

US EPA ARCHIVE DOCUMENT



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

MAY 11 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Acute Exposure Analysis for Baytan

FROM: J. Robert Tomerlin, Ph.D.
HED/SACB/TAS Staff (H7509C)

TO: Reto Engler, Ph.D.
Chief, HED/SACB (H7509C)

Action Requested

Provide a TAS analysis of acute dietary exposure to baytan using the ADI as the toxicologic endpoint.

Discussion

1. Toxicology Endpoint: The acute dietary exposure analysis for baytan was conducted using the chronic ADI of 0.038 (rounded to 0.04) mg/kg body weight/day as the toxicological endpoint (personal communication, R. Engler). The effects listed in the ADI data base state: "Changes in enzyme levels. (The two studies were combined to establish an NOEL and LEL.) Evidence of oncogenicity in mice; negative rats." Therefore, the validity of this analysis and the endpoint used will be subject to your interpretation.
2. Residues Used in the Acute Exposure Analysis: There are no permanent tolerances for baytan. Food uses evaluated in this analysis are tolerances proposed in petition 3F2854 for small grains, including secondary residues in meat, milk, poultry, and eggs (A. Smith memo, 1/4/84). The residue levels used in the analysis are summarized in Table 1.
3. TAS Acute Dietary Exposure Analysis: The TAS acute dietary exposure analysis estimates the distribution of single-day exposures for certain population subgroups. Each distribution represents the exposure profile for the individuals who consumed commodities presumed to contain baytan residues. The residue levels shown in Table 1 are assumed to be distributed uniformly in the commodity supply.

The acute dietary exposure to baytan is compared to the ADI of 0.038 mg/kg body weight (personal communication, R. Engler). Margins of Safety (MOS) are normally calculated as the ratio of the NOEL from the acute toxicity study to the observed exposure. In

this case, the ADI replaces the NOEL. Thus, for the overall U.S. population, the MOS for the typical consumer would be calculated as:

$$\begin{aligned} \text{MOS} &= (0.038 \text{ mg/kg}) / (0.000447 \text{ mg/kg}) \\ &= 85 \end{aligned}$$

The MOS calculated on the basis of the NOEL on which the ADI is based would be:

$$\begin{aligned} \text{MOS} &= (3.75 \text{ mg/kg}) / (0.000447 \text{ mg/kg}) \\ &= 8400 \end{aligned}$$

Based on the ADI, the lowest MOS is 19 for the overall U.S. population, infants, children, and males. The lowest MOS based upon the NOEL is 1900 and is for the same four population groups. The exposure distributions are shown in Table 2.

Attachments

cc: TAS (Tomerlin, SACB), DEB, Caswell #074A, Jaeger,
Ghali (TOX-HAFS)

Table 2: Acute Exposure Distributions for Baytan

	<u>Mean Daily Residue Contribution per User Day</u>		
	<u>% User Days</u>	<u>MG/KG/DAY</u>	<u>Average MOS</u>
U.S. Population:	99.7	0.000447	85 / 8400
Infants:	92.8	0.000956	40 / 3900
Children:	99.9	0.000981	39 / 3800
Females:	99.8	0.000305	125 / 12000
Males:	99.9	0.000386	98 / 9700

Estimated % of user days with residue contribution exceeding the exposure X in UG/KG, where X =

	0	.08	.16	.24	.32	.40	.48	.56	.64	.72	.80	1.2	1.6	2.0	4.0	6.0	8.0
U.S. Population:	100	96	86	71	56	43	33	25	20	15	12	4	1	0	0	0	0
Infants:	100	98	96	92	89	86	79	73	66	58	52	27	13	6	0	0	0
Children:	100	100	99	98	96	93	89	83	76	68	60	26	10	4	0	0	0
Females:	100	94	77	58	39	25	15	9	5	3	2	0	0	0	0	0	0
Males:	100	97	88	74	56	40	27	18	11	7	5	1	0	0	0	0	0
MOS (ADI):	475	238	158	119	95	79	68	59	53	48	32	24	19	9.5	6	5	
MOSx100 (NOEL):	470	230	160	120	93	78	67	58	52	47	31	23	19	9	6	5	

NOTE: The distributions shown above represent the exposure encountered by people who consume food containing residues at levels specified in the accompanying memorandum and tables.

