11-22-94

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

NOV 22 1994

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New Chemical/First Permanent Food Use: Carcinogenic and Chronic Dietary Risk Analysis for the Proposed Use of Fenbuconazole (Fenethanil) a.k.a Indar™ 2F and Indar™ 75 WSP in or on Pecans [PP# 1F3995] and Stone Fruit (Except Plums and Prunes) [PP# 1F3989]. {PC Code 129011; CAS No. 114369-43-6; Caswell # 723Q}

FROM: Teung F. Chin, Ph.D., Biologist
Dietary Risk Evaluation Section
Science Analysis Branch/ HED

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

THROUGH: Elizabeth Doyle, Ph.D., Acting Section Head
DRES/SAB
Health Effects Division

Action Requested

The Fungicide-Herbicide Branch has requested that a Dietary Risk Evaluation System (DRES) analysis be performed assessing the chronic dietary and carcinogenic risks resulting from proposed use of the herbicide fenbuconazole ((ANSI/ISO) or RH-7 592 [alpha-(2-(4-chlorophenyl)-ethyl)-alpha-phenyl-3-(1H-1,2,4-triazole)-1-propanenitrile] and its metabolites RH-9129 and RH-9130, at a tolerance of 2.0 ppm on stone fruits (except plums and prunes) (Undated CBTS memo: N. Dodd to C. Giles-Parker and A. Kocialski). Rohm and Haas Company, Philadelphia, PA filed the petition for permanent tolerance (PP# 1F3989), amended 5/17/94, to which CBTS has no objections to granting a time-limited tolerance providing certain Section B revisions are enacted and with the requirement that storage stability data for a 49 month period is levied.

Rohm and Haas Company furthermore filed a petition for permanent tolerance (PP# 1F3995), amended 5/3/94, for fenbuconazole technical on pecans at 0.1 ppm (10/25/94 CBTS memo: N. Dodd to C. Giles-Parker and A. Kocialski) to which CBTS tentatively recommends subject to specific labeling changes and stated revisions to the method of validation.

Discussion

1. Toxicological Information: For chronic toxicity, the reference dose (RfD) (rats, strain not indicated) was 0.03 mg/kg/day, based on body weight decrease in females and increased liver weights with centrilobular to midzonal hepatocellular enlargement and vacuolization in males and females. An uncertainty factor of 100 was used for the inter-species extrapolation and intra-species variability (4/25/94 TB2 memo; M. Van Gamert to J. Kariya et al. and 7/7/93 RfD/QA Peer Review Memo; G. Z. Ghali to C. Giles-Parker).

No acute dietary risk assessment was necessary (4/25/94 TB2 memo; M. Van Gamert to J. Kariya et al.).

The chemical was classified as a Group C carcinogen (possible human carcinogen) (4/25/94 TB2 memo; M. Van Gamert to J. Kariya et. al.). The unit risk, Q_1^* $(mg/kg/day)^{-1}$ of fenbuconazole, based upon male rat (Sprague-Dawley) thyroid follicular cell (adenomas and/or carcinomas) tumor rates, is $1.65X10^{-2}$ $(mg/kg/day)^{-1}$ in human equivalents (2/7/94 SAB memo; H. M. Pettigrew to S. Williams).

2. Residue Information: Apricots, cherries, nectarines, peaches, and pecans were the food uses evaluated in this analysis. Since this is a new chemical, there are no tolerances listed in §186 for meat, milk, poultry and eggs covering possible secondary residues resulting from feed additives and no § 185 tolerances, resulting its from use as a food additive. A new tolerance, set at 2.0 ppm was incorporated into the DRES for the following foods: apricots - fresh, apricots - dried, cherries - dried, cherries - juice, nectarines, peaches - fresh, and peaches - dried. Pecans were assessed at 0.1 ppm. A summary of the residues used in the chronic exposure analysis is attached as Table 1.

