

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

JUL 8 1994

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

New Chemical/First Permanent Food Use: Acute and Chronic Dietary Exposure Analyses for the Proposed

Use of Tebuconazole on Peanuts

(PP#9F3724/9F3818).

FROM:

Teung F. Chin, Biologist

Dietary Risk Evaluation Section -

Science Analysis Branch/ HED

TO:

Steve Robbins/Denise Greenway, Acting PM 21

Fungicide-Herbicide Branch

Registration Division (7505C)

THROUGH:

Jim Kariya Head

DRES/SAB

Health Effects Division

Action Requested

The Fungicide-Herbicide Branch has requested a Dietary Risk Evaluation System (DRES) analysis be performed for the new chemical tebuconazole at the listed proposed conditional tolerances for the following commodities: 0.1 ppm peanuts; peanut hulls 4.0 ppm (Expiration date: 7/96) (6/15/94 CBRS memo G.F. Otakie to S. Robbins).

Discussion

1. Toxicological Information:

For chronic exposure, the Dietary Risk Evaluation System (DRES) used a Reference Dose (RfD) of 0.01 mg/kg body weight/day, based on a lower no observed effect level (NOEL) of 1 mg/kg bwt/day in dogs and an uncertainty factor of 100 (7/11/91 memo G. Z. Ghali to S. Lewis and 8/6/93 memo A. Protzel to B. Chambliss/S. Lewis). The Carcinogenicity Peer Review Committee concluded that Tebuconazole is a Class C - possible human carcinogen and recommended that, for the purpose of risk characterization, the Reference Dose (RfD) approach should be used for quantification of human risk (9/15/93 memo A. Protzel to B. Chambliss/S. Lewis).



For developmental toxicity,, tebuconazole tested positive in mice, rats, and rabbits at levels less than those inducing maternal toxicity. NOEL = 10 mg/kg/day was utilized for this DRES analysis was based on NMRI/ORIG Kissleg pregnant mice (9/14/92 Memo G.J. Burin to S. Lewis).

The exposure being calculated in this analysis are from tebuconazole residues alone. In March 1, 1994, the HED/Metabolism Committee concluded on non-inclusion of triazolylalanine residues with the tolerance expression of the parent compound (4/1/94 memo A. Protzel to The Metabolism Committee).

- Residue Information: Food uses evaluated in this analysis, in terms of DRES vocabulary, were peanuts (0.1 ppm) (6/15/94 G.F. Otakie memo to S. Robbins/D. Greenway) and peanut oil (0.1 ppm). Although the proposed tolerance is for peanuts (whole), the DRES system also considers peanut oil when peanuts (whole) are considered. Since CBTS concluded that tebuconazole does not concentrate in peanut oil, a residue value of 0.1 ppm was used, the same as for peanuts. Peanut hulls were not assessed although the petition includes peanut hulls (4.0 ppm) because humans do not consume peanut hulls. Also, CBTS concluded that any hulls consumed by animals as a feed stuff would not result in secondary residues in meat, milk, poultry and eggs. The CBTS memo also concluded that tebuconazole does not concentrate in peanut meal. While residues do concentrate in peanut soapstock, EPA no longer considers peanut soapstock as an animal feed item. Furthermore, the label included a restriction against feeding peanut hay/vines to livestock temporary tolerances. Since tebuconazole is a new chemical, there are no § 185 food additive tolerances or § 186 tolerances. For the same reason, there were no tolerances in the Tolerance Index System (TIS) listing or the CFR. The proposed tolerance level of 0.1 ppm for peanuts (raw, cooked, baked) and 0.1 ppm for peanuts - oil were used as the residue values for both the acute and chronic exposure analyses.
- 3. Percent Crop Treated No percent crop treated information was utilized for both the DRES acute and chronic exposure analyses. None would be available since this is a new chemical/new use pattern. It was assumed that 100 percent of the peanut crop is treated with tebuconazole.
- 4. Anticipated Residues (AR) No anticipated residue (AR) information was utilized for both the DRES acute and chronic exposure analyses. The use of available processing data was considered unnecessary since the calculated risks were so extremely low even at tolerance levels.

Results

1. <u>Chronic Exposure</u>: The DRES chronic exposure analysis used tolerance level residues and assumed 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for

the overall U.S. population and 22 population subgroups. Because tebuconazole is a new chemical, there are no anticipated residues and percent crop treated information, and therefore no estimated Anticipated Residue Contribution (ARC). The ARC is considered the more refined estimate of exposure over the TMRC. A summary of the TMRCs and their representations as percentages of the RfD is in Table 1A. It should be noted again that the residue of interest in this analysis is tebuconazole.

