

Reg. Std.
8-18-87



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

18 AUG 1987

MEMORANDUM

Subject: Addendum to Residue Chemistry Chapter for Propanil
Registration Standard: Tolerance Assessment System
Tolerance Reassessment.

To: Amy Rispin
Science Integration Staff
Hazard Evaluation Division
and
Robert Taylor, PM# 25
Registration Division

From: C. Frick
Tolerance Assessment Program
Residue Chemistry Branch, HED

c. Frick 8/14/87

Thru. Charles L. Trichilo, Ph.D.
Chief, Residue Chemistry Branch
Hazard Evaluation Division

A large, stylized handwritten signature, likely of Charles L. Trichilo, written in dark ink.

Please find attached the Tolerance Assessment System (TAS) tolerance reassessment for Propanil, which is an addendum to the Registration Standard. This is in compliance with the recent policy established in HED that TAS will be used for all Registration Standards, Special Reviews, and tolerances on new chemicals.

CHEMICAL: PROPANIL

Discussion

1. The Provisional Acceptable Daily Intake (PADI) for this chemical is 0.005 mg/kg/day, and has been approved by the Toxicology Branch and Agency Reference Dose Committees (8/12/87).
2. The food uses evaluated by the Tolerance Assessment System (TAS) were published tolerances as established under CFR 180.274. A list of these tolerances is appended.
3. The TAS analysis estimates dietary exposure for the U.S. population average and for each of 22 subgroups. The theoretical dietary exposure of Propanil to the U.S. population average is 0.0015 mg/kg/day, which is equivalent to 29% of the PADI. The most highly exposed subgroups were non-nursing infants (0.0067 mg/kg/day, equivalent to 133% of the PADI) and children 1-6 years of age (0.0035 mg/kg/day, equivalent to 69% of the PADI).
4. The margin of safety used in deriving the Propanil PADI is 1000; when the toxicology data gaps are filled, the calculated dietary exposure relationship to the Propanil PADI may be considerably lower.

ATTACHMENT

cc. Registration Standard File
TAS File
Reading File
D. Edwards (RCB)
C. Frick (RBC)
Toxicology Branch
PMSD

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 08/12/87

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Propanil Caswell #325 CAS No. 709-98-8 A.I. CODE: 028201 CFR No. 180.274	2yr feeding- rat NOEL= 5.0000 mg/kg 100.00 ppm LEL= 20.0000 mg/kg 400.00 ppm ONCO: Undetermined	Increased relative spleen weight in females. No oncogenicity data available.	PADI 1000 OPP Rfd= 0.005000 EPA Rfd= 0.200000 WHO Rfd 0.000000 Type:	Chronic feeding- rat Chronic feeding- dog (Supplementary per 1987 Reg. Std.) 2yr mouse NOEL of 5 mg/kg is co-critical study.	TOX complete 8/04/86. ORD verified 9/02/86. TOX reassess 7/24/87.
	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)				
	CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC
	%RFD				
POPULATION SUBGROUP					
U.S. POPULATION - 48 STATES					
U.S. POPULATION - SPRING SEASON					
U.S. POPULATION - SUMMER SEASON					
U.S. POPULATION - FALL SEASON					
U.S. POPULATION - WINTER SEASON					
NORTHEAST REGION					
NORTH CENTRAL REGION					
SOUTHERN REGION					
WESTERN REGION					
HISPANICS					
NON-HISPANIC WHITES					
NON-HISPANIC BLACKS					
NON-HISPANICS OTHER					
NURSING INFANTS (<1 YEAR OLD)					
NON-NURSING INFANTS (<1 YEAR OLD)					
FEMALES (13+ YEARS, PREGNANT)					
FEMALES 13+ YEARS, NURSING					
CHILDREN (1-6 YEARS OLD)					
CHILDREN (7-12 YEARS OLD)					
MALES (13-19 YEARS OLD)					
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)					
MALES (20 YEARS AND OLDER)					
FEMALES (20 YEARS AND OLDER)					

*Current TMRC does not include new or pending tolerances.

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

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			PADI	1000		
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LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

NEW, PENDING & PUBLISHED TOLERANCES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		EXISTING TOLERANCES		NEW, PENDING & PUBLISHED TOLERANCES	
		NEW	PENDING	TMRC	(UG/KG/DAY)	%RfD	NEW %RfD
24001AA	BARLEY	0.2000		0.0115	0.0115	0.2292	
24003AA	OATS	0.2000		0.0165	0.0165	0.3303	
24004AA	RICE-ROUGH	2.0000		0.0061	0.0061	0.1224	
24004AB	RICE-MILLED	2.0000		0.3105	0.3105	6.2105	
24007AA	WHEAT-ROUGH	0.2000		0.0281	0.0281	0.5624	
24007GA	WHEAT-GERM	0.2000		0.0002	0.0002	0.0032	
24007HA	WHEAT-BRAN	0.2000		0.0024	0.0024	0.0486	
24007MA	WHEAT-FLOUR	0.2000		0.2515	0.2515	5.0290	

