



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

APR 11 1994

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for Propiconazole (Tilt®) through the Proposed Use on Peanuts (PP#8F3654).

FROM: Jennifer M. Wintersteen
Dietary Risk Evaluation Section
Science Analysis Branch/HED

Jennifer M. Wintersteen

(7509C)

TO: Sidney Jackson/D. Greenway, PM Team 21
Fungicide-Herbicide Branch
Registration Division

(7505C)

THROUGH: James P. Kariya, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

Kariya

WJ

Action Requested

Provide a Dietary Risk Evaluation System (DRES) analysis of the dietary exposure for propiconazole through the proposed time limited tolerance for use in/on peanuts. The following tolerances are being recommended due to this petition:

Commodity	Tolerance
· peanut hay	20 ppm
· peanut hulls	1.0 ppm
· peanuts	0.2 ppm

Discussion

1. Toxicological Endpoint: The chronic analysis used a Reference Dose (RfD) of 0.013 mg/kg body weight/day, based on a no observed effect level (NOEL) of 1.25 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is based on a one-year dog feeding study that demonstrated irritation of the stomach in males as an endpoint effect. The HED Carcinogenicity Peer Review Committee classified propiconazole as a Group C (possible human) carcinogen on 4/15/92. A data gap presently exists concerning dosing in the mouse carcinogenicity study.

2. Residue Information: Food uses evaluated in this analysis were the published tolerances listed in the Tolerance Index System (TIS) and 40 CFR §180.434, pending tolerances on pineapple and corn, and the proposed use on peanuts (M. Flood memo, 1/25/94). The tolerance level petitioned for propiconazole on peanuts is not for a permanent tolerance but a time-limited tolerance with an expiration date of 12/31/98.

Peanut hay and hulls are considered feed items yet the contribution to secondary residues in meat and milk is negligible.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

ARs for meat and milk already established for propiconazole from grasses and corn does not need to be increased due to this petition (M. Flood personal communication, 4/8/94).

Anticipated residue data used in this analysis was supplied by the Dietary Exposure Branch (now CBTS and CBRS) in a K. Arne memo dated 6/3/87 and a Debra Edwards memo dated 5/23/89. ARs for meat and milk due to grass and corn as feed items were supplied by M. Flood in a memo dated 5/12/93. Percent crop treated information used in the analysis was supplied by BEAD (J. Ferrante, 1/10/89 and R. Torla, 5/5/89).

Propiconazole and its metabolite 2,4-dichlorobenzoic acid, expressed as the parent compound, are to be considered for risk analyses (M. Flood memo, 6/15/93). A summary of the residue information used in the analysis is attached as Table 1.

3. Results: A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Anticipated residues and percent crop treated data were used to calculate the Anticipated Residue Contribution (ARC) for those same population subgroups for certain commodities.

Summaries of the TMRCs, ARCs and their representations as percentages of the RfD for propiconazole on peanuts are attached as Table 2 and 3. A commodity contribution for propiconazole (U.S. general population) is also attached.

The ARC for the general population from all published tolerances is 7.8×10^{-4} mg/kg bwt/day, representing 6% of the RfD for propiconazole. Peanuts contribute an additional 1.5×10^{-5} mg/kg bwt/day, less than 1% of the RfD. Pending tolerances contribute 6.6×10^{-5} mg/kg bwt/day, also representing <1% of the RfD. If pending and proposed uses were combined with published uses for propiconazole the resulting ARC would be 8.6×10^{-4} mg/kg bwt/day, or 7% of the RfD.

The most highly exposed subgroup, non-nursing infants <1 year, has an ARC from all published tolerances of 3.8×10^{-3} mg/kg bwt/day, or 29% of the RfD. If pending and proposed uses are included the resulting ARC would be 4.0×10^{-3} mg/kg bwt/day, or 31% of the RfD.

The analysis for propiconazole has been refined, using anticipated residues and percent crop treated, to give a more accurate estimate of the dietary risk from propiconazole. The commodity peanuts was considered at tolerance level and 100% crop treated, however. With these considerations, the dietary risk from exposure to propiconazole in/on peanuts appears to be minimal.

Normally percent crop treated data over five years old is not used by DRES. DRES considers the 1989 BEAD data no longer appropriate for refining the dietary risk from propiconazole. However, due to the urgency of the petition for the planting season, the DRES analysis used the 1989 BEAD data for exposure assessment. DRES recommends that RD request an update of percent crop treated data from BEAD for propiconazole for use in future DRES analyses.

