

US EPA ARCHIVE DOCUMENT

11-6-85



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

NOV 6 1985

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA ACCESSION NUMBER 073868. [RCB # 1487].
PP5E3214: Iprodione in or on Small Berries.
Amendment of September 20, 1985.

TO: H. Jacoby, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

FROM: R. W. Cook, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

In our previous review, several deficiencies were noted. We shall repeat the deficiency, then give the petitioner's response, and finally, our comments or conclusions in regard to the petitioner's responses.

Deficiency 1: Validation data (crop blank and recovery data) for the analytical method(s) used in gathering residue data.

Response: Validation data is provided in attached letter from the New Zealand Ministry of Agriculture and Fisheries to May and Baker (NZ). Additional data is provided in the attached analytical method (Tab B) published in the J.A.O.A.C. 66, 1003 (1983). The analytical method used gives recoveries of 95-97% for fortifications with 1 mg/kg levels of iprodione added to berry fruit.

Our comments or conclusions: Apparently, no crop blank and recovery data are available for the Ministry of Agriculture and Fisheries (MAF) for the submitted berry residue trials. Testimonial information is available in the 8/9/85 letter from P. T. Holland (MAF) to C. Surman (M&B, NZ) reporting 95-97% recovery at 1 mg/kg of iprodione in berry fruit. Historical crop blank and recovery data provide scant assurance that current analytical procedures are conducted properly.

Recovery data for New Zealand strawberries is submitted in lieu of recovery data on small berries. Strawberries are not part of this current tolerance petition. In New Zealand strawberries, crop blanks were <0.05, <0.05 and 0.01 ppm for iprodione, RP-30228, and RP-32490, respectively. Recovery data for these same strawberries at fortification levels of 0.5 to 5.0 ppm are shown below.

Sample	Iprodione	RP-30228	RP-32490
#5024 (Fort. Level)	109 (5)	112 (1)	87 (1)
#5026 (Fort. Level)	99 (1)	73 (0.5)	94 (0.5)

We consider this deficiency resolved.

Deficiency 2: The formulation inerts must be cleared under 40 CFR 180.1001. The petitioner should request his supplier(s) of these inerts to provide information to EPA, on a confidential basis, verifying that the tradenamed products do not contain other, non-disclosed, uncleared inert ingredient(s).

Response: The formulation is the same as used in the Rovral Kiwi fruit petition (PP No. 0E2414). Tolerance for use of this formulation on kiwifruit was published in the Federal Register on 8/19/81. The inerts in that formulation are cleared.

Our comments or conclusions: The deficiency is resolved.

Deficiency 3a: No information on the method of application (broadcast, backpack, aerial, ground, etc) is provided.

Response: More complete data sheets for the residue tests in question are attached (Tab C). These data sheets provide method of application.

Our comments or conclusions: This deficiency is resolved.

Deficiency 3b: The year in which the the residue trials took place should be provided.

Response: Data provided in data sheets attached (Tab C).

Our comments or conclusions: The more detailed reports provide the year of the field trial, while submitted summary reports did not provide this information. This deficiency is resolved.

Deficiency 3c: There are no storage stability data or information on the conditions of storage during the period of time between harvest and analysis.

Response: Storage stability data is provided in attached letter for the New Zealand Ministry of Agriculture and Fisheries (Tab A). Samples were frozen within 3 hours of sampling and maintained frozen until analysed. Results of a 1984 boysenberry storage stability trial showed excellent stability.

Our comments or conclusions: One 1984 boysenberry sample at 0 day was reanalyzed at 7 and 12 months. Parent iprodione was 5.0 ppm at 0 days, 5.0 ppm at 7 months and 4.9 ppm at 12 months. Iprodione appears to be stable in boysenberries in frozen storage for intervals up to 12 months. This deficiency is resolved.

Deficiency 3d: There are no crop blank values or recovery data available. (Same as Recommendation #1 above).

Response: Same as No. 1 above.

Our comments or conclusions: Same as No. 1 above.

Deficiency 3e: No residue data for metabolites are submitted.

