



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

MAR 22 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP# 8F 3595. Tolerance Assessment Analysis on the Request to Increase the Established Tolerance of Permethrin on Asparagus from 1.0 ppm to 2.0 ppm. RCB # 3306.

From: Charles Frick
Tolerance Assessment Program
Residue Chemistry Branch, HED

C. Frick 3/15/88

Thru: Karl Arne, Ph.D. *K. Arne*
Branch Senior Scientist
Residue Chemistry Branch, HED

To: George La Rocca, PM #15
Registration Division

The Tolerance Assessment System (TAS) has been requested to perform a tolerance assessment for a residue level of 2.0 ppm of Permethrin on asparagus. This tolerance value has been approved by RCB (memo. M.T. Flood, 2/29/88).

A permanent tolerance of 1.0 ppm of Permethrin in/on asparagus as well as numerous other tolerances have been established for this chemical (CFR 180.378).

TOLERANCE ASSESSMENT

CHEMICAL: PERMETHRIN

1. The Acceptable Daily Intake (ADI) for this chemical is 0.05 mg/kg/day, and has been approved by the Toxicology Branch Reference Dose Committee, 9/12/86.

2. The food uses evaluated by the Tolerance Assessment System (TAS) are the requested tolerance of 2.0 ppm of Permethrin on asparagus and the published and pending tolerances for this chemical. 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 Permethrin for the U.S. population average expressed as percent of the ADI was 0.015518 mg/kg/day, which utilized 31.0 % of the ADI. The population subgroups ranged from a low of 24.6 % to a high of 58.0 % of the ADI (see page 1a in the appended tables).

4. This analysis did not factor in percent of crops treated with Permethrin or actual residues on foods as eaten (data not available) as such, the actual exposure to this chemical is probably considerable lower than the calculated estimate.

Attachment

cc. Reading File
Permethrin SF
TAS File
C. Frick (RCB)
S. Rathman (TOX)
PMSD

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CHEMICAL INFORMATION FOR CASWELL NUMBER 6522B

DATE: 03/14/88

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CHEMICAL	STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
	2yr feeding- rat	NOEL=	Decreased liver weights.	Slight increase in liver weights noted at 5 mg/kg.	ADI	100	No data gaps.	Slight increase in liver weights at 5 mg/kg only noted in 1/3 rat studies, not considered toxicologically significant.	TOX complete 9/12/86.	ORD verified 10/28/86.
Pernethin										
Caswell #6522B		5.0000 mg/kg				0.050000				
CAS No. 52645-53-1		100.00 ppm				0.050000				
A.I. CODE: 109701		25.0000 mg/kg		Evidence of oncogenicity in mice (liver, lung),		0.050000				WHO last reviewed 1987; (ADI extended to 25.75 mixture).
CR No. 180.378		500.00 ppm								On IRIS.
	ONCO: Pending WOTE		negative rat.		Type: ADI					

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
03001AA	ALMONDS	2F2675			0.0500
03005AA	FLIBERTS/HAZELNUTS	4F3130			0.0500
03009AA	WALNUTS	4F3130			0.0500
03011AA	PISTACHIO NUTS	4F2995			0.1000
04001AA	APPLES-FRESH	1F2562			0.0500
04001DA	APPLES-DRIED	1F2562			0.0500
04001JA	APPLES-JUICE	1F2562			0.0500
04003AA	PEARS-FRESH	0F2425			3.0000
04003DA	PEARS-DRIED	0F2425			3.0000
05002AA	CHERRIES-FRESH	5F3271			3.0000
05002DA	CHERRIES-DRIED	5F3271			3.0000
05002JA	CHERRIES-JUICE	5F3271			3.0000
05004AA	PEACHES-FRESH	3F2802			5.0000
05004DA	PEACHES-DRIED	3F2802			5.0000
06001AA	AVOCADOS	4E3146		1.0000	
06010AA	PAPAYAS-UNSPECIFIED	4E3146		1.0000	
06010AB	PAPAYAS-PULP	4E3186		1.0000	
06010DA	PAPAYAS-DRIED	4E3186		1.0000	
06010JA	PAPAYAS-JUICE	4E3186		1.0000	
06018AA	KIWI	1E2514			
08022AA	HORSERADISH	0E2377			2.0000
10002AA	CANTALOUPE-UNSPECIFIED	5E3225			1.0000
10002AB	CANTALOUPE-PULP	5E3225			3.0000
10011AA	PUMPKIN	3E2861			2.0000
11001AA	EGGPLANT	3E2892			1.0000
11003AA	PEPPERS (SWEET/GARDEN)	3E2892			1.0000
11005AA	TOMATOES-WHOLE	4F2985			2.0000
11005JA	TOMATOES-JUICE	4F2985			2.0000
11005RA	TOMATOES-PUREE	4F2985			2.0000
11005TA	TOMATOES-PASTE	4F2985			2.0000
11005UA	TOMATOES-CATSUP	4F2985			2.0000
13002AA	CELERY	8F2099			5.0000
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	4F3018			20.0000
13005AA	BRUSSELS SPROUTS	9F2207			1.0000
13006AA	CABBAGE-GREEN AND RED	9F2192			6.0000
13007AA	CABBAGE-GREEN AND RED	9F2192			6.0000
13008AA	CABBAGE-GREEN AND RED	9F2207			1.0000
13009AA	CABBAGE-GREEN AND RED	9F2207			20.0000
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)	9F2192			6.0000
13013AA	LETTUCE-LEAFY VARIETIES	4F3018			20.0000

