

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

JUN 3 1963

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3G2856. Iprodione on beans. Evaluation of

analytical methods and residue data.

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Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief

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TO: H. M. Jacoby, Team Manager #21

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and

Toxicology Branch
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Rhone Poulenc Inc. is requesting the establishment of a temporary tolerance for residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide], its isomer [3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide] in or on beans (dry or succulent) at 2 ppm.

Tolerances for residues of iprodione have been established on cherries, peaches and nectarines at 20 ppm and on kiwi fruit at 10 ppm. Tolerance proposals of 0.8 ppm on meat and 0.15 ppm on milk are currently in reject status due to the need for storage stability data (see M. Kovacs review of PP#2F2788 dated 10/25/82).

The Company wishes to use a total of 610 lbs ai to treat 315 acres of beans in eight states in 1983. They are also requesting use of 1200 lbs ai for the year 1984.

Conclusions

- 1. If the petitioner's intention is to restrict all animal feeds, the label restriction should be revised to include forage as well as hay. In addition, use should be precluded on cowpeas since they are used almost exclusively as an animal feed.
- 2a. We consider the fate of iprodione on beans adequately delineated from data on other plants. The residue of concern will consist of the parent, its isomer and the des-isopropyl metabolite (compounds included in the tolerance expression).
 - 2b. The fate of iprodione in animals is adequately defined.
- 3. Adequate methods are available to enforce the requested tolerance.
- 4a. Residues in beans resulting from the proposed use will not exceed the requested 2 ppm tolerance.
- 4b. While no tolerances are requested for residues in forage and hay, data have been submitted for these feed items.
- 5. If the restrictions (see conclusion 1) noted above are revised, there will be no problems with secondary residues in meat and milk. If the revisions are not made, the storage stability data requested in PP# 2F2728 must be submitted along with proposals for appropriate meat and milk tolerances and forage and hay tolerances (see Conclusion 4b).

Recommendation

We recommend against the proposed tolerance because of the reasons cited in Conclusion 5. For further consideration, we will need revisions in the label (see Conclusion 1) or tolerance proposals for forage, meat and milk as well as the storage stability data requested in connection with PP# 2F2728.

For any permanent tolerance request, we will need additional residue data.

Detailed Considerations

Formulation

The manufacturing process along with the identity and amount of impurities was submitted in connection with PP#8G2084 (review of 3/2/79). The formulation is Rhone Poulenc's Rovral WP containing 53.16% technical material. All the inerts are cleared under Sec. 180.1001.

Proposed Use

The product is to be applied at the rate of 0.75-1 lb. ai/A. Applications may be made by either ground (20-30 gpa) or air (10-20 gpa). The product is to be applied at early bloom (25-50% of plants with at least 1 bloom) and again at peak bloom (maximum number of flowers open). There is a restriction against feeding treated hay to livestock.

Since it appears the intent here is to have no animal feed items, the restriction should be for forage and hay. Additionally, use should be precluded on cowpeas since they are used almost exclusively for animal feed.

Nature of the Residue

The fate of iprodione in plants has been discussed in detail most recently in the R. B. Perfetti review of PP#2F2596 dated 5/13/82. Studies have been submitted for iprodione on peaches, strawberries and wheat. These studies indicate that there is little migration after foliar treatment but that uptake via the root system after ground application occurs with subsequent translocation to aerial plant parts. In all three plants, the major portion of the radioactive residue was identified as iprodione, its isomer and its des-isopropyl metabolite (compounds in the tolerance expression). Data for these three components in beans indicate the majority of the residue to consist of the parent compound.

We consider the nature of the residue in beans to be adequately understood from data on other plants. The residue of concern will consist of the parent, its isomer and the desisopropyl metabolite.

