SR-Iprodione

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

OCT -2 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Danielle Larochelle
Rhone-Poulenc AG Company
P.O. Box 12014
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Research Triangle Park, N.C. 27709-2014

RECEIVED
OCT 03 1996
OPP PUBLIC DOCKET

Re: Iprodione

Dear Ms. Larochelle:

EPA has reviewed two papers on the efficacy of iprodione on peaches and other stone fruits. A copy of our September 17, 1996 review is enclosed. We found that the effects of iprodione treatment during the pre-harvest period persist after the fruit has been picked, indicating that iprodione is systemic in peaches and other stone fruits. These findings imply that iprodione residues will be found in measurable levels when the distribution of iprodione residues between peel and pulp is examined.

We also examined PDP data on fresh peaches from 1994 and earlier years to see whether we could identify which samples had received post-harvest treatment with iprodione and, if so, whether post-harvest treated peaches had higher residues than peaches that had not received post-harvest treatment with iprodione. This analysis did not provide definitive results. If it had, we might have been able to predict the effects of deleting the post-harvest application of iprodione on peaches. This analysis shows that monitoring data for peaches grown in 1996 and 1997 is needed to determine whether the levels of iprodione residues in peaches decline as a result of the label changes made in March, 1996.

Please call me at 703-308-8034 if you have any questions about this review.

Sincerely,

Vivian Prunier

Vivian Prunier, Review Manager
Special Review Branch
Special Review and
Reregistration Division

Enclosure

109801

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

9/17/96

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Iprodione (109801), Reregistration Case No. 2335, and Special Review. Examination of Information from BEAD. No CBRS No., No DP Barcode No., No MRID No.

FROM: John Abbotts, Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

THRU: Andrew R. Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

TO: Christina Scheltema
Special Review and Registration Section
Risk Characterization and Analysis Branch
Health Effects Division [7509C]

SRRD has requested that CBRS review and evaluate information received from BEAD members of the Special Review Team. Conclusions/Recommendations below pertain only to the data reviewed and their relevance to residue chemistry matters.

Tolerances are established for the combined residues of the fungicide iprodione parent, its isomer, and one metabolite in or on plant commodities, food commodities, and feed commodities (40 CFR 180.399(a) and (c), 185.3750, 186.3750). Tolerances are established for the combined residues of iprodione parent, its isomer, and two metabolites, all expressed as iprodione equivalents, in or on animal commodities (40 CFR 180.399(b)). Chemical structures and full chemical names of residues in tolerance expressions are given in Figure 1. Iprodione is a List B Chemical. Phase 4 Review was completed 3/15/91.

Conclusions/Recommendations

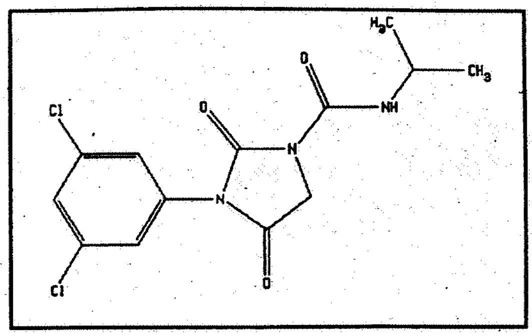
1. BEAD tabulated data obtained from USDA, PDP, on post-harvest treatment of peaches. There are significant limitations to these data, but it seems reasonable to conclude that with the elimination of post-harvest treatment, iprodione residues may decline somewhat on peaches, if other factors remain constant. However, additional information from BEAD indicates that recent changes in use directions might have secondary effects on residues from pre-harvest use. Growers could shift to other chemicals, which would reduce iprodione residues. Alternatively, the elimination of post-harvest treatment could lead to an increase in late season use, which would increase iprodione residues. The magnitudes of these secondary effects are difficult to predict, and they could be more significant than the direct effect from eliminating post-harvest use. It is not possible to predict with certainty how residues might change overall with the elimination of post-harvest use on stone fruits.

2. BEAD has also transmitted two papers from the scientific literature, Plant Disease 77, 1140-1143, 1993 and Plant Disease 78, 293-296, 1994. Because of laboratory application or other factors, these papers are not especially informative on magnitude of the residues in crops. However, they report that iprodione is systemic in several crops, including the stone fruits peaches and cherries, respectively.