CHEMICAL	STUDY TYPE	EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Permethrin	2yr feeding- rat		Decreased liver weights.	ADI 100		No data gaps.		TOX complete 9/12/86.	
Caswell #6528B	NOEL= 5.0000 mg/kg		Slight increase in liver	OPP RFD= 0.050000		Slight increase in liver		ORD verified 10/28/86.	
CAS No. 52645-53-1	100.00 ppm		weights noted at 5 mg/kg.	EPA RFD= 0.050000		weights at 5 mg/kg only		WHO last reviewed 1987;	
A.I. CODE: 109701	LEL= 25.0000 mg/kg		Evidence of oncogenicity			noted in 1/3 rat studies,		(ADI extended to 25.75	
CER No. 180.378	500.00 ppm		in mice (liver, lung),	WHO RFD 0.050000		not considered toxicolo-		mixture).	
	ONCO: Pending NOTE		negative rat.	Type: ADI		gically significant.		On IRIS.	

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PENDING PUBLISHED
13014AA	DANDELION	4F3018		20.0000
13015AA	ENDIVE (CURLEY AND ESCAROLE)	4F3018		20.0000
13016AA	FENNEL	8F2099		5.0000
13017AA	CRESS (GARDEN/FIELD)	4F3018		20.0000
13018AA	ARTICHOKES-GLOBE	4F3114		10.0000
13020AA	LETTUCE-UNSPECIFIED	4F3018		20.0000
13022AA	PARSLEY	4F3018		20.0000
13023AA	RHUBARB	4F3018		20.0000
13024AA	SPINACH	2E2701		20.0000
13025AA	SWISS CHARD	4F3018		20.0000
13026AA	TURNIPS-TOPS	6E3360		20.0000
13027AA	WATERCRESS	4E3113		5.0000
13039AA	CRESS/UPLAND	4F3018		20.0000
13045AA	LETTUCE-HEAD VARIETIES	9F2192		20.0000
14007AA	GARLIC	8E3583	0.1000	
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	8E3583	0.1000	
14011DA	ONIONS-DEHYDRATED OR DRIED	8E3583	0.1000	
14013AA	POTATOES(WHITE)-WHOLE	0F2307		0.0500
14013AB	POTATOES(WHITE)-UNSPECIFIED	0F2307		0.0500
14013AC	POTATOES(WHITE)-PEELED	0F2307		0.0500
14013DA	POTATOES(WHITE)-DRY	0F2307		0.0500
14013HA	POTATOES(WHITE)-PEEL ONLY	0F2307		0.0500
14017AA	SHALLOTS	8E3583	0.1000	
14019AA	TURNIPS-ROOTS	6E3360		1.0000
15004AA	CORN/POP	1F2476		0.0500
15005AA	CORN/SWEET	3F2781		0.1000
15029AA	SOYBEANS-SPROUTED SEEDS	9F2196		0.0500
16002AA	ASPARAGUS	3E2914		1.0000
16002AA	ASPARAGUS	8F3595	1.0000	
16003AA	MUSHROOMS	2E2752		6.0000
24002EA	CORN/GRAIN-ENDOSPERM	1F2476		0.0500
24002HA	CORN/GRAIN-BRAN	1F2476		0.0500
24002SA	CORN SUGAR	1F2476		0.0500
270020A	CORN/GRAIN-OIL	1F2476		0.0500
270030A	COTTONSEED-OIL			0.5000
27003WA	COTTONSEED-MEAL			0.5000
270100A	SOYBEANS-OIL	9F2196		0.0500
28023AA	SOYBEANS-UNSPECIFIED	9F2196		0.0500
28023AB	SOYBEANS-MATURE/SEEDS DRY	9F2196		0.0500
28023WA	SOYBEANS-FLOUR/FULL FAT	9F2196		0.0500