Comments - Chronic Dietary Risk: The TMRC from the proposed new uses of tebuconazole for the general population of the 48 States is 0.000007 mg/kg/bwt/day, which represents 0.07% of the RfD. There were no pending or published tolerances at the time of the calculations. The TMRCs for the most highly exposed subgroups, children (1-6 years old) and children (7-12 years old) are 0.000024 mg/kg bwt/day (0.24% of the RfD), and 0.000017 mg/kg bwt/day (0.17% of the RfD), respectively. All other groups were between 0.02 - 0.24 % of the RfD. Since calculated intake never exceeded the RfD, minimal to no risk for all subpopulations is expected from a chronic dietary intake of tebuconazole at this time.

2. <u>Acute Exposure</u>: The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of tebuconazole in the commodity (peanut) supply. Since the toxicological endpoint to which exposure is being compared in this analysis is developmental toxicity, the females (13+ years) is the subpopulation of particular interest.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL / exposure = MOE). For chemicals whose acute NOELS are derived from animal studies, the Agency is generally not concerned unless the MOE is below 100.

<u>Comments - Acute Dietary Risk</u>

Table 1B contains the distribution of acute exposures used for this analysis. $MOE_{100}=0.1$ mg/kg bwt/day (Calculations on Page 6 of Table 1B). Calculations (also on page 6, Table 1B) show that for the high-end of the subpopulation of concern, females (13+ yrs), MOE=83,000; therefore females (13+ yrs) have a negligible acute risk for developmental toxicity.

Attachments

cc: DRES, FHB, CCB, Tox II, CBTS I, Caswell # 463P

TABLE 1A: Chronic Dietary Exposure Analysis - Tebuconazole on Peanuts, Whole and Oil

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/30/94

PAGE:

CHEMICAL INFORMATION Tebuconazole (Folicur) CAS No. 107534-96-3 A.I. CODE: 128997 CFR No. ONCO: Negative- 1 species TOL STUDY TYPE 1yr feeding- dog WOEL= 1.0000 mg/kg 40.00 ppm '= 5.0000 mg/kg 200.00 ppm 'ative-' city in rat; MTD not reached in mouse study No evidence of oncogeniopacity and hepatic toxicity. Lenticular & corneal EFFECTS REFERENCE DOSES

PADI UF -->100

OPP RfD= 0.010000

EPA RfD= 0.000000 PAD1 DATA GAPS/COMMENTS
Chronic Feed/Onco- mouse
Devel Peer Review 6/92.
Devel toxicity NOEL=10 dermal studies were mg/kg/day (mouse oral); inconclusive. RfD/PR reviewed 03/05/91 RfD/PR reviewed 04/08/93

CHILDREN (7-12 YEARS OLD) MALES (13-19 YEARS OLD, NOT PREG. OR NURSING) FEMALES (13-19 YEARS OLDER) MALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	NURSING INFANTS (< 1 YEAR OLD) NON-NURSING INFANTS (< 1 YEAR OLD) FEMALES (13+ YEARS, PREGNANT) FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	HISPANICS NON-HISPANIC WHITES NON-HISPANIC BLACKS NON-HISPANIC OTHERS	NORTHEAST REGION NORTH CENTRAL REGION SOUTHERN REGION WESTERN REGION	U.S. POPULATION - SPRING SEASON U.S. POPULATION - SUMMER SEASON U.S. POPULATION - FALL SEASON U.S. POPULATION - WINTER SEASON	U.S. POPULATION - 48 STATES	POPULATION SUBGROUP
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						EFFECT OF ANTICIPATED RESIDUES ARC %FD

^{*}Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TABLE 1B: Acute Dietary Risk - Tebuconazole on Peanuts, Whole & Oil