Exposures being calculated in this analysis are from fenbuconazole (RH-7592) and its metabolites RH-9129 and RH-9130, expressed as parent equivalent residues (8/1/94 and 8/8/94 CBTS memos W.D. Wassell to C. Giles-Parker and A. Kocialski).

No processing studies were mentioned in the CBTS memos.

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i. Percent Crop Treated - No percent crop treated information was utilized for the carcincogenic risk assessment 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 stone fruits (except plums and prunes) and pecans were treated with fenbuconazole.

ii. Anticipated Residues (AR) - No anticipated residues (AR) were utilized for the carcinogenic risk assessment and chronic exposure analyses. None would be available since this is a new chemical/new use pattern.

Discussion of Results

1. Chronic Exposure

The DRES chronic exposure analysis used tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Because fenbuconazole 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 as 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 2. It should be noted again that the residue of interest in this analysis is the parent compound (RH7592) and the two metabolites, RH-9129 and RH-9130.

Stone Fruits (Except Plums and Prunes)

The TMRC from the proposed new use of fenbuconazole on stone fruits (except plums and prunes) for the general population of the 48 states is 6.04×10^{-4} mg/kg bwt/day which represents 2% of the RfD. The TMRC for non-nursing infants (< 1 year old) is 5.16×10^{-3} mg/kg bwt/day, accounting for 17% of the RfD for that population sub-group. The calculated exposure for children (1-6 years old), is 1.41×10^{-3} mg/kg bwt/day, accounting for less than 5% of the RfD for this population sub-group.

Pecans

The TMRC from the proposed new use of fenbuconazole on pecans for the general population of the 48 states is 9.64×10^{-7} mg/kg bwt/day which represents less than 1% of the RfD. The calculated TMRC for non-nursing infants (< 1 year old), is 7.2×10^{-8} mg/kg bwt/day accounting for less than 1% of the RfD. The TMRC for children (1-6 years old), is, 1.65×10^{-6} mg/kg bwt/day, accounting for less than 1% of the RfD.

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Summary of Chronic Dietary Risk for Use on Stone Fruits (Except Plums and Prunes) and Pecans

The total TMRC for all new uses, bananas, stone fruits (except plums and prunes), and pecans (there are no published or accepted tolerances at this time) is 6.28×10^{-4} mg/kg bwt/day or about 2% of the RfD for the general population. The TMRC for nursing infants (< 1 year old), non-nursing infants (< 1 year old), and children (1-6 years old), is, respectively, 3.13×10^{-3}, 5.27×10^{-3}, and 1.48×10^{-3} mg/kg bwt/day, accounting for 10%, 17%, and 5% of the RfD, respectively.

Therefore, minimal risk is expected from chronic dietary intake of fenbuconazole since the RfD is not exceeded for either the general population or any subgroup.

2. Carcinogenic Risk

Upper bound cancer risk from the proposed use of fenbuconazole on stone fruits (except plums and prunes), and pecans exceeds the de minimis value of 10^{-6} that the Agency generally considers negligible. Table 3 provides the total oncogenic risk from each commodity for the entire U. S. Population (48 states).

An oncogenic risk value of 9.97×10^{-6} was derived for stone fruits (except plums and prunes). A oncogenic risk value of 1.6×10^{-8} was derived for pecans. The total oncogenic risk, for bananas, stone fruits (except plums and prunes), and pecans, is 1.04×10^{-5}.