The fate of iprodione in animals has been discussed in detail in the M. Kovacs review of PP#2F2787 dated 10/25/82. If the Company makes the revisions in Sec. B requested above, there will be no animal feed items. However, we do consider the metabolism of iprodione in animals adequately defined

for this proposed temporary tolerance. Major extractable residues in animal tissues are the des-isopropyl metabolite and the parent compound. Milk residues consist primarily of the hydroxylated metabolite (1-(3,5-dichloro-4-hydroxyphenyl)-biuret), the des-isopropyl metabolite and parent.

Analytical Methods

Samples of beans (succulent and dry), forage and hay were analyzed by Method 151 (succulent beans and forage) and by a modification of Method 151 (dry beans and hay).

The method involves extraction with acetone, a liquid-liquid partition, further clean-up with a gel permeation column followed by a Florisil column. Two fractions are eluted from the Florisil column. One fraction contains the parent and its isomer. The other fraction contains the desisopropyl metabolite. Determination is made by GLC using a 63 Ni EC detector.

The modifications for the dry beans and hay involve the following: 1. an aqueous acetone solution was used in the initial extraction, 2. a more active Florisil was used, and 3. an acetonitrile:hexane clean-up step was used prior to the Florisil column.

Samples of beans (dry and succulent) forage and hay were fortified with parent, isomer and the des-isopropyl metabolite at levels ranging from 0.1-100 ppm. Recoveries ranged overall from 62-120% and averaged 100% for the parent compound, 76% for the isomer and 88% for the des-isopropyl metabolite. Blanks for beans ranged from 0.01-0.1 ppm and were generally less than 0.05 ppm. We consider the limit of detection to be 0.05 ppm.

A confirmatory TLC method is available. This method is similar to that on kiwi fruit. The method for residues in kiwi fruit has undergone a successful method trial.

We conclude that adequate analytical methods are available to enforce the requested tolerance on beans.

A method is available to determine residues in meat and milk (see M. Kovacs review of PP# 2F2728 dated 10/25/82).

If Sec. B is revised as requested, the use on beans will not result in any secondary residues in meat or milk.

Residue Data

A total of nine studies were submitted. Four of the studies were conducted on succulent (snap) beans and five on dry (kidney, pinto and lima) beans. In all the studies two applications of 1 lb ai/A were made as directed by the label. The applications were at 1-2 week intervals.

In the case of the snap beans, samples of beans and forage were taken at intervals of 18-33 days after the last application; with the dry beans, samples of beans and hay were taken at intervals of 49-72 days after the last application.

Residues in the snap beans were parent compound only; no (<0.05 ppm) isomer or des-isopropyl metabolite were detected. Residues ranged from <0.05-0.59 ppm. Residues in the dry beans ranged from <0.05-1.16 ppm. Only one sample contained any measurable amount of the isomer (0.13 ppm). None of the dry bean samples contained measurable levels of the des-isopropyl metabolite.

We consider these data adequate to support the 2 ppm tolerance proposed. For any permanent tolerance request, we will need additional residue data.

Even though no tolerances are proposed and we believe the petitioner's intent is to restrict the feeding of forage and hay, data were submitted for forage and hay. Maximum residues in forage were ca 25 ppm and the maximum residue in the hay was ca 86 ppm.

Residues in Meat and Milk

A cattle feeding study was submitted in connection with PP# 2F2728 (see M. Kovacs review dated 10/25/82). If the label is revised as suggested above, there will be no problem with secondary residues in meat and milk. If the restrictions are not revised, the storage stability data requested in the M. Kovacs review will be required along with appropriate meat and milk tolerance proposals (as well as a forage residue tolerance proposal).

cc: R.F.
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Reviewer
FDA
TOX
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PP# No. 3G2856

Robert E. Thompson (Res. Triangle Park, NC)
RDI: Section Head-RJH: Date-5/10/83:RDS: Date-5/10/83:DCR-17926
TS-769:RCB-21:Reviewer ini-ar:efs:Rm-810:CM#2:x77324:5/13/83
REVISED-5/16/83:DCR-17964:efs