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ESTIMATES BASED ON TOLERANCES:	OINFANTS(<1 YEAR)	TOLERANCES:	ESTIMATES BASED ON TOLERANCES: ANTICIPATED RESIDUES:	*FILE INFO: NO Tolerance Da ************************************	*NAME: DUMMYCIDE *CASWELL NO: 900 CFR NO: CFR *CAS NO: SHAUGHNESSY NO: *STATUS CODES: *BOY INFO: The ID value used in the	TOLERANCE SOURCES: P=PUBLISHED,	1500GAA PEANUTS-WHOLE 10 RAW-FRESH OR NFS 21 COOKED-NFS 22 COOKED-FRESH-BAKED	270070A PEANUTS-OIL 18 PROCESSED OIL MENU CATEGORY 19: DRY BEANS, PEANUTS (W/O OILS)	MENU CATEGORY 18: VEGETA	FOOD FOOD AND FOOD FORM DESCRIPTION	POPULATION = MALES(13+ YRS)	**************************************
PERSON DAYS THAT ARE USER-DAYS 0.00	ESTIMATED % OF POTENTIAL	0 0 0 0 0 0 100 9 6 4 3	PERSON DAYS THAT ARE USER-DAYS TO 0.00 96.79 ESTIMATED % OF POPULATION USER-DAYS 0 .2 .4 .6 .8 1	Are UsedWithout User Modific	STUDY RDV STR A 00000.1000 NO: 900999 B 00000.0500 C NO: 900999 B 00000.0500	TOLERANCE SOURCES: P=PUBLISHED, A=APPROVED, N=NEW ACTION, U=USER-SUPPLIED 1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION		ANS, PEANUTS (W/O OILS)	VEGETABLE OILS			**************************************
MG/KG BODY WEIGHT/DAY	MEAN DAILY RESIDUE CO	0 0 0 0 2 2 1 1	MG/KG BODY WEIGHT/DAY 0.000000 0.000008 0.000008 AYS WITH RESIDUE CONTRI 1 1.2 1.4 1.6		NOEL SF STUDY TYPE 000100 Chronic 001000 Terata R	SER-SUPPLIED ON USERS' DAILY CONSUM	0.52 9.20 1.50	98.44	•	NUMBER OF CONSUMER DAYS AS PERCENT OF V POTENTIAL PERSON DAYS :SORC (: TOLERANCE	DRY. MENU PATTERN = I-F
AS PERCENT OF RDV 0.00	MEAN DAILY RÉSIDUE CONTRIBUTION PER USER-DAY	0 0 0	PERCENT CO.00 7.91 EDING X	AR DATA	8 S	*	0.1000 0.1000 0.1000	0.1000	•	VALUE TYPE (PPM)	ANCE DATA AR DATA	对价格的 有效 计可以 化二甲基苯甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基甲基
₽V	4	000	TIMES THE RDV, FOR X=	DATA: User Modifications	EV. CORE GRADE tic Guideline ic Minimum	08:45 Friday, July 1, 1994 7			•• ••	RESIDUE	DAILY	****************************** : FOOD FORM CONTRIBUTION : TO EXPOSURE : (UG/KG BODY WT PER DAY)
		0 0	15 20	etions *	DOC. NO.*	1994 7	0.021764 0.049246 0.016681	0.000486		ANTICIPATED RESIDUE (INCL. AR)	DAILY	RIBUTION PER DAY)

