

US EPA ARCHIVE DOCUMENT



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

Caswell

FEB. 8 1995

FEB - 8 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fenbuconazole - Request for First Permanent Food Use on Stone Fruit (Except Plums and Prunes) (PP# 1F3989, Caswell No. 723Q, PC Code 129011)

FROM: Elizabeth A. Doyle, Ph.D., Section Head
Dietary Risk Evaluation Section
Science Analysis Branch / HED (7509C)

E. A. Doyle

TO: Cynthia Giles-Parker/James Stone, PM-22
Fungicide-Herbicide Branch
Registration Division (7505C)

W. Burnam

THRU: William Burnam, Chief
Science Analysis Branch
Health Effects Division (7509C)

Action Requested: Evaluate the effect of production limits on the chronic and oncogenic dietary risks due to the use of fenbuconazole on stone fruit (except plums and prunes).

Background: In a previously conducted DRES analysis (T. Chin to C. Giles-Parker/D. Wilson, Nov. 22, 1994), chronic and oncogenic dietary risk estimates were produced for proposed uses of fenbuconazole on pecans (0.1 ppm), bananas (0.05 ppm) and stone fruits (except plums and prunes) (2.0 ppm). The chronic analysis using the proposed tolerances indicated that the RfD was not exceeded for the general US population or any population subgroup. The oncogenic risk for the three uses combined was 1.04×10^{-5} , which exceeds the 1×10^{-6} oncogenic risk generally considered negligible by the Agency. The stone fruit (except plums and prunes) use alone had an oncogenic risk of 9.97×10^{-6} .

The registrant, Rohm and Haas, proposed pursuing the stone fruit registration only, at this time with the approach of limiting the

[redacted] treat 12.8% of the stone fruit crop, with a three year time-limited tolerance of 2.0 ppm (letter, R. Costlow of Rohm and Haas to D. Stubbs, Dec. 7, 1994).

Chronic Analysis: The chronic dietary risk from stone fruit (except plums and prunes) only was reevaluated using an estimate of 12.8% crop treated as an approximation of the impact of the

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[REDACTED] analysis, and limiting the analysis to stone fruit (except plums and prunes) only, no population subgroup had a %RfD used in excess of 2.5% (Table 2).

Oncogenic Risk: The same assumption of 12.8% crop treated based upon production limits and a q_1^* of 1.65×10^{-2} were used for the assessment of the oncogenic risk from fenbuconazole on stone fruit (except plums and prunes) only. An oncogenic risk of 1.28×10^{-6} was obtained (Table 3).

Table 1

CHEMICAL Fenbuconazole (Fenethanil) Caswell #723Q CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.	STUDY TYPE 2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	EFFECTS Decr body wts (F); incr liver wts with centriobular to midzonal hepatocellular enlargement & vacuolation (M&F).	REFERENCE DOSES PADI UF -->100 OPP RfD= 0.0300000 EPA RfD= 0.0000000	DATA GAPS/COMMENTS Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	STATUS RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

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	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	21 COOKED-NFS	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	22 COOKED-FRESH-BAKED	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	23 COOKED-FRESH-BOILED	1F03995	A 0.100000	0.100000		100.00	0.100000
03008AA	PECANS	62 COOKED-FRESH OR FROZEN-BAKED	1F03995	A 0.100000	0.100000		100.00	0.100000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	1F03989	N 2.000000	2.000000		12.80	0.256000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	1F03989	N 2.000000	2.000000		12.80	0.256000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05004DA	PEACHES-DRIED	21 COOKED-NFS	1F03989	N 2.000000	2.000000		12.80	0.256000
05002AA	BANANAS-FRESH	22 COOKED-FRESH-BAKED	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2F04154	A 0.050000	0.050000		100.00	0.050000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	21 COOKED-NFS	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2F04154	A 0.050000	0.050000		100.00	0.050000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2F04154	A 0.050000	0.050000		100.00	0.050000

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutazone (Fenethanil) Caswell #723q CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.	2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.0300000 EPA RfD= 0.0000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC**	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.000000	0.000616	2.054127	2.054127	0.000089	0.29786
U.S. POPULATION - SPRING SEASON	0.000000	0.000630	2.098630	2.098630	0.000090	0.30154
U.S. POPULATION - SUMMER SEASON	0.000000	0.000961	3.202823	3.202823	0.000134	0.44554
U.S. POPULATION - FALL SEASON	0.000000	0.000427	1.423033	1.423033	0.000065	0.21776
U.S. POPULATION - WINTER SEASON	0.000000	0.000449	1.495480	1.495480	0.000068	0.22706
NORTHEAST REGION	0.000000	0.000646	2.151707	2.151707	0.000093	0.30954
NORTH CENTRAL REGION	0.000000	0.000656	2.187720	2.187720	0.000094	0.31246
SOUTHERN REGION	0.000000	0.000461	1.536520	1.536520	0.000068	0.22729
WESTERN REGION	0.000000	0.000788	2.625653	2.625653	0.000115	0.38329
HISPANICS	0.000000	0.000671	2.238143	2.238143	0.000103	0.34491
NON-HISPANIC WHITES	0.000000	0.000635	2.117107	2.117107	0.000092	0.30605
NON-HISPANIC BLACKS	0.000000	0.000472	1.572533	1.572533	0.000067	0.22274
NON-HISPANIC OTHERS	0.000000	0.000584	1.947640	1.947640	0.000090	0.29873
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.003083	10.277767	10.277767	0.000435	1.44953
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.005216	17.386597	17.386597	0.000715	2.38309
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.000458	1.526680	1.526680	0.000064	0.21458
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.000000	0.000585	1.950250	1.950250	0.000083	0.27799
CHILDREN (7-12 YEARS OLD)	0.000000	0.001444	4.812677	4.812677	0.000217	0.72472
MALES (13-19 YEARS OLD)	0.000000	0.000905	3.017387	3.017387	0.000130	0.43168
FEMALES (13-19 YEARS OLD)	0.000000	0.000397	1.323817	1.323817	0.000058	0.19395
MALES (20 YEARS AND OLDER)	0.000000	0.000398	1.325973	1.325973	0.000057	0.19052
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURSING)	0.000000	0.000357	1.189397	1.189397	0.000052	0.17464
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURSING)	0.000000	0.000433	1.444720	1.444720	0.000062	0.20763

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

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Table 3.

