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Memorandum

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: ID# 92-FL-0005. Iprodione (**Rovral**): Section 18 Exemption on Tangerines and Tangelos to Control Alternaria Brown Spot in Florida. CBTS# 9308. HED# 2-1228. No MRID#. DP Barcode# D174237.

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The State of Florida, Department of Agriculture and Consumer Services, has requested a specific exemption under Section 18, as amended, for use of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide] (**Rovral 4F**, EPA Reg. No. 264-482, and **Rovral 50WP**, EPA Reg. No. 264-453) to control alternaria brown spot (*Alternaria citri*) on tangerines and tangelos. **Rovral 4F** is a flowable product containing 41.6% active ingredient (4 lbs ai/gal). **Rovral 50WP** is a wettable powder containing 50% a.i. **Rovral** is a product of Rhone-Poulenc Ag Company. Projected use is on 18,975 acres in Florida, and at the maximum use rate 113,850 lbs ai will be used. Application will be made during the period between February 1, 1992, and July 31, 1992.

This is the first Section 18 exemption request for iprodione against alternaria brown spot on citrus. Recent Section 18 requests have been made for iprodione on apples (J. Abbots, 92-NC-0003, 12/23/91), rape seed (C. Swartz, 91-GA-0011, 10/9/91), and stored corn (F. Toghrol, 90-IL-0011, 10/18/90). No tolerances are currently established for iprodione on any citrus commodities, nor are there any outstanding petitions for such tolerances.

Tolerances have been established for the combined residues of iprodione [RP26019], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP30228], and its metabolite 3-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP32490] in or on numerous raw agricultural commodities at levels ranging from 0.1 to 150 ppm under 40 CFR



V/S

§180.399(a). Under 40 CFR §180.399(b), tolerances are established for the compounds in (a) plus the metabolite N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide on numerous raw agricultural commodities of animal origin. Further food and feed additive tolerances have been established for iprodione, its isomers, and its metabolites, under 40 CFR §185.3750 and §186.3750. Iprodione is a List B chemical; Phase 4 Review was completed 3/15/91.

Proposed Use: Rovral 4F may be applied at 0.62-2.0 lbs ai/A/application with up to 3 applications per year. The first application should be made in the spring at the first sign of new growth. The second and third applications should follow at 30 to 45 day intervals. Application should be made with ground equipment, and should be made in "sufficient water to obtain thorough coverage". (No volume is specified for citrus, though for stone fruits a volume range of 20-400 gallons of water/A is recommended.) A 30-day PHI is stipulated. CBTS requests that the dilution volume be explicitly stated on the label. The remainder of the review is conducted based upon water being the only solvent allowed for the proposed use.

Nature of the Residue: It has been concluded in the Phase 4 review (C.L. Olinger, 3/15/91) that no data gaps exist for the metabolism of iprodione in plants. The metabolic fate of iprodione has been determined for three dissimilar crops - peanuts, rice, and peaches. For the purposes of this Section 18 request only, the residues of concern in plants are those for which tolerances have already been established; the parent, its isomer, and the metabolite 3-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide.

Analytical Methodology: An analytical method for detection of iprodione in kiwi fruit exists in PAM II as Method I. Briefly, residues of iprodione, its isomer (RP30228), and a potential metabolite (RP32490) are extracted with acetone. The sample extract is cleaned up by partitioning with methylene chloride and by column chromatography on Florisil. Iprodione and its isomer are eluted with ethyl acetate/methylene chloride (3:97) and collected as Fraction I. The metabolite is eluted with ethyl acetate/methylene chloride (1:1) and collected as Fraction 2. The three compounds are detected individually on 2 different columns by GLC with electron capture detection. CBTS concludes that adequate analytical methodology exists for enforcement.

Residue Data: No residue data reflecting the proposed use of iprodione on tangerines and tangelos was included in this request. There is no data currently available to the Agency describing iprodione residue levels in citrus. Residue data does exist for iprodione applied to peaches (PP#2F2596), though the use pattern is somewhat different from that proposed in this request. In five trials, 7 applications of 1.0 lb ai/A were made, with a 0-1 day PHI. Since the current request involves a maximum total application of 6 lbs ai/A with a 30-day PHI, i.e. a smaller total rate with a longer PHI, it is likely that residues in tangerines and tangelos will not exceed the levels seen in these studies on peaches. For the purposes of this Section 18 request only, CBTS is willing to translate the data for peaches to tangerines, for application of this

pesticide in water only.

Table 1 shows the residue levels of the parent (RP26019) and its isomer (RP30228) resulting from the above application pattern. Levels of the metabolite RP32490 were below the detection limit of 0.05 ppm.

