

US EPA ARCHIVE DOCUMENT



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

JUL 15 1988

7-15-88 KF

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#6F3419. Bayleton in or on Rotational Crops: TAS
Dietary Exposure Analysis.

FROM: Susan L. Stanton
Tolerance Assessment Program *Susan L. Stanton 07/15/88*
HED/RCB (TS-769C)

THRU: Karl Arne, Ph.D. *K.A.*
Branch Senior Scientist
HED/RCB (TS-769C)

TO: Lois Rossi, PM 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

Action Requested

Provide TAS estimates of dietary exposure to the fungicide bayleton from establishment of proposed rotational crop tolerances on the following raw agricultural commodities: Legume vegetables, corn, cottonseed, lettuce, potatoes, and sorghum.

RCB has reviewed the petition and, TOX and EAB considerations permitting, recommends that the proposed tolerances be established (memo. Chin to Rossi, 06/21/88).

Discussion

1. A routine chronic exposure analysis was conducted using a Reference Dose (ADI) of 0.025 mg/kg body weight/day based on a NOEL of 2.5 mg/kg/day from a 2-year rat feeding study with a safety factor of 100. This value has been approved by the Tox Branch ADI Committee (02/21/86) and verified by the Agency reference dose committee (03/11/86).

2. The food uses evaluated were those established under 40 CFR 180.410 and 21 CFR 193.83, the proposed rotational crop tolerances, and proposed uses on the following commodities: strawberries (4F3124), mangoes (5E3168), coffee beans (3F2938), hops (7E3497), tomatoes (4F3148, 4H5443), and sugar (4H5433). Table 1 provides a complete listing of residues used in the analysis.

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3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case).

The TMRC from all established and proposed food uses (including the current action on rotational crops) for the overall U.S. Population was calculated to be 0.007390 mg/kg body weight/day, which occupies approximately 30% of the ADI. The two most highly exposed population subgroups were non-nursing infants (TMRC = 0.029946 mg/kg/day or 120% of the ADI) and children, 1-6 years (TMRC = 0.016507 or 66% of the ADI). The effect of the current action (PP#6F3419; rotational crop tolerances) on exposure is shown below:

	<u>Established Tolerances</u>	<u>Current Action (Rot. Crops)</u>	<u>Other Proposed Uses</u>	<u>Total Exposure</u>
U.S. Population	0.006561 ^a (26.2%) ^b	0.000133 (0.5%)	0.000696 (2.8%)	0.007390 (29.6%)
Infants (Non-Nurs)	0.029420 (117.7%)	0.000280 (1.1%)	0.000245 (1.0%)	0.029946 (119.8%)
Children, 1-6 yrs.	0.015519 (62.1%)	0.000267 (1.1%)	0.000721 (2.9%)	0.016507 (66.0%)

^aTMRC expressed as mg/kg body wt/day.

^bTMRC as a percent of the ADI.

4. These exposure estimates are based on the assumption that residues would be present at tolerance levels on foods as eaten and that 100% of crops would be treated with bayleton, a conservative approach that may overestimate exposure significantly. Actual exposure to bayleton would likely be somewhat lower. analysis.

CC: Stanton (RCB), Chin (RCB), TAS File, PP#6F3419, Bayleton SF, TOX, Circulation (7), RF, PMSD.

