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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: 93-NC-0003, Section 18 Emergency Exemption for **Iprodione** on **Apples** in the State of North Carolina. Resubmission: Evaluation of Processing Study and Comment on Expected Residue Levels.
CBTS No: 12071
DP Barcode: D192482
MRID No: None.

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The North Carolina Department of Agriculture has submitted preliminary results from an apple processing study in support of their Section 18 exemption request. In addition to reviewing the processing study, RD has requested that CBTS comment on the current status of dry apple pomace as an animal feed item, and that we further provide an updated estimate of residues in the whole fruit and processed commodities.

Background

CBTS reviewed the original Section 18 Specific Exemption request from the State of North Carolina in our memo dated 4/26/93 (D. Davis). The fungicide, iprodione, formulated either as Rovral® 50W or Rovral® 4F was to be applied to apples at an application rate of 0.5 to 1.0

1/6

lb ai/A. A maximum number of three treatments with a corresponding seasonal application rate of 1.5 to 3.0 lb ai/A was specified. The fungicide application was intended to control *alternaria* blotch in apples caused by *Alternaria mali* in approximately 6,000 acres of apple orchards in North Carolina.

Citrus residue data generated from a similar use pattern were translated to apples to estimate the surface residues of iprodione likely on the whole fruit as a result of the proposed Section 18 use. CBTS concluded that residues of iprodione, its isomer, and its 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide metabolite were not likely to exceed 2 ppm on apples. Based on maximum theoretical concentration factors and our experience with iprodione in/on grapes, we further concluded that residues of iprodione and its metabolites were not likely to exceed 54 ppm in apple pomace (wet and dry), and that residues were not likely to concentrate in apple juice.

CONCLUSIONS

1. While the apple processing study submitted is not an acceptable study on which CBTS would make a registration decision, the results do support the contention that residues of iprodione and its metabolites are not likely to concentrate in the processed commodity, wet apple pomace. The results further indicate that residues of iprodione are likely to concentrate in the processed commodity, dry apple pomace.

2. CBTS notes that residues of iprodione and its metabolite did not concentrate in the related commodity, wet grape pomace as noted in our memo dated 2/21/84 (R. Cook, PP#3F2964). We, therefore conclude that residues of iprodione and its metabolites are not likely to concentrate in the processed commodity, wet apple pomace.

3. We continue to support our original conclusion that residues of iprodione and its metabolites are likely to concentrate in the processed commodity, dry apple pomace based on our experience with the related commodity, dry grape pomace.

4. The apple residue data contained in the most recent processing study submission was a result of a post harvest application. This use pattern differs substantially from that proposed in this Section 18, making translation of the residue data inappropriate to this request. Further, since there is no actual apple residue data reflecting this use pattern, we are unable to generate anticipated residues with which to revise our original expected residue level estimate. Therefore, CBTS continues to conclude that residues of iprodione and its metabolites are unlikely to exceed 2 ppm in/on apples as a result of this Section 18 use.

5. In the absence of substantial evidence that dry apple pomace is not fed to livestock, CBTS will continue to consider dry apple pomace a feed item. Prior to removing dry apple pomace from Table II of the *Pesticide Assessment Guidelines, Subdivision O*, we must be reassured that dry apple pomace is not fed to livestock throughout the country,

as well as in the State of North Carolina. It is our understanding that members of industry are in the process of conducting a survey to demonstrate that apple pomace is not dried prior to feeding, and that information will be considered upon formal submission to the Agency.

Detailed Considerations

Apple Processing Study

Study Description

The North Carolina Department of Agriculture has submitted the preliminary residue results from a processing study conducted by Rhone-Poulenc on **post harvest** treated apples.

Harvested, mature, Washington State "red delicious" apples were treated with two applications of Rovral® 50W. Samples harvested on 9/30/91 were drenched with a solution containing 1.0 lb ai/100 gallons H_2O and allowed to drain for approximately one hour on 12/12/91. This treatment was repeated on 1/3/92. A randomly selected subsample of fruit (approximately 60 lbs.) was selected to generate the required processing fractions (whole fruit, juice and wet and dry pomace). Sample processing was complete within 16 hours after the last drenching. The processed commodities were stored frozen until analysis. Preliminary residue analysis began on 3/18/92 (approx. 55 days after treatment) and was completed on 4/1/92 (approx. 68 days after treatment).

CBTS has the following concerns about the processing study.

- The preliminary results submitted have not been reviewed by Rhone-Poulenc's Quality Assurance Unit.

- The iprodione residues on the apples used in this study were a result of the post harvest drenching of apples, while the actual use pattern for this chemical on apples involves three preharvest applications to the growing crop. The *Pesticide Assessment Guidelines, Subdivision O* §171-4 (c) (iv) notes that "*RAC samples used in processing studies must contain field-treated detectable residues, preferably at or near the proposed tolerance level... Processing studies utilizing spiked samples are not acceptable, unless it can be demonstrated that the RAC residue consists entirely of a surface residue.*"

- No information is provided on the actual apple processing method used in this study. CBTS requires documentation on the specific processing methods used to generate the processed commodities as well as a comparison to accepted industrial processing techniques.

- No details are provided on the extraction method used to generate the samples for

instrumental analysis.