Attachments

cc: DRES, CBTS, Tox II, Caswell #323EE.

Table 1.

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323EE

DATE: 06/08/94

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.	1yr feeding- dog NOEL = 1.2500 mg/kg 50.00 ppm 6.2500 mg/kg 250.00 ppm ONCO: C (HED)	Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.	ADI OPP RfD = 0.013000 EPA RfD = 0.013000	Questions concerning dos- ing in the mouse study.	HED complete 05/05/87 EPA verified 07/15/8 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
03008AA	PECANS	10 RAW-FRESH OR NFS	4F3007	P 0.100000	0.050000	FIELD TRIAL	100.00	0.050000
03008AA	PECANS	21 COOKED-NFS	4F3007	P 0.100000	0.050000	FIELD TRIAL	100.00	0.050000
03008AA	PECANS	22 COOKED-FRESH-BAKED	4F3007	P 0.100000	0.050000	FIELD TRIAL	100.00	0.050000
03008AA	PECANS	23 COOKED-FRESH-BOILED	4F3007	P 0.100000	0.050000	FIELD TRIAL	100.00	0.050000
03008AA	PECANS	62 COOKED-FRESH OR FROZEN-BAKED	4F3007	P 0.100000	0.050000	FIELD TRIAL	100.00	0.050000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	9F3758	P 1.000000	1.000000		100.00	1.000000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	9F3758	P 1.000000	1.000000		100.00	1.000000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05004AA	PEACHES-FRESH	21 COOKED-NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	9F3758	P 1.000000	1.000000		100.00	1.000000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	9F3758	P 1.000000	1.000000		100.00	1.000000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05005AA	PLUMS-FRESH	21 COOKED-NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	9F3758	P 1.000000	1.000000		100.00	1.000000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	9F3758	P 1.000000	1.000000		100.00	1.000000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	9F3758	P 1.000000	1.000000		100.00	1.000000
05005JA	PRUNE-JUICE	22 COOKED-FRESH OR FROZEN-BAKED	9F3758	P 1.000000	1.000000		100.00	1.000000
06002AA	BANANAS-UNSPEC	62 COOKED-FRESH-BAKED	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06002AA	BANANAS-FRESH	10 RAW-FRESH OR NFS	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06002AA	BANANAS-FRESH	21 COOKED-NFS	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06002AA	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06002DA	BANANAS-DRIED	21 COOKED-NFS	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06013AA	PINEAPPLE-PULP	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000
06013AA	PINEAPPLE-PULP	21 COOKED-NFS	8F3674	A 0.100000	0.100000		100.00	0.100000
06013AA	PINEAPPLE-PULP	31 COOKED-FRESH OR CANNED	8F3674	A 0.100000	0.100000		100.00	0.100000
06013JA	PINEAPPLE-DRIED	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000
06013JA	PINEAPPLE-DRIED	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000
06013JA	PINEAPPLE-JUICE	15 RAW-FRESH OR CANNED	8F3674	A 0.100000	0.100000		100.00	0.100000
06013JA	PINEAPPLE-JUICE	21 COOKED-NFS	8F3674	A 0.100000	0.100000		100.00	0.100000
06013JA	PINEAPPLE-JUICE	31 COOKED-FRESH OR CANNED	8F3674	A 0.100000	0.100000		100.00	0.100000
06016AA	PLANTAINS	21 COOKED-NFS	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000

Table 1 (continued)