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 862AA DATE: 07/15/88 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->100		
Bayleton (Triadimeform)	2yr feeding- rat	Decreased body weight, decreased red cell count, hemoglobin.			No data gaps.	TOX complete 2/21/86.
Caswell #862AA	NOEL= 2.5000 mg/kg		OPP RFD= 0.025000			EPA verified 3/11/86.
CAS No. 43121-43-3	50.00 ppm		EPA RFD= 0.025000			WHO last reviewed 1984.
A.I. CODE: 109901	LEL= 25.0000 mg/kg	No evidence of oncogenic effects in rats or mice.				
CFR No. 180.410	500.00 ppm					
	ONCO: Negative- 2 species					On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
01006AA	RASPBERRIES	4E3088			2.000000
01014AA	GRAPES-FRESH	1F2474			1.000000
01014DA	GRAPES-RAISINS	1F2474			1.000000
01014JA	GRAPES-JUICE	1F2474			1.000000
01016AA	STRAWBERRIES	4F3124		0.300000	
03001AA	ALMONDS	3F2837			0.050000
04001AA	APPLES-FRESH	1F2474			1.000000
04001DA	APPLES-DRIED	1F2474			1.000000
04001JA	APPLES-JUICE	1F2474			1.000000
04003AA	PEARS-FRESH	1F2474			1.000000
04003DA	PEARS-DRIED	1F2474			1.000000
05001AA	APRICOTS-FRESH	3F2887			4.000000
05001DA	APRICOTS-DRIED	3F2887			4.000000
05003AA	NECTARINES	3F2887			4.000000
05004AA	PEACHES-FRESH	3F2887			4.000000
05004DA	PEACHES-DRIED	3F2887			4.000000
05005AA	PLUMS(DAMSONS)-FRESH	3F2887			4.000000
05005DA	PLUMS-PRUNES(DRIED)	3F2887			4.000000
05005JA	PLUMS, PRUNE-JUICE	3F2887			4.000000
06007AA	MANGOES	5E3168		0.070000	
06013AA	PINEAPPLE-FRESH, PULP	2F2688			3.000000
06013DA	PINEAPPLE-DRIED	2F2688			3.000000
06013JA	PINEAPPLE-FRESH, JUICE	2F2688			3.000000
07002AA	COFFEE	3F2938		0.050000	
08020AA	HOPS	7E3497		15.000000	
10002AA	CANTALOUPE-UNSPECIFIED				0.300000
10002AB	CANTALOUPE-PULP				0.300000
10003AA	CASABAS				0.300000
10004AA	CRENSHAW				0.300000
10005AA	HONEYDEW MELONS				0.300000
10007AA	PERSION MELONS				0.300000
10008AA	WATERMELON				0.300000
10010AA	CUCUMBERS				0.300000
10011AA	PUMPKIN				0.300000
10013AA	SQUASH-SUMMER				0.300000
10014AA	SQUASH-WINTER				0.300000
10017AA	BITTER MELON				0.300000
10020AA	TOMELGOURD				0.300000
11005AA	TOMATOES-WHOLE			0.200000	
11005JA	TOMATOES-JUICE			0.200000	

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Table 1 (con't.)

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF		
Bayleton (Triadimeform)	2yr feeding- rat	Decreased body weight,	ADI	SF -->100	No data gaps.	TOX complete 2/21/86.
Caswell #862AA	NOEL= 2.5000 mg/kg	decreased red cell count,	OPP RfD= 0.025000			EPA verified 3/11/86.
CAS No. 43121-43-3	50.00 ppm	hemoglobin.	EPA RfD= 0.025000			WHO last reviewed 1984.
A.I. CODE: 109901	LEL= 25.0000 mg/kg	No evidence of oncogenic				
CFR No. 180.410	500.00 ppm	effects in rats or mice.				
	ONCO: Negative- 2 species					

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
11005RA	TOMATOES-PURÉE	4F3148	0.200000	
11005TA	TOMATOES-PASTE	4H5443	1.000000	H
11005UA	TOMATOES-CATSUP	4H5443	1.000000	H
13013AA	LETTUCE-LEAFY VARIETIES	6F3419	0.010000	
13020AA	LETTUCE-UNSPECIFIED	6F3419	0.010000	
13045AA	LETTUCE-HEAD VARIETIES	6F3419	0.010000	
14013AA	POTATOES(WHITE)-WHOLE	6F3419	0.050000	
14013AB	POTATOES(WHITE)-UNSPECIFIED	6F3419	0.050000	
14013AC	POTATOES(WHITE)-PEELED	6F3419	0.050000	
14013DA	POTATOES(WHITE)-DRY	6F3419	0.050000	
14013HA	POTATOES(WHITE)-PEEL ONLY	6F3419	0.050000	
15001AA	BEANS-DRY-GREAT NORTHERN	6F3419	0.050000	
15001AB	BEANS-DRY-KIDNEY	6F3419	0.050000	
15001AC	BEANS-DRY-LIMA	6F3419	0.050000	
15001AD	BEANS-DRY-NAVY (PEA)	6F3419	0.050000	
15001AE	BEANS-DRY-OTHER	6F3419	0.050000	
15001AF	BEANS-DRY-PINTO	6F3419	0.050000	
15002AA	BEANS-SUCCULENT-LIMA	6F3419	0.050000	
15003AA	BEANS-SUCCULENT-GREEN	6F3419	0.050000	
15003AB	BEANS-SUCCULENT-OTHER	6F3419	0.050000	
15003AC	BEANS-SUCCULENT-YELLOW, MAX	6F3419	0.050000	
15005AA	CORN, SWEET	6F3419	0.100000	
15007AA	PEAS(GARDEN)-MATURE SEEDS, DRY	6F3419	0.050000	
15009AA	PEAS(GARDEN)-GREEN IMMATURE	6F3419	0.050000	
15011AA	LENTILES-WHOLE	6F3419	0.050000	
15011AB	LENTILES-SPLIT	6F3419	0.050000	
15013AA	MUNG BEANS (SPROUTS)	6F3419	0.050000	
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	6F3419	0.050000	
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	6F3419	0.050000	
15023AA	BEANS-DRY-PIGEON BEANS	6F3419	0.050000	
15027AA	BEANS-UNSPECIFIED	6F3419	0.050000	
15029AA	SOYBEANS-SPROUTED SEEDS	6F3419	0.050000	
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	6F3419	0.050000	
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	6F3419	0.050000	
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)	6F3419	0.050000	
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	1E2459	0.050000	
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	6F3419	0.100000	
24001AA	BARLEY	2F2665	0.050000	
24002EA	CORN, GRAIN-ENDOSPERM	6F3419	1.000000	
24002HA	CORN, GRAIN-BRAN	6F3419	0.010000	

