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

AUG 6 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Reregistration of Iprodione. Rhone-Poulenc study "Rovral 4F/Beans/Ground/Cannery Waste/Magnitude of the Residue, Study No. USA91R55." MRID #423487-01. DP Barcode D179622. CBRS #10075.

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In support of reregistration of the List B contact fungicide iprodione, Rhone-Poulenc Ag Company has submitted a field trial study entitled "Rovral 4F/Beans/Ground/Cannery Waste/Magnitude of the Residue, Study No. USA91R55.", dated June 9, 1992. Rhone-Poulenc Ag Company committed to performing a processed food/feed study for beans in their Phase 3 submission. Subdivision O, Table II, identifies bean cannery waste as the processed commodity for the crop beans. The objective of this study was to generate magnitude of residue data needed to establish a tolerance for iprodione on bean cannery waste.

Tolerances are established (40 CFR 180.399, 185.3750, and 186.3750) for the combined residues of iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide)](RP-26019), its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-30228), and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-32490) in or on numerous raw agricultural commodities, food commodities, and animal feed commodities, including succulent beans at 2.0 ppm, bean forage at 90.0 ppm, dry beans at 2.0 ppm, and dried bean vine hay at 90 ppm.

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Conclusions

1. Iprodione was not applied at a rate sufficient to produce detectable residues (with one exception) in the raw agricultural commodity (rac) beans. Therefore, the effect of processing on the magnitude of the residue in bean cannery waste cannot be determined.

2. The manner in which the rac was processed does not reflect actual commercial processing. No leaves/stems were included in the cannery waste samples analyzed in this study. Bean cannery waste obtained from commercial processing can contain up to 52% leaves/stems. Since plants are treated with iprodione via foliar application, residues on leaves and stems ~~could~~ contribute to the total amount found in or on cannery waste.

3. The residue study protocol receipt verification page was not signed by either the field development representative or the trial director.

4. A copy of the analytical method was not included.

5. The analytical method was not validated prior to analysis of samples as called for in the study protocol. This was properly noted as a deviation from the study protocol. An explanation as to why recovery samples were fortified at 50X the limit of quantitation is needed.

6. Raw data were not provided for any of the samples.

Recommendations

The study is unacceptable for reasons stated in Conclusions 1 - 6. The study is not upgradeable and a new study must be initiated to fulfill reregistration requirements.

Detailed Considerations

Application

Iprodione (EPA Reg No. 264-482, Rovral 4F, flowable s.c., 4 lbs ai/gal product, lot no. X06238007, 42.3% by analysis on 5/23/91) was applied to the foliage of bean plants at a rate of 1.0 lb ai/A in each of two applications. The first application at 1 lb ai/A (1X) took place when approximately 10% of the plants were in bloom (3/26/92), and the second application at 1 lb ai/A (1X) 5 days later when plants were in full bloom (3/31/92). The field trial took place in Florida. Applications were made using a tractor mounted boom sprayer equipped with hollow cone nozzles (18 nozzles,

12 inches apart), boom height 12 inches, speed 2.78 ft/sec, and spray pressure 60 PSI, directed spray with two nozzles per row. Plot size was 50.0 ft X 9.0 ft. A control (untreated) plot was located at the same site, 410 feet away from the treated plot.

A single untreated sample (RL5487) and triplicate treated samples RL5488, RL5489, and RL5490) of whole, unwashed bean pods were taken 15 days after the last application of iprodione (15 day PHI). Samples were placed in freezer at -5°C within one hour after harvest and were stored frozen for a maximum of 6 days before shipment. Samples were shipped to Rhone-Poulenc, RTP, in boxes containing dry ice, using an overnight delivery service.

Processing

Samples were processed 7 days after harvest. Ends of whole bean pods (cannery waste) were removed by hand or cut off with a utility knife; a method the registrant stated was equivalent to the commercial process. In December, 1984, the registrant submitted similar residue data on beans and cannery waste (MRID #00151345, "Iprodione residue data on beans and cannery waste fraction, 1984 Field Program E-15, ASD No. 84/119). In that study, beans were harvested by mechanical pickers and immediately processed at the Friday Canning Corporation (Gillett, WI). The report states, "After the crop was processed, a representative sample from the cannery waste pile was taken for residue determination. At Friday's Canning Corporation the **cannery waste pile is typically composed of snipped ends from the snap beans and leaves/stems at 48-60% and 40-52% amounts respectively.** (Information from Mr. Gordon Mitchell, plant manager)."

The manner in which the rac was processed in the current study does not reflect actual commercial processing. No leaves/stems were included in the cannery waste samples analyzed. Since plants are treated with iprodione via foliar application, residues on leaves and stems would contribute to the total amount found in or on cannery waste.

Analytical Method

Storage time from sampling until analysis of cannery waste edible pods was 12 days; samples were frozen for this entire ti Rhone-Poulenc Ag Company performed all laboratory analysis. I samples (edible pods and cannery waste) were analyzed using Rhone Poulenc Ag Company analytical method SOP 90277 "Rov Determination of RP-26019 and its Metabolites in/on Dry, Succul Oily and Non-Oily Crops by Gas-Liquid Chromatography and Thin Chromatography." A summary of the analytical method was prov however, a copy of the complete analytical method was not incl The method used is a variation of that submitted in Phase 3 (MRID #92083073).

