

US EPA ARCHIVE DOCUMENT



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

MAY 18 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis of Assure, PP#F3532  
and FAP#6H5479

FROM: J. Robert Tomerlin, Ph.D. *J.R. Tomerlin*  
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TO: Robert J. Taylor/Vickie Walters, PM 25  
Fungicide-Herbicide Branch  
Registration Division (TS 767C)

Action Requested

Provide a dietary exposure analysis for proposed tolerances on the new herbicide, Assure.

Discussion

1. A routine chronic TAS analysis was conducted with a reference dose (PADI) of 0.009 mg/kg body weight/day, based upon a NOEL of 0.9 mg/kg body weight/day and a safety factor of 100 from a 2 year rat feeding study. This value was approved by TOX Branch (12/11/87) and Agency (1/21/88) reference dose committees.
2. There are no current published tolerances for Assure. The TAS analysis was conducted using tolerances which have been tentatively approved, pending resolution of method validation. A summary of the tolerance information used in the analysis is attached as Table 1.
3. The TAS routine chronic analysis estimates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and 22 population sub-groups. The TMRC for the U.S. population is 0.000216 mg/kg body weight/day (2.4 % of the ADI). The most highly exposed subgroups are non-nursing infants with a TMRC of 0.000922 mg/kg body weight/day (10.2 % of the ADI) and children aged 1 to 6 with a TMRC of 0.000515 mg/kg body weight/day (5.7 % of the ADI). The TMRC summary is attached as Table 2.

4. Proposed tolerances included poultry fat. The TAS analysis assigned the fat tolerance to the food form 'flesh plus skin'. The analysis was conducted assuming that tolerance levels occurred on 100 per cent of the crop. Therefore, the TMRCs from this analysis are higher than what would probably occur.

cc: TAS Files  
Reading File  
PMSD  
PP#3F3532

TOX (Rathman)  
circ.  
Assure SF

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 215D DATE: 05/18/88 PAGE: 1

