

TAS

FEB 17 1989



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

FEB 17 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F2854. Baytan on Small Grains: TAS Dietary Exposure Analysis.

FROM: Susan L. Stanton *Susan L. Stanton* 02/13/89
Tolerance Assessment Staff
HED/SACB (TS-769C)

THRU: Bruce Jaeger *Bruce Jaeger* 02/16/89
Head, Special Analysis and Outreach Section
HED/SACB (TS-769C)

TO: Susan Lewis/Mario Fiol, PM 21
Herbicide-Fungicide Branch
Registration Division TS-767C

Action Requested

SACB has been asked to provide a TAS analysis of dietary exposure from the proposed use of Baytan on small grains (PP#3F2854).

The Dietary Exposure Branch reviewed the petition and recommended in January of 1984 that tolerances be established for residues of Baytan in or on barley, corn, oats, rye, and wheat; and in or on eggs; milk; and meat, fat, and meat by-products of cattle, goats, hogs, horses, sheep, and poultry (memo. A. Smith to H. Jacoby, 01/04/84). Establishment of the tolerances has been delayed pending resolution of toxicological issues.

Discussion

1. Toxicology Endpoint: A TAS chronic exposure analysis was conducted using a reference dose (PADI) of 0.038 mg/kg body wt/day, based on the NOEL of 3.75 mg/kg/day from 6-month and 2-year dog feeding studies with an uncertainty factor of 100. This value has been approved by HED (01/06/89) but not verified by the Agency reference dose committee.

2. Residues Used in the Analysis: No permanent tolerances have been established for residues of Baytan. The present analysis estimates exposure from the proposed uses in permanent petition #3F2854 only (grains), including secondary residues in meat, milk, poultry, and eggs. The analysis is based on

tolerance level residues and assumes that 100% of all crops would be treated. Table 1 contains a complete listing of residues for all TAS foods evaluated in the analysis.

3. Analysis Summary: The TAS routine chronic exposure analysis estimates average daily exposure for the overall U.S. population and each of 22 population subgroups and compares the exposure estimates to the acceptable daily intake (Provisional ADI in this case). The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population is estimated to be 0.000446 mg/kg/day which occupies 1.2% of the PADI. The TAS subgroups with the highest estimated exposures from the proposed tolerances are non-nursing infants less than 1 year old (TMRC = 0.001051 mg/kg/day or 2.8% of the PADI) and children, 1 to 6 years of age (TMRC = 0.000987 mg/kg/day or 2.6% of the PADI). A summary of the analysis for these and the remaining subgroups may be found in the attached Table 2.

The above estimates are based on tolerance level residues and assume 100% of all crops are treated. Actual exposure would likely be lower, since tolerances generally overestimate residues that would be found in foods as eaten. However, since no TAS subgroups have estimated exposures which exceed the acceptable daily intake using this conservative approach, a more refined analysis is not deemed necessary.

CC: Stanton (SACB), Caswell File #074A, TAS File, DEB (Loranger), Jaeger (SACB), Ghali (TOX).

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 074A

DATE: 02/13/89

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Bartar (Carcinogen)	2 yr 5 Sinc Feed- J0q	Changes in enzyme levels.	IPADI SF -->100	Teratology- rat.	HED complete 09/14/88.
Caswell #074A	NOEL= 3.7500 mg/kg	(The two studies were	OPP RfD= 0.038000	Teratology- rabbit.	EPA deferred 10/12/88.
CAS No. 55219-65-3	150 00 ppm	combined to establish an	EPA RfD= 0.000000	(Both studies are core	HED complete 01/06/89.
A.I. CODE 127201	LEL= 15.0000 mg/kg	NOEL and LEL.)		grade supplementary).	
CFR No. 180	600 00 ppm	Evidence of oncogenicity			
	ONCO: Class C (TOX MOTE)	in mice, negative rats.			

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
15001AA	CCRN, POP	3F2854	0.050000	
15005AA	CCRN, 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	CATS	3F2854	0.050000	
24005AA	RYE-ROUGH	3F2854	0.050000	
24005GA	RYE-GERM	3F2854	0.050000	
24005NA	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	
27302CA	CCRN, GRAIN-OIL	3F2854	0.050000	
50000DB	MILK-NON-FAT SOLIDS	3F2854	0.010000	
50003FA	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	
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	3F2854	0.100000	
53003AA	HORSE	3F2854	0.100000	
530055A	SHEEP-MEAT BYPRODUCTS	3F2854	0.100000	
530055B	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	
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	3F2854	0.100000	
53006BA	PORK-MEAT BYPRODUCTS	3F2854	0.100000	
530065B	PORK(ORGAN MEATS)-OTHER	3F2854	0.100000	

