

US EPA ARCHIVE DOCUMENT



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

10-18-90

OCT 18 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 90-IL-11 and 90-IL-12; Section 18 for Iprodione [(Rovral 4 flowable) and/or (Rovral 50WP)], and Thiabendazole (Mertect 340F) for the use on Stored Corn to Control Fungi (Aspergillus and penicillium species).
(No MRID #, DEB # 7019).

From: Freshteh Toghrol Ph.D., Chemist *F. Toghrol*
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

To: R. S. Cool/J. Tompkins, PM-41
Emergency Response Branch
Registration Division (H7505C)

The Illinois Department of Agriculture requests a Section 18 exemption for the use of Iprodione (Rovral 4 flowable and Rovral 50WP) and Thiabendazole (Mertect 340F) on field corn during drying and storage to control fungi (Aspergillus and penicillium species).

Rovral 4F, flowable (EPA Reg. No. 264-482) and Rovral 50WP, Wettable power (EPA Reg. No. 264-453) are registered pesticides of Rhone-Poulenc Ag. Company; containing iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide] as their active ingredient.

Mertect 340F (EPA Reg. No. 618-75) is a registered pesticide of Merck & Co., Inc. the formulation contains 42% (3.8 lbs ai/gallon) thiabendazole (2-(4-thiazolyl)-benzimidazole) as its active ingredient.

Tolerances are established (40 CFR 180.399 (a)) for residues

1/10

of fungicide iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolite 3-(3,5-dichlorophenyl)2,4-dioxo-1-imidazolidine-carboxamide in or on numerous commodities ranging from 0.1 to 150 ppm.

Tolerances are established (40 CFR 180.399 (b)) for residues of fungicide iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolites 3-(3,5-dichlorophenyl)2,4-dioxo-1-imidazolidine-carboxamide and [N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide] all expressed as iprodione in or on fat, meat, and meat by-products of cattle, goats, hogs, horses and sheep at 0.5 ppm; kidney and liver of cattle, goats, hogs, horses and sheep at 3.0 ppm; milk at 0.5 ppm; meat, meat by-products of poultry at 0.5 ppm; poultry fat at 2.0 ppm; poultry liver at 0.3 ppm and eggs at 0.8 ppm.

Tolerances are established (40 CFR 185.3750) for combined residues of fungicide iprodione, its isomer and its metabolite in or on food additives as follow: dried ginseng at 4.0 ppm and raisins at 300 ppm.

Tolerances are established (40 CFR 186.3750) for combined residues of fungicide iprodione, its isomer and its metabolite in or on feed as follow: dry grape pomaces at 225.0 ppm; raisin waste at 300.0 ppm and soapstock 10.0 ppm.

DEB recommended in favor of a temporary tolerance for combined residues of iprodione/metabolite on stored corn grain at 20 ppm (PP#7G3525, L. Propst, 6/8/88).

No registration standard has been established for iprodione. Iprodione is on list B.

Tolerances are established (40 CFR 180.242(a)) for residues of fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) ranging from 0.02 to 40.0 ppm in or on numerous commodities, including (but not limited to) wheat grain at 1.0 ppm.

Tolerances are established (40 CFR 180.242(b)) for residues of fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite 5-hydroxythiabendazole at 0.1 ppm in or on numerous commodities, including: eggs, meat, and meat by-product of cattle, goats, hogs, horses, poultry and sheep; and milk at 0.4 ppm.

Tolerances are established (40 CFR 185.5550) for residues of fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) in or on wheat milled fraction (except flour) resulting from pre-harvest application to growing wheat) at 3.0 ppm.

Tolerances are established (40 CFR 186.5550) for residues of fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) in or on numerous processed feeds (when present as result of pre-harvest or post-harvest application to crops) at 3.0 to 150.0 ppm including (but not limited to) rice hull at 8.0 ppm wheat milled fractions (except flour) at 3.0 ppm.

A Permanent tolerance petition for thiabendazole on stored corn grain at 25 ppm is pending; data for grain dust are required (PP#7F3553/FAP#7H5541, J. B. Stokes, 10/18/89).

No registration standard have been established for thiabendazole. Thiabendazole is on list B.

Nature of the Residue

Plant:

Plant metabolism data for iprodione were not submitted with this request. However based on plant metabolism data submitted earlier in support of other petitions (strawberries and wheat PP#8G2087, peaches PP#2F2596, lettuce PP#3G2801, peanuts PP#4G3037, and rice PP#6F3443/FAP#6H5507), it was concluded that the nature of residue is adequately understood. The residue of concern is iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolite 3-(3,5-dichlorophenyl)2,4-dioxo-1-imidazolidine-carboxamide.