Attachments

cc: DRES, FHB, CCB, Tox 2, CBTS, Caswell # 723Q

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TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 723Q DATE: 11/21/94 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
03008AA	PECANS	1F3995	0.100000		
03008AA	PECANS	1F3005	0.100000		
05001AA	APRICOTS-FRESH	1F03989	2.000000		
05001DA	APRICOTS-DRIED	1F03989	2.000000		
05002AA	CHERRIES-FRESH	1F03989	2.000000		
05002DA	CHERRIES-DRIED	1F03989	2.000000		
05002JA	CHERRIES-JUICE	1F03989	2.000000		
05003AA	NECTARINES	1F03989	2.000000		
05004AA	PEACHES-FRESH	1F03989	2.000000		
05004DA	PEACHES-DRIED	1F03989	2.000000		
06002AA	BANANAS-UNSPECIFIED	2F04154	0.050000		
06002AA	BANANAS-UNSPECIFIED	2F4154	0.050000		
06002AB	BANANAS-FRESH	2F04154	0.050000		
06002AB	BANANAS-FRESH	2F4154	0.050000		
06002DA	BANANAS-DRIED	2F04154	0.050000		
06002DA	BANANAS-DRIED	2F4154	0.050000		
06016AA	PLANTAINS	2F4154	0.050000		
06106AA	PLANTAINS	2f04154	0.050000		

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 11/18/94 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) 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) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000000	0.000628	2.093917	2.093917		
U.S. POPULATION - SPRING SEASON	0.000000	0.000641	2.136063	2.136063		
U.S. POPULATION - SUMMER SEASON	0.000000	0.000973	3.243323	3.243323		
U.S. POPULATION - FALL SEASON	0.000000	0.000439	1.463767	1.463767		
U.S. POPULATION - WINTER SEASON	0.000000	0.000461	1.535977	1.535977		
NORTHEAST REGION	0.000000	0.000657	2.190023	2.190023		
NORTH CENTRAL REGION	0.000000	0.000667	2.224640	2.224640		
SOUTHERN REGION	0.000000	0.000471	1.571630	1.571630		
WESTERN REGION	0.000000	0.000804	2.679783	2.679783		
HISPANICS	0.000000	0.000691	2.302503	2.302503		
NON-HISPANIC WHITES	0.000000	0.000647	2.157210	2.157210		
NON-HISPANIC BLACKS	0.000000	0.000479	1.597047	1.597047		
NON-HISPANIC OTHERS	0.000000	0.000601	2.001947	2.001947		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.003129	10.431400	10.431400		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.005270	17.567343	17.567343		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.000464	1.548110	1.548110		
FEMALES 13+ YEARS, NURSING	0.000000	0.000592	1.973973	1.973973		
CHILDREN (1-6 YEARS OLD)	0.000000	0.001481	4.936963	4.936963		
CHILDREN (7-12 YEARS OLD)	0.000000	0.000921	3.069367	3.069367		
MALES (13-19 YEARS OLD)	0.000000	0.000406	1.351880	1.351880		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.000405	1.349790	1.349790		
MALES (20 YEARS AND OLDER)	0.000000	0.000364	1.214870	1.214870		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.000441	1.470417	1.470417		

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

TABLE 2 (Continued)

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 11/18/94 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RFD
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000165	0.0005
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000165	0.0005
06002AB	BANANAS-FRESH	0.05000					0.011202	0.0373
06002AB	BANANAS-FRESH	0.05000					0.011202	0.0373
06002DA	BANANAS-DRIED	0.05000					0.000088	0.0002
06002DA	BANANAS-DRIED	0.05000					0.000088	0.0002
06016AA	PLANTAINS	0.05000					0.000082	0.0002
06106AA	PLANTAINS	0.05000					0.000000	0.0000
CROP GROUP TOTALS FOR UNSPECIFIED:							0.022992	0.0766
GRAND TOTAL TMRC: 0.022992 GRAND TOTAL % OF THE RfD: 0.0766								
05001AA	APRICOTS-FRESH	2.00000					0.067379	0.2245
05001DA	APRICOTS-DRIED	2.00000					0.004848	0.0161
05002AA	CHERRIES-FRESH	2.00000					0.064351	0.2145
05002DA	CHERRIES-DRIED	2.00000					0.000008	0.0000
05002JA	CHERRIES-JUICE	2.00000					0.010224	0.0340
05003AA	NECTARINES	2.00000					0.025932	0.0864
05004AA	PEACHES-FRESH	2.00000					0.430783	1.4359
05004DA	PEACHES-DRIED	2.00000					0.000694	0.0023
CROP GROUP TOTALS FOR STONE FRUITS:							0.604219	2.0141
GRAND TOTAL TMRC: 0.604219 GRAND TOTAL % OF THE RfD: 2.0141								
03008AA	PECANS	0.10000					0.000482	0.0016
03008AA	PECANS	0.10000					0.000482	0.0016
CROP GROUP TOTALS FOR TREE NUTS:							0.000964	0.0032
GRAND TOTAL TMRC: 0.000964 GRAND TOTAL % OF THE RfD: 0.0032								
POPULATION SUBGROUP TOTALS					0.000000	0.0000	0.628175	2.0939
POPULATION TOTAL TMRC 0.628175 POPULATION TOTAL % OF THE RfD 2.0939								

