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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#2F04111. Iprodione on Cottonseed. Anticipated Residues on Cottonseed to be Used in Both Acute and Chronic Iprodione Dietary Risk Assessments.
(MRID#: 434540-01, DP Barcode#: D210829, CBTS#: 14991).

From: G. Jeffrey Herndon, Chemist
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

G. Jeffrey Herndon

Through: Edward Zager, Acting Chief
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

E. Zager

To: Susan Lewis/Carl Grable, PM #21
Fungicide/Herbicide Branch
Registration Division (7505C)

and

Jane Smith, Acting Head
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

In conjunction with PP#2F04111 (Section 3 registration and permanent tolerance request for use of iprodione on cotton), Rhone-Poulenc has requested that the Agency perform both acute and chronic anticipated residue estimates from the use of iprodione. In coordination with the reregistration of iprodione, CBTS will only calculate acute and chronic anticipated residues relating to this at-plant use of iprodione on cotton; CBRS (J. Abbotts) is currently calculating the acute and chronic anticipated residues from currently-registered uses of iprodione.

CBTS has not recommended in favor of the Section 3 registration, and the associated permanent tolerance on cottonseed,

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for the at-plant use of iprodione on cotton (PP#2F04111). However, enough of the deficiencies concerning that petition have been resolved (see memo of G.J. Herndon dated 2/6/95) where CBTS is in a position to calculate anticipated residues. However, based on the petitioner's response to the linearity/spike recovery issue (Deficiency 2a of the 2/6/95 memo), the anticipated residues calculated in this memo may have to be updated upon resolution of Deficiency 2a.

Conclusions and Recommendations

CBTS recommends that the residue values shown below be used in the acute and chronic dietary risk assessment for the proposed new preplant use of iprodione on cotton:

<u>DRES entry</u>	<u>Entry for ACUTE Risk Assessment (ppm)</u>	<u>Entry for CHRONIC Risk Assessment (ppm)</u>
cottonseed meal	0.10	0.02
cottonseed oil	0.10	0.02

Detailed Considerations

Cotton

General

Based on the remaining deficiencies concerning PP#2F04111 and the low residue and tolerance values for cottonseed and related commodities from this at-plant use versus the much higher (orders of magnitude) residues from the up-to-harvest uses on other crops, CBTS calculated rather conservative anticipated residues. CBTS did not believe that making additional assumptions and using additional factors (such as applying a percent crop treated factor to the residue data) would make a significant impact on the overall dietary risk from iprodione.

The current label has a restriction against feeding cotton gin byproducts (gin trash), so no residue data have been submitted to the Agency for this commodity. The new Table II (June 1994) no longer allows a feeding restriction for cotton gin byproducts. When Rhone-Poulenc submits additional iprodione residue data from cotton gin byproducts to the Agency, a new risk assessment will need to be performed taking this cow feed item into account in beef and milk tolerances.

Acute

The pending tolerance for residues of iprodione on cottonseed is 0.1 ppm. Cottonseed meal (the animal feed item), meal (the DRES commodity - taken from the residue value for the seed), hulls (animal feed item), and oil (the DRES commodity) are the processed commodities. Based on the field trial residue data and processing factors listed below (under Chronic), CBTS recommends that the following values be used in the analysis for determining the acute anticipated residues in cotton products.

cottonseed (RAC)	RAC = 0.10 ppm
meal (DRES entry)	RAC = 0.10 ppm
oil (DRES entry)	RAC = 0.10 ppm
meal (animal feed item)	RAC = 0.10 ppm
hulls (animal feed item)	RAC = 0.10 ppm

Chronic

Residue data for cottonseed was taken from that submitted to support PP#1G3998 and PP#2F04111.

Field Trial Data

Individual Moiety Benzene Method

Iprodione was applied to cotton at-plant at 10 sites. All applications were at 2X the proposed rate, except SDL90-227, in which iprodione was applied at 3.3X the proposed rate. Cottonseed was harvested when mature, between 129 and 169 days after application. The results of the analysis are shown in Table 1.

Table 1

Residues of Iprodione and Related Moieties in Cottonseed from At-Plant Use of Iprodione

trial site	Residue (ppm)		
	Iprodione	RP-30228	RP-32490
JRC90-117	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
GGB90-050	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
GGB90-051	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
MLC90-208	< 0.05	< 0.05	0.06
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
SDL90-227	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
CWH90-028	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
RAS90-213	0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
RAS90-214	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
RAS90-215	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
AMW90-008	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05
	< 0.05	< 0.05	< 0.05

Additional data from one field trial were provided where iprodione was applied at-plant at 8.4X the proposed rate and the resulting cottonseed was processed. None of the 3 regulated moieties were found in the cottonseed RAC (< 0.05 ppm) or any of the processed fractions (hulls, meal, crude oil, refined oil, and soapstock).