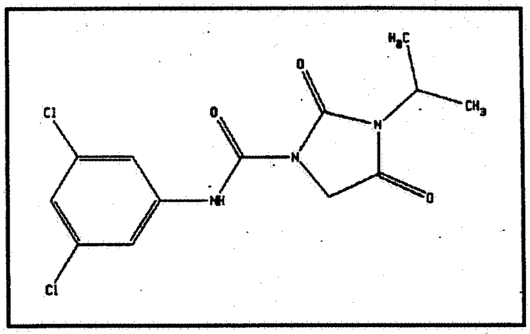
We recommend that a copy of this review be provided to Registrant Rhône-Poulenc. CBRS has previously advised that additional data on the distribution of residues in peaches between peel and pulp might have a limited impact on estimated dietary risk (CBRS 17266, 6/28/96, J. Abbotts). The report that iprodione is systemic in peaches provides further indication that the usefulness of such additional data may be limited.

Figure 1. Iprodione Tolerance Residues:

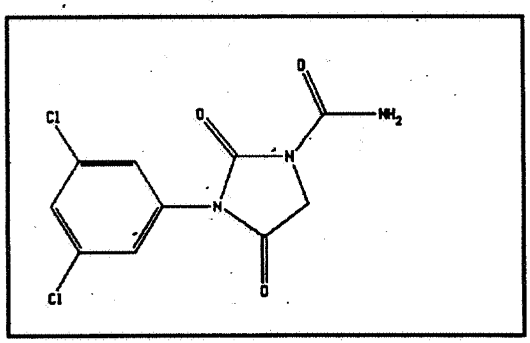
Iprodione parent;
3-(3,5-dichlorophenyl)-
N-(1-methylethyl)-2,4-dioxo-
1-imidazolidine-carboxamide



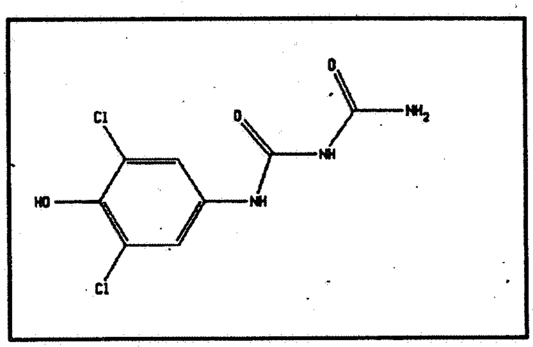
Iprodione isomer, RP-30228;
3-(1-methylethyl)-
N-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP-32490
(animals and plants);
3-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP-36114
(animals); N-(3,5-dichloro-
4-hydroxyphenyl)-ureido-carboxamide



DETAILED CONSIDERATIONS

Post-Harvest Use on Peaches

CBRS has previously determined anticipated residues for peaches and other commodities, based on information from the USDA Pesticide Data Program (PDP) for calendar years 1992-94 (CBRS 16521, 2/16/96, J. Abbotts). Interim risk mitigation measures for stone fruits included eliminating post-harvest use, reducing the number of applications per season from 5 to 4, and increasing the PHI from 0 to 7 days (V. Prunier, SRRD, personal communication).

BEAD has obtained information from PDP on potential post-harvest treatment of peaches with iprodione and has tabulated that information (E. Brandt, BEAD, personal communication to the Special Review Team). PDP peach samples for calendar years 1992-94 were sorted into two groups, "suspected" post-harvest treatment with iprodione, or "unknown" as to post-harvest treatment with iprodione. For 1992 and 1993, information on potential post-harvest treatment was available only for samples with detectable residues; for 1994, this information was available for all samples. Samples and iprodione residues were then tabulated as shown in Table 1 below.

There are several factors that make interpretation of the data in Table 1 difficult; these factors reflect the limitations of the data, and certainly do not reflect the analyses that BEAD has performed. For example, the classifications for post-harvest use are equivocal. Some of the "unknown" samples may have been treated post-harvest, and some of the "suspected" samples may have received no post-harvest treatment. In addition, the pre-harvest treatment history of each sample in either category was not specified, and probably was not known by the analytical chemists measuring residues for PDP.

