



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

AUG 26 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis (Using Percent Crop
Treated and Anticipated Residue Information) for the
Proposed Use of Clethodim (Select®) in/on Soybeans,
Cottonseed, and Animal Commodities (PP#09F3743)

FROM: Stephen A. Schaible *Stephen A. Schaible*
HED/SACB (H7509C)

TO: Joanne I. Miller, PM 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

THROUGH: James P. Kariya *James P. Kariya*
Chief, Dietary Exposure Section *W. B. B. B.*
Health Effects Division *8/23/91*

Action Requested

Provide a dietary exposure analysis for the proposed use of clethodim in/on soybeans, cottonseed, and animal commodities. A previous analysis for this chemical on these commodities was performed using tolerance level residues and 100 percent crop treated (S. Schaible memo dated 6/26/91). This analysis is to be performed using percent crop treated information from BEAD and anticipated residue information from Chemistry Branch. Clethodim is a new chemical with no established tolerances.

Discussion

1. Toxicological Endpoint: The DRES chronic exposure analysis used a Reference Dose (RfD) of 0.01 mg/kg body weight/day based on a no observed effect level (NOEL) of 1.0 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is based upon a 1 year feeding study in dogs which demonstrated as effects increase in absolute and relative liver weights in females and alterations in hematology and clinical chemistry of males and females. The RfD has been reviewed by the Peer Review Committee (RfD work group) (9/7/90). This RfD has not been reviewed by the HED or Agency reference dose committees.

2. Residue Information: Food uses evaluated were the proposed uses of clethodim on soybeans, cottonseed, and animal commodities (milk, eggs, and meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry). Percent crop treated information on soybeans was provided by BEAD (D. Szuhay memo

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liver) will be present at half of the limit of detection and that the kidney residue of 0.0008 ppm also applies to the "meat byproducts" and "others" (see Table 1) for the cattle, goats, hogs, and sheep, as well as for the commodity "horse", the ARC value may possibly still be an overestimate. However, it seems from these values that chronic risk through dietary exposure to clethodim is minimal.

Attachments

cc: DES, CBTS, C. Frick, Caswell # 721F

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ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 721F

DATE: 08/22/91

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Clethodim (Select) Caswell #721F CAS No. 99129-21-2 A.I. CODE: 121011 CFR No. 180.	1yr feeding- dog NOEL = 1.0000 mg/kg 0.00 ppm LEL = 75.0000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Incr absolute & relative liver wts in F; Altera- tions in hematology & clinical chemistry M & F. No evidence of oncogenic- ity in rat and mouse.	ADI UF -->100 OP Rfd = 0.010000 EPA Rfd = 0.000000	Review of historical con- trol data for reproduc- tion and teratology studies is requested.	Rfd/PR reviewed 09/07/90.

CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
530011A	BEEF-LIVER	31 COOKED-FRESH OR CANNED	09F3743	N 0.200000	0.000700		100.00	0.000700
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	09F3743	N 0.200000	0.000100		100.00	0.000100
53001MA	BEEF-LEAN	21 COOKED-NFS	09F3743	N 0.200000	0.000100		100.00	0.000100
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	09F3743	N 0.200000	0.000100		100.00	0.000100
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	09F3743	N 0.200000	0.000100		100.00	0.000100
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	09F3743	N 0.200000	0.000100		100.00	0.000100
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000800		100.00	0.000800
53002BA	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000800		100.00	0.000800
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	09F3743	N 0.200000	0.000200		100.00	0.000200
53002FA	GOAT-KIDNEY	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.000200		100.00	0.000200
53002KA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000800		100.00	0.000800
53002KA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000700		100.00	0.000700
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	09F3743	N 0.200000	0.000100		100.00	0.000100
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.000100		100.00	0.000100
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000800		100.00	0.000800
53003BA	SHEEP-MEAT BYP	21 COOKED-NFS	09F3743	N 0.200000	0.000800		100.00	0.000800
53003BA	SHEEP-OTH ORGAN	21 COOKED-NFS	09F3743	N 0.200000	0.000800		100.00	0.000800
53003FA	SHEEP-FAT	21 COOKED-NFS	09F3743	N 0.200000	0.000200		100.00	0.000200
53003FA	SHEEP-KIDNEY	21 COOKED-NFS	09F3743	N 0.200000	0.000800		100.00	0.000800
53003LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	09F3743	N 0.200000	0.000700		100.00	0.000700
53003MA	SHEEP-LEAN	21 COOKED-NFS	09F3743	N 0.200000	0.000100		100.00	0.000100
53003MA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	09F3743	N 0.200000	0.000800		100.00	0.000800
53006BA	PORK-MEAT BYP	21 COOKED-NFS	09F3743	N 0.200000	0.000800		100.00	0.000800
53006BA	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	09F3743	N 0.200000	0.000800		100.00	0.000800
53006BA	PORK-OTH ORGAN	10 RAW-FRESH OR NFS	09F3743	N 0.200000	0.000200		100.00	0.000200
53006FA	PORK-FAT	21 COOKED-NFS	09F3743	N 0.200000	0.000200		100.00	0.000200
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	09F3743	N 0.200000	0.000200		100.00	0.000200
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.000200		100.00	0.000200
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	09F3743	N 0.200000	0.000200		100.00	0.000200
53006FA	PORK-FAT	21 COOKED-NFS	09F3743	N 0.200000	0.000800		100.00	0.000800
53006LA	PORK-KIDNEY	21 COOKED-NFS	09F3743	N 0.200000	0.000700		100.00	0.000700
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.000700		100.00	0.000700
53006LA	PORK-LIVER	21 COOKED-NFS	09F3743	N 0.200000	0.000100		100.00	0.000100
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.000100		100.00	0.000100
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	09F3743	N 0.200000	0.000100		100.00	0.000100
55008BA	TURKEY-BYP	21 COOKED-NFS	09F3743	N 0.200000	0.011000		100.00	0.011000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	09F3743	N 0.200000	0.011000		100.00	0.011000
55008LA	TURKEY ORGAN	21 COOKED-NFS	09F3743	N 0.200000	0.001000		100.00	0.001000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	09F3743	N 0.200000	0.001000		100.00	0.001000

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TOLERANCE ASSESSMENT SUMMARY FOR Clethodim (Select)
USING ANTICIPATED RESIDUES
CASWELL #721F

DATE: 08/22/91

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)
RESULT IN AN ARC OF: 0.000000 MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO: 0.000 % OF THE ADI.

PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)
RESULT IN AN ARC OF: 0.000022 MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY: 0.217 % OF THE ADI.

IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)
ARE APPROVED THE RESULTANT ARC WILL BE: 0.000022 MG/KG/DAY
THE NEW ARC WILL OCCUPY 0.217 % OF THE ADI.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)
RESULT IN AN ARC OF: 0.000000 MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO: 0.000 % OF THE ADI.

PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)
RESULT IN AN ARC OF: 0.000133 MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY: 1.330 % OF THE ADI.

IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)
ARE APPROVED THE RESULTANT ARC WILL BE: 0.000133 MG/KG/DAY
THE NEW ARC WILL OCCUPY 1.330 % OF THE ADI.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

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