- ANIIC		ESTIMATE ANTIC	ANTIC	ESTIMATES ANTICIO	-FEMALES(13+	*NAME: DUMMYCIDE *CASWELL NO: 900 *CAS NO: *STATUS CODES: *RDV INFO: The *FILE INFO: No	ANTIC	ESTIMATES ANTICIO	T ANTICIPATED OCHILDREN(1-6 YRS)	O ANTIC
WILLCILMIED KESTOCS	TOLERANCES:	ESTIMATES BASED ON TOLERANCES: ANTICIPATED RESIDUES:	TOLERANCES: ANTICIPATED RESIDUES: 13+ YRS)	IMATES BASED ON TOLERANCES: ANTICIPATED RESIDUES:	YRS)	YCIDE : 900 ES: The LD No Tole	TOLERANCES: 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	IMATES BASED ON TOLERANCES: ANTICIPATED RESIDUES:	TOLERANCES: ANTICIPATED RESIDUES: EN(1-6 YRS)	ANTICIPATED RESIDUES:
	. s.	PERSON DAYS S: S: ESTIMATED %	S: 100 ESTIMATED	PERSON DAYS S: S: ESTIMATED %	ESTIMAI	STUDY RDV NOEL CFR NO: CFR . A 00000.1000 SHAUGHNESSY NO: 900999 B 00000.0500 C Value used in this analysis is .0001 MG/K rance Data Are UsedWithout User Modifications.	CES: 0 JES: 100 INCLUDING AR'S:	PERSON DAYS S: ESTIMATED X		S: ESTIMATED
	70	YS THAT 0.00 98.54 % OF P	0 0 0 6 3 2	. * 5	ESTIMATED % OF POTENTIAL	STUDY A A A A A A A A A A A A A A A A A A A	0 18 18 1	DAYS THAT 0.00 97.70 FED % OF PC	0 0 0 0 0 0 100 5 4 4 4 ESTINATED % OF POTENTIAL	
	× 0	S THAT ARE USER-DAYS 0.00 98.54 % OF POPULATION USER .2 .4 .6 .8	O O O O O O O O O O O O O O O O O O O	THAT ARE USER-DAYS 0.00 0.00 76.98 OF POPULATION USER 2 .4 .6 .8	TENTIAL	97 RDV 00000.1000 00000.0500 is is .0001 sut User Mod	0 0 16 14 STATISTICS	ARE USER-DAYS OPULATION USER .4 .6 .8	O O O	27.86 % OF POPULATION U .2 .4 .6
	20	AYS MG/KG SER-DAYS WITH .8	1 0 MEA 1 0	AYS MG/KG SER-DAYS WITH	MEA	NOEL O O dification	0 0 11 9 BASED ON U	AYS MG/	0 MEA	SER-DAYS W
-	- 0	-DAYS MG/KG BODY WEIGHT/DAY 0.000000 0.000005 0.000005 USER-DAYS WITH RESIDUE CONTRI .8 1 1.2 1.4 1.6	0 0 1 1 0 1 MEAN DAILY RE	DAYS MG/KG BODY WEIGHT/DAY 0.000000 0.000004 0.000004 USER-DAYS WITH RESIDUE CONTRI .8 1 1.2 1.4 1.6	N DAILY RES	SF 000100 001000 001000 0015	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	S THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY 0.00 0.000000 0.0000000 97.70 0.000024 CONTRI RESIDUE CONTRI CON	0 0 3 3	USER-DAYS WITH RESIDUE .8 1 1.2 1.4
	0	GHT/DAY CONTRIBU	O O O O O O O O O O O O O O O O O O O	IGHT/DAY	SIDUE CONTR	F STUDY TYPE 0100 Chronic 11000 Terata R of BODY WEIGHT/DAY	0 0 6 5 Y CONSUMPTI	GHT/DAY CONTRIBU	SIDUE CONTR	CONTRIBU
	50	AS PER	O O O	AS PER	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	SPECIES Rat Rabbit	0 0 4 3 ON	AS PER	0 0 0 0 0 0 0 0 0 0 0 3 3 3 3 2 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	EXCEEC 2
	00	CENT OF RDV 0.00 5.45 NING X TIMES	0 0 0 0 0 0	. 01	R USER-DAY	EFF. LEV. Enzymatic Systemic AR DATA:	0 0 1 0 08:45	. 0	0 0 1 0 R USER-DAY	PING X TIMES
	0 0	THE RDV,	0	F RDV TIMES THE RDV,		*	0 0 0 0 0 0 0 0 1 0 0 0 0 0 0 0	F RDV 11 MES THE RDV, FOR X=	00	THE RDV,
,5	00	FOR X=	0 0	FOR X=		ADE ne difica	36 to 1	FOR X=	0 0	FOR X=
,		20	0 0	20		DOC. NO.*	***	20	00	8

Infants (Llyr)

4 x 0.0001 = 0.0004 MDE = 10/ = 25,000

Kids (1-byrs)

H X 0.0001 = 0.000H MOE = 10/000 = 25,000

£ (13+ yrs)

1.2 x 0.0001 = 0.00012 MDE = 10/ = 83,333 > 83,000 0.00012

07 (13+ yrs)

410000'0 = 1000'0 X h'I MOE = 10 0.00014 = 71,4% =71,000

NOEL = 10 mg/kg bw+/day

R, V = 0.0001

MOE 100 = 10/00 = 0.1 mg/kg but/day

CHEMICAL
INFORMATION
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CASWELL
NUMBER
463P

DATE: 06/24/94

FOOD FOOD NAME	CHEMICAL Tebuconazole (Folicur) Caswell #463P CAS No. 107534-96-3 A.I. CODE: 128997 CFR No.
	STUDY TYPE 1yr feeding- dog NOEL= 1.0000 mg/kg 40.00 ppm LEL= 5.0000 mg/kg 200.00 ppm ONCO: Negative- 1 species
PETITION T	Lenticular & corneal opacity and hepatic toxicity. No evidence of oncogenicity in rat; MTD not reached in mouse study.
TOLERANCE (PPM) PENDING PUBLISHED	REFERENCE DOSES PADI UF>100 OPP RfD= 0.010000 EPA RfD= 0.000000
	DATA GAPS/COMMENTS Chronic Feed/Onco- mouse Devel Peer Review 6/92. Devel toxicity NOEL=10 mg/kg/day (mouse oral); dermal studies were inconclusive.
	STATUS RfD/PR reviewed 03/05/91 RfD/PR reviewed 04/08/93

15006AA PEANUTS-WHOLE 27007OA PEANUTS-OIL

9F3724 9F3724

0.100000 0.**1**00000