Table 1

PAGE: 1

DATE: 04/13/89

CHEMICAL INFORMATION FOR CASWELL NUMBER 074A

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			PADI	SF		
Baytan (Triadimenol)	2yr & 6mo feed-dog	Changes in enzyme levels.	100	100	Teratology- rat.	HED complete 09/14/88.
Caswell #074A	NOEL= 3,7500 mg/kg	(The two studies were	0.038000	0.038000	Teratology- rabbit.	EPA deferred 10/12/88.
CAS No. 55219-65-3	150.00 ppm	combined to establish an	0.000000	0.000000	(Both studies are core	HED complete 01/06/89.
A.I. CODE: 127201	IEL= 15.0000 mg/kg	NOEL and IEL.)			(grade supplementary).	
CFR No. 180.	600.00 ppm	Evidence of oncogenicity				
	ONCO: Class C (HED NOTE).	in mice; negative rats.				

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
01014AA	GRAPES-FRESH	4G3154		0.500000	
01014DA	GRAPES-RAISINS	4G3154		0.500000	
01014JA	GRAPES-JUICE	4G3154		0.500000	
15004AA	CORN, POP	3F2854	0.050000		
15005AA	CORN, SWEET	3F2854	0.050000		
24001AA	BARLEY	3F2854	0.050000		
24002EA	CORN, GRAIN-ENDOSPERM	3F2854	0.050000		
24002HA	CORN, GRAIN-BRAN	3F2854	0.050000		
24002SA	CORN SUGAR	3F2854	0.050000		
24003AA	OATS	3F2854	0.050000		
24005AA	RYE-ROUGH	3F2854	0.050000		
24005GA	RYE-GERM	3F2854	0.050000		
24005WA	RYE-FLOUR	3F2854	0.050000		
24007AA	WHEAT-ROUGH	3F2854	0.050000		
24007GA	WHEAT-GERM	3F2854	0.050000		
24007HA	WHEAT-BRAN	3F2854	0.050000		
24007WA	WHEAT-FLOUR	3F2854	0.050000		
270020A	CORN, GRAIN-OIL	3F2854	0.050000		
50000DB	MILK-NON-FAT SOLIDS	3F2854	0.010000		
50000FA	MILK-FAT SOLIDS	3F2854	0.010000		
50000SA	MILK SUGAR (LACTOSE)	3F2854	0.010000		
53001BA	BEEF-MEAT BYPRODUCTS	3F2854	0.100000		
53001BB	BEEF (ORGAN MEATS)-OTHER	3F2854	0.100000		
53001DA	BEEF-DRIED	3F2854	0.100000		
53001FA	BEEF (BONELESS)-FAT (BEEF TALLOW)	3F2854	0.100000		
53001KA	BEEF (ORGAN MEATS)-KIDNEY	3F2854	0.100000		
53001LA	BEEF (ORGAN MEATS)-LIVER	3F2854	0.100000		
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	3F2854	0.100000		
53002BA	GOAT-MEAT BYPRODUCTS	3F2854	0.100000		
53002BB	GOAT (ORGAN MEATS)-OTHER	3F2854	0.100000		
53002FA	GOAT (BONELESS)-FAT	3F2854	0.100000		
53002KA	GOAT (ORGAN MEATS)-KIDNEY	3F2854	0.100000		
53002LA	GOAT (ORGAN MEATS)-LIVER	3F2854	0.100000		
53002WA	GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	3F2854	0.100000		
53003AA	HORSE	3F2854	0.100000		
53005BA	SHEEP-MEAT BYPRODUCTS	3F2854	0.100000		
53005BB	SHEEP (ORGAN MEATS)-OTHER	3F2854	0.100000		
53005FA	SHEEP (BONELESS)-FAT	3F2854	0.100000		
53005KA	SHEEP (ORGAN MEATS)-KIDNEY	3F2854	0.100000		
53005LA	SHEEP (ORGAN MEATS)-LIVER	3F2854	0.100000		

Table 1, continued

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			PADI	SF		
Baytan (Triadimenol)	2yr & 6mo feed- dog	Changes in enzyme levels. (The two studies were combined to establish an NOEL and LEL.)	100	100	Teratology- rat.	HED complete 09/14/88.
Caswell #074A	NOEL= 3.7500 mg/kg		OPP RED= 0.038000		Teratology- rabbit.	EPA deferred 10/12/88.
CAS No. 55219-65-3	150.00 ppm		EPA RED= 0.000000		(Both studies are core grade supplementary).	HED complete 01/06/89.
A.I. CODE: 127201	LEL= 15.0000 mg/kg					
CFR No. 180.	500.00 ppm	Evidence of oncogenicity in mice; negative rats.				
	ONCO: Class C (HED NOTE).					