Response: The letter from the New Zealand government (Tab A) states that in their opinion the metabolites of iprodione are not present in major amounts on berry fruit. Their relative retention times to iprodione on OV 225 column are approximately 1.1 and 0.62 respectively. The chromatograms of berry fruit from Rovral field trials are free of significant peaks in this retention region. Representative chromatograms from a boysenberry trial are attached (Tab D) which show these retention times. In addition Tab E contains a residue study on New Zealand strawberries treated with Rovral. These strawberries were analysed by Rhone-Poulenc's Agricultural Laboratory in the U.S. Both parent compound and metabolites (RP-30228 and RP-32490) were analysed. Results show that these metabolites are not present in significant amounts with the parent compound accounting for over 90% of the total residue. Similar results would be expected for the small berries for which tolerances have been proposed.

Our comments or conclusions: While the submitted chromatograms show no peak at the reported relative retention times of RP-30228 and RP-32490, there are no authentic chromatograms of these metabolites to indicate that the GC conditions will chromatograph these compounds. In regard to the strawberry analyses, the analytical method #151 using aqueous acetone extraction was employed. The method detects parent and the metabolites individually. The submitted data show 91-93% of the residue is present as parent compound and between 7 and 9% as metabolites. For the purposes herein, we can assume that about 90% of the residue present on small berries is present as parent iprodione. The petitioner should be advised that future submissions regarding iprodione should contain detailed residue reports, in that summary data reports do not provide adequate information for our purposes.

Deficiency 3f: We do not know if the reported values are corrected for crop blank values and or recovery factors.

Response: According to the New Zealand government all reported residue levels are uncorrected for recovery. Based on their reported recoveries of 95-97% a maximum recovery factor of 1.05 would be used. No residues reported exceeded 12 ppm (boysenberries), which

corresponds to 12.6 ppm corrected for recovery. The proposed tolerance of 15 ppm is sufficient to cover this correction.

Our comments or conclusions: The response is adequate to resolve this deficiency.

Deficiency 3g: There is no information which assures us that the submitted analytical method was used by both May & Baker and by the Government of New Zealand.

Response: The submitted analytical method and that used by the government of New Zealand are very similar (see Tab A and Tab B).

Our comments or conclusions: The Ministry of Agriculture and Fisheries (MAF) method uses methanol extraction, while the Rhone-Poulenc method uses acetone extraction. Otherwise the toluene partition, Florisil carbon-cellulose cleanup, and gas chromatography are similar. This response is adequate.

Deficiency 3h: There is no information regarding possible presence of the metabolites in small berries. We need some data demonstrating the expected level of the metabolites on these commodities.

Response: See response to 3e above.

Our comments or conclusions: See our comments and conclusions regarding 3e above. This is resolved.

Deficiency 4: A revised Section F including the term "(expressed as iprodione equivalents)" is needed.

Response: A revised Section F is attached (Tab F).

Our comments or conclusions: The revised section F expresses the residue of concern as we request: "(expressed as iprodione equivalents). This deficiency is resolved.

Conclusions:

We conclude that combined residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerances of 15 ppm in or on small berries: raspberries, boysenberries, blueberries, and currants.

RECOMMENDATIONS:

We recommend, TOX considerations permitting, for the establishment of the proposed tolerance of 15 ppm for combined residues of iprodione and its metabolites in blueberries, boysenberries, currants, and raspberries.

DETAILED CONSIDERATIONS:

Residue Data:

Almost all residue data are for the parent compound only, with no information available for the isomer or the metabolite. The available residue data in support of the proposed uses is derived from several sources:

- 1) May & Baker Ltd (a subsidiary of Rhone-Poulenc, Inc., performed field residue trials on grapes and strawberries in New Zealand;
- 2) New Zealand government agencies performed residue trials on other small fruits and berries.
- 3) FAO/WHO JMPR Pesticide residues in food: 1977 evaluations, pages 316-7, iprodione, Table 6, supervised trials: residues in berry fruit and currants.

Currants: Summary data on currants consists of 3 trials in New Zealand with 3 to 7 applications totaling 1.68 to 5.75 kg/ha. Maximum residues of parent iprodione were 15 ppm 3 days after 1.68 kg/ha. The 0-day value in this same study was 11.4 ppm. The other two trials showed <5.0m ppm at all intervals from all dose rates.

Blueberries: Summary data on blueberries consists of 5 trials in New Zealand with 3 applications at 1 X totaling 3.45 to 5.2 kg/ha. Maximum residues of parent iprodione were 9.4 ppm 0 days after 4.03 kg/ha.