Based on thiabendazole plant metabolism data submitted previously in conjunction with other petitions (citrus PP#8F0724, apple and pear PP#1F1031, potatoes PP#5F1537, and cotton and soybean PP#2603), it was concluded that the nature of the residue is adequately understood. The residue of concern in plants thiabendazole per se.

Animal:

Animal metabolism data for iprodione were not submitted with this request. However based on animal metabolism data submitted in support of other petitions (cow and goats PP#2F2728, poultry PP#2964/FAP#4H5415), it was concluded that the nature of residues in animal is adequately understood. The residues of concern in animals are iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolites 3-(3,5-dichlorophenyl)2,4-dioxo-1-imidazolidine-carboxamide and [N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide] all expressed as iprodione.

Based on thiabendazole animal metabolism data submitted previously in conjunction with other petitions (PP#2F1237, and

3F1332), it was concluded that the nature of the residues in animals is adequately understood. The residue of concern in animals are thiabendazole and its metabolite 5-hydroxythiabendazole.

Proposed Use:

Iprodione:

The proposed use for Rovral 4F (iprodione) on stored corn calls for a single application at 3.6 fl. oz. of product Rovral 4F or 4 fl. oz. of Rovral 50 WP (2 oz ai) per 100 bushels (bushel = 56 lbs) of corn in 300 oz of water.

Thiabendazole:

The proposed use for Mertect 340-F (thiabendazole) on stored corn calls for treatment immediately after harvest using 3.0 fl. oz. of product (1.46 oz ai) per 100 bushels of corn.

90-IL-11 and 90-IL-12 proposes the treatment of 30 million bushel (1,680,000,000 lbs) of corn; 15 million bushels of corn for each product. This Section 18 will be effective from September 25, 1990 to Dec., 31 1990.

The corn will be treated by certified applicators as follow:

a) Ambient natural air drying (low temperature).

Harvest grain at 25% or less moisture content. Treat corn immediately with one product. Turn fan on immediately to achieve 1 CFM air flow, and continue to dry till grain moisture is 16%.

b) Combination drying (heat and ambient air)

Harvest grain at 25% or less moisture content. Use heat to dry to 18% moisture. Treat fan on immediately to achieve 0.5 to 1 CFM air flow, and continue to dry till grain moisture is 16%.

Residue Data

No residue data were submitted with this request. However, data were submitted in connection with PP#7G3525 for iprodione and PP#7F3553 for thiabendazole on stored corn grain.

The available data reflect one application of 4 oz. Rovral

50 WP (2 oz. ai) or 3.6 fl. oz. of Rovral 4F (1.8 oz. ai)/100 bushels of corn, in a maximum of 300 ounce of water (PP#7G3525, L. S. Propst, 6/8/88). This rate is the same as proposed in 90-IL-11 and 90-IL-12.

Table 1. The following residue data were submitted in conjunction of PP#7G3525, for Rovral in or on stored corn grain. Corn grain was treated with 4 fl. oz of Rovral (2 oz ai) per 100 bushels of corn in a special mixing chamber before being stored.

<u>rate oz. ai/100 bushels corn</u>	<u>PHI day</u>	<u>PPM Iprodione, isomer, metabolite</u>		
2.0	0	20.06	0.00	0.51
2.0	28	19.23	0.00	0.14
2.0	56	14.36	0.34	0.76
2.0	84	14.07	0.25	0.11

Based on these data DEB previously concluded that the temporary tolerance of 20 ppm is adequate to cover all residues of iprodione in on stored corn as a result of the proposed use (PP#7G3525, L. S. Propst, 6/8/88).

Table 2. The following residue data were submitted in conjunction with petition PP#7F3553 for thiabendazole on stored corn grain. Corn grain was treated with 3.0 fl. oz of Mertect 340F (1.46 oz ai) per 100 bushels of corn in a special mixing chamber immediately after harvest and prior to storage stored (see J. Stock, 6/29/88).

<u>rate oz. ai/100 bushels corn</u>	<u>PHI Week</u>	<u>PPM Thiabendazole/metabolite</u>
1.46	0-40	6.67-14.22
1.46	0-40	10.04-23.22
1.46	0-24	11.98-23.58
1.46	0-26	8.54-10.04
1.46	0	8.07-17.33
1.46	0	11.40-17.49
1.46	0	8.15-13.20
1.46	0	11.32-11.62
1.46	0	8.74-14.65
1.46	0	17.56-22.46
1.46	0	9.95-10.44
1.46	0	8.68-17.88
1.46	0	9.68-19.32
1.46	0	16.71-19.15
1.46	0	13.77-14.75
1.46	0	10.06-23.71
1.46	0	11.23-15.46

Based on these data and the amendment of 6/9/89 (revised Section F) DEB previously concluded that the proposed tolerance of 25 ppm is adequate to cover all residues of thiabendazole in or on stored corn as a result of the proposed use (PP#7F3553, J. Stokes 10/18/89).