ANTICIPATED RESIDUE INFORMATION FOR CASSELL NUMBER 323EE

DATE: 04/11/94

PAGE: 2

CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.		1yr feeding- dog NOEL= 1.2500 mg/kg 50.00 ppm LEL= 6.2500 mg/kg 250.00 ppm ONCO: C (HED)		Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.		ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000		Questions concerning dos- ing in the mouse study. Triazole-alanine is plant metabolite		HED complete 05/05/87 EPA verified 07/15/8 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.	
FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)			
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	4E3026	P 0.200000	0.050000	FIELD TRIAL	100.00	0.050000			
13002AA	CELERY	10 RAW-FRESH OR NFS	0F3869	P 5.000000	5.000000		100.00	5.000000			
13002AA	CELERY	21 COOKED-NFS	0F3869	P 5.000000	5.000000		100.00	5.000000			
13016AA	FENNEL	00 NOT SPECIFIED (NO CONSUMPTION)	0F3869	P 5.000000	5.000000		100.00	5.000000			
15005AA	CORN, SWEET	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
15005AA	CORN, SWEET	21 COOKED-NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
15005AA	CORN, SWEET	31 COOKED-FRESH OR CANNED	8F3674	A 0.100000	0.100000		100.00	0.100000			
15006AA	PEANUTS-WHOLE	10 RAW-FRESH OR NFS	8F3654	N 0.200000	0.200000	Exp. 12/31/98	100.00	0.200000			
15006AA	PEANUTS-WHOLE	21 COOKED-NFS	8F3654	N 0.200000	0.200000	Exp. 12/31/98	100.00	0.200000			
15006AA	PEANUTS-WHOLE	22 COOKED-FRESH-BAKED	8F3654	N 0.200000	0.200000	Exp. 12/31/98	100.00	0.200000			
24001AA	BARLEY	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	5.00	0.002500			
24002EA	CORN, GRAIN-ENDO	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002EA	CORN, GRAIN-ENDO	21 COOKED-NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002EA	CORN, GRAIN-ENDO	22 COOKED-FRESH-BAKED	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002EA	CORN, GRAIN-ENDO	23 COOKED-FRESH-BAKED	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002EA	CORN, GRAIN-ENDO	00 NOT SPECIFIED (NO CONSUMPTION)	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002SA	CORN SUGAR	10 RAW-FRESH OR NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002SA	CORN SUGAR	21 COOKED-NFS	8F3674	A 0.100000	0.100000		100.00	0.100000			
24002SA	CORN SUGAR	22 COOKED-FRESH-BAKED	8F3674	A 0.100000	0.100000		100.00	0.100000			
24004AA	RICE-ROUGH	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24004AA	RICE-ROUGH	23 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24004AB	RICE-MILLED	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24004AB	RICE-MILLED	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24004AB	RICE-MILLED	23 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24004AB	RICE-MILLED	31 COOKED-FRESH OR CANNED	4F3074	P 0.100000	0.050000	FIELD TRIAL	15.00	0.007500			
24005AA	RYE-ROUGH	00 NOT SPECIFIED (NO CONSUMPTION)	4F3074	P 0.100000	0.050000	FIELD TRIAL	5.00	0.002500			
24005AA	RYE-ROUGH	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	5.00	0.002500			
24005MA	RYE-GERM	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	5.00	0.002500			
24005MA	RYE-GERM	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	5.00	0.002500			
24007AA	WHEAT-ROUGH	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007AA	WHEAT-ROUGH	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007AA	WHEAT-ROUGH	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007AA	WHEAT-ROUGH	23 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007GA	WHEAT-GERM	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007GA	WHEAT-GERM	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007HA	WHEAT-BRAN	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007HA	WHEAT-BRAN	21 COOKED-NFS	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007HA	WHEAT-BRAN	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.050000	FIELD TRIAL	2.00	0.001000			
24007MA	WHEAT-FLOUR	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.010000	PROCESSING	2.00	0.000200			
24007MA	WHEAT-FLOUR	21 COOKED-NFS	4F3074	P 0.100000	0.010000	PROCESSING	2.00	0.000200			

Table 1 (continued)

