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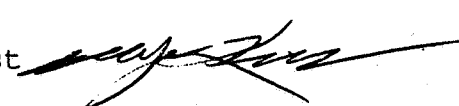
8-20-97
PP# 6F4664

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 8/20/97

SUBJECT: PP# 6F04664. Isoxaflutole in/on Field Corn and Animal RACs. **Request for Anticipated Residues.** Barcode D237699. Chemical 123000. Case 287353.

FROM: George F. Kramer, Ph.D., Chemist 
RABI/HED (7509C)

THROUGH: Melba Morrow, Branch Senior Scientist *MSM*
RABI/HED (7509C) *8/20/97*

TO: Barbara Madden, RCAB
Health Effects Division (7509C)

Rhône-Poulenc Ag Company has proposed permanent tolerances for the combined residues of the herbicide isoxaflutole and its metabolites 1-(2-methylsulfonyl-4-trifluoromethylphenyl-2-cyano-3-cyclopropyl propane-1,3-dione (RPA 202248) and 2-methylsulfonyl-4-trifluoromethyl benzoic acid (RPA 203328), calculated as the parent compound, in/on:

Field Corn, Grain	--	0.20 ppm		Field Corn, Fodder	--	0.50 ppm
Field Corn, Forage	--	1.0 ppm				

Tolerances are also proposed for the combined residues of the



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herbicide isoxaflutole and its metabolite RPA 202248, calculated as the parent compound, in/on:

Milk	--	0.02 ppm		Liver*	--	2.0 ppm
Poultry, Liver	-	2.0 ppm		Kidney*	--	0.40 ppm
Meat Byproducts (except liver and kidney)*	--	0.20 ppm				

*of cattle, goat, hogs, poultry and sheep

The DRES run using tolerance level residues resulted in a cancer risk (3×10^{-6}) which exceeded HED's level of concern. RCAB has thus requested that RAB1 provide anticipated residues for isoxaflutole in corn and animal RACs and processed commodities.

Anticipated Residues

Table 1. Summary of Isoxaflutole Anticipated Residues for Dietary Risk Assessment (Chronic Endpoints).

Commodity	Recommended Tolerance (ppm)	Anticipated Residue for DRES Run (ppm)
Corn Grain	0.20	0.015
Corn Forage	1.0	0.087
Corn Stover	0.50	0.057
Corn Silage	1.0	0.11
Corn grits	-	0.014
Corn oil	-	0.005
Corn sugar	-	0.022
Liver	0.50	0.024 ¹
Meat by-products (except liver)	0.02	0.0049 ¹
Milk ²	0.02	0.00012
Poultry meat by-products	0.30	0.015

¹ These anticipated residues should be used for beef, horses, hogs, goats and sheep in the DRES run.

² Based on the results of the feeding studies and the chemical nature of isoxaflutole and its metabolites, concentration of residues in milk fat is not expected.

DETAILED CONSIDERATIONS

CORN RACS

HED reviewed a total of 32 corn residue trials. Isoxaflutole was applied prior to emergence at a rate of 0.223 lbs. ai/A (1.2X). For samples with residue levels below the LOQ (0.01), a value of ½ LOQ used in calculating average residues. The average level of isoxaflutole and its metabolites in grain was 0.015 ppm; in silage, was 0.11 ppm; in forage, was 0.087 ppm; and in stover, was 0.057 ppm.

Corn was treated with isoxaflutole at a rate of 4X and the grain processed after harvest. The following concentration factors were observed: grits, 0.9X; meal, 0.9X; and oil, <0.3X. Data were not provided for corn sugar.

Meat, Milk & Eggs

Table 3. Anticipated Dietary Burden for Beef and Dairy Cattle.

Feed Item	Average AR/%DM ¹	% in Diet ²		Anticipated Dietary Burden ³	
		Beef	Dairy	Beef	Dairy
Corn Grain	0.017	60	40	0.01	0.01
Corn Silage	0.28	40	50	0.11	0.14
Total				0.12	0.15

1 Average AR/%DM = average of anticipated residues in feed items divided by the % dry matter (%DM) for the feed item. %DM: 88% for corn grain and 40% for silage.

2 The % of each feed type assumed to be included in the diet was based on information contained in the revised Table I of the OPPTS Test Guidelines Series 860.

3 The anticipated dietary burden is calculated by multiplying the average AR/%DM by the % of the feed item in the diet.

The dosing levels used in the ruminant feeding study correspond to 38X, 115X and 380X the anticipated dietary burden for beef cattle and 31X, 92X and 310X the anticipated dietary burden for dairy cattle. Based on this information, and based on the residues found in meat, meat by-products, fat and milk in the ruminant feeding

study, the anticipated residues in livestock commodities to be used in the chronic dietary risk assessments are shown below:

liver	0.024	ppm
meat by-products (except liver)	0.0049	ppm
milk	0.00012	ppm

Table 3. Anticipated Dietary Burden for Poultry.

Feed Item	AR	% in Diet ¹	Anticipated Dietary Burden ²
Corn Grain	0.015	80	0.012

- 1 The % assumed to be included in the diet was based on information contained in the revised Table I of the OPPTS Test Guidelines Series 860.
- 2 The anticipated dietary burden is calculated by multiplying the average AR by the % of the feed item in the diet.

The dosing levels used in the poultry feeding study correspond to 15X, 45X and 150X the anticipated dietary burden for poultry. Based on this information, and based on the residues found in meat, liver, eggs, and fat in the poultry feeding study, the anticipated residues in poultry commodities to be used in the chronic dietary risk assessments are shown below:

meat by-products	0.015	ppm
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cc: PP#6F04664, G. Kramer (RAB1), Dan Kenny (RD)
 RDI: M. Morrow (8/19/97), A. Rathman (8/19/97)
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