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7-14-69

PP #9F0743

Petitions Control Branch and
Division of Pharmacology and Toxicology

July 14, 1969

Petitions Evaluation Branch
Division of Pesticides

AF 25-202
(Diamond Shamrock Corp.)

PP #9F0743 Daconil 2787 on potatoes. Evaluation of amendment of May 23, 1969.

As a follow-up to the conference of 3/27/69 on the subject petition, the petitioner has submitted amended Sections C and D, which are designed to overcome the deficiencies in the PCB (J. Lamb) reject letter of 3/3/69.

1. Metabolism and degradation of Daconil 2787 in the plant

No additional metabolic studies are included with this present submission. We questioned the possible presence of metabolites (other than the 4-hydroxy metabolite), particularly 2,4,5-trichloroisophthalonitrile and trichlorodicyanociline (the petitioner now refers to the latter as 4-amino-2,5,6-trichloroisophthalonitrile). The petitioner has commented on the two metabolites we specifically mentioned to the effect that they would have responded as separate peaks to the GLC method of analyses used for the determination of residues of the parent compound on potatoes.

He supports this position with chromatograms for potatoes which had received season-long weekly applications of 1.5 lbs active/acre of Daconil 2787. No residues of the two possible metabolites were found. The validation studies do in fact show different retention times for the two possible metabolites being discussed and show recoveries for both compounds of ca 90 percent at the 0.05 ppm fortification level. From the sample chromatograms, the lower level of detectability is ca 0.02 ppm for both compounds.

The petitioner believes that 2,4,5-trichloroisophthalonitrile was present in the fecal samples of test animals [redacted]

[redacted] The 4-amino-2,4,5-trichloroisophthalonitrile is regarded as a minor animal metabolite which is not present on crops.

In view of the data showing absence (< 0.02 ppm) of the two possible metabolites in or on potatoes, our question concerning their possible presence has been answered satisfactorily in the negative.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Additional validation data and chromatograms now submitted for the 4-hydroxy metabolite (found in Daconil 2787 treated soil) to resolve the question of sensitivity are also useful in our obtaining a better picture on the metabolism of Daconil 2787. These data show the lower limit of detectability to be about 0.02 ppm. No residues (< 0.02 ppm) were found in potatoes from field experiments.

Even though we do not consider the metabolic picture to be completely elucidated for plants in general, we believe that enough data have been presented to conclude that residues in potatoes will consist primarily of the parent compound with a possibility that the 4-hydroxy metabolite may also be present.

2. Analytical Method

Since we are no longer concerned with all possible Daconil 2787 metabolites for this potato tolerance, we are no longer raising questions about its ability to detect all metabolites.

Validation data, using the petitioner's method, entitled "Analytical Method for Determination of Daconil 2787 and DAC-3701 Residues," have now been submitted for Daconil 2787 and additional data have been submitted for the 4-hydroxy metabolite. Representative chromatograms have also been included in this amendment. Recoveries range from 83-110% (ave. 95%) for Daconil 2787 and from 76-117% (ave. 91%) for the 4-hydroxy metabolite at the 0.05 ppm fortification level. Blanks are < 0.02 ppm. We consider this validation data adequate for the proposed tolerance level and judge the method sensitivity to be at least 0.05 ppm for both compounds.

To clarify our question of specificity the petitioner has presented a rationale showing that compounds (with established tolerances on potatoes) that would be carried through the procedure have sufficiently different retention times on the column used (20% DC 200 on gaschrom P) to make the method specific for regulatory purposes.*

No method trial was initiated; in an earlier successful trial for the parent compound only, adequate results were obtained in two locations (see memo F. R. Fazzari 10/24/67). As noted above, we expect no residues (< 0.02 ppm) of the 4-hydroxy metabolite to be present on potatoes and there was no need to perform a trial of this metabolite in connection with this potato tolerance. We now consider the method adequate to enforce the proposed tolerance.

*A number of the compounds would not respond to the MCGC determinative step even if they had come through the extraction and clean-up procedures.

Conclusions

1. The fate of Daconil 2787 is sufficiently detailed for this proposed potato tolerance.
2. The analytical method is adequate to enforce the proposed tolerance.

Recommendation

Pharmacological considerations permitting, we recommend for the establishment of the 0.1 ppm tolerance for combined residues of 2,4,5,6-tetrachloroisophthalonitrile and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile on potatoes.

A. Roger Rathman

cc:
SC-13
SC-12
SC-1
SC-970
SC-300
SC-320
CF-40
PP #9F0743

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7/14/69
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