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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SECTION 18 EXEMPTION FOR USE OF **IPRODIONE** ON **APPLES**

TO: S. Stanton/R. Cool, PM Team 41
Registration Division (H7505C)

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ID#: 93-NC-0003
DP Barcode: D190208
CBTS#: 11726

Chemical
EPA Approved Common Name: Iprodione
Chemical Name: 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide
Formulation Trade Name: Rovral® 50W and Rovral® 4F
Registration#: 264-453 (50W) and 264-482 (4F)
Class: Fungicide

State or Agency applying for exemption: State of North Carolina, Department of Agriculture

Type of exemption: specific

Reason: To control *alternaria* blotch in apples caused by *Alternaria mali* in approximately 6,000 acres of apple orchards in North Carolina.

BACKGROUND

CBTS reviewed a 1992 specific exemption request from North Carolina (92-NC-003, 12/23/91, J. Abbotts and 12/31/91, F. Shure) for the same use as proposed in this section 18. Residue

1/c

data from peach field trials were translated to apples in determining expected residue levels.

EPA granted this exemption to the North Carolina Department of Agriculture effective May 15, 1993. However, RD requests an updated estimate of the residues likely to occur based on newly submitted citrus residue data. The peach field trial residue levels previously translated to apples involved four applications of iprodione at 1.0 lb ai/A with a 0 day PHI. The citrus data is a result of four applications of iprodione at 2.0 lb ai/A and a 30 day PHI. Since the requested use on apples is for a maximum of three applications at 1.0 lb ai/A with a 30 day PHI, the citrus data is more appropriately translated to this use of iprodione on apples.

RECOMMENDATION

TOX considerations permitting, CBTS has no objection to the issuance of this Section 18 exemption. An agreement should be made with FDA regarding the legal status of the treated apples in interstate commerce.

CONCLUSIONS

1. The metabolism of iprodione in/on apples is adequately understood. The residues of concern are 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.

2. The nature of the residue in/on animals has been adequately delineated. The residues of concern are those currently regulated; the parent compound, its isomer and its metabolites, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboximide.

3. The method published in PAM II, Pesticide Reg. Sec. 180.399, Method I has been validated by EPA on kiwi fruit and is adequate for enforcement purposes for combined residues of iprodione in plant commodities. Rhone-Poulenc method 159, and method ADC #623 (PP#2F2728) are adequate for enforcement purposes for combined residues of iprodione in animal commodities.

4. Analytical reference standards and MSDS's for iprodione, its isomer and its 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide metabolite are available from the USEPA Chemical Standards Repository, RTP, NC as verified by telephone conversation with P. Beyer on 4/21/93. The animal metabolite, N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide is not available. Since the animal analytical methods are based on a common moiety, CBTS concludes that adequate standards are available for enforcement

purposes.

5. CBTS anticipates that the combined residues of iprodione, its isomer and its 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide metabolite are not likely to exceed **2 ppm on apples** as a result of this use.

6. No studies were submitted for the processed commodities, apple pomace and apple juice. The agency files indicate that iprodione residues concentrate in the related feed item, dry grape pomace. Based on theoretical considerations, CBTS does not expect the combined residues of iprodione, its isomer and its 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide metabolite to exceed **54 ppm in apple pomace (wet and dry)**. Since iprodione is relatively insoluble in water, and residues did not concentrate in the related processed commodity, grape juice, we would not expect residues to concentrate in apple juice.

7. Apple pomace is not a feed item for laying hens; therefore a discussion of the secondary residues in eggs resulting from this use is not relevant to this section 18 request. CBTS recognizes that apple pomace is a feed item for beef and dairy cattle, as well as for turkey and broilers. We conclude that the existing tolerances for meat, poultry and milk are adequate to cover the possible secondary residues resulting from the proposed use of iprodione on apples.

8. The residue data used in the evaluation of this Section 18 request were generated by Rhone-Poulenc Ag Company, Environmental Chemistry Section, Research and Development Department, RTP, NC.