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FOOD CODE	FOOD NAME	STUDY TYPE	EFFECTS	REFERENCE DOSES			DATA GAPS/COMMENTS	STATUS
				ADI	SF	OPR RfD		
24002SA	CORN SUGAR	2yr feeding- rat	Decreased body weight,					
24006AA	SORGHUM (INCLUDING MILO)	NOEL= 2.5000 mg/kg	decreased red cell count,	0.010000				TOX complete 2/21/86.
24007AA	WHEAT-ROUGH	50.00 ppm	hemoglobin.	0.010000				EPA verified 3/11/86.
24007GA	WHEAT-GERM	LEL= 25.0000 mg/kg	No evidence of oncogenic					WHO last reviewed 1984.
24007HA	WHEAT-BRAN	500.00 ppm	effects in rats or mice.					
24007WA	WHEAT-FLOUR	ONCO: Negative- 2 species						
25002SA	BEET SUGAR							
25003SA	CANE SUGAR							
25003SB	SUGAR-MOLASSES			0.050000				
26011AA	GUAR BEANS			0.100000				
27001OA	CASTOR BEANS							
27002OA	CORN, GRAIN-OIL							
27003OA	COTTONSEED-OIL							
27003WA	COTTONSEED-MEAL							
27010OA	SOYBEANS-OIL							
28023AA	SOYBEANS-UNSPECIFIED							
28023AB	SOYBEANS-NATURE, SEEDS DRY							
28023WA	SOYBEANS-FLOUR, FULL FAT							
28023WB	SOYBEANS-FLOUR, LOW FAT							
28023WC	SOYBEANS-FLOUR, DEFATTED							
50000DB	MILK-NON-FAT SOLIDS							
50000FA	MILK-FAT SOLIDS							
50000SA	MILK SUGAR (LACTOSE)							
53001BA	BEEF-MEAT BYPRODUCTS							
53001BB	BEEF (ORGAN MEATS)-OTHER							
53001DA	BEEF-DRIED							
53001FA	BEEF (BONELESS)-FAT (BEEF TALLOW)							
53001KA	BEEF (ORGAN MEATS)-KIDNEY							
53001LA	BEEF (ORGAN MEATS)-LIVER							
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVABLE FAT)							
53002BA	GOAT-MEAT BYPRODUCTS							
53002BB	GOAT (ORGAN MEATS)-OTHER							
53002FA	GOAT (BONELESS)-FAT							
53002KA	GOAT (ORGAN MEATS)-KIDNEY							
53002LA	GOAT (ORGAN MEATS)-LIVER							
53002MA	GOAT (BONELESS)-LEAN (W/O REMOVABLE FAT)							
53003AA	HORSE							
53005BA	SHEEP-MEAT BYPRODUCTS							
53005BB	SHEEP (ORGAN MEATS)-OTHER							
53005FA	SHEEP (BONELESS)-FAT							

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Table 1 (con't.)