The most complete data are those from 1994, where average residues for the "unknown" category were less than half the average for the "suspected" category. For 1992 and 1993, data were only available for samples with detectable residues. Averages for the two categories in 1993 for samples with detects are comparable to 1994, but the difference between the two categories narrowed in 1992. In addition, the relative number of samples with detectable residues in the "suspected" category, compared to the "unknown" category, was smaller in the earlier years.

Table 1. Iprodione residues on peaches and post-harvest use.

Residue range, ppm	1994				1993			1992		
	Total Samples	Samples with residues detected	Total residues in ppm	Average ppm	Samples with residues detected	Total residues in ppm	Average ppm	Samples with residues detected	Total residues in ppm	Average ppm
Post-harvest treatment Unknown:										
<0.05	120	15	2.675		12	0.327		14	0.446	
0.05-<0.1	15	8	1.051		8	0.558		10	0.730	
0.1-<0.4	48	48	11.280		68	15.350		65	14.530	
0.4-<0.7	27	27	13.810		39	20.750		26	14.610	
0.7-<1.0	23	23	18.854		17	13.550		19	15.840	
1.0-<4.0	23	23	34.000		23	43.700		31	52.400	
4.0-<7.0	1	1	5.400		1	4.000		4	18.000	
≥7.0	1	1	9.200		2	21.000		2	26.200	
Totals:	258	146	96.270	0.373 0.659 (D)	170	119.235	0.701 (D)	171	142.756	0.835 (D)
Post-harvest treatment Suspected:										
<0.05	21	5	0.598		1	0.025		1	0.025	
0.05-<0.1	7	3	0.462		5	0.333		0		
0.1-<0.4	44	44	10.420		16	3.710		9	2.340	
0.4-<0.7	30	30	15.870		15	8.730		3	1.470	
0.7-<1.0	19	19	16.230		11	9.100		3	2.490	
1.0-<4.0	25	25	38.820		17	31.800		8	10.500	
4.0-<7.0	1	1	5.500		0			0		
≥7.0	4	4	44.600		2	18.500		1	7.400	
Totals:	151	131	132.500	0.877 1.011 (D)	67	72.198	1.078 (D)	25	24.225	0.969 (D)

Source: E. Brandt, BEAD, from data supplied by USDA, PDP.
Table notes: Total residues are all residues summed across each category.
Averages are calculated only for totals; (D) = average for samples with detectable residues only.

With the limitations of the available data, a reasonable interpretation of the information in Table 1 is that with the elimination of post-harvest treatment, iprodione residues on peaches may decline somewhat, if other factors remain constant. However, BEAD has also provided information to indicate that other factors may not remain constant (D. Gurian-Sherman, personal communication to the Team).

On one hand, the more restrictive use directions pre-harvest, including loss of the opportunity for application on the day of harvest, may cause growers to shift from iprodione to other chemicals; this would have the effect of reducing iprodione residues on peaches and other stone fruits. On the other hand, BEAD has indicated that with present cultural practices, iprodione is applied more heavily at early times in the growing season. With the elimination of post-harvest treatment, growers may continue to use iprodione, but increase applications later in the season; this would have the effect of increasing iprodione residues on peaches and other stone fruits.

An additional relevant observation is that current iprodione tolerances on stone fruits, 20 ppm, were initially established on the basis of pre-harvest treatment only. When limited data on post-harvest treatment were submitted later, the tolerances were not changed (CBRS 16636, 2/6/96, J. Abbotts). The considerations described above lead to the following comment:

Conclusion 1: BEAD tabulated data obtained from USDA, PDP, on post-harvest treatment of peaches. There are significant limitations to these data, but it seems reasonable to conclude that with the elimination of post-harvest treatment, iprodione residues may decline somewhat on peaches, if other factors remain constant. However, additional information from BEAD indicates that recent changes in use directions might have secondary effects on residues from pre-harvest use. Growers could shift to other chemicals, which would reduce iprodione residues. Alternatively, the elimination of post-harvest treatment could lead to an increase in late season use, which would increase iprodione residues. The magnitudes of these secondary effects are difficult to predict, and they could be more significant than the direct effect from eliminating post-harvest use. It is not possible to predict with certainty how residues might change overall with the elimination of post-harvest use on stone fruits.