Table 2 (Continued)

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

LISTING OF EXPOSURE BY RAC FOR: NON-NURSING INFANTS (<1 YEAR OLD)

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RFD
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000203	0.0006
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000203	0.0006
06002AB	BANANAS-FRESH	0.05000					0.050552	0.1685
06002AB	BANANAS-FRESH	0.05000					0.050552	0.1685
06002DA	BANANAS-DRIED	0.05000					0.003433	0.0114
06002DA	BANANAS-DRIED	0.05000					0.003433	0.0114
06016AA	PLANTAINS	0.05000					0.000000	0.0000
06106AA	PLANTAINS	0.05000					0.000000	0.0000
CROP GROUP TOTALS FOR UNSPECIFIED:							0.108376	0.3613
GRAND TOTAL TMRC: 0.108376 GRAND TOTAL % OF THE RfD: 0.3613								
05001AA	APRICOTS-FRESH	2.00000					0.770715	2.5690
05001DA	APRICOTS-DRIED	2.00000					0.000000	0.0000
05002AA	CHERRIES-FRESH	2.00000					0.138929	0.4630
05002DA	CHERRIES-DRIED	2.00000					0.000000	0.0000
05002JA	CHERRIES-JUICE	2.00000					0.078633	0.2621
05003AA	NECTARINES	2.00000					0.000000	0.0000
05004AA	PEACHES-FRESH	2.00000					4.173478	13.9115
05004DA	PEACHES-DRIED	2.00000					0.000000	0.0000
CROP GROUP TOTALS FOR STONE FRUITS:							5.161755	17.2059
GRAND TOTAL TMRC: 5.161755 GRAND TOTAL % OF THE RfD: 17.2059								
03008AA	PECANS	0.10000					0.000036	0.0001
03008AA	PECANS	0.10000					0.000036	0.0001
CROP GROUP TOTALS FOR TREE NUTS:							0.000072	0.0002
GRAND TOTAL TMRC: 0.000072 GRAND TOTAL % OF THE RfD: 0.0002								
POPULATION SUBGROUP TOTALS					0.000000	0.0000	5.270203	17.5673
POPULATION TOTAL TMRC 5.270203 POPULATION TOTAL % OF THE RfD 17.5673								

TABLE 2 (Continued)

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

LISTING OF EXPOSURE BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RFD
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000405	0.0013
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000405	0.0013
06002AB	BANANAS-FRESH	0.05000					0.035833	0.1194
06002AB	BANANAS-FRESH	0.05000					0.035833	0.1194
06002DA	BANANAS-DRIED	0.05000					0.000225	0.0007
06002DA	BANANAS-DRIED	0.05000					0.000225	0.0007
06016AA	PLANTAINS	0.05000					0.000109	0.0003
06016AA	PLANTAINS	0.05000					0.000000	0.0000
	CROP GROUP TOTALS FOR UNSPECIFIED:						0.073035	0.2435
	GRAND TOTAL TMRC: 0.073035 GRAND TOTAL % OF THE RfD: 0.2435							
05001AA	APRICOTS-FRESH	2.00000					0.202319	0.6743
05001DA	APRICOTS-DRIED	2.00000					0.011432	0.0381
05002AA	CHERRIES-FRESH	2.00000					0.167883	0.5596
05002DA	CHERRIES-DRIED	2.00000					0.000000	0.0000
05002JA	CHERRIES-JUICE	2.00000					0.044175	0.1472
05003AA	NECTARINES	2.00000					0.035319	0.1177
05004AA	PEACHES-FRESH	2.00000					0.945280	3.1509
05004DA	PEACHES-DRIED	2.00000					0.000000	0.0000
	CROP GROUP TOTALS FOR STONE FRUITS:						1.406408	4.6880
	GRAND TOTAL TMRC: 1.406408 GRAND TOTAL % OF THE RfD: 4.6880							
03008AA	PECANS	0.10000					0.000823	0.0027
03008AA	PECANS	0.10000					0.000823	0.0027
	CROP GROUP TOTALS FOR TREE NUTS:						0.001646	0.0055
	GRAND TOTAL TMRC: 0.001646 GRAND TOTAL % OF THE RfD: 0.0055							
	POPULATION SUBGROUP TOTALS				0.000000	0.0000	1.481089	4.9369
	POPULATION TOTAL TMRC 1.481089 POPULATION TOTAL % OF THE RfD 4.9369							