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
53005WA	SHEEP (BONELESS) -LEAN (W/O REMOVEABLE FAT	3F2854	0.100000	
53006BA	PORK-MEAT BYPRODUCTS	3F2854	0.100000	
53006BB	PORK(ORGAN MEATS) -OTHER	3F2854	0.100000	
53006FA	PORK(BONELESS) -FAT (INCLUDING LARD)	3F2854	0.100000	
53006KA	PORK(ORGAN MEATS) -KIDNEY	3F2854	0.100000	
53006LA	PORK(ORGAN MEATS) -LIVER	3F2854	0.100000	
53006WA	PORK (BONELESS) -LEAN (W/O REMOVEABLE FAT)	3F2854	0.100000	
55008BA	TURKEY-BYPRODUCTS	3F2854	0.010000	
55008LA	TURKEY-GIBLETS (LIVER)	3F2854	0.010000	
55008WA	TURKEY-FLESH(W/O SKIN, W/O BONES)	3F2854	0.010000	
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	3F2854	0.010000	
55008MC	TURKEY-UNSPECIFIED	3F2854	0.010000	
55013BA	POULTRY, OTHER-BYPRODUCTS	3F2854	0.010000	
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	3F2854	0.010000	
55013WA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	3F2854	0.010000	
55014AA	EGGS-WHOLE	3F2854	0.010000	
55014AB	EGGS-WHITE ONLY	3F2854	0.010000	
55014AC	EGGS-YOLK ONLY	3F2854	0.010000	
55015BA	CHICKEN-BYPRODUCTS	3F2854	0.010000	
55015LA	CHICKEN-GIBLETS(LIVER)	3F2854	0.010000	
55015WA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	3F2854	0.010000	
55015WB	CHICKEN-FLESH(+SKIN, W/O BONES)	3F2854	0.010000	

8:30 THURSDAY, MAY 11, 1989 11

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

 *NAME: BAYTAN
 *CASWELL NO: 074A CFR NO: CFR180.999
 *CAS NO: 55219-65-3 SHAUGHNESSY NO: 127201 B
 *STATUS CODES: C
 *RDV INFO: The LD value used in this analysis is 0.0004 MG/KG of BODY WEIGHT/DAY
 *FILE INFO: NEW ACTION: No User Modifications APPROVED: Data Used PUBLISHED: Data NOT Used

U.S. POP. --48 STATES

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

ESTIMATES BASED ON PERSON DAYS THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY AS PERCENT OF RDV
 PRIOR TOLERANCES: 99.74 0.000447 111.76
 NEW TOLERANCES: 99.74 0.000447 111.76

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15
100	96	86	71	56	43	33	25	20	15	12	4	1	0	0	0
100	96	86	71	56	43	33	25	20	15	12	4	1	0	0	0

46875 23438 15633 114 7375 712 488 575 244 1375 938 625

INFANTS (<1 YEAR)

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

ESTIMATES BASED ON PERSON DAYS THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY AS PERCENT OF RDV
 PRIOR TOLERANCES: 92.84 0.000956 238.90
 NEW TOLERANCES: 92.84 0.000956 238.90

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15
100	98	96	92	89	86	79	73	66	58	52	27	13	6	0	0
100	98	96	92	89	86	79	73	66	58	52	27	13	6	0	0

CHILDREN (1-6 YRS)

ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

ESTIMATES BASED ON PERSON DAYS THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY AS PERCENT OF RDV
 PRIOR TOLERANCES: 99.90 0.000981 245.20
 NEW TOLERANCES: 99.90 0.000981 245.20

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15
100	100	99	98	96	93	89	83	76	68	60	26	10	4	0	0
100	100	99	98	96	93	89	83	76	68	60	26	10	4	0	0

 *NAME: BAYTAN
 *CASWELL NO: 074A CFR NO: CFI180.999 A
 *CAS NO: 55219-65-3 SHAUGHNESSY NO: 127201 B
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 *FILE INFO: NEW ACTION: No User Modifications APPROVED: Data Used PUBLISHED: Data NOT Used

 FEMALES(13+ YRS)

 ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY
 PERSON DAYS THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY AS PERCENT OF RDV
 PRIORITY TOLERANCES: 99.78 0.000305 76.24
 NEW TOLERANCES: 99.78 0.000305 76.24

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
100	94	77	58	39	25	15	9	5	3	2	0	0	0	0	0	0
NEW TOLERANCES:	100	94	77	58	39	25	15	9	5	3	2	0	0	0	0	0

 MALES(13+ YRS)

 ESTIMATED % OF POTENTIAL MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY
 PERSON DAYS THAT ARE USER-DAYS MG/KG BODY WEIGHT/DAY AS PERCENT OF RDV
 PRIORITY TOLERANCES: 99.89 0.000386 96.57
 NEW TOLERANCES: 99.89 0.000386 96.57

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
100	97	88	74	56	40	27	18	11	7	5	1	0	0	0	0	0
NEW TOLERANCES:	100	97	88	74	56	40	27	18	11	7	5	1	0	0	0	0