Scientific Papers on Stone Fruits

BEAD (D. Gurian-Sherman) has also transmitted to CBRS the following papers from the scientific literature:

Osorio, Adaskaveg, and Ogawa, Comparative Efficacy and Systemic Activity of Iprodione and the Experimental Anilide E-0858 for Control of Brown Rot on Peach Fruit, 1993, Plant Disease 77, 1140-1143.

Adaskaveg and Ogawa, Penetration of Iprodione into Mesocarp Fruit Tissue and Suppression of Gray Mold and Brown Rot of Sweet Cherries, 1994, Plant Disease 78, 293-296.

In one experiment in the 1993 paper, peach trees were treated with iprodione or other chemicals at various times preharvest. Application was described as spray to runoff with a 300 μg ai/ml solution, and it is difficult to convert this information to lb ai/A. Peaches were collected at mature harvest, then inoculated with solutions of fungi *Monilinia fructicola*, known to be benomyl-sensitive, at two sites near the stem, each 1 cm into the peach. Peaches were stored at room temperature for 7 days, then sliced perpendicularly to the injection sites. Sections were photographed, decay was scored, and results were expressed as percent of the exposed slice surface area that had not decayed (i.e., increasing nondecayed area indicating increasing efficacy). Results of this experiment are summarized in Table 2. Data on an experimental chemical and postharvest spray have been deleted for simplicity:

Table 2. Nondecayed peach area with chemical treatment.

Treatment	Percent nondecayed area with Preharvest spray, days			
	21	14	7	1
Untreated	0.9	0.9	0.8	0.7
Benomyl	1.7	2.4	2.3	3.4
Iprodione	2.6	3.7	13.0	17.6

Table notes:
Data summarized from 1993, Plant Disease 77, 1140-1142. Experiment is described in the text. Values are averages of two experiments, each with six replications.

With the data in Table 2 for application at 7 and 1 days preharvest, the authors concluded that nondecayed areas with iprodione treatment were significantly different statistically from areas in peaches that were untreated or treated with benomyl. The authors further noted that benomyl is considered a systemic chemical. That iprodione was able to inhibit decay more effectively than benomyl indicates that iprodione is even more systemic.

In the 1994 paper, experiments were performed with sweet cherries. Cherries were harvested and then sprayed with iprodione or other chemicals in the laboratory; therefore, comparison to label rates in the field is not appropriate. Cherries were then inoculated with solutions of the fungi *Botrytis cinera* or *Monilinia fructicola* at a surface wound, or near the pit. In one experiment, harvested cherries were inoculated on the surface, then sprayed with chemical. Inoculated cherries were stored at room temperature for 24 h for the surface wounds, or 7 days for the injection at pit. The diameter of lesions at surface or pit were determined.

Experimental details will not be described here, but iprodione treatment reduced damage at the surface or pit, and the authors concluded that iprodione showed systemic activity in a harvested stone fruit. The paper also made the following comment:

"Furthermore, the efficacy of iprodione against several pathogens of potato, tomato, lettuce, and turfgrass has also been linked to the systemicity of the fungicide in plant tissue [scientific citations]."

The considerations above lead to the following comment:

Conclusion 2: BEAD has also transmitted two papers from the scientific literature, Plant Disease 77, 1140-1143, 1993 and Plant Disease 78, 293-296, 1994. Because of laboratory application or other factors, these papers are not especially informative on magnitude of the residues in crops. However, they report that iprodione is systemic in several crops, including the stone fruits peaches and cherries, respectively.

cc:Circ, Abbotts, RF, Iprodione List B File, SF,
Vivian Prunier (SRRD), Edward Brandt (BEAD),
Douglas Gurian-Sherman (BEAD)
RDI:ARRathman:9/13/96:RBPerfetti:9/16/96
7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:9/17/96
JA19\iprodion.23