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 01/30/95 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutaconazole (Fenethanil) Cashell #7230 CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.	2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Deer body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF -->100 OPP Rfd= 0.030000 EPA Rfd= 0.000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	Rfd/PR reviewed 04/15/93 Rfd/PR reviewed 04/29/93

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMRC TYPE	TMRC (UG/KG/DAY)	%RFD	ONCO RISK	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	ONCO RISK
06002AA	BANANAS-UNSPECIFIED	0.050	A	0.000165	0.001	0.00000000272	0.05000	0.000165	0.001	0.00000000272
	22 COOKED-FRESH-BAKED									
06002AB	BANANAS-FRESH	0.050	A	0.011202	0.037	0.00000018483	0.05000	0.009888	0.033	0.0000016315
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	31 COOKED-FRESH OR CANNED									
06002DA	BANANAS-DRIED	0.050	A	0.000088	0.000	0.00000000145	0.05000	0.000027	0.000	0.00000000045
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
06016AA	PLANTAINS	0.050	A	0.000082	0.000	0.00000000135	0.05000	0.000000	0.000	0.00000000000
	21 COOKED-NFS									
	23 COOKED-FRESH-BOILED									
	25 COOKED-FRESH-FRIED									
CROP GROUP TOTALS FOR UNSPECIFIED:										
				0.011537	0.038	0.00000019036		0.011536	0.038	0.00000019036
05001AA	APRICOTS-FRESH	2.000	N	0.067379	0.225	0.00000011175	0.25600	0.001463	0.005	0.00000002414
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	31 COOKED-FRESH OR CANNED									
05001DA	APRICOTS-DRIED	2.000	N	0.004848	0.016	0.00000007999	0.25600	0.001992	0.007	0.00000003287
	10 RAW-FRESH OR NFS									
	22 COOKED-FRESH-BAKED									
05002AA	CHERRIES-FRESH	2.000	N	0.064351	0.215	0.00000106179	0.25600	0.005170	0.017	0.00000008531
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	31 COOKED-FRESH OR CANNED									
	62 COOKED-FRESH OR FROZEN-BAKED									
05002DA	CHERRIES-DRIED	2.000	N	0.000008	0.000	0.00000000013	0.25600	0.000526	0.002	0.00000000868
	00 NOT SPECIFIED (NO CONSUMPTION)									
05002JA	CHERRIES-JUICE	2.000	N	0.010224	0.034	0.00000016870	0.25600	0.000094	0.000	0.0000000155
	15 RAW-FRESH OR CANNED									
	21 COOKED-NFS									
05003AA	NECTARINES	2.000	N	0.025932	0.086	0.00000042788	0.25600	0.001888	0.006	0.00000003115
	10 RAW-FRESH OR NFS									
05004AA	PEACHES-FRESH	2.000	N	0.430783	1.436	0.00000010792	0.25600	0.001129	0.004	0.0000001863
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	31 COOKED-FRESH OR CANNED									
	51 COOKED-CANNED									
05004DA	PEACHES-DRIED	2.000	N	0.000694	0.002	0.00000001145	0.25600	0.003211	0.011	0.00000005298
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	31 COOKED-FRESH OR CANNED									
	51 COOKED-CANNED									

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CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbutazone (Fenethanil) Caswell #723q CAS No. 114369-43-6 A.I. CODE: 129011 CFR No.		2yr feeding - rat NOEL= 3.0300 mg/kg 80.00 ppm LEL= 30.6200 mg/kg 800.00 ppm ONCO: Pending	Decr body wts (F); incr liver wts with centrilobular to midzonal hepatocellular enlargement & vacuolation (M&F).	PADI UF -->100 OPP Rfd= 0.030000 EPA Rfd= 0.000000	Developmental tox- rabbit (current study maybe up-graded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	Rfd/PR reviewed 04/15/93 Rfd/PR reviewed 04/29/93

COMMODITY CONTRIBUTION BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMRC TYPE (UG/KG/DAY)	ANTICIPATED RESIDUE (PPM)		TMRC ONCO RISK	%RFD	ARC (UG/KG/DAY)	%RFD	ARC ONCO RISK
				RESIDUE (PPM)	ARC (UG/KG/DAY)					
CROP GROUP TOTALS FOR STONE FRUITS:										
03008AA	PECANS	0.100	A	0.000482	0.000000	0.000000996961	0.000	0.000042	0.000	0.00000000069
	10 RAW-FRESH OR NFS									
	21 COOKED-NFS									
	22 COOKED-FRESH-BAKED									
	23 COOKED-FRESH-BOILED									
	62 COOKED-FRESH OR FROZEN-BAKED									
CROP GROUP TOTALS FOR TREE NUTS:										
		0.000482		0.000482	0.00000000795	0.002	0.002	0.000483	0.002	0.00000000797

GRAND TOTALS FOR U.S. POPULATION - 48 STATES

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED
 TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION
 ARC = ANTICIPATED RESIDUE CONTRIBUTION
 RFD = REFERENCE DOSE

0.616238	2.054	0.00001016793	0.089357	0.298	0.00000147439
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