9-1295

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

SEP 12 1995

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Iprodione (109801), Reregistration Case No. 2335. Special Review, Anticipated Residues, Additional. CBRS No. 16038, DP Barcode No. 218049, No MRID No.

FROM: John Abbotts, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

THRU: Andrew R. Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

TO: Vivian Prunier, PM Team 60
Special Review Branch
Special Review and Reregistration Division [7508W]

and Christina Scheltema
Special Review and Registration Section
Risk Characterization and Analysis Branch
Health Effects Division [7509C]

CBRS previously determined anticipated residues for iprodione (CBRS 15099, 5/1/95, J. Abbotts). Instructions for this assignment are to refine anticipated residues for cancer risk for milk and chinese mustard. Also advise whether there are any data to show whether grapes are washed before being dried and turned into raisins and if so, if washing the grapes would reduce the iprodione residues. Are there data to show whether iprodione residues are reduced when table grapes, fruits, or berries are washed before they are eaten?

Tolerances are established for the combined residues of the fungicide iprodione parent, its isomer, and one metabolite in or on plant commodities, food commodities, and feed commodities (40 CFR 180.399(a) and (c), 185.3750, 186.3750). Tolerances are established for the combined residues of iprodione parent, its isomer, and two metabolites, all expressed as iprodione equivalents, in or on animal commodities (40 CFR 180.399(b)).

1/7

Chemical structures and full chemical names of residues in tolerance expressions are given in Figure 1. Iprodione is a List B Chemical; Phase 4 Review was completed 3/15/91.

Conclusions/Recommendations

1. Peanut production is widespread across several regions, and peanut hay should be considered a feed commodity in national commerce. Anticipated residues previously determined for milk should therefore be considered potential values for national consumption, rather than estimates for local "milksheds."

2. Based on translation from monitoring data for broccoli, we recommend revised anticipated residues, cancer risk, for Chinese mustard of 0.0034 ppm, rather than the tolerance value of 15 ppm (FL only). This anticipated residue value was determined taking percent crop treated data into account; we therefore recommend for the purposes of DRES evaluation that percent crop treated be set to the default value of 100%.

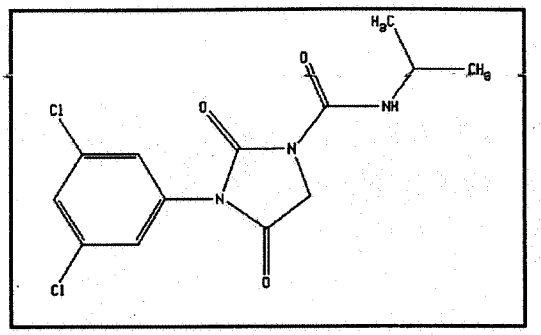
3. Once grapes are dried to raisins, raisins may be washed prior to packaging. Residue data submissions do not describe a washing step during raisin production, and do not contain information on whether washing raisins would reduce iprodione residues.

4. A thorough review of Chemistry Branch files has not found any data on consumer washing practices with regard to stone fruits, small fruits, or berries; or on whether iprodione residues are reduced on food items by washing. Data from metabolism studies indicate that some iprodione residues are systemic.

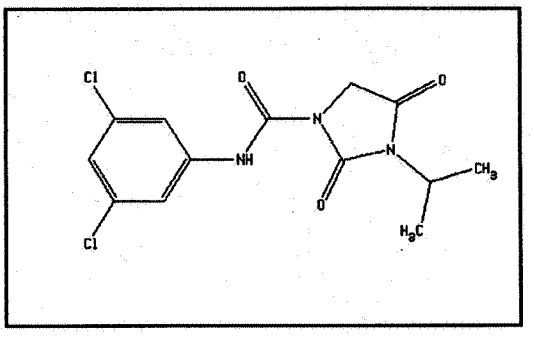
2

Figure 1. Iprodione Tolerance Residues:

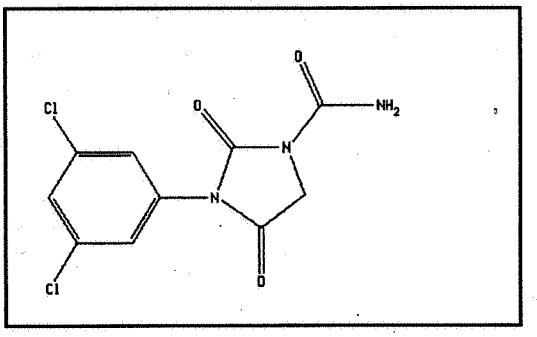
Iprodione parent;
3-(3,5-dichlorophenyl)-
N-(1-methylethyl)-2,4-dioxo-
1-imidazolidine-carboxamide



