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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Note: The following memorandum supercedes the HED residue chemistry review dated 10/11/01 (J. Tyler; Barcodes D254989 and D267664).

DATE: 04-DEC-2001

SUBJECT: ID#007969-00157. PP#7F04848. **Diflufenzopyr in Field Corn. Amendment of 3/12/99 and 1/31/00 Submitted in Response to the Health Effects Division (HED) Review Dated 11/2/98.** Chemical 005107. MRID#s 44791402 and 45040203. DP Barcode D279529. Case 062041. Submission S560028.

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BASF Corporation recently submitted a registration application for use of diflufenzopyr on field corn, including a petition to establish permanent tolerances in/on field corn grain at 0.05 ppm, field corn forage at 0.05 ppm, and field corn stover (fodder) at 0.05 ppm. Concurrently, the petitioner requested Section 3 registration of Distinct Herbicide (EPA Reg. No. 7969-150), a multiple-active-ingredient, water-dispersible granule (WDF) formulation containing 21.4% diflufenzopyr and 55% dicamba. In a memo dated 11/2/98, HED made the following recommendations (L. Cheng; D239675):

> Diflufenzopyr has not met all the residue chemistry data requirements for registration. However, we can recommend that diflufenzopyr be permitted for use on field corn with the following stipulations: revise the tolerance expression to "residues of diflufenzopyr and metabolites convertible to M1, expressed in diflufenzopyr equivalents", and corn fodder to corn stover in Section F; specify PHI's of 32 days for forage and 72 days for corn grain and stover; a successful validation in EPA laboratories of the GC/MS enforcement method; additional frozen storage stability data showing stability of M1 and M10 for a period

of 22 months; and only field corn can be grown in fields treated within 12 months with diflufenzopyr. For future crop registration, additional radiovalidation data will be required.

Permanent tolerances are currently established for the combined residues of diflufenzopyr [2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid] and its metabolites convertible to M1 (8-methylpyrido[2,3-d]pyridazin-5(6H)-one) in/on field corn forage, grain, and stover at 0.05 ppm [40 CFR §180.549(a)].

The current amendment addresses deficiencies identified in HED's 11/2/98 review.

Executive Summary of Chemistry Deficiencies

- Revised Section B to include a 30-day plantback interval (PBI).

CONCLUSIONS/RECOMMENDATIONS

Provided a revised Section B is submitted, the available residue chemistry database supports unconditional registration and permanent tolerances for residues of diflufenzopyr and its metabolites convertible to M1 in/on field corn forage, grain, and stover at 0.05 ppm. A human health risk assessment was completed by HED on 11/17/98 (Memo, William Dykstra, et. al; D238413).

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1 (L. Cheng, 11/2/98, D239675)

1. No preharvest interval (PHI) has been specified on the proposed label. The label should specify PHI's for grain, forage, and fodder (the new term is "stover") that are supported by the residue data.

Deficiency - Recommendations (L. Cheng, 11/2/98, D239675)

Diflufenzopyr has not met all the residue chemistry data requirements for registration. However, we can recommend that diflufenzopyr be permitted for use on field corn with the following stipulations: revise the tolerance expression to "residues of diflufenzopyr and metabolites convertible to M1, expressed in diflufenzopyr equivalents", and corn fodder to corn stover in Section F; **specify PHI's of 32 days for forage and 72 days for corn grain and stover**; a successful validation in EPA laboratories of the GC/MS enforcement method; additional frozen storage stability data showing stability of M1 and M10 for a period of 22 months; **and only field corn can be grown in fields treated within 12 months with diflufenzopyr.** For future crop registration, additional radiovalidation data will be required.

Petitioner's Response: The petitioner submitted a revised label specifying PHI's of 32 days for corn forage and 72 days for corn grain and stover. However, the label has not been revised to include a 1-year label restriction prohibiting rotation to any non-labeled crop.

HED's Conclusion: The requested information concerning PHI's has been submitted. This deficiency is now resolved. The 1-year label restriction is no longer required (see Deficiency 8

below). **However, the petitioner should submit a revised Section B to include a 30-day PBI restriction.**

Deficiency - Conclusion 7 (L. Cheng, 11/2/98, D239675)

7. Interim storage stability data show that M1 is stable in corn grain, forage, and fodder for 14 months, and M10 in the same matrices for 18 months. Additional stability data under frozen conditions are needed since residue samples were stored for up to 22 months before residue analysis.

Petitioner's Response: In response to this deficiency, the petitioner submitted the following freezer storage stability data:

> MRID# 44791402. Freezer Storage Stability of the BAS 654 H (Diflufenzopyr) Metabolites M1 and M10 in Corn Forage, Grain, and Fodder. BASF Study Number: 97223.

Control corn forage, grain and stover (fodder) samples were fortified at a level of 0.1 ppm with metabolites M1 and M10. They were analyzed for residues and recoveries initially after fortification (0 months), and after 4, 14, 19, and 24 months of frozen storage (<10°C). The 0- and 4-month samples were analyzed at Sandoz Agro, Inc. and the data were summarized in an interim report. The remainder of the sample analyses were performed at BASF Corporation, Research Triangle Park, NC. The samples were analyzed by BASF Method Numbers D9709 and D9702 for residues of M1 and M10, respectively. Analysis of the samples indicate that M1 and M10 residues remained stable between the 0-month and 24-month storage intervals (Table 1).