CROP GROUP TOTALS FOR CEREAL GRAINS:

12.5357

53001BA	BEEF-MEAT BYPRODUCTS	0.1000		0.0018	0.0018	0.0353	
53001BB	BEEF(ORGAN MEATS)-OTHER	0.1000		0.0006	0.0006	0.0121	
53001DA	BEEF-DRIED	0.1000		0.0003	0.0003	0.0051	
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0.1000		0.0372	0.0372	0.7442	
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000	0.0010	
53001LA	BEEF(ORGAN MEATS)-LIVER	0.1000		0.0021	0.0021	0.0414	
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.1162	0.1162	2.3240	
53002BA	GOAT-MEAT BYPRODUCTS	0.1000		0.0000	0.0000	0.0000	
53002BB	GOAT(ORGAN MEATS)-OTHER	0.1000		0.0000	0.0000	0.0000	
53002FA	GOAT(BONELESS)-FAT	0.1000		0.0000	0.0000	0.0001	
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000	0.0000	
53002LA	GOAT(ORGAN MEATS)-LIVER	0.1000		0.0000	0.0000	0.0000	
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.0000	0.0000	0.0004	
53003AA	HORSE	0.1000		0.0000	0.0000	0.0000	
53005BA	SHEEP-MEAT BYPRODUCTS	0.1000		0.0000	0.0000	0.0001	
53005BB	SHEEP(ORGAN MEATS)-OTHER	0.1000		0.0000	0.0000	0.0000	
53005FA	SHEEP(BONELESS)-FAT	0.1000		0.0004	0.0004	0.0086	
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000	0.0000	
53005LA	SHEEP(ORGAN MEATS)-LIVER	0.1000		0.0000	0.0000	0.0000	
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	0.1000		0.0012	0.0012	0.0250	
53006BA	PORK-MEAT BYPRODUCTS	0.1000		0.0025	0.0025	0.0502	
53006BB	PORK(ORGAN MEATS)-OTHER	0.1000		0.0004	0.0004	0.0077	
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0.1000		0.0208	0.0208	0.4164	
53006KA	PORK(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000	0.0000	
53006LA	PORK(ORGAN MEATS)-LIVER	0.1000		0.0005	0.0005	0.0096	
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.0391	0.0391	0.7825	

CROP GROUP TOTALS FOR RED MEAT:

4.4635

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		EXISTING TOLERANCES		NEW, PENDING & PUBLISHED TOLERANCES	
		NEW	PENDING	PUBLISHED	TMRC (UG/KG/DAY)	%Rfd	NEW TMRC (UG/KG/DAY) NEW %RFD
55008BA	TURKEY-BYPRODUCTS						
55008LA	TURKEY-GIBLETS (LIVER)	0.1000			0.0000	0.0005	
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	0.1000			0.0000	0.0001	
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	0.1000			0.0008	0.0159	
55008MC	TURKEY-UNSPECIFIED	0.1000			0.0048	0.0963	
55013BA	POULTRY, OTHER-BYPRODUCTS	0.1000			0.0000	0.0002	
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	0.1000			0.0000	0.0000	
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	0.1000			0.0000	0.0005	
55015BA	CHICKEN-BYPRODUCTS	0.1000			0.0005	0.0108	
55015LA	CHICKEN-GIBLETS(LIVER)	0.1000			0.0000	0.0000	
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	0.1000			0.0005	0.0101	
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	0.1000			0.0060	0.1203	
					0.0379	0.7586	
CROP GROUP TOTALS FOR POULTRY:							
					0.0507	1.0133	
50000DB	MILK-NON-FAT SOLIDS						
50000FA	MILK-FAT SOLIDS	0.0500			0.3568	7.1363	
50000SA	MILK SUGAR (LACTOSE)	0.0500			0.1697	3.3948	
55014AA	EGGS-WHOLE	0.0500			0.0019	0.0374	
55014AB	EGGS-WHITE ONLY	0.0500			0.0282	0.5645	
55014AC	EGGS-YOLK ONLY	0.0500			0.0005	0.0092	
					0.0003	0.0066	
CROP GROUP TOTALS FOR DAIRY PRODUCTS:							
					0.5574	11.1489	

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LISTING OF EXPOSURE BY RAC FOR: NON-NURSING INFANTS (<1 YEAR OLD)