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF		
Bayleton (Triadimeform) Caswell #862AA CAS No. 43121-43-3 A.I. CODE: 109901 CFR No. 180.410	2yr feeding- rat NOEL= 2.5000 mg/kg 50.00 ppm LEL= 25.0000 mg/kg 500.00 ppm ONCO: Negative- 2 species	Decreased body weight, decreased red cell count, hemoglobin. No evidence of oncogenic effects in rats or mice.	--	100	No data gaps.	TOX complete 2/21/86. EPA verified 3/11/86. WHO last reviewed 1984.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		PUBLISHED
			NEW	PENDING	
53005KA	SHEEP (ORGAN MEATS)-KIDNEY	2F2665			1.000000
53005LA	SHEEP (ORGAN MEATS)-LIVER	2F2665			1.000000
53005MA	SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT)	2F2665			1.000000
53006BA	PORK-MEAT BYPRODUCTS	2F2665			0.040000
53006BB	PORK (ORGAN MEATS)-OTHEP	2F2665			0.040000
53006FA	PORK (BONELESS)-FAT (INCLUDING LARD)	2F2665			0.040000
53006KA	PORK (ORGAN MEATS)-KIDNEY	2F2665			0.040000
53006LA	PORK (ORGAN MEATS)-LIVER	2F2665			0.040000
53006MA	PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT)	2F2665			0.040000
55008BA	TURKEY-BYPRODUCTS	2F2665			0.040000
55008LA	TURKEY-GIBLETS (LIVER)	2F2665			0.040000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	2F2665			0.040000
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	2F2665			0.040000
55008MC	TURKEY-UNSPECIFIED	2F2665			0.040000
55013BA	POULTRY, OTHER-BYPRODUCTS	2F2665			0.040000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	2F2665			0.040000
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	2F2665			0.040000
55014AA	EGGS-WHOLE	2F2665			0.040000
55014AB	EGGS-WHITE ONLY	2F2665			0.040000
55014AC	EGGS-YOLK ONLY	2F2665			0.040000
55015BA	CHICKEN-BYPRODUCTS	2F2665			0.040000
55015LA	CHICKEN-GIBLETS(LIVER)	2F2665			0.040000
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	2F2665			0.040000
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	2F2665			0.040000

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 07/15/98

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->100		
Bayleton (Triadimeform)	2yr feeding- rat	Decreased body weight,			No data gaps.	TOX complete 2/21/86.
Caswell #862AA	NOEL= 2.5000 mg/kg	decreased red cell count,	OPP RfD= 0.025000			EPA verified 3/11/86.
CAS No. 43121-43-3	50.00 ppm	hemoglobin.	EPA RfD= 0.025000			WHO last reviewed 1984.
A.I. CODE: 109901	LEL= 25.0000 mg/kg	No evidence of oncogenic				
CFR No. 180.410	500.00 ppm	effects in rats or mice.				
	ONCO: Negative- 2 species					On IRIS.

TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

POPULATION SUBGROUP	NEW TMRC**		DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**		ARC	%RFD
U.S. POPULATION - 48 STATES	0.006561	0.007390	29.560972	3.315280	
U.S. POPULATION - SPRING SEASON	0.006209	0.007063	28.250680	3.415152	
U.S. POPULATION - SUMMER SEASON	0.007308	0.008172	32.686264	3.456248	
U.S. POPULATION - FALL SEASON	0.006420	0.007225	28.900412	3.222308	
U.S. POPULATION - WINTER SEASON	0.006314	0.007104	28.417748	3.163540	
NORTHEAST REGION	0.007069	0.008020	32.078252	3.802824	
NORTH CENTRAL REGION	0.006598	0.007427	29.706536	3.315816	
SOUTHERN REGION	0.005654	0.006344	25.376912	2.760808	
WESTERN REGION	0.007399	0.008303	33.210452	3.613688	
HISPANICS	0.007181	0.008016	32.062996	3.337296	
NON-HISPANIC WHITES	0.006711	0.007583	30.333148	3.489572	
NON-HISPANIC BLACKS	0.005299	0.005855	23.421904	2.224800	
NON-HISPANIC OTHERS	0.006600	0.007313	29.250936	2.849468	
NURSING INFANTS (< 1 YEAR OLD)	0.016545	0.016699	66.795076	0.614084	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.029420	0.029946	119.783176	2.101316	
FEMALES (13+ YEARS, PREGNANT)	0.004784	0.005220	20.878312	1.742884	
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.005492	0.006106	24.424588	2.456116	
CHILDREN (7-12 YEARS OLD)	0.015519	0.016507	66.029148	3.953844	
MALES (13-19 YEARS OLD)	0.009580	0.010347	41.387492	3.066344	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.005889	0.006600	26.399920	2.844436	
MALES (20 YEARS AND OLDER)	0.005027	0.005535	22.140328	2.031664	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.004738	0.006081	24.324964	5.374612	
	0.004406	0.004948	19.793040	2.167368	

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.