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

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CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Permethrin		2yr feeding- rat		Decreased liver weights.		ADI 100		No data gaps.		TOX complete 9/12/86.	
Caswell #652BB		NOEL=		Slight increase in liver		OPP RfD= 0.050000		Slight increase in liver		ORD verified 10/28/86.	
CAS No. 52645-53-1		100.00 ppm		Weights noted at 5 mg/kg.		ERA RfD= 0.050000		weights at 5 mg/kg only		WHO last reviewed 1987.	
A.I. CODE: 109701		25.0000 mg/kg		Evidence of oncogenicity		WHO RfD 0.050000		not considered toxicologically significant.		(ADI extended to 25:75 mixture).	
CFR No. 180.378		500.00 ppm		in mice (liver, lung),		Type: ADI				On IRIS.	
		ONCO: Pending NOTE		negative rat.							
FOOD		PETITION		TOLERANCE (PPM)							
CODE	FOOD NAME	NUMBER	NEW	PENDING	PUBLISHED						
28023WB	SOYBEANS-FLOUR/LOW FAT	9F2196			0.0500						
28023WC	SOYBEANS-FLOUR/DEFATTED	9F2196			0.0500						
50000FA	MILK-FAT SOLIDS	3F2781			3.7500	H					
53001BA	BEEF-MEAT BYPRODUCTS	1F2564			1.0000						
53001BB	BEEF (ORGAN MEATS)-OTHER	1F2564			1.0000						
53001DA	BEEF-DRIED	1F2564			0.1500						
53001FA	BEEF (BONELESS)-FAT (BEEF TALLOW)	1F2564			2.0000						
53001KA	BEEF (ORGAN MEATS)-KIDNEY	1F2564			1.0000						
53001LA	BEEF (ORGAN MEATS)-LIVER	1F2564			1.0000						
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2564			0.1500						
53002BA	GOAT-MEAT BYPRODUCTS	1F2564			1.0000						
53002BB	GOAT (ORGAN MEATS)-OTHER	1F2564			1.0000						
53002FA	GOAT (BONELESS)-FAT	1F2564			2.0000						
53002KA	GOAT (ORGAN MEATS)-KIDNEY	1F2564			1.0000						
53002LA	GOAT (ORGAN MEATS)-LIVER	1F2564			1.0000						
53002MA	GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2564			0.1500						
53003AA	HORSE	1F2564			2.0000						
53005BA	SHEEP-MEAT BYPRODUCTS	1F2564			1.0000						
53005BB	SHEEP (ORGAN MEATS)-OTHER	1F2564			1.0000						
53005FA	SHEEP (BONELESS)-FAT	1F2564			2.0000						
53005KA	SHEEP (ORGAN MEATS)-KIDNEY	1F2564			1.0000						
53005LA	SHEEP (ORGAN MEATS)-LIVER	1F2564			1.0000						
53005MA	SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2564			0.1500						
53006BA	PORK-MEAT BYPRODUCTS	1F2546			3.0000						
53006BB	PORK (ORGAN MEATS)-OTHER	1F2546			3.0000						
53006FA	PORK (BONELESS)-FAT (INCLUDING LARD)	1F2546			2.0000						
53006KA	PORK (ORGAN MEATS)-KIDNEY	1F2546			3.0000						
53006LA	PORK (ORGAN MEATS)-LIVER	1F2546			3.0000						
53006MA	PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT)	1F2546			0.1500						
55008BA	TURKEY-BYPRODUCTS	1F2564			0.0500						
55008LA	TURKEY-GIBLETS (LIVER)	1F2564			0.0500						
55008MA	TURKEY-FLESH (W/O SKIN & W/O BONES)	1F2564			0.0500						
55008MB	TURKEY-FLESH (+SKIN & W/O BONES)	1F2564			0.0500						
55008MC	TURKEY-UNSPECIFIED	1F2564			0.0500						
55013BA	POULTRY/OTHER-BYPRODUCTS	1F2564			0.0500						
55013LA	POULTRY/OTHER-GIBLETS (LIVER)	1F2564			0.0500						
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	1F2564			0.0500						
55014AA	EGGS-WHOLE	1F2564			0.0500						
55014AB	EGGS-WHITE ONLY	1F2564			0.0500						
55014AC	EGGS-YOLK ONLY	1F2564			0.0500						