FOOD CODE	FOOD NAME	STUDY TYPE	EFFECTS	REFERENCE DOSES			DATA GAPS/COMMENTS	STATUS
				IPADI	SF -->	100		
Assure	Caswell #215D	2yr feeding- rat	Generalized hepatocyte enlargement in M & F. Red cell destruction in M & F	OPP RfD= 0.009000			Teratology- rabbit (study under review).	TOX complete 12/11/87.
	CAS No. 76578-14-8	NOEL=		EPA RfD= 0.009000				EPA verified 1/21/88.
	A. I. CODE: 128201	LEL=	Negative oncogen in rats; positive in mice (liver tumors).				ADI based on actual food consumption.	
	CFR No. 180.	ONCO: Class D (TOX NOTE).						
FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED		
15029AA	SOYBEANS-SPROUTED SEEDS	3F3252		0.050000		0.050000		
270100A	SOYBEANS-OIL	3F3532		0.050000		0.050000		
28023AA	SOYBEANS-UNSPECIFIED	3F3532		0.050000		0.050000		
28023AB	SOYBEANS-MATURE, SEEDS DRY	3F3532		0.050000		0.050000		
28023WA	SOYBEANS-FLOUR, FULL FAT	3F3532		0.500000		0.500000		
28023WB	SOYBEANS-FLOUR, LOW FAT	3F3532		0.500000		0.500000		
28023WC	SOYBEANS-FLOUR, DEFAITTED	3F3532		0.500000		0.500000		
50000DB	MILK-NON-FAT SOLIDS	3F3532		0.010000		0.010000		
50000FA	MILK-FAT SOLIDS	3F3532		0.050000H		0.050000H		
50000SA	MILK SUGAR (LACTOSE)	3F3532		0.010000		0.010000		
53001BA	BEEF-MEAT BYPRODUCTS	3F3532		0.050000		0.050000		
53001BB	BEEF (ORGAN MEATS) -OTHER	3F3532		0.020000		0.020000		
53001DA	BEEF-DRIED	3F3532		0.020000		0.020000		
53001FA	BEEF (BONELESS) -FAT (BEEF TALLOW)	3F3532		0.050000		0.050000		
53001KA	BEEF (ORGAN MEATS) -KIDNEY	3F3532		0.020000		0.020000		
53001LA	BEEF (ORGAN MEATS) -LIVER	3F3532		0.020000		0.020000		
53001MA	BEEF (BONELESS) -LEAN (W/O REMOVEABLE FAT)	3F3532		0.020000		0.020000		
53002BA	GOAT-MEAT BYPRODUCTS	3F3532		0.050000		0.050000		
53002BB	GOAT (ORGAN MEATS) -OTHER	3F3532		0.020000		0.020000		
53002FA	GOAT (BONELESS) -FAT	3F3532		0.050000		0.050000		
53002KA	GOAT (ORGAN MEATS) -KIDNEY	3F3532		0.020000		0.020000		
53002LA	GOAT (ORGAN MEATS) -LIVER	3F3532		0.020000		0.020000		
53002MA	GOAT (BONELESS) -LEAN (W/O REMOVEABLE FAT)	3F3532		0.020000		0.020000		
53003AA	HORSE	3F3532		0.050000		0.050000		
53005BA	SHEEP-MEAT BYPRODUCTS	3F3532		0.050000		0.050000		
53005BB	SHEEP (ORGAN MEATS) -OTHER	3F3532		0.020000		0.020000		
53005FB	SHEEP (BONELESS) -FAT	3F3532		0.050000		0.050000		
53005FA	SHEEP (BONELESS) -FAT	3F3532		0.050000		0.050000		
53005KA	SHEEP (ORGAN MEATS) -KIDNEY	3F3532		0.020000		0.020000		
53005LA	SHEEP (ORGAN MEATS) -LIVER	3F3532		0.020000		0.020000		
53005MA	SHEEP (BONELESS) -LEAN (W/O REMOVEABLE FAT)	3F3532		0.020000		0.020000		
53006BA	PORK-MEAT BYPRODUCTS	3F3532		0.050000		0.050000		
53006BB	PORK (ORGAN MEATS) -OTHER	3F3532		0.020000		0.020000		
53006FA	PORK (BONELESS) -FAT (INCLUDING LARD)	3F3532		0.050000		0.050000		
53006KA	PORK (ORGAN MEATS) -KIDNEY	3F3532		0.020000		0.020000		
53006LA	PORK (ORGAN MEATS) -LIVER	3F3532		0.020000		0.020000		
53006MA	PORK (BONELESS) -LEAN (W/O REMOVEABLE FAT)	3F3532		0.020000		0.020000		
55008BA	TURKEY-BYPRODUCTS	3F3532		0.050000		0.050000		
55008LA	TURKEY-GIBLETS (LIVER)	3F3532		0.020000		0.020000		
55008MA	TURKEY-FLESH (W/O SKIN, W/O BONES)	3F3532		0.020000		0.020000		
55008NB	TURKEY-FLESH (+SKIN, W/O BONES)	3F3532		0.020000		0.020000		

Table 1, continued

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES			DATA GAPS/COMMENTS	STATUS
			PADI	SF	-->		
Assure	2yr feeding- tat	Generalized hepatocyte enlargement in M & F. Red cell destruction in M & F	100	100	100	Teratology- rabbit (study under review).	TOX complete 12/11/87.
Caswell #215D	NOEL= 0.9000 mg/kg						EPA verified 1/21/88.
CAS No. 76578-14-8	25.00 ppm						
A.I. CODE: 128201	LEL= 3.7000 mg/kg	Negative oncogen in rats; positive in mice (liver tumors).				ADI based on actual food consumption.	
CFR No. 180.	100.00 ppm						
	ONCO: Class D (TOX NOTE).						

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
55008MC	TURKEY-UNSPECIFIED	3F3532		0.050000
55013BA	POULTRY, OTHER-BYPRODUCTS	3F3532		0.050000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	3F3532		0.020000
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	3F3532		0.050000
55014AA	EGGS-WHOLE	3F3532		0.020000
55014AB	EGGS-WHITE ONLY	3F3532		0.020000
55014AC	EGGS-YOLK ONLY	3F3532		0.020000
55015BA	CHICKEN-BYPRODUCTS	3F3532		0.050000
55015LA	CHICKEN-GIBLETS(LIVER)	3F3532		0.020000
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	3F3532		0.020000
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	3F3532		0.050000

Table 2

## TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/18/88

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
Assure	2yr feeding- rat	Generalized hepatocyte enlargement in M & F. Red cell destruction in M & F	Generalized hepatocyte enlargement in M & F. Red cell destruction in M & F	ADI based on actual food consumption.	ADI based on actual food consumption.	ADI based on actual food consumption.	ADI based on actual food consumption.	ADI based on actual food consumption.	ADI based on actual food consumption.	ADI based on actual food consumption.
Caswell #215D	NOEL= 0.9000 mg/kg									TOX complete 12/11/87.
CAS No. 76578-14-8	LEL= 3.7000 mg/kg									EPA verified 1/21/88.
A.I. CODE: 128201	100.00 ppm									
CFR No. 180.	QNC0: Class D (TOX MOTE).									
POPULATION SUBGROUP										
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)										
		CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF REF		DIFFERENCE AS PERCENT OF REF		EFFECT OF ANTICIPATED RESIDUES ARC		%REF
U.S. POPULATION - 48 STATES										
		0.000216	0.000216	2.397378		0.000000				
U.S. POPULATION - SPRING SEASON										
		0.000208	0.000208	2.309456		0.000000				
U.S. POPULATION - SUMMER SEASON										
		0.000215	0.000215	2.385233		0.000000				
U.S. POPULATION - FALL SEASON										
		0.000222	0.000222	2.470989		0.000000				
U.S. POPULATION - WINTER SEASON										
		0.000218	0.000218	2.424133		0.000000				
NORTHEAST REGION										
		0.000217	0.000217	2.408856		0.000000				
NORTH CENTRAL REGION										
		0.000218	0.000218	2.420711		0.000000				
SOUTHERN REGION										
		0.000205	0.000205	2.280356		0.000000				
WESTERN REGION										
		0.000230	0.000230	2.550967		0.000000				
HISPANICS										
		0.000269	0.000269	2.990056		0.000000				
NON-HISPANIC WHITES										
		0.000211	0.000211	2.345600		0.000000				
NON-HISPANIC BLACKS										
		0.000217	0.000217	2.416456		0.000000				
NON-HISPANIC OTHERS										
		0.000244	0.000244	2.707022		0.000000				
NURSING INFANTS (< 1 YEAR OLD)										
		0.000229	0.000229	2.544189		0.000000				
NON-NURSING INFANTS (< 1 YEAR OLD)										
		0.000922	0.000922	10.240922		0.000000				
FEMALES (13+ YEARS, PREGNANT)										
		0.000148	0.000148	1.648622		0.000000				
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)										
		0.000180	0.000180	1.995322		0.000000				
CHILDREN (7-12 YEARS OLD)										
		0.000515	0.000515	5.725078		0.000000				
CHILDREN (13-19 YEARS OLD)										
		0.000334	0.000334	3.705822		0.000000				
MALES (13-19 YEARS OLD, NOT PREG. OR NURSING)										
		0.000230	0.000230	2.589900		0.000000				
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)										
		0.000182	0.000182	2.020789		0.000000				
MALES (20 YEARS AND OLDER)										
		0.000155	0.000155	1.717689		0.000000				
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)										
		0.000133	0.000133	1.480944		0.000000				

\*Current TMRC does not include new or pending tolerances.

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