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323EE

DATE: 06/11/94

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.		1yr feeding- dog MOEL= 1.2500 mg/kg 50.00 ppm LEL= 6.2500 mg/kg 250.00 ppm ONCO: C (HED)		Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.		ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000		Questions concerning dos- ing in the mouse study. Triazole-alanine is plant metabolite		HED complete 05/05/87 EPA verified 07/15/88 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.	
FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)			
24007MA	WHEAT-FLOUR	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.010000	PROCESSING	2.00	0.000200			
24007MA	WHEAT-FLOUR	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.010000	PROCESSING	2.00	0.000200			
270020A	CORN, GRAIN-OIL	18 PROCESSED OIL	8F3674	A 0.100000	0.100000		100.00	0.100000			
270070A	PEANUTS-OIL	18 PROCESSED OIL	8F3654	N 0.200000	0.200000		100.00	0.200000			
500000B	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	1F3974	P 0.050000	0.007000	Exp. 12/31/98	100.00	0.007000			
500000B	MILK-NON-FAT SOL	21 COOKED-NFS	1F3974	P 0.050000	0.007000		100.00	0.007000			
500000A	MILK-FAT SOLIDS	51 COOKED-CANNED	1F3974	P 0.050000	0.007000		100.00	0.007000			
500000A	MILK-FAT SOLIDS	21 COOKED-NFS	1F3974	P 0.050000	0.007000		100.00	0.007000			
500000A	MILK-FAT SOLIDS	51 COOKED-CANNED	1F3974	P 0.050000	0.007000		100.00	0.007000			
500000A	MILK SLUG (LACT)	21 COOKED-NFS	1F3974	P 0.050000	0.007000		100.00	0.007000			
500000A	MILK SLUG (LACT)	51 COOKED-CANNED	1F3974	P 0.050000	0.007000		100.00	0.007000			
530018A	BEEF-MEAT BYP	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018A	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018B	BEEF-OTH ORGAN	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018B	BEEF-OTH ORGAN	51 COOKED-CANNED	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018A	BEEF-DRIED	21 COOKED-NFS	1F3974	P 0.100000	0.010000		100.00	0.010000			
530018A	BEEF-FAT	10 RAW-FRESH OR NFS	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-FAT	21 COOKED-NFS	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-FAT	22 COOKED-FRESH-BAKED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-FAT	23 COOKED-FRESH-BOILED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-FAT	24 COOKED-FRESH-BROILED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-FAT	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530018A	BEEF-KIDNEY	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018A	BEEF-LIVER	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.460000		100.00	0.460000			
530018A	BEEF-LIVER	31 COOKED-FRESH OR CANNED	1F3974	P 0.100000	0.420000		100.00	0.420000			
530018A	BEEF-LIVER	10 RAW-FRESH OR NFS	1F3974	P 0.100000	0.010000		100.00	0.010000			
530018A	BEEF-LEAN	21 COOKED-NFS	1F3974	P 0.100000	0.010000		100.00	0.010000			
530018A	BEEF-LEAN	22 COOKED-FRESH-BAKED	1F3974	P 0.100000	0.010000		100.00	0.010000			
530018A	BEEF-LEAN	23 COOKED-FRESH-BOILED	1F3974	P 0.100000	0.010000		100.00	0.010000			
530018A	BEEF-LEAN	24 COOKED-FRESH-BROILED	1F3974	P 0.100000	0.010000		100.00	0.010000			
530028A	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 0.100000	0.460000		100.00	0.460000			
530028B	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 0.100000	0.460000		100.00	0.460000			
530028A	GOAT-FAT	23 COOKED-FRESH-BOILED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530028A	GOAT-FAT	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.020000		100.00	0.020000			
530028A	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 0.100000	0.460000		100.00	0.460000			
530028A	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 0.100000	0.460000		100.00	0.460000			
530028A	GOAT-LEAN	23 COOKED-FRESH-BOILED	1F3974	P 0.100000	0.420000		100.00	0.420000			
530028A	GOAT-LEAN	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.010000		100.00	0.010000			
530033A	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 2.000000	0.460000		100.00	0.460000			

Table 1 (continued)

