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Petitions Control Branch and
Division of Toxicological Evaluation

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Pesticides Branch, Division of Food
Standards and Additives

AF 9-577

PP #7F0610. Benefin on direct-seeded lettuce. Evaluation of analytical method and residue data.

The Elanco Products Company proposes a tolerance of 0.05 ppm for residues of the herbicide, Benefin (N-butyl-N-ethyl- γ,α,α -trifluoro-2,6-dinitro-p-toluidine, trade name Balan) in or on direct-seeded lettuce.

A "no-residue" registration is in effect for the use of Benefin on seeded lettuce.

A tolerance of 0.05 ppm for residues of Benefin on peanuts was established in connection with PP #7F051A. A petition (PP #7F0588) for a tolerance for Benefin on alfalfa, bird's-foot trefoil and clover is presently under consideration by FDA.

Conclusions

1. While we have no metabolic data for Benefin, DTE has stated that, because of its close similarity to trifluralin, there is no need for specific metabolic data for Benefin. The metabolic routes are considered to be the same.
2. The gas chromatographic method utilizing electron capture detection is adequate for determining residues of Benefin in or on lettuce at the proposed tolerance level. A TLC clean-up modification makes it specific and adequate for enforcement purposes.
3. When Benefin is used as directed, residues in or on lettuce (direct seeded) would not exceed the proposed 0.05 ppm tolerance.
4. We would expect Benefin to be persistent in soil; but we believe that, with a label restriction on the rotation of certain crops in arid irrigated areas, there would be no problem of illegal residues in follow-up crops. The restriction included in the label of 5/5/67 (see proposed use below) is considered satisfactory.

Recommendations

Pharmacological considerations permitting, we recommend establishment of a 0.05 ppm tolerance for residues of Benefin in or on lettuce.

This favorable recommendation is contingent upon the inclusion in all labels of the 5/5/67 label restriction against the rotation of certain crops in arid irrigated areas of the western states.

In order to avoid an increase in the number of commodities, the petitioner should be asked to modify his Section F and change his request for a tolerance on direct-seeded lettuce to one for lettuce (unqualified as to method of planting). This change is based on the expectation that if Benefin is to be used in the future and ^{on} transplanted lettuce, supporting data including residue data will be presented to USDA and FDA for review under the inter-departmental agreement.

Detailed Considerations

Proposed Use

Two descriptions of the proposed use are submitted with this petition. One of these is in the form of a label which was a part of the initial, incomplete submission of this petition on 5/5/67 and the other is part of Section B of the completed petition submitted on 5/31/67. Our conclusions and recommendations are based on the latter label. The label submitted on 5/5/67 gives a more complete description of the same proposed use but includes, in addition, a crop rotation restriction for the Western United States. The question of the need for the crop rotation restriction will be taken up later in this review. ^R Benefin is formulated as a 1.5 lb active/gal. concentrate.

Benefin is to be applied broadcast and incorporated into the soil at rates of 0.75-1.5 lb act/A. The lower rates of application are for lighter soils and the higher rates for heavy soils.

Application is to be made within three weeks before planting and there is a restriction against application after planting.

Nature of the Residue

No metabolic data have been submitted for Benefin. However, by its memo of November 2, 1966, DTK stated that, because of its close similarity to trifluralin, there was no need for specific metabolic data for Benefin.

The metabolic fate of trifluralin has been discussed in detail in our review of FP #7F0555 dated 5/24/67. The major metabolic routes are the same for both chemicals, and involve dealkylation and reduction.

Since the major metabolite of trifluralin appears to be monopropyl trifluralin, we would by analogy, expect the major metabolites of Benefin to be the monoethyl or monobutyl derivatives. Residues of these two possible metabolites were looked for in lettuce at 119

days after treatment at the rate of 1 and 2 lbs act/A. Neither metabolite was detected under these conditions, the method being sensitive to 0.005-0.01 ppm.

Residue Methods

The gas chromatographic method (General Procedure 5801230), utilizing electron capture detection was discussed in detail in our evaluation dated 7/21/67 (PP #7F0588).

Validation data are reported for various lettuce varieties. Control values for all varieties are less than 0.01 ppm and recoveries for samples fortified at the 0.01 ppm level range from 77-100%. We consider these recoveries to be adequate and we estimate the method sensitivity with lettuce to be 0.01 ppm. Considering the satisfactory results obtained in our method trial with peanuts (See our forementioned evaluation of 7/21/67), we did not recommend a method trial with lettuce.