Since the cottonseed processing study was not definitive (due to the non-quantifiable residues in the RAC), CBTS examined a previous processing study on peanuts (submitted in conjunction with PP#4F3129, see memo of R.W. Cook dated 2/15/85), another oily commodity, in order to determine any potential for concentration in meal and oil. The results are shown in Table 2

Table 2

Residues of Iprodione and Its Metabolites in Peanut Fractions

compound	Residue (in ppm) by Compound and Rate (lbs.ai./A.)					
	RP-26019		RP-30228		RP-32490	
	1.0	2.0	1.0	2.0	1.0	2.0
nutmeats	0.21	0.27	0.11	0.18	< 0.05	< 0.05
hulls	2.27	4.32	0.57	0.87	0.67	0.74
crude oil (pressed)	0.54	0.67	0.15	0.15	< 0.05	< 0.05
crude oil (pressed and solvent extracted)	N/A	< 0.05	N/A	< 0.05	N/A	< 0.05
refined oil	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
soapstock	1.33	2.65	0.32	0.32	< 0.05	< 0.05
meal	N/A	< 0.05	N/A	< 0.05	N/A	< 0.05

The results of the peanut processing study shown above were reinforced in the ¹⁴C peanut metabolism study (no cottonseed metabolism study is available) submitted in conjunction with PP#4G3037 (see memo of N. Dodd dated 5/31/84). The study showed the following total TRR (expressed as parent equivalents) in peanut fractions:

peanut nutmeats	0.047 ppm
peanut oil	0.037 ppm
peanut meat after extraction for oil	0.085 ppm

Common Moiety Method

Iprodione was applied at-plant at 2X the proposed rate to cotton at 9 sites in 1991. Cottonseed was harvested when mature, between 126 and 177 days after application. The samples were analyzed by a common moiety method (iprodione residues were converted to 3,5-DCPA). The results of the analysis are shown in Table 3.

Table 3

Residues of Iprodione and Related Moieties in Cottonseed from At-Plant Use of Iprodione

trial site	PPM Iprodione Equivalents
91-028/LA	< 0.05
	< 0.05
	< 0.05
91-051/CA	< 0.05
	< 0.05
	< 0.05
91-080/TX	< 0.05
	< 0.05
	< 0.05
91-109/GA	< 0.05
	< 0.05
	< 0.05
91-234/TX	< 0.05
	< 0.05
	< 0.05
91-252/MS	< 0.05
	< 0.05
	< 0.05

Conclusions

The data from Table 1 (individual moiety method) are of limited value for estimating **chronic** anticipated residues due to the relatively high limit of quantitation (0.05 ppm) and the fact

that all 3 moieties in the tolerance expression are measured individually, resulting in a net limit of quantitation of 0.15 ppm (0.05 + 0.05 + 0.05 ppm).

The data from Table 3 (common moiety method) are of more value in estimating chronic anticipated residues; all three moieties are measured as one, resulting in a 0.05 ppm limit of quantitation for the entire tolerance expression (as opposed to 0.15 from the individual moiety method). Since the chromatograms and integration reports were provided, CBTS estimated that, for all samples that exhibited any peak in the retention time window of 3,5-DCPA, the maximum height of any peak was less than one third (average was one seventh) the height of the lowest standard analyzed as part of the curve (0.016 ppm). For the purposes of a conservative risk assessment, CBTS will assume that the field trial data in Table 3 (all < 0.05 ppm) represent a value of 0.02 ppm for cottonseed.

The data from the 8.4X cottonseed processing study (in which no quantifiable residues were found in the RAC), coupled with the peanut processing and peanut metabolism studies (which were used to determine where iprodione moieties would likely fractionate in an oily commodity), show that residues of iprodione would be likely to concentrate in cottonseed soapstock, but would not be likely to concentrate to any appreciable extent in cottonseed meal (animal feed item) or refined oil (DRES commodity). Therefore CBTS will apply a concentration factor of 1 to the RAC to determine the estimated chronic anticipated residues in processed commodities.

CAR = chronic anticipated residue of the RAC

cottonseed (RAC)	CAR = 0.02 ppm
meal (DRES entry)	CAR = 0.02 ppm
oil (DRES entry)	CAR = 0.02 ppm
meal (animal feed item)	CAR = 0.02 ppm
hulls (animal feed item)	CAR = 0.02 ppm

Meat, Milk, Poultry, and Eggs

Cottonseed meal, seed, hulls, and gin byproducts are outlined in Table II of Subdivision O as potential feed items in the diet of beef and dairy cattle. The only cotton commodity that is routinely fed to poultry or swine is cottonseed meal. However, based on the relatively low residue and tolerance values for cottonseed and related commodities from this at-plant use versus the much higher (orders of magnitude) from the up-to-harvest uses on other crops, [examples include: dried bean hay at 90 ppm, peanut forage and hay at 150 ppm, dry grape pomace at 225 ppm, raisin waste at 300 ppm, etc.], CBTS does not believe that the addition of the proposed use of iprodione on cottonseed will change any previously calculated acute or chronic anticipated residue values for meat, milk, poultry, or eggs. New estimates for currently-registered uses of iprodione are currently being calculated by CBRS (J. Abbotts).

cc: circu., J. Abbotts (CBRS), E. Haeberer, RF, SF, G. Herndon.

RDI: Section Head: E. Haeberer: 2/9/95,
Branch Senior Scientist: R. Loranger: 2/9/95,
Acting Branch Chief: E. Zager: 2/9/95.

H7509C: CBTS: G.J.Herndon: 305-6363: CM#2: Rm804C: 2/8/95.