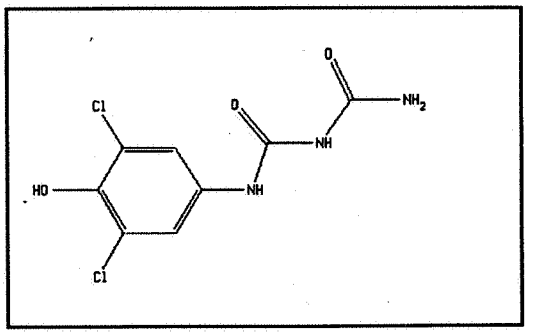
Iprodione isomer, RP30228;
3-(1-methylethyl)-
N-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP32490
(animals and plants);
3-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP36114
(animals); N-(3,5-dichloro-
4-hydroxyphenyl)-ureido-carboxamide



Milk

The determination of anticipated residues for animal commodities was based on assumed animal diets and data from animal feeding ~~studies (CBRS 15099, 5/1/95, J. Abbotts)~~. ~~The major contributor~~ of iprodione anticipated residues in the diets of beef and dairy cattle was peanut hay. We have been asked to evaluate whether the anticipated residues in milk could be expected on a national basis, or whether a dairy cattle diet including peanut hay would more likely be expected to occur in local "milksheds" only.

We have been advised that peanut hay is considered a highly desirable feed item for cattle (B. Schneider, personal communication). Data on peanut production are available from the publication Pesticide Registration Rejection Rate Analysis, Residue Chemistry, Follow-up Guidance, EPA 738-K-94-001, June 1994. That publication divides the U.S. into growing regions, and Table 6 reports that 72% of U.S. peanut production occurs in Region 2 (the southeast); 5% in Region 3 (FL); 16% in Region 6 (east TX and OK); and 7% in Region 8 (west TX and parts of CO, KS, OK, and NM). Although most of the production occurs in two regions, peanuts are grown throughout Region 2, which extends through VA, NC, SC, GA, and AL, and parts of KY and TN. Because peanut production is widespread across several regions, peanut hay should be considered a commodity in national commerce (R. Griffith, personal communication).

Conclusion 1: Peanut production is widespread across several regions, and peanut hay should be considered a feed commodity in national commerce. Anticipated residues previously determined for milk should therefore be considered potential values for national consumption, rather than estimates for local "milksheds."

Chinese mustard

In the previous determination of anticipated residues, we noted that the DRES run of 4/29/93 (R. Griffin) did not include a few commodities, including Chinese mustard, for which iprodione tolerances are established for FL only at 15.0 ppm (40 CFR 180.399(c)). We recommended anticipated residues at the tolerance value; if this value generated a significant estimated risk, then CBRS could refine anticipated residues at a later time (CBRS 15099, 5/1/95, J. Abbotts).

In the revised crop groups, final rule, Chinese mustard falls into Crop Subgroup 5-A, head and stem brassica. Of the other crops in that subgroup, an iprodione tolerance is established only for broccoli, at 25 ppm (40 CFR 180.399(a)). For broccoli, the 1X label rate is 1 lb ai/A as a directed spray after thinning (2-4 leaf stage). If disease conditions persist or reoccur, a second application may be made up to the day of harvest. Field

4

trial data for 2 applications at the 1X rate, with a 0 day PHI, gave maximum combined iprodione residues (parent, isomer, and metabolite) of 22.34 ppm (RCB 9, PP 6F3305, 12/5/85, W.T. Chin, and Accession No. 073875). Phase 4 Review (3/15/91, C.L. Olinger) found a summary of broccoli field trial data adequate for Phase 5 review, contingent upon adequate storage stability data. Storage stability data for plant commodities, including leafy vegetables, were subsequently found acceptable (CBRS 14162, 12/27/94, S.A. Knizner).

For Chinese mustard, registered use is 1 lb ai/A, applied as a foliar spray with 10 to 14 day intervals as long as conditions favor disease development. Maximum number of applications is 4, with a PHI of 10 days. Field trial data for 4 applications at the 1X rate, with a 10 day PHI, in FL gave maximum combined iprodione residues of 7.92 ppm (DEB 5693, 11/28/89, F. Toghrol).

Although registered use patterns are different for broccoli and Chinese mustard, field trial data support the establishment of a higher tolerance for broccoli than for Chinese mustard, and it seems appropriate to translate anticipated residues from broccoli to Chinese mustard. Anticipated residues for broccoli were determined from monitoring data, using the equation derived in the previous review (CBRS 10599, 5/1/95, J. Abbotts):

$a = [(np-d)(0.005) + \Sigma]/n$ (1), where

a = average anticipated residues in ppm,
p = the portion of the crop treated, expressed as a decimal,
d = the number of samples with detectable residues,
(0.005) = half the combined limit of quantitation for iprodione residues in ppm,
Σ = the sum of all residues in ppm over d samples, and
n = the total number of samples (counts), with or without detectable residues.