Processing Study:

Data from processing studies utilizing iprodione treated corn were submitted and reviewed previously in connection with PP#7G3525 (L. Propst, 9/29/87). Based on these data DEB previously concluded that the residues of iprodione/metabolite do not concentrate in processed corn fractions. Data were not available for grain dust.

Data from processing studies utilizing corn containing residues of thiabendazole were reviewed in connection with PP#7F3553 (J. Stokes 7/29/88). Based on these data DEB concluded that thiabendazole residues concentrate in milled corn fraction and feed and food additive tolerances should be established for corned milled bran and soapstock at 40 ppm and corn bran at 145 ppm (PP#3553, J. Stokes, 10/18/89).

Meat, Milk, Poultry, and Eggs:

Iprodione:

Corn grain may constitute up to 80% of the diet for beef cattle, 50% of the diet for dairy cattle, 70% of the diet for poultry and 80% of the diet for swine.

If the beef diet consists of 80% corn grain (80% X 20.0 ppm = 16 ppm) and 20% dried beans (20% X 2.0 ppm = 0.4 ppm), the maximum dietary burden for beef cattle is 16.4 ppm.

A cattle feeding study was submitted previously in conjunction with PP#2F2728. Lactating cow were fed iprodione at 5, 15, 50, and 200 ppm for 28 days. Maximum combined residue of iprodione/metabolite found in milk and tissues are summarized below:

<u>Commodity</u>	<u>feeding level</u>			
	<u>15</u>	<u>ppm</u> <u>50</u>	<u>200</u>	<u>established tolerances</u>
meat	<0.05	0.07	0.13	0.5
kidney	0.16	0.80	2.87	3.0
fat	0.05	0.21	0.52	0.5
liver	0.13	0.66	1.95	3.0
cattle milk			0.389	0.5

Based on these data and calculated dietary burden of 16 ppm, DEB concludes that established tolerances for milk, meat will not be exceeded as a result of this proposed Section 18 use.

If the poultry diet consists of 70% corn grain (70% X 20.0 ppm = 14 ppm) 15% dried beans (15% X 2.0 ppm = 0.3 ppm), 5% grape (5% X 60 ppm = 3.0 ppm) and 10% peanut nut (10% X 0.5 ppm = 0.05 ppm), the maximum dietary burden for poultry is 17.35 ppm.

Poultry feeding study were submitted in support of PP#4F3129. The chicks were dosed with iprodione at 2, 20, and 100 ppm for 28 days, combined residues of iprodione/metabolite are summarized below:

<u>commodity:</u>	<u>maximum Residue level of</u>			<u>Established Tolerance</u>
	<u>iprodione/metabolite</u>			
	<u>2.0</u>	<u>20</u>	<u>100</u>	
meat	<0.05	0.32	1.68	0.5
fat	0.18	2.57	8.62	2.0
kidney	0.33	2.3	6.87	3.0
liver	0.61	4.1	13.40	3.0
eggs	0.137	0.75	2.17	0.8

Based on linear regression analysis utilizing these data and a calculated dietary burden of 17.0 ppm, DEB concludes residues of iprodione/metabolite will not exceed the established tolerances for poultry fat (2.0 ppm) and liver (3.0).

Thiabendazole:

Corn grain may constitute up to 80% of the diet for beef cattle, 50% of the diet for dairy cattle, 70% of the diet for poultry and 80% of the diet for swine.

If the beef diet consists of 80% corn grain (80% X 25.0 ppm = 20 ppm) and 20% dried beans (20% X 0.4 ppm = 0.08 ppm), the maximum dietary burden for beef cattle is 20.08 ppm.

Feeding study data for thiabendazole in or on lactating cow

were submitted in conjunction with petitions PP#OG1001 and PP#F3553/7H5541. In first study lactating cows were dosed daily with thiabendazole at 10 ppm for 4 weeks, then cows were dosed with thiabendazole at 30 ppm for another 4 weeks. No detectable residue of thiabendazole/ metabolite were found in milk samples (PP# OG1001). However the cattle feeding study submitted in conjunction with petition (PP#7F3553/7H5541) showed that lactating cows dosed daily with thiabendazole at 25, 75 and 250 ppm for 28, 29 or 57 days contained following residues:

<u>Commodity</u>	<u>Residue levels, ppm TBZ/5-OH-TBZ</u>		
	<u>25</u>	<u>75</u>	<u>250</u>
<u>milk</u>			
2-28 days	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246
35-57 days	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246
<u>Fat</u>			
29 days	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246
57 days	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246
<u>Kidney</u>			
29 days	<0.05/<0.05	<0.05/0.094-0.468	<0.05/0.316-0.553
57	<0.05/<0.05	<0.05/<0.05	<0.05/<0.05
<u>Liver</u>			
29 days	<0.05/0.05	0.041-0.131	0.054-0.083
57 days	<0.05/0.05	0.035-0.061	0.120-0.161
<u>Muscle</u>			
29 day	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246
57 day	<0.05/<0.05	<0.05/0.016-0.148	<0.05/0.064-0.246

TBZ=thiabendazole
5-OH-TBZ=5-hydroxythiabendazole

Based on these data and calculated dietary burden of 20 ppm, DEB concludes that the residue of iprodione/metabolites will not exceed the established tolerances for milk, meat, meat by-products and fat as a result of this proposed Section 18 use.