Table 1 (con't)

CHEMICAL INFORMATION FOR CASWELL NUMBER 074A

DATE: 02/13/89

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			IPADI	SF		
Ba'tar: 21242-0001	2yr & 6mo feed: dog	Changes in enzyme levels.	---	100	Teratology- rat.	HED complete 09/14/88.
Caswell #074A	NOEL= 3 7500 mg/kg	(The two studies were	OPP	RfD= 0.038000	Teratology- rabbit.	EPA deferred 10/12/88.
CAS No 55219-65-3	150.00 ppm	combined to establish an	EPA	RfD= 0.000000	(Both studies are core	HED complete 01/06/89.
A : CODE 127201	LEL= 15.0000 mg/kg	NOEL and LEL)			grade supplementary)	
CFR No 180	600.00 ppm	Evidence of oncogenicity				
	ONCO: Class C (TOX WOTE)	in mice, negative rats				

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
53006FA	PORK (BONELESS)-FAT (INCLUDING LARD)	3F2854	0.100000	
53006FA	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	
55008SA	TURKEY-BYPRODUCTS	3F2854	0.010000	
55008LA	TURKEY-GIBLETS (LIVER)	3F2854	0.010000	
55008WA	TURKEY-FLESH (W/O SKIN, W/O BONES)	3F2854	0.010000	
55008ME	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	
55015MB	CHICKEN-FLESH (+SKIN, W/O BONES)	3F2854	0.010000	

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 02/13/89

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Baytan (Triadimenol)	2yr & 6mo feed- dog	Changes in enzyme levels.	PADI SF -->100	Teratology- rat.	HED complete 09/14/88.
Caswell #074A	NOEL= 3.7500 mg/kg	(The two studies were	OPP RfD= 0.038000	Teratology- rabbit.	EPA deferred 10/12/88.
CAS No. 55219-65-3	150.00 ppm	combined to establish an	EPA RfD= 0.000000	(Both studies are core	HED complete 01/06/89.
A.I. CODE: 127201	LEL= 15.0000 mg/kg	NOEL and LEL.)		grade supplementary).	
CFR No. 180.	600.00 ppm	Evidence of oncogenicity			
	ONCO: Class C (TOX NOTE).	in mice; negative rats.			
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)					
CURRENT TMRC*		NEW TMRC**		DIFFERENCE AS PERCENT OF RFD	ARC
POPULATION SUBGROUP					
U.S. POPULATION - 48 STATES					
U.S. POPULATION - SPRING SEASON		0.000000	0.000446	1.174613	1.174613
U.S. POPULATION - SUMMER SEASON		0.000000	0.000433	1.140726	1.140726
U.S. POPULATION - FALL SEASON		0.000000	0.000449	1.181413	1.181413
U.S. POPULATION - WINTER SEASON		0.000000	0.000457	1.202497	1.202497
U.S. POPULATION - WINTER SEASON		0.000000	0.000446	1.173966	1.173966
NORTHEAST REGION					
NORTH CENTRAL REGION		0.000000	0.000450	1.183976	1.183976
SOUTHERN REGION		0.000000	0.000463	1.218332	1.218332
WESTERN REGION		0.000000	0.000424	1.115766	1.115766
HISPANICS		0.000000	0.000456	1.200095	1.200095
NON-HISPANIC WHITES		0.000000	0.000534	1.406329	1.406329
NON-HISPANIC BLACKS		0.000000	0.000442	1.163055	1.163055
NON-HISPANIC OTHERS		0.000000	0.000430	1.132350	1.132350
NURSING INFANTS (< 1 YEAR OLD)		0.000000	0.000471	1.240232	1.240232
NON-NURSING INFANTS (< 1 YEAR OLD)		0.000000	0.000322	0.847889	0.847889
FEMALES (13+ YEARS, PREGNANT)		0.000000	0.001051	2.766682	2.766682
FEMALES 13+ YEARS, NURSING		0.000000	0.000317	0.834753	0.834753
CHILDREN (1-6 YEARS OLD)		0.000000	0.000357	0.938463	0.938463
CHILDREN (7-12 YEARS OLD)		0.000000	0.000987	2.596137	2.596137
MALES (13-19 YEARS OLD)		0.000000	0.000689	1.814239	1.814239
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.000000	0.000496	1.306416	1.306416
MALES (20 YEARS AND OLDER)		0.000000	0.000385	1.013158	1.013158
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.000000	0.000360	0.946255	0.946255
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.000000	0.000289	0.761571	0.761571

*Current TMRC does not include new or pending tolerances.

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

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