

US EPA ARCHIVE DOCUMENT



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

9-11-86 *RJ*

*Dep 11 11 86*

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA ACCESSION NUMBER 263586, 263748 [RCB # 1191, 1194]  
PP6E3426/FAP6H5504: Iprodione in or on Ginseng and Dried  
Ginseng. Evaluation of Analytical Method and Residue  
Data.

TO: H. Jamerson, PM 43  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

THRU: R. S. Quick, Section Head, *RSQ*  
Tolerance Petition Section I  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

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

The petitioner, J. J. Baron, Assistant Coordinator, and R. H. Kupelian, National Director, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey, on behalf of the IR-4 Technical Committee, and the Agricultural Experiment Station of North Carolina and Kentucky, proposes the tolerances for the combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide (tradename Rovral® Fungicide)] and 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 in or on the raw agricultural commodity ginseng at 2 ppm. A food additive tolerance for residues of the same compounds in the processed commodity dried ginseng at 4 ppm is also proposed.

Note: Established tolerances are "(expressed as iprodione equivalents)". We presume the petitioner intended to express the residues as above, but a revised Section F including this expression is needed.

No registration standard has been completed for iprodione.

*1/6*

Tolerances for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] and 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 (expressed as iprodione equivalents) have been established under 40 CFR 180.399(a) in or on the raw agricultural commodities: kiwifruit (10 ppm); apricots, cherries, nectarines, peaches, plums, prunes (20 ppm); almond nutmeats (0.05 ppm), almond hulls (0.25 ppm); and grapes (60 ppm);

Conclusions:

1. Based on the metabolism data on other crops, the residues of concern in ginseng are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidine carboxamide [iprodione, RP-26019], 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-30228], and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-32490].
2. Adequate methods are available for enforcement purposes in PAM II.
3. Combined residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerances of 2 ppm in or on ginseng, or the food additive tolerance of 4 ppm in dried ginseng.
4. We conclude no additional residue data are required for the very minor amounts of ginseng used in ginseng "tea", in chewing roots, or in the preparation of an infusion prepared by boiling the root.
5. A revised Section F proposing tolerances in terms of residues "(expressed as iprodione equivalents)" is needed.
6. There are no Codex, Mexican or Canadian tolerances for iprodione on ginseng, therefore no compatibility problems are expected.

Recommendations:

We recommend, TOX considerations permitting, and providing a revised Section F proposing tolerances including the term "(expressed as iprodione equivalents)", per #5 above, for the establishment of the proposed tolerances.

DETAILED CONSIDERATIONS

Formulation:

The formulation proposed for use is Rovral® Fungicide, EPA Reg. No. 359-685, a wettable powder formulation containing 50% iprodione. Formulation inerts are cleared under 40 CFR 180.1001.

We have previously concluded residue problems are not anticipated from either inert ingredients or manufacturing impurities.

Directions for Use:

For Alternaria blight, apply 2.0 lbs. Rovral® (1.0 lbs. a.i.) per acre using ground equipment in minimum of 100 gallons of water per acre. Make the first application as conditions become favorable for disease development in the spring. Continue applications on a 7 day interval as long as conditions favor disease development. Do not make more than 12 applications of Rovral per season. Do not apply within 36 days of harvest.

Nature of the Residue:

Plants:

Plant metabolism studies have been reported on strawberries and wheat (A. Rathman, 3/2/79, PP8G2087), peaches (R. Perfetti, 5/13/84, PP2F2596), lettuce (N. Dodd, 4/11/83, PP3G2801), and ginseng (N. Dodd, 5/31/84, PP4G3037). In <sup>14</sup>C-iprodione plant metabolism studies in strawberries, wheat, peaches, and peanuts, the primary residue from foliar application was the parent compound iprodione and smaller amounts of its isomer RP-30228. Soil applications resulted in these two compounds plus small amounts of the metabolite RP-32490.

We reiterate our conclusion that the residues of concern in plants are iprodione [3-(3,5-dichlorophenyl)N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide]; 3-(1-methylethyl)-N(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-30228]; and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-32490]. We extend these conclusions to ginseng.

Animals:

The metabolism of iprodione in animals is not of concern herein, since there are no animal feed items from ginseng. See discussion under Meat, Milk, Poultry, and Eggs, below.

Analytical Methods:

The analytical method for iprodione is entitled "DETERMINATION OF IPRODIONE AND ITS METABOLITES IN/ON GRAIN AND HAY BY GLC AND TLC" (Analytical Method No. 162). The method determines RP26019, RP30228, and RP32490.

In principle, the method for iprodione in ginseng and dried ginseng involves extraction by shaking and blending with 10% water in acetone. The method was modified for dried ginseng by an additional rehydration step prior to initial extraction. A liquid-liquid partition step of ethyl acetate:methylene chloride at pH 3 is used to extract aqueous residue after acetone has been evaporated off. Remove solvent on rotary evaporator and take up residue in 10 ml.

ethyl acetate. Then, gel permeation chromatography on Biobeads using mobile phase of ethyl acetate:toluene provides additional cleanup. Take collected fraction to dryness. Use 50 ml. each of acetonitrile:hexane as partition step on the residue from above step, use another 50 ml. acetonitrile and discard hexane. Take residue to dryness and dissolve in 10-15 ml. of 3% ethyl acetate:hexane. A Florisil column is eluted with 20% (Fraction I) and 30% (Fraction II) ethyl acetate:hexane. Fraction I contains RP-26019 and RP-30228, while Fraction II contains the metabolite RP-32490. Both fractions are analyzed by GLC with  $^{63}\text{Ni}$  electron capture detection. The limit of detection is 0.05 ppm each of the three residues of concern.