Table 1. Frozen storage stability and concurrent method recoveries (fresh fortification recovery) of diflufenzopyr metabolites M1 and M10 residues from samples of fortified field corn forage, grain and stover.

Matrix	Relative Recovery [2] (%)				
	0-Month	4-Month	14-Month	19-Month	24-Month
M1					
Forage	NA[1]	106	88	86	85
Grain	NA	99	96	89	86
Stover (Fodder)	NA	103	99	86	96
M10					
Forage	NA	102	115	120	85
Grain	NA	93	121	107	83
Stover (Fodder)	NA	102	101	103	97

1. NA = Not Applicable. Relative recoveries were not determined for 0-month analyses.
2. Relative Recovery = (Average Recovery/Average Procedural Recovery)/100

The efficiency of the methods were determined by fortifying control samples with M1 and M10. The overall average recoveries of M1 and M10 were 98±13% (n=24) and 85±8% (n=17), respectively.

HED's Conclusion: The submitted storage stability data indicate that residues of diflufenzopyr (M1 and M10 residues) are relatively stable under frozen storage conditions in/on fortified samples of field corn forage, grain and stover for up to 24 months. The submitted storage stability data are adequate to support the storage conditions and intervals of the samples from the field corn field trial study (22 months). This deficiency is now resolved.

Deficiency - Conclusion 8 (L. Cheng, 11/2/98, D239675)

8. The confined accumulation rotational crop study is not adequate. Rotational crops studies must be conducted according to Guidelines 860 in which the pesticide is applied directly to the soil and the radioactivity in crop matrices above the trigger level are identified.

Petitioner's Response: The petitioner has not submitted a new confined rotational crop study. However, the following limited field trial study was submitted:

> MRID# 45040203. Limited Rotational Crop Study for the Use of Diflufenzopyr in Corn. BASF Study Number: 97158.

A total of six field trials were conducted in Regions 2 (GA; 3 trials) and 10 (CA; 3 trials) in order to determine the magnitude of residue in the raw agricultural commodities (RACs) of rotational crops with a minimum PBI of 30 days after the last application of Distinct to corn. Each trial consisted of two plots: an untreated and a treated plot. The treated plots received 2 foliar applications of Distinct for a total application rate of 0.125 lb. diflufenzopyr/A (1x the maximum seasonal application rate). The first application of 0.025 lb. diflufenzopyr/A was made when the corn was 3-6 inches tall. The second application of 0.1 lb. diflufenzopyr/A was made when the corn was 24 inches tall.

The corn was harvested at normal maturity and radishes, lettuce and winter wheat were planted into both plots at 30 and 60 day after treatment. Samples of radish, lettuce, and wheat RACs were collected at normal crop maturity. All samples were shipped frozen to the analysis facility and remained frozen until analysis. Samples were analyzed for residues of M1 and all residues convertible to M1 (including diflufenzopyr) using BASF Draft Analytical Method Number D9709. Analysis of the samples (Table 2) indicate that residues of diflufenzopyr were below the limit of quantitation (LOQ; 0.05 ppm) in all radish, lettuce and wheat 30-day PBI samples when treated with 2 applications of Distinct for a total of 0.125 lb. diflufenzopyr/A (1x). The 60-day samples were not analyzed.

Table 2. Diflufenzopyr Residues in Rotational Crop Samples Following BAS 662 H (Distinct™) Applied at 0.125 lb. diflufenzopyr /A (1x).

Commodity	State/Region	PBI[1] (days)	Residue (ppm)	Average Residue (ppm)
RADISH				
Roots	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05
Tops	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05
LETTUCE				
Tops	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05
WHEAT				
Forage	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05
Hay	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05
Grain	GA	30	<0.05, <0.05	<0.05
	CA	30	<0.05, <0.05	<0.05

1. PBI = Plantback Interval

The efficiency of the method was determined by fortifying control radish, lettuce, and wheat samples with diflufenzopyr and M1. The average overall recovery was 94±13% (n=22).

HED's Conclusion: In a memo dated 11/23/98, RD requested that the registrant be given the option to submit either a new confined rotational crop study or limited field rotational crop study to fulfill the rotational crop data gap (Memo, J. Miller, no DP Barcode). The registrant would need to submit trials for 3 representative crops (2 sites for each crop): a small grain crop, a root crop, and a leafy vegetable crop. In a memo dated 1/13/99, HED concurred with RD's request (Memo, O. Odiott, no DP Barcode).

The results of the limited field rotational crop study are acceptable. Residues of diflufenzopyr were less than the method's LOQ of 0.05 ppm in/on all treated representative rotational crops (radish roots and tops, lettuce, and winter wheat grain, forage, and hay) from the 30-day PBI. Therefore, no tolerances on rotational crops are needed. However, as residues were found at a 30-day PBI in the previously submitted confined rotational crop study, a PBI is required. **The petitioner should submit a revised Section B to include a 30-day PBI restriction.**

cc: J. Tyler
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