A Comparison of Proposed Label and the Residue Data
Parameters Used in CBTS's Decision

	Proposed Use	Residue Data
Chemical	Iprodione	Iprodione
Formulation	Rovral® 50W Rovral® 4F	Rovral® 4F
Crop	Apples	citrus (oranges, limes, grapefruit, tangerines and tangelos)
Method of Application	Apply with an air blast sprayer equipped with nozzles directed to insure thorough coverage of the fruit and foliage using 100-400 gal water per acre	Commercial orchard air blast sprayer, spray volume of 100-500 gal per acre
# of Applications	Maximum of three applications allowed	Four applications
Timing	The first application should be made during the period 1 June - 15 July, subsequent applications will be made at two week intervals.	The first application was made in the spring when the majority of the blossoms on the trees were at 2/3 petal fall. The second spray was applied between April 15 - 30. The third application was made between July 15 - 30, and the fourth application was make the last week of September to the first week of October.
Application Rate	0.5 - 1.0 lb ai/A	2.0 lb ai/A
Rate/year or season	1.5 - 3.0 lb ai/A/crop	8.0 lb ai/A/crop
Maximum Residue	n/a	Iprodione 0.8 ppm isomer 0.2 ppm dichlorophenyl metabolite <0.1ppm Total: 1.1 ppm
Restrictions	30 day PHI	30 - 31 day PHI

Citrus residue data was taken from EUP ID# 000264-EUP-OU (DP Barcode: D190035) for translation to apples.

ADDITIONAL INFORMATION

Tolerances are established under 40CFR §180.399(a) for the combined residues of the fungicide, iprodione, its isomer and its dichlorophenyl metabolite in or on various plant commodities ranging from 0.1 ppm (garlic) to 150 ppm (peanut hay and forage). Tolerances are established under 40CFR §180.399(b) for the combined residues of iprodione, its isomer and its metabolites, 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide and N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboximide in or on animal commodities as follows:

milk at 0.5ppm

cattle, goats, hogs, horses and sheep
fat at 0.5 ppm
kidney at 3.0 ppm
liver at 3.0 ppm
meat at 0.5 ppm
meat by-products (exc. kidney & liver) at 0.5 ppm
poultry
fat at 3.5 ppm
liver at 5.0 ppm
meat at 1.0
meat by-products (exc. liver) at 1.0
eggs at 0.5 ppm

Food additive tolerances are established under 40CFR §185.3750 on dried ginseng at 4 ppm and raisins at 300 ppm. Feed additive tolerances are established under 40CFR §186.3750 for dry grape pomace at 225 ppm, raisin waste at 300 ppm, rice bran at 30 ppm, rice hulls at 50 ppm and soapstock at 10 ppm.

Citrus Field Trials: Ten crop field trials were conducted in 1991 in various counties throughout the state of Florida on citrus. The highest combined residue level was found in oranges grown and treated in Seminole county (Trial # 91-238) at 1.1 ppm. Combined residues for the remaining trials ranged from 0.3 ppm to 0.9 ppm. The crop field trials were conducted according to GLP standards, but had not been audited by Rhone-Poulenc's Quality Compliance group. However, sufficient raw data was provided to allow verification of the residue levels reported based on the chromatograms and standards supplied. Additionally, the method of analysis was not provided, however, recovery data reported were sufficient to validate the method used in the generation of the residue data.

Processing Studies: No apple processing studies were submitted with this section 18 request. The CBTS Cultural Practices file indicates that 100 lbs of apples will yield 80 lbs of cider and 4 lbs of dried pomace with a moisture content of 10%. Based on this information, it is expected that residues could concentrate by a factor of up to 1.25x in apple juice and 25x in dry apple pomace. However, we will use 27x as the factor for pomace based on the comparison of proposed and established food additive tolerances to proposed and established RAC tolerances as reported in the Jan. 1993 document on Maximum Theoretical Concentration Factors. Calculations are shown below.

juice: 2 ppm (max residue in apple) x 1.25 = 2.50; therefore the combined residues of iprodione, its isomer and its dichlorophenyl metabolite would not be expected to exceed 3 ppm in apple juice as a worst case. However, since iprodione is relatively insoluble in water and residues did not concentrate in grape juice, we would expect that actual residues would not concentrate in apple juice.

apple pomace (wet and dry): 2 ppm (max residue in apple) x 27 = 54 ppm; therefore, the

combined residues of iprodione, its isomer and its dichlorophenyl metabolite are not expected to exceed 50 ppm in apple pomace. It should be noted that iprodione residues were observed to concentrate in the related feed item, dry grape pomace.

Meat, Milk, Poultry and Eggs: Apple pomace is not a feed item for laying hens; therefore a discussion of the secondary residues in eggs resulting from this use is not relevant to this section 18 request. CBTS recognizes that apple pomace is a feed item for beef and dairy cattle, as well as for turkey and broilers. Given the existing tolerances on animal feed items (dry grape pomace at 225 ppm, raisin waste at 300 ppm, peanut forage and hay at 150 ppm, and bean forage and vines at 90 ppm), we conclude that this proposed use will not significantly increase the animal dietary burden, and as a result the existing tolerances for meat and milk are adequate to cover the possible secondary residues resulting from the proposed use of iprodione on apples.

cc: RF, Iprodione SF, List B File, Section 18 File, circ., D. Davis, R. Griffin.
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