For broccoli, there were no detects among 506 FDA monitoring samples, and two detects among 261 FOODCONTAM samples, with a sum of residues of 1.12 ppm. Percent crop treated for broccoli was reported as <1%. However, the most recent DRES run used a value for Chinese mustard of 40% crop treated (Memo, J. Wintersteen, 6/29/95). Substituting these values into equation (1) gives anticipated residues for Chinese mustard of:

$a = [(506)(0.4)(0.005) + \{261(0.4)-2\}(0.005) + 1.12]/(506+261)]$
$= 0.0034$ ppm.

When anticipated residues were previously determined, no iprodione data were available from USDA monitoring (CBRS 15099, 5/1/95, J. Abbotts). CBRS has subsequently received the 1993 Annual Summary of the Pesticide Data Program, USDA, reporting monitoring results on 12 fruits and vegetables. For broccoli,

5

one detect at 0.16 ppm was reported among 630 samples; these results are comparable to those with FDA monitoring. We note that for an infinite number of samples with few detects, equation (1) collapses to 0.005 x percent crop treated, which for Chinese mustard would equal 0.002 ppm. For this commodity, further refinement using PDP data on broccoli would not significantly reduce anticipated residues, and we therefore recommend the value above obtained from translating FDA and FOODCONTAM monitoring data.

Conclusion 2: Based on translation from monitoring data for broccoli, we recommend revised anticipated residues, cancer risk, for Chinese mustard of 0.0034 ppm, rather than the tolerance value of 15 ppm (FL only). This anticipated residue value was determined taking percent crop treated data into account; we therefore recommend for the purposes of DRES evaluation that percent crop treated be set to the default value of 100%.

Raisins

Grape processing data were provided as part of petitions PP 3F2964 and PP 3G2787. Submissions for both petitions describe harvesting of grapes and sun-curing in the field to produce raisins; washing steps are not mentioned (PP 3G2787, 3/21/83, N. Dodd, and Accession No. 071240; PP 3F2964, 2/21/84, R.W. Cook, and Accession No. 072096). Information on raisin cultural practices is provided in Foods and Food Production Encyclopedia, Van Nostrand Reinhold Company, 1982. Most raisins are produced by a sun drying process, under which grapes are harvested and placed in wooden trays or paper trays between rows for drying in the field. Hot and dry weather conditions are necessary during curing. Rainfall during the curing period, typically 1 to 2 weeks, can significantly increase the prospects for mold damage. Once grapes have been dried to raisins, raisins may be washed at a processing plant prior to packaging. Data on iprodione for raisins does not indicate whether such a washing step would reduce residues. This information leads to the following conclusion:

Conclusion 3: Once grapes are dried to raisins, raisins may be washed prior to packaging. Residue data submissions do not describe a washing step during raisin production, and do not contain information on whether washing raisins would reduce iprodione residues.

Washing

A thorough review of Chemistry Branch files has not found any data on consumer washing practices with regard to stone fruits, small fruits, or berries; or on whether iprodione residues are reduced on food items by washing.

Phase 3 submission on iprodione included summaries of three plant metabolism studies: peaches, peanuts, and rice. Of these, peach is the commodity most likely to be washed by consumers. However, data in both the Phase 3 summary (MRID 92083026) and the original submission (PP 2F2596) were limited to residues in whole peaches. No data were provided that indicate the distribution of residues between peel and pulp, nor the relative portion represented by surface residues.

Data in the other Phase 3 submissions indicate that some residues translocate from the surface. Among rice fractions, total radioactive residues on (TRR) mill feed were 8.3 ppm, of which 67% was identified as iprodione tolerance residues; TRR in polished rice was 0.26 ppm, of which 63% was identified as iprodione tolerance residues (MRID 92083027). In peanuts, TRR in hulls was 0.13 ppm, of which 49% was identified as iprodione tolerance residues; TRR in nutmeat was 0.047 ppm, which was not characterized (MRID 92083025).

These data lead to the following conclusion pertaining to residue reduction by washing:

Conclusion 4: A thorough review of Chemistry Branch files has not found any data on consumer washing practices with regard to stone fruits, small fruits, or berries; or on whether iprodione residues are reduced on food items by washing. Data from metabolism studies indicate that some iprodione residues are systemic.

cc:Circ, Abbotts, RF, Iprodione List B File, SF, DRES (E. Doyle)
RDI:ARRathman:9/6/95:RBPerfetti:9/12/95:EZager:9/12/95
7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:9/12/95
JA14\iprodion.4

7