An earlier GLC method entitled "Determination of Benefin Residues in Lettuce" and designated as Procedure #5800820 has also been used. This procedure differs from #5801230 in that a methylene chloride partitioning step of the clean-up is eliminated.

A limited amount of validation data for this earlier procedure show recoveries ranging from 46-110% for lettuce fortified at the 0.01 ppm level. Control values were less than 0.01 ppm but the modified clean-up used in this procedure manifests itself in the rather irregular base-line on the gas chromatograms. This could account in part for the poorer recoveries at low levels using this procedure. Because of the apparent poorer cleanup the lower recoveries and because we have already had a successful tryout of General Procedure 5801230, we are not recommending the earlier procedure for enforcing the proposed tolerance for lettuce. ?

Ethion, BHC and zineb alone amongst about 70 pesticides tested, were shown to interfere with the GLC method. Procedure 5801110 (discussed in our memo of 5/24/64, PP #7F0555) utilizes a TLC clean-up step which would eliminate these interferences. Thus, the GLC method (Procedure 5801230) with the incorporation of the TLC procedure is capable of a very high degree of specificity for Benefin.

We conclude that the GLC method (Procedure 5801230) with the TLC clean-up is adequate to enforce the proposed tolerance for lettuce.

Residue Data

Lettuce

The proposed use is for a pre-planting application to direct-seeded lettuce. Nearly all lettuce grown in the western states is grown

from seed planted in the field whereas a large portion of commercial head-lettuce in the eastern states is started in protected beds and transplanted to the field. Therefore, the majority of the data submitted (that from Arizona and California) reflect important producing areas of direct-seeded lettuce. While we are recommending that the tolerance be established for lettuce, without qualification as to method of planting, limitation of the use to direct-seeded lettuce by a label restriction is practical.

Greenhouse-grown lettuce is a sizeable industry in certain areas. We have no residue data for direct-seeded greenhouse lettuce. However, the greenhouse soil is generally sterilized with steam which ^{eliminates} the need for herbicides.

None of the residue values are corrected for blanks. Residue data for head lettuce varieties with applications at the rate of 0.5-2 lb act/A and reflecting harvest intervals of 107-135 days showed less than 0.01 ppm Benafin in both the wrapper leaves and the heads. The normal PHI's for head lettuce vary widely from approximately 65-150 days whereas the interval for the data submitted reflect PHI's of above 100 days. However, data for leaf lettuce do show that residues resulting from exaggerated rates at the shorter 50-60 day intervals are also less than 0.01 ppm.

Residue data for butterhead lettuce with application at the rate of 0.75-1.5 lb. act/A and leaf lettuce with application at 0.75-4 lb. act/A showed less 0.01 ppm Benafin residue while observing PHI's of 52-64 days.

We therefore can conclude that residues of Benafin in or on direct-seeded lettuce (all varieties) from the proposed use would not exceed the proposed 0.05 ppm tolerance.

Soil Persistence

Soil persistence data for trifluralin were discussed in our memo dated 10/31/66 (PP #760533 by T. Woodward). Trifluralin is relatively persistent in soil, but with label restrictions as to the rotation of crops in arid areas, we believe that there would be no problem of residues in certain follow-up crops. Since Benafin is very similar structurally to trifluralin, Benafin residues, would by analogy be expected to persist in soil. In recognition of this problem, the petitioner's label (dated 5/31/67) should also include restrictions on the rotation of certain crops in arid irrigated areas of the western states. This restriction was probably omitted through an oversight since it was included in the initial labels of 5/5/67. We believe that with this restriction there will be no problem of Benafin residues in follow-up crops.

Other Considerations

The petitioner has proposed a tolerance for direct-seeded lettuce. We feel, that in order to avoid an increase in the number of commodities, the petitioner should be asked to modify his request to one for lettuce (unqualified as to method of planting). We consider the label directions with the proposed use for direct-seeded lettuce to be a partical means of limiting the usage on lettuce.

Although a lower tolerance would suffice, we are not recommending that the proposed 0.05 ppm tolerance be reduced. A tolerance of 0.05 ppm for residues of Benafin on peanuts has been established and a tolerance of 0.05 ppm is pending for alfalfa, bird's-foot trefoil and clover. A reduction in this proposed tolerance for lettuce would have no significance and would only result in an unnecessary increase in the number of tolerance levels.

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R. S. Quick

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FP #770610

FP #770514 FP #770588 FP #770555 FP #770533

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RD/I--JAlpert