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

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CHEMICAL	STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Permethrin	2yr feeding- rat	Decreased liver weights.	ADI	100	No data gaps.	TOX complete 9/12/86.				
Caswell #652BB	NOEL= 5,000 mg/kg	Slight increase in liver weights noted at 5 mg/kg.	OPP RfD= 0.050000		Slight increase in liver weights at 5 mg/kg only.	ORD verified 10/28/86.				
CAS No. 52645-53-1	100.00 ppm	Evidence of oncogenicity in mice (liver, lung),	EPA RfD= 0.050000		noted in 1/3 rat studies,	WHO last reviewed 1987.				
A.I. CODE: 109701	LET= 25,000 mg/kg		WHO RfD 0.050000		not considered toxicologically significant.	(ADI extended to 25:75 mixture).				
CFR No. 180.378	500.00 ppm	negative rat.	Type: ADI			On IRIS.				
	ONCO: Pending NOTE									

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
55015BA	CHICKEN-BYPRODUCTS	1F2564			0.0500
55015LA	CHICKEN-GIBLETS(LIVER)	1F2564			0.0500
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	1F2564			0.0500
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	1F2564			0.0500
90997AA	INEST. RACS--TOLERANCE TOO SPECIFIC	1F2546			
90999AA	FEED RACS--INEST. FROM USDA SURVEY	2F2675			

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Pernethin		2yr feeding- rat		Decreased liver weights.		ADI 100		No data gaps.		TOX complete 9/12/86.	
Caswell #652JB		NOEL= 5.0000 mg/kg		Slight increase in liver		OPP RfD= 0.050000		Slight increase in liver		ORD verified 10/28/86.	
CAS NO. 52645-53-1		100.00 ppm		weights noted at 5 mg/kg.		EPA RfD= 0.050000		weights at 5 mg/kg only		WHO last reviewed 1987;	
A.I. CODE: 109701		LEL= 25.0000 mg/kg		Evidence of oncogenicity		WHO RfD 0.050000		noted in 1/3 rat studies,		(ADI extended to 25.75	
CFR NO. 180.378		500.00 ppm		in mice (liver, lung),				not considered toxicolo-		mixture).	
		ONCO: Pending NOTE		negative rat.		Type: ADI		gically significant.		On IRIS.	
POPULATION SUBGROUP		TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD		DIFFERENCE AS PERCENT OF RFD		EFFECT OF ANTICIPATED RESIDUES		ARC	
		CURRENT TMRC*	NEW TMRC**								
U.S. POPULATION - 48 STATES		0.015461	0.015518	31.035484	0.114450						
U.S. POPULATION - SPRING SEASON		0.015735	0.015816	31.632966	0.163060						
U.S. POPULATION - SUMMER SEASON		0.016169	0.016211	32.421304	0.083812						
U.S. POPULATION - FALL SEASON		0.014907	0.014956	29.911318	0.098278						
U.S. POPULATION - WINTER SEASON		0.015028	0.015084	30.168878	0.112104						
NORTHEAST REGION		0.015873	0.015926	31.852960	0.107250						
NORTH CENTRAL REGION		0.015109	0.015154	30.307594	0.089436						
SOUTHERN REGION		0.014257	0.014302	28.603256	0.088750						
WESTERN REGION		0.017503	0.017606	35.212142	0.205202						
HISPANICS		0.015958	0.016040	32.080802	0.165342						
NON-HISPANIC WHITES		0.015344	0.015402	30.804192	0.117176						
NON-HISPANIC BLACKS		0.015686	0.015723	31.446256	0.074080						
NON-HISPANICS OTHER		0.017983	0.018033	36.065184	0.098652						
NURSING INFANTS (<1 YEAR OLD)		0.013301	0.013302	26.604720	0.003636						
NON-NURSING INFANTS (<1 YEAR OLD)		0.029004	0.029017	58.033128	0.025908						
FEMALES (13+ YEARS, PREGNANT)		0.012279	0.012308	24.615716	0.058142						
FEMALES 13+ YEARS, NURSING		0.016248	0.016290	32.580194	0.084408						
CHILDREN (1-6 YEARS OLD)		0.024570	0.024635	49.269102	0.128978						
CHILDREN (7-12 YEARS OLD)		0.020830	0.020866	41.732750	0.072988						
MALES (13-19 YEARS OLD)		0.014273	0.014309	28.617258	0.071022						
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.013113	0.013166	26.331920	0.106742						
MALES (20 YEARS AND OLDER)		0.012813	0.012874	25.748524	0.121896						
FEMALES (20 YEARS AND OLDER)		0.013810	0.013876	27.751846	0.132020						

*Current TMRC does not include new or pending tolerances.

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