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		EXISTING TOLERANCES		NEW, PENDING & PUBLISHED TOLERANCES	
		NEW	PENDING	TMRC (UG/KG/DAY)	%RFD	NEW TMRC (UG/KG/DAY)	NEW %RFD
CROP GROUP TOTALS FOR CEREAL GRAINS:							
24001AA	BARLEY	0.2000		0.0279	0.5581		
24003AA	OATS	0.2000		0.1498	2.9963		
24004AA	RICE-ROUGH	2.0000		0.0000	0.0000		
24004AB	RICE-MILLED	2.0000		2.6441	52.8828		
24007AA	WHEAT-ROUGH	0.2000		0.0245	0.4892		
24007GA	WHEAT-GERM	0.2000		0.0001	0.0017		
24007HA	WHEAT-BRAN	0.2000		0.0002	0.0041		
24007MA	WHEAT-FLOUR	0.2000		0.1816	3.6322		
				3.0282	60.5645		
CROP GROUP TOTALS FOR CEREAL GRAINS:							
53001BA	BEEF-MEAT BYPRODUCTS	0.1000		0.0011	0.0220		
53001BB	BEEF(ORGAN MEATS)-OTHER	0.1000		0.0003	0.0062		
53001DA	BEEF-DRIED	0.1000		0.0000	0.0000		
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0.1000		0.0191	0.3826		
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000		
53001LA	BEEF(ORGAN MEATS)-LIVER	0.1000		0.0031	0.0625		
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.1228	2.4557		
53002BA	GOAT-MEAT BYPRODUCTS	0.1000		0.0000	0.0000		
53002BB	GOAT(ORGAN MEATS)-OTHER	0.1000		0.0000	0.0000		
53002FA	GOAT(BONELESS)-FAT	0.1000		0.0000	0.0000		
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000		
53002LA	GOAT(ORGAN MEATS)-LIVER	0.1000		0.0000	0.0000		
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.0000	0.0000		
53003AA	HORSE	0.1000		0.0000	0.0000		
53005BA	SHEEP-MEAT BYPRODUCTS	0.1000		0.0000	0.0000		
53005BB	SHEEP(ORGAN MEATS)-OTHER	0.1000		0.0000	0.0000		
53005FA	SHEEP(BONELESS)-FAT	0.1000		0.0007	0.0145		
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000		
53005LA	SHEEP(ORGAN MEATS)-LIVER	0.1000		0.0000	0.0000		
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	0.1000		0.0063	0.1261		
53006BA	PORK-MEAT BYPRODUCTS	0.1000		0.0006	0.0115		
53006BB	PORK(ORGAN MEATS)-OTHER	0.1000		0.0002	0.0031		
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0.1000		0.0147	0.2930		
53006KA	PORK(ORGAN MEATS)-KIDNEY	0.1000		0.0000	0.0000		
53006LA	PORK(ORGAN MEATS)-LIVER	0.1000		0.0015	0.0301		
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.1000		0.0442	0.8835		
				0.2145	4.2908		
CROP GROUP TOTALS FOR RED MEAT:							

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LISTING OF EXPOSURE BY RAC FOR: NON-NURSING INFANTS (<1 YEAR OLD)

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		EXISTING TOLERANCES TMRC		NEW, PENDING & PUBLISHED TOLERANCES NEW TMRC	
		NEW	PENDING	PUBLISHED	(UG/KG/DAY)	%Rfd	(UG/KG/DAY) NEW %RFD
550088A	TURKEY-BYPRODUCTS			0.1000	0.0000	0.0000	
550088A	TURKEY-GIBLETS (LIVER)			0.1000	0.0000	0.0000	
550088A	TURKEY-FLESH(W/O SKIN, W/O BONES)			0.1000	0.0120	0.2398	
550088B	TURKEY-FLESH(+SKIN,W/O BONES)			0.1000	0.0081	0.1627	
550088C	TURKEY-UNSPECIFIED			0.1000	0.0000	0.0000	
550138A	POULTRY, OTHER-BYPRODUCTS			0.1000	0.0000	0.0000	
550138A	POULTRY, OTHER-GIBLETS(LIVER)			0.1000	0.0000	0.0000	
550138A	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)			0.1000	0.0000	0.0000	
550158A	CHICKEN-BYPRODUCTS			0.1000	0.0000	0.0000	
550158A	CHICKEN-GIBLETS(LIVER)			0.1000	0.0016	0.0320	
550158A	CHICKEN-FLESH(W/O SKIN, W/O BONES)			0.1000	0.0328	0.6567	
550158B	CHICKEN-FLESH(+SKIN, W/O BONES)			0.1000	0.0508	1.0169	
CROP GROUP TOTALS FOR POULTRY:							
					0.1054	2.1081	
500000B	MILK-NON-FAT SOLIDS			0.0500	2.5597	51.1935	
500000A	MILK-FAT SOLIDS			0.0500	0.5628	11.2556	
500000A	MILK SUGAR (LACTOSE)			0.0500	0.1515	3.0305	
55014AA	EGGS-WHOLE			0.0500	0.0236	0.4714	
55014AB	EGGS-WHITE ONLY			0.0500	0.0002	0.0041	
55014AC	EGGS-YOLK ONLY			0.0500	0.0064	0.1289	
CROP GROUP TOTALS FOR DAIRY PRODUCTS:							
					3.3042	66.0840	