Boysenberries: Summary data on boysenberries consists of 10 trials in New Zealand with 4 to 9 applications at 1 X totaling 3.0 to 10.35 kg/ha. Maximum residues of parent iprodione were 12 ppm 5 days after 8.4 kg/ha. The 2-day value in the same study was 9.0 ppm. Additional boysenberry data (submitted 9/20/85) from 7 applications of 1 kg/ha showed maximum of 5 ppm at day 0, declining thereafter.

Raspberries: Summary data on raspberries consists of 4 trials in New Zealand with 1 to 6 applications at 0.75X totaling 0.84 to 5.0 kg/ha. Maximum residues of parent iprodione were 5.2 ppm 3 days after 5.0 kg/ha.

Additional supporting data:

FAO/WHO JMPR Pesticide Residue Reports:

Residue data from the 1977 FAO/WHO JMPR evaluations consist of 2 trials with raspberries (France and U.K) in 1974 with 3-5 applications of 50% WP iprodione at 0.5 to 1.1 kg/ha. Maximum residues of parent were 8 ppm at 0-1 days, and about 2 ppm at 13-17 days. These data support the proposed tolerance.

Two UK trials on black currants treated 4 times with 1.1 kg/ha of 50% WP in 1974 showed 3.9 to 4.6 ppm of iprodione at 62 days (earliest sample interval). Since the earliest sample interval is 62 days and the proposed label specifies a 'withholding period' of 1 day for berryfruit, we cannot consider this blackcurrant data supportive of the proposed use.

Additional data submitted but not considered includes approximately 25 trials on strawberries in Belgium, Canada, France, Germany, Netherlands, Switzerland, and U.K. Maximum residues of iprodione were 26 ppm at 0-1 day and 14 ppm at 7-10 days from 5 applications of 0.75 kg/ha in the Netherlands (1974). All other strawberry data showed less than 10 ppm iprodione at all dosage rates and sample intervals up to 36 days. These data do not support the proposed use since the maximum residue levels exceed the proposed 15 ppm tolerance level.

New Zealand: Grapes and Strawberries (May & Baker data): Maximum residues of iprodione in grapes (Report RES/2664; not submitted) after 4 applications of 62.5 g a.i./100 liters at 0.5 kg/ha was 9.6 ppm at 0 days and 8.9 ppm at 14 days. At higher rates (187.5 g a.i./100 liters at 1.5 kg/ha) residues of iprodione were 30 ppm (0 days) and 26 ppm (14 days). Established US tolerances for iprodione in grapes indicate a tolerance level of 60 ppm is needed to adequately cover anticipated residues on grapes. These data do not support the proposed 15 ppm tolerance level.

Strawberries (Report AR/1639; report not submitted; only summary available) were treated 5 times with 47 g a.i./100 liters at 0.75 kg/ha) and showed 2.5 ppm of iprodione at 4 days post treatment. In light of the above discussed FAO/WHO JMPR Pesticide Residue Reports on strawberries, use on strawberries can result in residue levels above 15 ppm level, and thus do not support the proposed action on small berries.

We conclude that combined residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerances of 15 ppm in or on small berries: raspberries, boysenberries, blueberries, and currants.

OTHER CONSIDERATIONS:

International Tolerances:

There are Codex, New Zealand, or German tolerances for residues of iprodione in or on raspberries, boysenberries, blueberries, and currants at levels of 5-15 ppm. Therefore, we anticipate compatibility problems. Since the petitioner states that these tolerances are requested on behalf of the government of New Zealand, we anticipate that the Government of New Zealand will reestablish iprodione tolerance levels commensurate with the levels proposed herein. A Codex sheet was attached to our previous review.

The petitioner reports the following International tolerances:

	<u>New Zealand</u>	<u>W. Germany</u>	<u>FAO/WHO JMPR</u>
Raspberries	10		5
Currants	10		5
Strawberries	10	15	7
Grapes	10	10	10

cc: R.F., Circu, R. W. Cook, FDA, PP5E3214, TOX, PMSD/ISB.
TS-769:RCB:Reviewer:RWCook:Date:10/15/85:CM#2:RM:810:557-7377
RDI:Section Head:RSQuick:Date:11/4/85:RDSchmitt:Date:11/4/85