The method summary provided stated that samples were extracted with acetone, interfering substances were removed by liquid-liquid partitioning and Florisil column cleanup. Concentrations of the three analytes were determined using GC with ECD. The Phase 4 Review of the plant residue analytical method indicated a data gap, stating that toluene should be substituted for benzene in the clean-up. Since a copy of the method was not provided, CBRS cannot determine if this substitution was made.

The analytical method limit of detection is 0.05 ppm, and limit of quantitation is 0.1 ppm, for iprodione, its isomer, and its metabolite. External standard calibration was used.

The analytical method was not validated prior to analysis of samples as called for in the study protocol. This was noted as a deviation from the study protocol. The registrant stated that the method had recently (no date given) been validated by the same analytical lab and personnel using a similar (snapbean) substrate, documented in laboratory notebook EC-25-83. This data should have been provided in this report.

No raw data (peak heights, retention times, or calibration curves) were provided. Representative chromatograms of iprodione (0.5 ppm standard, untreated commodity, 1 ppm fortified commodity, and a treated commodity sample) were provided. The iprodione isomer and metabolite had representative chromatograms consisting of: 0.5 ppm standards, untreated commodity, 0.5 ppm fortified commodity, and treated commodity provided. No notation was made as to whether the samples were cannery waste or the edible portion of the bean pod. Retention times and peak heights were not provided. The chromatograms were not properly labeled with attenuation or chart speed. No standard chromatograms for iprodione, its isomer, or metabolite were provided for the 0.1 ppm limit of quantitation, or at the 0.5 and 1.0 ppm fortification levels. No data concerning external standard curves was presented. No data depicting mixed standards (iprodione, its isomer, and its metabolite in the same sample) were provided.

Fortified samples were analyzed with each sample set. Iprodione was fortified at 1.0 ppm in edible pods and 5.0 ppm in cannery waste; recoveries were 113% for edible pods and 106% for cannery waste. The registrant needs to explain why edible pods and cannery waste were fortified at different levels. An explanation as to why cannery waste was fortified at 50X the limit of quantitation is also needed.

The iprodione isomer and metabolite were fortified at 5.0 ppm in both edible pods and cannery waste. Recoveries for the isomer were 75 and 72% in edible pods and cannery waste respectively. Recoveries of the iprodione metabolite were 73 and 87% in edible pods and cannery waste respectively. The registrant must explain why samples were fortified at 50X the limit of quantitation.

Results

Total residues measured on edible bean pods and cannery waste ranged from <0.05 ppm (ND) to 0.07 ppm (see Table I). There were measurable residues in only one of the three treated samples analyzed (0.07 ppm in edible pods, and 0.06 ppm in cannery waste), and these residues were due to the presence of the iprodione metabolite. Raw data and chromatograms were not provided for this sample.

Although measurable residues were present in one of the samples, and the concentration was higher in edible pods than cannery waste, the concentration of the residues were just above the limit of detection of the method. CBRS does not think that scientifically valid conclusions can be drawn from the limited data presented.

Table I. Results of analysis (uncorrected for recovery) of snapbean edible pods and cannery waste for iprodione (RP-26019), its isomer (RP-30228), and its metabolite (RP-32490) residues.

Sample No.	Rate lb ai/A	RP26019 ppm	RP26019 %recov	RP30228 ppm	RP30228 %recov	RP32490 ppm	RP32490 %recov
Edible Pods							
RL5487-P	0	<0.05	113[a]	<0.05	75[b]	<0.05	73[b]
RL5488-P	2 x 1.0	<0.05		<0.05		0.07	
RL5489-P	2 x 1.0	<0.05		<0.05		<0.05	
RL5490-P	2 x 1.0	<0.05		<0.05		<0.05	
Cannery Waste							
RL5487-E	0	<0.05	106[b]	<0.05	72[b]	<0.05	87[b]
RL5488-E	2 x 1.0	<0.05		<0.05		0.06	
RL5489-E	2 x 1.0	<0.05		<0.05		<0.05	
RL5490-E	2 x 1.0	<0.05		<0.05		<0.05	

[a]Fortified at 1.0 ppm.
[b]Fortified at 5.0 ppm.

Iprodione was not applied at a rate sufficient to produce detectable residues (with one exception) in the raw agricultural commodity (rac) beans. Iprodione was applied at the maximal rate (1 lb ai/A) and for the maximum number of times (2), but was not applied at an exaggerated rate in an attempt to get detectable residues. As part of the acceptance criteria for processed food/feed studies, the Phase III Technical Guidance Document, Subdivision O, Section 171-4(l) (12/24/89) requires that rac samples that are processed contain field treated detectable

residues (preferably at or above the tolerance, or that the rac was treated in the field at exaggerated rates in an attempt to get detectable residues. In the cover letter accompanying this study, the registrant indicates that Subdivision O, Section 171-4(k) guidelines were being followed. Since cannery waste is a processed commodity, this was not the appropriate guideline. Instead, Subdivision O, Section 171-4(l) should have been use as a guideline.

A primary objective in performing processing studies is to determine if the regulated compounds will concentrate on the processed commodity as a result of normal commercial processing of the rac. Therefore, it is critical that the rac contain the compound(s) of interest at detectable levels. The registrant should have applied iprodione at an exaggerated rate in an attempt to obtain residues on the rac.

cc: Iprodione S.F., S.F., circ., R.F., List B File, Reg. Stnd. File, S.Knizner
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H7509C:CBRS:SAK:sak:Iprod1.rev:CM#2:7/23/92