8:30 THURSDAY, MAY 11, 1989

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

*NAME: BAYTAN
*CASWELL NO: 074A CFR NO: CFR180.999
*STATUS CODES:
*RDV INFO: The LD value used in this analysis is 0.0004 MG/KG of BODY WEIGHT/DAY
*FILE INFO: NEW ACTION: No User Modifications APPROVED: Data Used PUBLISHED: Data NOT Used

LISTING OF RELEVANT FOODS, ORDERED BY MENU CATEGORY. MENU PATTERN = I
CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL)

POPULATION = U.S. POP.--48 STATES
FOOD CODE DESCRIPTION : NUMBER OF CONSUMER : DAYS AS PERCENT OF : POTENTIAL PERSON DAYS : PUBLISHED APPROVED NEW : TOLERANCE VALUE (PPM) & TYPE : (UG/KG BODY WT PER DAY) : FOOD CONTRIBUTION : TO EXPOSURE

Table with columns: MENU CATEGORY, FOOD CODE, DESCRIPTION, NUMBER OF CONSUMER, DAYS AS PERCENT OF, POTENTIAL PERSON DAYS, PUBLISHED, APPROVED, NEW, TOLERANCE VALUE (PPM) & TYPE, (UG/KG BODY WT PER DAY), FOOD CONTRIBUTION, TO EXPOSURE. Rows include categories like BEEF-MEAT BYPRODUCTS, SHEEP-MEAT BYPRODUCTS, PORK-MEAT BYPRODUCTS, etc.

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

 *NAME: BAYTAN
 *CASWELL NO: 074A CFR NO: CFRL80.999 A
 *CAS NO: 55219-65-3 SHRAUGHNESSY NO: 127201 B
 *STATUS CODES: C
 *RDV INFO: The LD value used in this analysis is 0.0004 MG/KG of BODY WEIGHT/DAY
 *FILE INFO: NEW ACTION: No User Modifications APPROVED: Data Used PUBLISHED: Data NOT Used

LISTING OF RELEVANT FOODS, ORDERED BY MENU CATEGORY. . . MENU PATTERN = I
 CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL)

FOOD CODE	DESCRIPTION	POPULATION = U.S. POP.--48 STATES	NUMBER OF CONSUMER DAYS AS PERCENT OF POTENTIAL PERSON DAYS	TOLERANCE VALUE (PPM) & TYPE	SPECIES	STUDY TYPE	RDV	NOEL	SF	EFF. LEV.	CORE GRADE	DOC. NO.*
				APPROVED	Other	Terata						
MENU CATEGORY 4: MILK: NON-FAT SOLIDS												
50000DB	MILK-NON-FAT SOLIDS	97.40	0.0100T	0.0100T								0.073878
50000SA	MILK SUGAR (LACTOSE)	0.57	0.0100	0.0100								0.067397
MENU CATEGORY 5: MILK: FAT SOLIDS												
50000FA	MILK-FAT SOLIDS	97.57	0.0100	0.0100								0.035014
MENU CATEGORY 6: GRAINS(EXCL. RICE), SOYBEANS, VEG. OILS												
15004AA	CORN, POP	2.35	0.0500C	0.0500C								0.014728
24001AA	BARLEY	11.25	0.0500C	0.0500C								0.024779
24002EA	CORN, GRAIN-ENDOSPERM	38.88	0.0500C	0.0500C								0.021348
24002HA	CORN, GRAIN-BRAN	0.00	0.0500C	0.0500C								0.000000
24003AA	OATS	14.34	0.0500C	0.0500C								0.029085
24005AA	RYE-ROUGH	0.00	0.0500C	0.0500C								0.000000
24005GA	RYE-GERM	0.30	0.0500C	0.0500C								0.004631
24005WA	RYE-FLOUR	3.92	0.0500C	0.0500C								0.005193
24007AA	WHEAT-ROUGH	22.40	0.0500C	0.0500C								0.031522
24007GA	WHEAT-GERM	1.70	0.0500C	0.0500C								0.002359
24007HA	WHEAT-BRAN	4.98	0.0500C	0.0500C								0.012312
24007WA	WHEAT-FLOUR	94.87	0.0500C	0.0500C								0.066789
270020A	CORN, GRAIN-OIL	96.73	0.0500C	0.0500C								0.001186
MENU CATEGORY 9: OTHER VEGETABLES, INCL. BRASSICA												
15005AA	CORN, SWEET	13.13	0.0500C	0.0500C								0.091194
MENU CATEGORY 12: SUGARS												
24002SA	CORN SUGAR	58.84	0.0500C	0.0500C								0.008311