms for pesticides on lettuce. These compounds are distinguishable from DCAD in the chromatograms. Methamidophos was examined by HPLC but not by GLC.

See u Fig +

We consider the analytical methods adequate for enforcement of tolerances requested in this petition. For permanent tolerances, verification by method tryout by EPA chemists may be required.

We consider this deficiency resolved.

Deficiency 5a:

(+)

We judge the proposed tolerance of 10 ppm inadequate to cover residues in or on lettuce which may result from this use. We will require additional residue data reflecting the proposed use in order to determine an appropriate tolerance level.

Response to 5a:

The petitioner has submitted a revised label specifying a preharvest interval of 30 days for lettuce. We consider it unlikely that residues will exceed the proposed tolerance of 10 ppm after 30 days. Only one sample was tested at the proposed maximum rate and PHI; it contained residues of 7.3 ppm at 30 days PHI following 3 treatments at 1 lb a.i./a. The dissipation studies, however, indicate a rapid decline of residues, with a half-life of 2-3 days observed in some samples. Therefore, despite high levels of residues

Initially, the rapid decline should insure that residues will not exceed the proposed tolerance of 10 ppm at 30 days PHI.

We consider this deficiency resolved.

Deficiency 5b:

The available residue data for stone fruits do not specify the application rates in terms of lb ai/100 gal or indicate the concentration or spray volume per acre for most samples. We are therefore unable to determine the adequacy of the proposed tolerances for stone fruits. Additional data reflecting the proposed application rates in terms of lb ai/100 gal will be required. The petitioner should also be asked to consider expressing the tolerance for nectarines in whole numbers.

Response to 5b:

Peaches

The petitioner has requested a tolerance of 25 ppm for peaches. Limited data reflecting the proposed use with a PHI of 10 days are available. For most samples, application rates were less than maximal. Values of 18.9, 16.4, 21.0, and 27.3 ppm were obtained after 6-9 applications at 0.33 -1 lb ai/100 gal with a 0 or 1 day PHI. The first sample also received a postharvest dip at 1 lb ai/100 gal.

Although only a few samples were included in the decline study, preliminary data indicate a half- life of approximately 6-12 days. Because of the 7 day period between applications and the 10-14 day PHI, we consider it unlikely that residues will exceed the tolerance.

For apricots, a 25 ppm tolerance is also requested. The only samples analyzed reflect 1-3 applications at a 0.5 x application rate. Based on the data for peaches, however, we consider it unlikely that residues on apricots will exceed the 25 ppm tolerance.

low 3.3 pt

Cherries

For cherries, a 5 ppm tolerance is requested. Residues ranged from 1.4-2.9 ppm at 6-7 days PHI in three samples treated 3-4 times at the maximum rate. We will require additional residue data reflecting the proposed use in order to determine the level of residues present.

nectarines

The petitioner has revised the original request for a 2.5 ppm tolerance for nectarines and, responding to our request that the petitioner consider expressing the tolerance in whole numbers, now requests a tolerance of 3 ppm. Only two nectarine samples have been analyzed, however, and additional residue data reflecting the proposed use are needed to support the tolerance.

Plums

A tolerance of 1 ppm is requested for plums. Data were collected from plums treated 2-3 times at 0.5x the application rate (0.5 lb ai/100 gal) and harvested at 0 - 8 days. Additional data reflecting the proposed use will be required to permit determination of the adequacy of the proposed tolerance.

In summary, we consider the data adequate to support the tolerance for peaches, but additional residue data reflecting the proposed use are needed to support the tolerances for cherries, nectarines, and plums. The proposed tolerance for nectarines is now expressed in whole numbers.

This deficiency has been resolved for peaches and apricots, but additional data are needed for cherries, nectarines, and plums.

Conclusions

1. The petition for exemption of [redacted] is pending. The petitioner will need to obtain clearance for the inert [redacted] or substitute a suitable alternate.

2. The inappropriate label restrictions have been deleted on the revised label for lettuce.

3. The inappropriate label restrictions have been deleted on the revised label for stone fruits. We note that the revised label contains an error, reading 1½ lb product per acre for application rate for treatment of brown fruit rot when disease pressure is high rather than 2 lb product per acre which would correspond to application of 1 lb product per 100 gal.

4. The analytical method is adequate for enforcement of tolerances requested in this petition. A confirmatory method has also been submitted. For permanent tolerances, a successful method tryout by EPA chemists will be required.

5. We consider the proposed tolerance of 10 ppm adequate to cover residues on lettuce resulting from the maximum proposed use at the revised PHI of 30 days.

6a. Residues in or on peaches and apricots resulting from the proposed use will not exceed the proposed 25 ppm tolerance.

6b Residues in or on cherries, nectarines, and plums resulting from the proposed use may exceed the proposed tolerances. Additional residues data reflecting the maximum proposed use are needed to determine the appropriate tolerance levels.

6c. We note that the petitioner has submitted a revised tolerance for nectarines expressing the tolerance in whole numbers.

Recommendation

We recommend that the proposed tolerances not be established because of the reasons given in Conclusions 1 and 6b. We also note an error in the label under Conclusion 3b. The actions needed to resolve these deficiencies are discussed in the conclusions above.

cc: Reading file
Reviewer
Circu
FDA
PP# No.
TOX
EEB
EFE
Watts

TS-769:RCB:Reviewer:B.D.Davis:LDTX:77324.CM#2:RM:810:Date:4/9/80
RDI:Section Head:R.M:Date:4/7/80:PDS:Date:4/7/80

INERT INGREDIENT INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED