

US EPA ARCHIVE DOCUMENT



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

MAY 16 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7G3547. Amitraz on Cotton -
TAS Dietary Exposure Analysis.

FROM: Susan L. Stanton
Tolerance Assessment Program *Susan L. Stanton 05/12/88*
HED/RCB (TS-769C)

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

TO: Dennis Edwards, PM-12
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Action Requested

Provide an analysis of dietary exposure from the proposed use of Amitraz on cotton (PP#7G3547; 45639-EUP-YY).

RCB has reviewed the petition and recommends that the proposed temporary tolerance of 0.3 ppm be established for residues of Amitraz in or on cotton (memo F. Suhre to Edwards, 05/11/88). A temporary tolerance of 0.2 ppm (expiration date 04/89) has previously been established for cotton in connection with PP#5G3185 (45639-EUP-XX). The present analysis estimates exposure that would result from this increase of 0.1 ppm.

Discussion

1. The Reference Dose (ADI) used in the analysis is 0.0025 mg/kg body wt/day, based on the NOEL of 0.25 mg/kg body wt/day from a 2-year dog feeding study with a safety factor of 100. This value has been approved by the TOX Branch ADI Committee (07/24/87) and verified by the Agency reference dose committee (10/14/87).

2. The food uses evaluated in the analysis include those established under 40 CFR 180.287, the proposed use on cotton, and

a proposed use on citrus (7G3505). See Table 1 for a complete listing of residue information.

3. The TAS routine chronic analysis estimates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2). The TMRC for the U.S. population from all established and proposed uses is calculated to be 0.005699 mg/kg body weight/day, which occupies approximately 228% of the ADI. The two most highly exposed subgroups are non-nursing infants (TMRC = 0.017001 mg/kg/day or 680% of the ADI) and children, ages 1 to 6 (TMRC = 0.015240 mg/kg/day or 610% of the ADI). The contribution of the established and proposed uses to Amitraz exposure is shown below:

	Overall U.S. <u>Population</u>	Non-Nursing <u>Infants</u>	Children <u>Ages 1-6</u>
Established Uses ^c :	0.000875 ^a (35.0%) ^b	0.006926 (277.0%)	0.002101 (84.0%)
New Action Only ^d (7G3547:Cotton)	0.000002 (0.08%)	<0.000001 (0.02%)	0.000004 (0.15%)
Other ^e	0.004822 (192.9%)	0.010075 (403.0%)	0.013135 (525.4%)
Total Theoretical Exposure	0.005699 (228.0%)	0.017001 (680.1%)	0.015240 (609.6%)

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

^bTMRC expressed as percent of the ADI.

^cIncludes established permanent tolerances and the established temporary tolerance of 0.2 ppm on cotton.

^dRepresents exposure from the proposed increase in the temporary tolerance for cotton of 0.1 ppm.

^eIncludes citrus and secondary residues of 0.01 ppm in goats, horses, and sheep.

4. This analysis assumes that residues of Amitraz would be present at tolerance levels on foods as eaten and that 100% of crops are treated. This conservative approach likely overestimates exposure significantly, since the proposed EUP for cotton would involve the application of Amitraz to a total of

3825 acres in 10 states or less than 0.1% of the total U.S. acres planted to cotton (from USDA's Agricultural Statistics, 1986). Also the proposed EUP for citrus, the use which represents the greatest theoretical exposure, would involve less than 1% of the total U.S. citrus crop.

cc: TAS File
Reading File
circ.
PP#7G3547

TOX (Rathman)
Amitraz SF
PMSD

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 374A DATE: 05/13/88 PAGE: 1

AMITRAZ	CASWELL #374A	CAS NO. 33089-61-1	A.I. CODE: 106201	CFR NO. 180.287	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
							ADI	SF -->		
					2yr feeding- dog	Increased blood glucose,	100	No data gaps.	TOX complete 7/24/87.	
					NOEL= 0.2500 mg/kg	slight hypothermia after	OPP RED= 0.002500		EPA verified 10/14/87	
					0.00 ppm	dosing.	EPA RED= 0.002500		WHO last reviewed 1984.	
					LEL= 1.0000 mg/kg	No evidence of oncogeni-				
					0.00 ppm	city in rats, mouse data				
					ONCO: C (CAG); D (SAP)	equivocal (lymphoret.).				

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
02001AA	CITRUS CITRUS	7G3505		2.000000	
02002AA	GRAPEFRUIT-UNSPECIFIED	7G3505		2.000000	
02002AB	GRAPEFRUIT-PULP	7G3505		2.000000	
02002JA	GRAPEFRUIT-JUICE	7G3505		2.000000	
02003AA	KUMQUATS	7G3505		2.000000	
02004AA	LEMONS-UNSPECIFIED	7G3505		2.000000	
02004AB	LEMONS-PULP	7G3505		2.000000	
02004HA	LEMONS-PEEL	7G3505		2.000000	
02004JA	LEMONS-JUICE	7G3505		2.000000	
02005AA	LIMES-UNSPECIFIED	7G3505		2.000000	
02005AB	LIMES-PULP	7G3505		2.000000	
02005HA	LIMES-PEEL	7G3505		2.000000	
02005JA	LIMES-JUICE	7G3505		2.000000	
02006AA	ORANGES-UNSPECIFIED	7G3505		2.000000	
02006AB	ORANGES-PULP	7G3505		2.000000	
02006HA	ORANGES-PEEL	7G3505		2.000000	
02006JA	ORANGES-JUICE	7G3505		2.000000	
02007AA	TANGELOS	7G3505		2.000000	
02008AA	TANGERINES	7G3505		2.000000	
02008JA	TANGERINE-JUICE	7G3505		2.000000	
04003AA	PEARS-FRESH	6F1817		3.000000	
04003DA	PEARS-DRIED	6F1817		3.000000	
270030A	COTTONSEED-OIL	7G3547	0.100000		
270030A	COTTONSEED-OIL, TEMP. TOL. EXPS. 04/89				
270030A	COTTONSEED-MEAL	7G3547	0.100000		
27003WA	COTTONSEED-MEAL, TEMP. TOL. EXPS. 04/89				
50000B	MILK-NON-FAT SOLIDS	4F2968		0.200000	
50000FA	MILK-FAT SOLIDS	4F2968		0.030000	
50000SA	MILK SUGAR (LACTOSE)	4F2968		0.300000	H
53001BA	BEEF-MEAT BYPRODUCTS	4F2968		0.030000	
53001BB	BEEF (ORGAN MEATS)-OTHER	4F2968		0.300000	
53001DA	BEEF-DRIED	4F2968		0.050000	
53001FA	BEEF (BONELESS)-FAT (BEEF TALLOW)	4F2968		0.100000	
53001KA	BEEF (ORGAN MEATS)-KIDNEY	4F2968		0.300000	
53001LA	BEEF (ORGAN MEATS)-LIVER	4F2968		0.300000	
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F2968		0.300000	
53002BA	GOAT-MEAT BYPRODUCTS	7G3505		0.050000	
53002BB	GOAT (ORGAN MEATS)-OTHER	7G3505		0.010000	
53002FA	GOAT (BONELESS)-FAT	7G3505		0.010000	
53002KA	GOAT (ORGAN MEATS)-KIDNEY	7G3505		0.010000	

Table 1 (con't)

CHEMICAL INFORMATION FOR CASWELL NUMBER 374A DATE: 05/13/88 PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI SF -->	OPF RfD=		
Amitraz Caswell #374A CAS No. 33089-61-1 A.I. CODE: 106201 CFR No. 180.287	2yr feeding- dog NOEL= 0.2500 mg/kg 0.00 ppm IEL= 1.0000 mg/kg 0.00 ppm ONCO: C (CAG); D (SAP)	Increased blood glucose, slight hypothermia after dosing. No evidence of oncogeni- city in rats, mouse data equivocal (lymphoret.).	100	0.002500 0.002500	No data gaps.	TOX complete 7/24/87. EPA verified 10/14/87 WHO last reviewed 1984.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
53002LA	GOAT(ORGAN MEATS)-LIVER	7G3505	0.010000	
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	7G3505	0.010000	
53003AA	HORSE	7G3505	0.010000	
53005BA	SHEEP-MEAT BYPRODUCTS	7G3505	0.010000	
53005BB	SHEEP(ORGAN MEATS)-OTHER	7G3505	0.010000	
53005FA	SHEEP(BONELESS)-FAT	7G3505	0.010000	
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	7G3505	0.010000	
53005LA	SHEEP(ORGAN MEATS)-LIVER	7G3505	0.010000	
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	7G3505	0.010000	0.300000
53006BA	PORK-MEAT BYPRODUCTS	4F3081	0.300000	0.300000
53006BB	PORK(ORGAN MEATS)-OTHER	4F3081	0.100000	0.100000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	4F3081	0.200000	0.200000
53006KA	PORK(ORGAN MEATS)-KIDNEY	4F3081	0.200000	0.200000
53006LA	PORK(ORGAN MEATS)-LIVER	4F3081	0.200000	0.200000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3081	0.050000	0.050000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/13/88

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Amtraz	2yr feeding- dog	Increased blood glucose,	ADI SF --> 100	No data gaps.	TOX complete 7/24/87.	
Caswell #374A	NOEL= 0.2500 mg/kg	slight hypothermia after	OPP RfD= 0.002500		EPA verified 10/14/87	
CAS No. 33089-61-1	0.00 ppm	dosing.	EPA RfD= 0.002500		WHO last reviewed 1984.	
A.I. CODE: 106201	LEL= 1.0000 mg/kg	No evidence of oncogeni-				
CFR No. 180.287	0.00 ppm	city in rats, mouse data				
	ONCO: C (CAG); D (SAP)	equivocal (Lymphoret.)				

TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

POPULATION SUBGROUP	CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES
U.S. POPULATION - 48 STATES	0.000875	0.005699	227.963760	192.955520	
U.S. POPULATION - SPRING SEASON	0.000797	0.005646	225.828520	193.931080	
U.S. POPULATION - SUMMER SEASON	0.000826	0.005264	210.556760	177.514000	
U.S. POPULATION - FALL SEASON	0.000962	0.005840	233.605760	195.115840	
U.S. POPULATION - WINTER SEASON	0.000915	0.006046	241.829160	205.221560	
NORTHEAST REGION	0.000956	0.007164	286.540560	248.284800	
NORTH CENTRAL REGION	0.000907	0.005668	226.736480	190.455200	
SOUTHERN REGION	0.000699	0.004494	179.742520	151.773360	
WESTERN REGION	0.001025	0.005859	234.372520	193.389160	
HISPANICS	0.001044	0.007645	305.811560	264.036320	
NON-HISPANIC WHITES	0.000891	0.005510	220.387560	184.763400	
NON-HISPANIC BLACKS	0.000677	0.005715	228.595680	201.508080	
NON-HISPANIC OTHERS	0.001041	0.008242	329.664280	288.035400	
NURSING INFANTS (< 1 YEAR OLD)	0.004645	0.009366	374.622400	188.837120	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.006926	0.017001	680.050680	403.026600	
FEMALES (13+ YEARS, PREGNANT)	0.000528	0.004578	183.135640	162.026160	
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.000989	0.004718	188.711520	149.152320	
CHILDREN (7-12 YEARS OLD)	0.002101	0.015240	609.587160	525.554080	
MALES (13-19 YEARS OLD)	0.001358	0.008408	336.309400	281.975840	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000787	0.004725	189.019880	157.533120	
MALES (20 YEARS AND OLDER)	0.000631	0.004456	178.236680	152.978320	
FEMALES (20 YEARS AND OLDER)	0.000546	0.003381	135.239280	113.396560	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000513	0.004238	169.507880	148.975680	

*Current TMRC does not include new or pending tolerances.

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