There is a method in PAM Volume II for the determination of residues of iprodione. We conclude that adequate analytical methods are available for enforcement purposes.

#### Residue Data:

##### Residues in ginseng:

Two residue trials are available in support of the proposed use: a trial in Wisconsin conducted during 1983, 1984, and 1985, and another trial in North Carolina in 1985.

In Wisconsin, the ginseng was treated with 12 applications at weekly intervals at 1 lb ai/A for each of three years. Since ginseng is a slow growing crop requiring 4-5 years to reach maturity, it is important that the residue data reflect the multiyear nature of ginseng. The submitted trial data from Wisconsin satisfies the need for multiyear trials. The interval between last application and harvest was 36 days. Harvested ginseng roots were air-dried for 2 weeks and samples were taken and frozen prior to analysis.

In North Carolina, ginseng was treated with 13 applications at weekly intervals at the label rate of 1 lb ai/A. The interval between last application and harvest was 15 days. Freshly harvested roots were sampled and frozen; additional samples of the harvested root were allowed to air-dry according to commercial practice and then frozen prior to analysis.

The dried ginseng roots were analyzed by Method 162, including a rehydration step. Untreated control samples showed 0.03 to 0.07 ppm in 'fresh' roots and <0.01 to 0.04 ppm in dried roots. Recovery values for 'fresh' roots were 104% for iprodione at 1 ppm. Recoveries for dried ginseng roots were 83% for iprodione at 1 to 5 ppm, 79 to 124% for 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide [RP-30228], and 86 to 102% for 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine carboxamide [RP-32490].

Residues in field trials described above:

Wisconsin		RP-26019	RP-30228	RP-32490	Total
Dried roots	36 @ 1 lb	0.35	0.10	0.70	1.15
North Carolina					
Fresh roots	13 @ 1 lb	1.03	0.18	0.15	1.36
Dried roots	13 @ 1 lb	2.19	0.78	0.29	3.26

We conclude that combined residues of iprodione and its isomer and metabolite are not likely to exceed the proposed tolerance of 2 ppm in or on the raw agricultural commodity ginseng. In addition, we conclude that combined residues of iprodione and its isomer and its metabolite are not likely to exceed the proposed food additive tolerance of 4 ppm in or on the food commodity dried ginseng root.

Meat, Milk, Poultry and Eggs:

Three letters from agricultural experts at North Carolina State University, University of Kentucky, and University of Florida, indicate no animal food use of ginseng roots. The tops of the ginseng roots are destroyed during the digging process. Further, livestock are not grazed on ginseng fields. According to the information available about ginseng cultural practices, a crop requires 4 to 6 years to reach maturity. It is highly unlikely that a crop which produces only once every 4 to 6 years would be diverted to animal feed items. Thus, we conclude that there are no animal feed items of concern from ginseng.

OTHER CONSIDERATIONS:

Other human food uses of Ginseng:

Air dried ginseng root is ground up for use in ginseng "tea". Some small amounts of roots are consumed by chewing part of the root or by drinking an infusion prepared by boiling the root. Uses such as these are evidently a very small part of the crop, which in turn is a very minor human food item. We conclude no residue data are required for these very minor ginseng fractions.

International Tolerances:

There are no Codex, Canadian, or Mexican tolerances for residues of iprodione in or on ginseng or dried ginseng. Therefore, we do not anticipate any compatibility problems.

cc: R.F., Circu, R. W. Cook, FDA, PP#6E3426/FAP6H5504, TOX  
EEB, EAB, Robert E. Thompson, PMSD/ISB, F. Boyd  
TS-769:RCB:Reviewer:RWCook:Date:9/11/86:CM#2:RM:810:557-7377  
RDI:Section Head:RSQuick:Date:9/22/86:RDSchmitt:Date:9/23/86

C.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione  
[ Rovral® ]

PETITION NO. 6E3426 / 6H5504

R. W. Cook

9/8/86

*J. Lee 9/8/86*

CCPR NO. 111

Codex Status

Proposed U.S. Tolerances

No Codex Proposal Step  
6 or above

Residue (if Step 9):  
Iprodione

*Parent only*

Residue:  
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

Crop(s)                      Limit (mg/kg)

*None*                      (*on ginseng*)

Crop(s)                      Tol. (ppm)

Ginseng                      2

Ginseng (dried-FA)                      4

CANADIAN LIMIT

Residue: Iprodione including metabolites 3-isopropyl-N-(3,5-dichlorophenyl)-2,4-dioxo-imidazolidine-1-carboxamide and 3-(3,5-dichlorophenyl)-2,4-dioxo-imidazolidine-1-carboxamide.

Crop                      Limit (ppm)

*None*                      (*on ginseng*)

Comments:

MEXICAN TOLERANCIA

Residue:

Crop                      Tolerancia (ppm)

*None*