If the poultry diet consists of 70% corn grain (70% X 25.0 ppm = 17.5 ppm) 15% dried beans (15% X 0.1 ppm = 0.015 ppm), 5% grapes (5% X 10 ppm = 0.5 ppm) and 10% soybeans (10% X 0.1 ppm = 0.01 ppm), the maximum dietary burden for poultry is 18.01 ppm.

Poultry feeding study submitted in support of PP#6F1860 are summarized below. In this study three day old broiler chicks were dosed with thiabendazole at 2, 20, 200, and 2000 ppm for 46 days, and combined residues of thiabendazole/its 5- hydroxy metabolite were analyzed.

commodity:	Residue level of TBZ+5-OH-TBZ		
	ppm TBZ fed	2.0	20
muscle	<0.05	<0.05	0.035-0.093
fat	<0.05	<0.05	0.053-0.102
kidney	0.04-0.081	0.068-0.121	0.328-0.847
liver	<0.05	0.056-0.081	0.204-0.631
egg yolk	---	0.023-0.053	0.071-1.31
egg white	---	<0.05	0.047-0.648

Based on these data and calculated dietary burden, DEB estimates that the residues of thiabendazole/metabolites in poultry meat, meat by-products, fat and eggs will not exceed the established tolerances as a result of this proposed Section 18 use.

Conclusions

1a. DEB has previously recommended in favor of a temporary tolerance petition for combined residues of iprodione/metabolite on stored corn grain at 20 ppm (PP#7G3525, L. Propst, 6/8/88).

1b. A Permanent tolerance petition for thiabendazole on stored corn grain at 25 ppm is pending. Additional data for grain dust are required (PP#7F3553/FAP#7H5541, J. B. Stokes, 10/18/89).

2a. The nature of the residue for iprodione in plants and animals is adequately understood. The residues of concern are fungicide iprodione, its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide.

2b. The nature of the residues for iprodione in animals is adequately understood. The residues of concern are iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazoladinecarboxamide], its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide], and its metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide and [N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide] all expressed as iprodione.

2c. The nature of the residue for thiabendazole in plants and animals is understood. The residues of concern in plants is thiabendazole, and in animals thiabendazole and its metabolite 5-hydroxythiabendazole.

3a. Analytical methods to determine iprodione/metabolite are available (PAM II) for enforcement purposes.

3b. Analytical methods to determine thiabendazole/metabolite (MRID Nos. 402717-06,-07) in corn grain and animal commodities are available for enforcement purposes.

4a. Residues of iprodione/metabolites are not expected to exceed 20 ppm in or on corn grain as a result of this Section 18.

4b. Residues of thiabendazole are not expected to exceed 25 ppm in or on corn grain as a result of this Section 18.

5a. Residues of iprodione/metabolites do not concentrate in processed corn fractions. No data on grain dust are available.

5b. Residue of thiabendazole in fractions of processed corn do concentrate. The residues of thiabendazole are not expected to exceed 145 ppm on corn bran, 40 ppm on corn fines and corn germ, 8 ppm on corn grits, 11 ppm in corn crud oil, and 9 ppm in refined oil. Additional data on grain dust are required (PP#7F3553/FAP#7H5541, J. B. Stocks, 10/18/89).

6a. Residues of iprodione/metabolite in milk, meat, poultry and eggs are not likely to exceed the established tolerances as a result of this proposed use.

6b. Residues of thiabendazole/metabolite in milk, meat, poultry and eggs are not likely to exceed the established tolerances as a result of this proposed use.

Recommendation:

Tox considerations permitting, DEB has no objection to this Section 18. An agreement should also be made with the FDA regarding the legal status of treated commodities in commerce. An agreement should also be made with the USDA regarding the legal status of animal commodities which may exceed established tolerances.

cc: Thiabendazole S.F., R.F., Section 18, iprodione SF., RF., Section 18, Circ., R. Schmitt, Branch Chief, F. Toghrol, FOD/PIB (C. Furlow).

RDI: F. B. Suhre: Section Head (10/18/90): E. Zager: Deputy Chief (10/18/90):

H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:557-7887:10/18/90.