Table 1. Iprodione Residues on Peaches.			
Site	Iprodione Residues, ppm [†]		
	Parent (RP26019)	Isomer (RP30228)	Combined
OH	13.39	0.30	13.69
TX	4.13	0.16	4.29
SC	11.51	0.44	11.95
NY	23.25	0.39	23.64
NJ	16.06	0.30	16.36

† - Based on 7 applications of 1.0 lbs ai/A each, 0-1 day PHI.

In the review of these data (R. Perfetti, 5/13/82), storage stability data for peaches were deemed adequate, and the analytical method used was that which is presently published in PAM, Volume II. Based on the data from Table 1, combined residues of iprodione, its isomer, and its metabolite RP32490 resulting from this Section 18 proposed use will not exceed 25 ppm in or on tangerines and tangelos.

Information in our Cultural Practices files states that tangerines are 87% water. Thus we can assume that if iprodione residues concentrate in water, then those residue levels should not exceed 1.15X (100%/87%) the level of the rac, or 29 ppm, in juice.

Meat, Milk, Poultry, and Eggs

Since tangerine and tangelos do not comprise a significant part of farm animal diets, we expect no transfer of secondary residues of iprodione, its isomer, or its metabolites to meat, milk, poultry, or eggs from this emergency use. Since this is not necessarily true for other citrus products, this conclusion must be reevaluated for any additional citrus raw agricultural commodities included in this or future Section 18 exemption requests.

Other Considerations - Exposure Analysis

Since this is the first incidence of iprodione use on tangerines, a partial DRES analysis is presented. The RfD is 0.04 mg/kg/day using a chronic toxicity effect endpoint. The results are presented in Table 2. In brief, the proposed use will contribute very little to the exposure of non-nursing infants (< 1%), children aged 1-6 (~ 2%), and the population as a whole (~ 1%).

	Tangerines - Raw			Tangerines - Juice			Tangelos		
	PCC ¹ g/kg/day	Exposure ² mg/kg/day	%RfD	PCC ¹ g/kg/day	Exposure ² mg/kg/day	%RfD	PCC ¹ g/kg/day	Exposure ² mg/kg/day	%RfD
US Population	8.8440 x 10 ⁻³	2.211 x 10 ⁻⁴	0.55%	8.40 x 10 ⁻⁵	2.436 x 10 ⁻⁶	.006%	2.556 x 10 ⁻³	6.39 x 10 ⁻⁵	.16%
Non-Nursing Infants	2.308 x 10 ⁻³	5.77 x 10 ⁻⁵	0.14%	0.000	0.000	0%	0.000	0.000	0%
Children 1-6	2.253 x 10 ⁻²	5.633 x 10 ⁻⁴	1.4%	0.000	0.000	0%	7.210 x 10 ⁻³	1.802 x 10 ⁻⁴	.45%

1 - Per Capita Consumption of the food commodity. 2 - Based on residue levels of 25 ppm for tangerines and tangelos, and 29 ppm for tangerine juice.

Conclusions

1. For the purposes of this Section 18 request only, the residues of concern in plants are those for which tolerances have already been established; the parent, its isomer, and the metabolite 3-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide.
2. Adequate analytical methodology exists in PAM II for enforcement purposes for the combined residues of iprodione in tangerines and tangelos.
3. The proposed label for this use does not specify the dilution volume. The petitioner should explicitly state this information.
4. Based on data translated from peaches, combined residues of iprodione, its isomer, and its metabolite RP32490 resulting from this Section 18 proposed use will not exceed 25 ppm in or on tangerines and tangelos, or 29 ppm in tangerine juice.
5. We expect no transfer of residues of iprodione, its isomer, or its metabolites to meat, milk, poultry, or eggs from this emergency use.
6. Analytical standards are available for the Pesticides and Industrial Chemicals Laboratory, Research Triangle Park, NC.

7. The proposed emergency use constitutes 0.72% of the RfD for the general US population, 0.14% of the RfD for non-nursing infants, and 1.85% of the RfD for children aged 1-6 years.
8. No Craven data was used to complete this review.

Recommendation

TOX considerations permitting, and provided that the dilution volume is explicitly stated on the label, CBTS has no objection to the issuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of treated tangerines, tangerine juice, and tangelos in commerce.

cc: Iprodione SF, RF, Section 18 SF, Circ., D. Edwards, R. Lascola,
FOD/PIB (C. Furlow).
RDI: P.V. Errico: 2/26/92; R. Loranger: 2/26/92
H7509C:CBTS:RLascola:rjl:CM#2:Rm803C:305-7478:3/6/92.
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