- Insufficient data has been provided on the storage conditions.

- Adequate supporting storage stability data for the RAC and its processed commodities has not been submitted.

Due to the unique nature of a Section 18 request, CBTS is willing to consider this data as it pertains to this Section 18 request from the State of North Carolina for iprodione use on apples. Any formal submission of this data to the Agency would require satisfactory resolution of the issues raised above prior to consideration.

CBTS has recalculated the residue levels based on the chromatograms submitted. A summary of the results of the study are presented below.

Table 1. Apple Processing Residue Results

Commodity	Iprodione ppm[1]	RP-30228 ppm[1]	RP-32490 ppm[1]	Total Residue ppm[1]
Whole Fruit	5.50	0.20	<0.10	5.80
Apple Juice	3.42	0.31	<0.10	3.83
Wet Pomace	4.78	0.40	0.15	5.33
Dry Pomace	47.2	4.32	1.39	52.9

[1] Residue levels are not corrected for concurrent recoveries.

The following deficiencies are noted in the study.

- Standard chromatograms ranging from 0.1 to 0.5 ppm are presented for the parent compound and its two metabolites. These chromatograms have been cut from a continuous strip chart recorder. The chromatograms are not dated, initialled or labelled in a consecutive manner to identify when they were run. Not only is this a GLP violation, but it calls into question when the actual standards were run in relation to the sample chromatograms.

- Based on the calculations presented, the reviewer assumes that the injection volume for the standard chromatograms for all three compounds was 2.0 μl, however, this is not documented. Further, the analyst apparently varied the injection volume on the 0.5 ppm standard run with the samples from 1.0 μl to 3.0 μl. It appears that a similar variance in injection volume occurred during sample analysis based on the actual peak heights measured from the chromatograms and the "corrected" peak heights written below each peak. However, this is not documented, and in one instance the standard preceding the

samples was injected at 1.0 μl, but the peak heights on the samples were corrected for an injection volume of 1.3 μl.

- Whole fruit extracts were diluted 45X through a series of three dilutions (5X, 3X, 3X) and analyzed for residues of the parent compound. Given the error introduced by each successive dilution, and the fact that the final concentration of the extract injected was <0.3 ppm, we question the accuracy of the residue results reported.

- The spiking level used for concurrent recovery samples in the analysis of iprodione was not appropriate based on the actual residue values in the samples.

- Concurrent recoveries should not be corrected for residues below the limit of detection in control samples.

- Numerous calculation/typographical errors were noted.

CBTS concludes that the apple processing study submitted is not acceptable to support a registration decision.

While no definitive conclusions can be drawn, due to the deficiencies noted above, the results of this apple processing study do support the contention that iprodione and its metabolites are unlikely to concentrate in wet apple pomace. CBTS notes that residues of iprodione and its metabolite did not concentrate in the related commodity, wet grape pomace as noted in our memo dated 2/21/84 (R. Cook, PP#3F2964). We therefore conclude that residues of iprodione and its metabolites are not likely to concentrate in the processed commodity, wet apple pomace.

We continue to support our original conclusion that residues of iprodione and its metabolites are likely to concentrate in the processed commodity, dry apple pomace based on our experience with the related commodity, dry grape pomace, and further substantiated by the results of the processing study submitted.

Expected Residue Reevaluation

Our original residue estimate for apples was based on citrus data submitted in support of an EUP. While CBTS would not generally be willing to make this sort of translation for registration purpose, given the unique circumstances surrounding a Section 18 request, we have used the residue data on a sufficiently similar crop with a use pattern closely corresponding to that indicated in this Section 18 request to make an estimate of expected residues. The apple residue data contained in the most recent processing study submission was a result of a post harvest application. This use pattern differs substantially from that proposed in this Section 18, making translation of the residue data inappropriate to this request. Further, since there is no actual apple residue data reflecting this use pattern, we are unable to generate anticipated

residues with which to revise our original expected residue level estimate. Therefore, CBTS continues to conclude that residues of iprodione and its metabolites are unlikely to exceed 2 ppm in/on apples as a result of this Section 18 use.

Apple Pomace as a Feed Item

Historically, CBTS has considered apple pomace to be a livestock feed item, and as such, both wet and dry pomace have been included in the *Pesticide Assessment Guidelines, Subdivision O* Table II. Industry comments have been received questioning the use of dry apple pomace as a livestock feed item, and limited evidence has been submitted to demonstrate that dry apple pomace is not manufactured or fed. The Chemistry Branches of HED are in the process of reviewing Table II. In the absence of substantial evidence that dry apple pomace is not fed, dry apple pomace will remain in Table II as a livestock feed item. Prior to removing dry apple pomace from Table II, we must be reassured that it is not a livestock feed item throughout the country, as well as in the State of North Carolina. It is our understanding that members of industry are in the process of conducting a survey to demonstrate that apple pomace is not dried prior to feeding, and that information will be considered upon formal submission to the Agency.

cc: RF, List B File, Iprodione Section 18 File, circ., D. Davis, R. Griffin.
H-7509C:CBTS:DSD:CM#2:Rm804:305-7085:dd:7/1/93.
RDI:SecHd:RSQuick:7/1/93:BrCh:DFEdwards:7/1/93.
Disk:DSD-1 File:IPRONC2.S18