ANTICIPATED RESIDUE INFORMATION FOR CASSELL NUMBER 323EE

DATE: 06/08/94

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.		1yr feeding- dog NOEL= 1.2500 mg/kg 50.00 ppm LEL= 6.2500 mg/kg 250.00 ppm ONCO: C (HED)		Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.		ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000		Questions concerning dos- ing in the mouse study.		HED complete 05/05/87 EPA verified 07/15/8 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.	
FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)			
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
53005FA	SHEEP-FAT	21 COOKED-NFS	1F3974	P 0.100000	0.020000		100.00	0.020000			
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	1F3974	P 2.000000	0.460000		100.00	0.460000			
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	1F3974	P 2.000000	0.420000		100.00	0.420000			
53005MA	SHEEP-LEAN	21 COOKED-NFS	1F3974	P 0.100000	0.010000		100.00	0.010000			
53005NA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	1F3974	P 0.100000	0.010000		100.00	0.010000			
53006BA	PORK-MEAT BYP	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	1F3974	P 0.100000	0.460000		100.00	0.460000			
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006FA	PORK-FAT	21 COOKED-NFS	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	1F3974	P 0.100000	0.020000		100.00	0.020000			
53006KA	PORK-KIDNEY	21 COOKED-NFS	1F3974	P 2.000000	0.460000		100.00	0.460000			
53006LA	PORK-LIVER	21 COOKED-NFS	1F3974	P 2.000000	0.420000		100.00	0.420000			
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	1F3974	P 2.000000	0.420000		100.00	0.420000			
53006MA	PORK-LEAN	21 COOKED-NFS	1F3974	P 0.100000	0.010000		100.00	0.010000			
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	1F3974	P 0.100000	0.010000		100.00	0.010000			
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	1F3974	P 0.100000	0.010000		100.00	0.010000			
53006BA	TURKEY-BYP	21 COOKED-NFS	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030			
53006BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030			
53008BA	TURKEY-ORGAN	21 COOKED-NFS	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030			
53008BA	TURKEY-ORGAN	25 COOKED-FRESH-FRIED	4F3074	P 0.200000	0.000030	EXTRAPOLATED	100.00	0.000030			
53008MA	TURKEY W/O SKIN	21 COOKED-NFS	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005			
53008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005			
53008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005			
53008MB	TURKEY+SKIN	21 COOKED-NFS	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007			
53008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007			
53008MC	TURKEY-UNSPEC	21 COOKED-NFS	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007			
53013BA	POULTRY,OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030			
53013LA	POULTRY,ORGAN	25 COOKED-FRESH-FRIED	4F3074	P 0.200000	0.000030	EXTRAPOLATED	100.00	0.000030			
53013MA	POULTRY,OTHER	21 COOKED-NFS	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007			
53014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			
53014AA	EGGS-WHOLE	21 COOKED-NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			
53014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			
53014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			
53014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			
53014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015			

Table 1 (continued)

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323EE

DATE: 04/08/94

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.	1yr feeding- dog NOEL= 1.2500 mg/kg 50.00 ppm LET= 6.2500 mg/kg 250.00 ppm ONCO: C (HED)	Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.	ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000	Questions concerning dos- ing in the mouse study. Triazole-alanine is plant metabolite	HED complete 05/05/87 EPA verified 07/15/8 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AB	EGGS-WHITE ONLY	62 COOKED-FRESH OR FROZEN-BAKED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AB	EGGS-WHITE ONLY	81 COOKED-FROZEN	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AC	EGGS-YOLK ONLY	10 RAW-FRESH OR NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AC	EGGS-YOLK ONLY	21 COOKED-NFS	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AC	EGGS-YOLK ONLY	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55014AC	EGGS-YOLK ONLY	31 COOKED-FRESH OR CANNED	4F3074	P 0.100000	0.000015	EXTRAPOLATED	100.00	0.000015
55015BA	CHICKEN-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030
55015LA	CHICKEN-ORGAN	21 COOKED-NFS	4F3074	P 0.200000	0.000030	EXTRAPOLATED	100.00	0.000030
55015LA	CHICKEN-ORGAN	25 COOKED-FRESH-FRIED	4F3074	P 0.200000	0.000030	EXTRAPOLATED	100.00	0.000030
55015LA	CHICKEN-ORGAN	26 COOKED-FRESH-PICKLED, CORNED, OR CURED	4F3074	P 0.100000	0.000030	EXTRAPOLATED	100.00	0.000030
55015MA	CHICKEN-W/O SKIN	21 COOKED-NFS	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005
55015MA	CHICKEN-W/O SKIN	22 COOKED-FRESH-BAKED	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005
55015MA	CHICKEN-W/O SKIN	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005
55015MA	CHICKEN-W/O SKIN	31 COOKED-FRESH OR CANNED	4F3074	P 0.100000	0.000005	EXTRAPOLATED	100.00	0.000005
55015MA	CHICKEN-W/O SKIN	53 COOKED-CANNED-BOILED	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007
55015MB	CHICKEN+SKIN	21 COOKED-NFS	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007
55015MB	CHICKEN+SKIN	25 COOKED-FRESH-FRIED	4F3074	P 0.100000	0.000007	EXTRAPOLATED	100.00	0.000007

Table 2.

