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

JAN 28 1993

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID #93FL0003 (CBTS #11177; Barcode #D186804). Iprodione (Rovral®) on Tobacco in FL. Section 18 Exemption. (No MRID #).

FROM: Nancy Dodd, Chemist Nancy Dodd
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (H7509C)

THRU: Elizabeth Haeberer, Section Head Elizabeth Haeberer
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (H7509C)

TO: Rebecca Cool/Susan Stanton, PM #41
Emergency Response Branch
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

The Florida Department of Agriculture & Consumer Services has requested a specific exemption to use the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide] on tobacco in FL to control Target Spot (Rhizoctonia solani). The formulations to be used are Rovral 4 Flowable (EPA Reg. No. 264-482) and Rovral 50 WP (EPA Reg. No. 264-453).

Permanent tolerances are established for combined residues of iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide on various raw agricultural and processed commodities at levels ranging from 0.1 to 300 ppm (40 CFR 180.399 (a) and (c), 40 CFR 185.3750, and 40 CFR 186.3750). Permanent tolerances are also established for combined residues of iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide, and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-

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imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide on animal commodities at levels ranging from 0.5 to 5.0 ppm and on rice bran at 30 ppm and rice hulls at 50 ppm [40 CFR 180.399(b)].

Use on tobacco is not permitted on current labels. Rhone-Poulenc Ag Company expects to submit a petition for a section 3 registration for iprodione on tobacco during the fourth quarter of 1994. The data will include a pyrolysis study.

No Registration Standard has been completed for iprodione. Iprodione is a List B chemical.

CBTS/CBRS previously had no objection to Section 18's for iprodione on tobacco in FL (91-FL-15, L. Cheng, 7/5/91) and NC (91-NC-08, L. Cheng, 5/31/91). However, the proposed Section 18 in FL involves a different use pattern (ie. one seedbed application and two field applications).

Under the proposed Section 18, a total of 1800 acres (50 seedbed acres and 1750 field acres) of tobacco in FL will be treated during 1993. The submission states "100 pounds/equivalent for seedbed; 1750 pounds/equivalent field use."

CBTS assumes that the statement " 100 pounds/equivalent for seedbed; 1750 pounds/equivalent field use" is intended to mean the total lbs active ingredient to be applied in each specified use.

Proposed Use

Rovral 4F or Rovral 50 WP will be applied to tobacco seedbeds and tobacco fields in FL. The application rate will be 0.5 lb ai/A (1 pt Rovral 4F or 1 lb Rovral 50 WP/A). Rovral will be applied by ground equipment in 50-100 gals. water/A, using drop nozzles to obtain thorough coverage of the leaves. A maximum of 3 applications (one seedbed application and two field applications) will be made. Rovral should be applied with a high-quality non-ionic spreader and sticker surfactant. Spreader-activator surfactants should not be used. An interval between treatments and a preharvest interval have not been specified.

Nature of the Residue

The nature of the residue in tobacco is adequately understood for the purpose of this proposed Section 18. The residues of concern on tobacco are iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP30228), and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP32490) (PP#7E3554, M. Nelson, 8/25/87).

Analytical Method

An adequate analytical method is available in PAM II (Method I). A similar method containing additional clean-up procedures, Rhone-Poulenc Analytical Method 151, was also sent to FDA for inclusion in PAM II. (See PP#7E3554, M. Nelson, 8/25/87).

Analytical reference standards are available at the Pesticides and Industrial Chemicals Repository, RTP, NC.

Residue Data

No residue data are available on tobacco. In the previous Section 18's, CBRS estimated residues on tobacco based on residue data on lettuce produced by Rhone-Poulenc Inc. (PP#3G2801, N. Dodd, 4/11/83).

The previous Section 18 in NC (91-NC-08, L. Cheng, 5/31/91) involved a different use (ie. use on greenhouse transplants and plantbed transplants). CBRS concluded for the previous Section 18 in NC that residues in green and cured/dried tobacco would not exceed 0.1 ppm if a 60-day PHI was observed. CBRS considered the size of the leaf at treatment vs. harvest and loss of leaves between treatment and harvest to arrive at this conclusion.

The previous Section 18 in FL (91-FL-15, L. Cheng, 7/5/91) also involved a different use (ie. two seedbed applications and one field application and a 7-day PHI).

Residue data (for combined residues of parent, its isomer, and its metabolite) reflecting 7- and 9- day PHI's are available on leaf lettuce from PP#3G2801 (N. Dodd, 4/11/83):

# applications	rate (lb ai/A)	PHI	Residues (ppm)
3	1	7	1.60
3	2	7	2.64
3	1	7	1.58
3	2	7	5.76
2	1	9	0.65
2	2	9	1.47

Residue data reviewed for a permanent tolerance on leaf lettuce (PP#7F3481, M.J.Nelson, 4/8/87) are summarized below. Three applications at the rate of 1.0 lb ai/A were made. Combined residues of parent, its isomer, and metabolite were reported.

crop	PHI (days)	residue (ppm)
escarole	10-15	0.22-22.5
endive	10-15	0.00-16.1
romaine	10-14	0.12-20.5
bibb	5-14	1.02-14.2
bunching	5-14	0.00-14.1

The reviewer concluded that residues in lettuce reflecting 3 applications 10 days apart at the rate of 1.0 lb ai/A and a 14-day PHI would not exceed 25 ppm.

Based on the available residue data on leaf lettuce, CBTS concludes for the purposes of this Section 18 only that residues in green tobacco will not exceed 25 ppm from the proposed use, providing a 10-day interval between applications and a 14-day PHI are observed.

No data on cured or dried tobacco have been submitted. No pyrolysis study has been provided. For the purposes of this Section 18 only, CBTS will assume that residues in dried/cured tobacco and smoke will not exceed 25 ppm.

Meat, Milk, Poultry, and Eggs

There are no feed items connected with this use on tobacco. Therefore, no secondary residues are expected in meat, milk, poultry, and eggs as a result of this use.

Conclusions

1.. The nature of the residue in tobacco is adequately understood for the purpose of this proposed Section 18. The residues of concern on tobacco are iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP30228), and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP32490).

2. An adequate analytical method is available in PAM II (Method I). A similar method containing additional clean-up procedures, Rhone-Poulenc Analytical Method 151, was also sent to FDA for inclusion in PAM II.

3. Analytical reference standards are available at the Pesticides and Industrial Chemicals Repository, RTP, NC.

4a. No residue data on green tobacco have been submitted. Based on the available residue data on leaf lettuce, CBTS concludes for the purposes of this Section 18 only that residues in green tobacco will not exceed 25 ppm from the proposed use, providing a 10-day interval between applications and a 14-day PHI are observed.

4b. No data on cured or dried tobacco have been submitted. No pyrolysis study has been provided. For the purposes of this Section 18 only, CBTS will assume that residues in dried/cured tobacco and smoke will not exceed 25 ppm.

5. There are no feed items connected with this use on tobacco. Therefore, no secondary residues are expected in meat, milk, poultry, and eggs as a result of this use.

Recommendations

TOX considerations permitting and providing a 10-day interval between applications and a 14-day preharvest interval are observed, CBTS has no objection to this Section 18 exemption for use of iprodione on tobacco. An agreement should be made with FDA in regard to treated commodities in commerce.

CBTS recommends that any future Section 18 requests on tobacco be supported with residue data on tobacco.

cc: RF, SF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS), Section 18 File, R. Griffin (CBTS)

RDI:E. Haeberer:01/27/93:R. Loranger:01/27/93
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