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TABLE 3 - Oncogenic Risk

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 11/18/94 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Fenbuconazole (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 enlargment & vacuolation (M&F).	PADI UF -->100 OPP RfD= 0.030000 EPA RfD= 0.000000	Developmental tox- rabbit (current study maybe upgraded) Chemical was referred to HED Carcinogenicity Peer Review Committee.	RfD/PR reviewed 04/15/93 RfD/PR reviewed 04/29/93

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RFD	TOTAL ONCOGENIC RISK
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000165	0.0005	0.000000003
06002AA	BANANAS-UNSPECIFIED	0.05000					0.000165	0.0005	0.000000003
06002AB	BANANAS-FRESH	0.05000					0.011202	0.0373	0.000000185
06002AB	BANANAS-FRESH	0.05000					0.011202	0.0373	0.000000185
06002DA	BANANAS-DRIED	0.05000					0.000088	0.0002	0.000000001
06002DA	BANANAS-DRIED	0.05000					0.000088	0.0002	0.000000001
06016AA	PLANTAINS	0.05000					0.000082	0.0002	0.000000001
06106AA	PLANTAINS	0.05000					0.000000	0.0000	0.000000000
CROP GROUP TOTALS FOR UNSPECIFIED:							0.022992	0.0766	0.000000379
GRAND-TOTAL TMRC: 0.022992 GRAND TOTAL % OF THE RfD: 0.0766									
05001AA	APRICOTS-FRESH	2.00000					0.067379	0.2245	0.000001112
05001DA	APRICOTS-DRIED	2.00000					0.004848	0.0161	0.000000080
05002AA	CHERRIES-FRESH	2.00000					0.064351	0.2145	0.000001062
05002DA	CHERRIES-DRIED	2.00000					0.000008	0.0000	0.000000000
05002JA	CHERRIES-JUICE	2.00000					0.010224	0.0340	0.000000169
05003AA	NECTARINES	2.00000					0.025932	0.0864	0.000000428
05004AA	PEACHES-FRESH	2.00000					0.430783	1.4359	0.000007108
05004DA	PEACHES-DRIED	2.00000					0.000694	0.0023	0.000000011
CROP GROUP TOTALS FOR STONE FRUITS:							0.604219	2.0141	0.000009970
GRAND TOTAL TMRC: 0.604219 GRAND TOTAL % OF THE RfD: 2.0141									
03008AA	PECANS	0.10000					0.000482	0.0016	0.000000008
03008AA	PECANS	0.10000					0.000482	0.0016	0.000000008
CROP GROUP TOTALS FOR TREE NUTS:							0.000964	0.0032	0.000000016
GRAND TOTAL TMRC: 0.000964 GRAND TOTAL % OF THE RfD: 0.0032									
POPULATION SUBGROUP TOTALS					0.000000	0.0000	0.628175	2.0939	0.000010364
POPULATION TOTAL TMRC 0.628175 POPULATION TOTAL % OF THE RfD 2.0939									

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