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 04/08/94

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
Propiconazole (Banner/Tilt) Caswell #323EE CAS No. 60207-90-1 A.I. CODE: 122101 CFR No. 180.		1yr feeding- dog NOEL= 1.2500 mg/kg 50.00 ppm LEL= 6.2500 mg/kg 250.00 ppm ONCO: C (HED)	Irritation of the stomach in males. Evidence of oncogenicity in mice (male liver), negative in rats.	ADI OP RfD= 0.013000 EPA RfD= 0.013000	Questions concerning dos- ing in the mouse study.	Triazole-alanine is plant metabolite	HED complete 05/05/87 EPA verified 07/15/88 WHO last reviewed 1987 EPA verified 05/25/88 On IRIS.
POPULATION SUBGROUP		TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD		EFFECT OF ANTICIPATED RESIDUES	
		CURRENT TMRC*	NEW TMRC**	DIFFERENCE AS PERCENT OF RFD		ARC	%RFD
U.S. POPULATION - 48 STATES		0.001751	0.001832	14.092000	0.626485	0.000864	6.64262
U.S. POPULATION - SPRING SEASON		0.001694	0.001772	13.627146	0.598708	0.000845	6.50112
U.S. POPULATION - SUMMER SEASON		0.001946	0.002033	15.640700	0.670938	0.001072	8.24825
U.S. POPULATION - FALL SEASON		0.001692	0.001772	13.629923	0.613438	0.000768	5.90708
U.S. POPULATION - WINTER SEASON		0.001667	0.001748	13.442631	0.623115	0.000765	5.88583
NORTHEAST REGION		0.001833	0.001907	14.665892	0.564454	0.000911	7.00781
NORTH CENTRAL REGION		0.001763	0.001843	14.178262	0.614669	0.000870	6.69577
SOUTHERN REGION		0.001526	0.001610	12.381200	0.643946	0.000709	5.45259
WESTERN REGION		0.002004	0.002095	16.115246	0.697346	0.001052	8.09225
HISPANICS		0.002114	0.002216	17.042477	0.782600	0.000987	7.59254
NON-HISPANIC WHITES		0.001757	0.001836	14.125954	0.609277	0.000882	6.78478
NON-HISPANIC BLACKS		0.001500	0.001587	12.205815	0.664731	0.000669	5.14918
NON-HISPANIC OTHERS		0.001987	0.002067	15.901431	0.618477	0.000931	7.16515
NURSING INFANTS (< 1 YEAR OLD)		0.002938	0.002996	23.045131	0.444400	0.001970	15.15728
NON-NURSING INFANTS (< 1 YEAR OLD)		0.007406	0.007599	58.451731	1.480131	0.003974	30.57034
FEMALES (13+ YEARS, PREGNANT)		0.001284	0.001344	10.334777	0.456862	0.000681	5.23631
FEMALES 13+ YEARS, NURSING		0.001653	0.001711	13.160715	0.443623	0.000891	6.85472
CHILDREN (1-6 YEARS OLD)		0.003843	0.004061	31.241654	1.679077	0.001688	12.98224
CHILDREN (7-12 YEARS OLD)		0.002548	0.002701	20.776215	1.174815	0.001182	9.08985
MALES (13-19 YEARS OLD)		0.001624	0.001709	13.147354	0.654446	0.000678	5.21876
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.001369	0.001437	11.053277	0.523908	0.000643	4.94400
MALES (20 YEARS AND OLDER)		0.001275	0.001327	10.208308	0.404277	0.000632	4.86311
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.001251	0.001297	9.973931	0.354431	0.000701	5.38934

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

Table 3.

TOLERANCE ASSESSMENT SUMMARY FOR Propiconazole (Banner/Tilt)
 USING ANTICIPATED RESIDUES
 CASWELL #323EE

DATE: 04/08/94

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000782	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	6.016	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000015	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	0.115	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000797	MG/KG/DAY
THE NEW ARC WILL OCCUPY	6.131	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000066	MG/KG/DAY
THIS ARC WILL OCCUPY	0.511	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000864	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	6.643	% OF THE ADI.

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.003782	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	29.090	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000006	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	0.045	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.003788	MG/KG/DAY
THE NEW ARC WILL OCCUPY	29.135	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000187	MG/KG/DAY
THIS ARC WILL OCCUPY	1.435	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.003974	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	30.570	% OF THE ADI.

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.001913	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	14.713	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000004	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	0.028	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.001916	MG/KG/DAY
THE NEW ARC WILL OCCUPY	14.741	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000054	MG/KG/DAY
THIS ARC WILL OCCUPY	0.417	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.001970	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	15.157	% OF THE ADI.