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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).

1

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

2

CHEMICAL INFORMATION FOR CASWELL NUMBER 6522B

DATE: 03/14/88

PAGE: 1

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 #6522B	NOEL= 5.0000 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, not considered toxicologically significant.	WHO last reviewed 1987; (ADI extended to 25:75 mixture).
A.I. CODE: 109701	LEL= 25.0000 mg/kg		WHO RFD 0.050000		(ADI extended to 25:75 mixture).
CFR No. 180.378	500.00 ppm		Type: ADI		On IRIS.
	ONCO: Pending WOTE	negative rat.			

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
03001AA	ALMONDS	2F2675		1.0000		0.0500
03005AA	FILBERTS/HAZELNUTS	4F3130		1.0000		0.0500
03009AA	WALNUTS	4F3130		1.0000		0.0500
03011AA	PISTACHIO NUTS	4F2995		1.0000		0.1000
04001AA	APPLES-FRESH	1F2562		1.0000		0.0500
04001DA	APPLES-DRIED	1F2562		1.0000		0.0500
04001JA	APPLES-JUICE	1F2562		1.0000		0.0500
04003AA	PEARS-FRESH	0F2425		1.0000		0.0500
04003DA	PEARS-DRIED	0F2425		1.0000		0.0500
05002AA	CERRIES-FRESH	5F3271		1.0000		3.0000
05002DA	CERRIES-DRIED	5F3271		1.0000		3.0000
05002JA	CERRIES-JUICE	5F3271		1.0000		3.0000
05004AA	PEACHES-FRESH	3F2802		1.0000		5.0000
05004DA	PEACHES-DRIED	3F2802		1.0000		5.0000
06001AA	AVOCADOS	4E3146		1.0000		2.0000
06010AA	PAPAYAS-UNSPECIFIED	4E3146		1.0000		1.0000
06010AB	PAPAYAS-PULP	4E3186		1.0000		1.0000
06010DA	PAPAYAS-DRIED	4E3186		1.0000		1.0000
06010JA	PAPAYAS-JUICE	4E3186		1.0000		1.0000
06018AA	KIWI	1E2514		1.0000		2.0000
08022AA	HORSERADISH	0E2377		1.0000		1.0000
10002AA	CANTALOUPE-UNSPECIFIED	5E3225		1.0000		3.0000
10002AB	CANTALOUPE-PULP	5E3225		1.0000		3.0000
10011AA	PUMPKIN	3E2861		1.0000		2.0000
11001AA	EGGPLANT	3E2892		1.0000		1.0000
11003AA	PEPPERS (SWEET/GARDEN)	3E2892		1.0000		1.0000
11005AA	TOMATOES-WHOLE	4F2985		2.0000		2.0000
11005JA	TOMATOES-JUICE	4F2985		2.0000		2.0000
11005BA	TOMATOES-PUREE	4F2985		2.0000		2.0000
11005TA	TOMATOES-PASTE	4F2985		2.0000		2.0000
11005UA	TOMATOES-CATSUP	4F2985		2.0000		2.0000
13002AA	CELERY	8F2099		5.0000		5.0000
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	4F3018		20.0000		20.0000
13005AA	BRUSSELI	9F2207		1.0000		1.0000
13006AA	BRUSSEL SPROUTS	9F2207		1.0000		1.0000
13007AA	CABBAGE-GREEN AND RED	9F2192		6.0000		6.0000
13008AA	CAULIFLOWER	9F2207		1.0000		1.0000
13009AA	COLLARDS	6E3360		20.0000		20.0000
13010AA	CABBAGE-CHINESE/CELERY (INC. BOK CHOY)	9E2192		6.0000		6.0000
13013AA	LETTUCE-LEAFY VARIETIES	4F3018		20.0000		20.0000

3

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

DATE: 03/14/88

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	100		
Permethrin	2yr feeding- rat	Decreased liver weights.	ADJ	100	No data gaps.	TOX complete 9/12/86.
Caswell #652BB	NOEL=	Slight increase in liver weights noted at 5 mg/kg.	OPP RED=	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	EPA RED=	0.050000	noted in 1/3 rat studies, not considered toxicologically significant.	WHO last reviewed 1987; (ADI extended to 25.75 mixture).
A.I. CODE: 109701	LEL=	in mice (liver, lung), negative rat.	WHO RED	0.050000		On IRIS.
CFR No. 180.378	500.00 ppm		Type: ADI			
	ONCO: Pending NOTE					

FOOD CODE	FOOD NAME	PETTITON 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		0.0500
14019AA	TURNIPS-ROOTS	6E3360	0.1000	1.0000
15004AA	CORN/POP	1F2476		0.0500
15005AA	CORN/SWEET	3F2781		0.1000
15029AA	SOYBEANS-SPROUTED SEEDS	9F2196		0.0500
16002AA	ASPARAGUS	3E2914		0.0500
16002AA	ASPARAGUS	8F3595	1.0000	1.0000
16003AA	MUSHROOMS	2F2752		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 6528B

DATE: 03/14/88

PAGE: 3

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	100		
Permethrin	2yr feeding- rat	Decreased liver weights.		100	No data gaps.	TOX complete 9/12/86.
Caswell #6528B	NOEL= 5.0000 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 noted in 1/3 rat studies, not considered toxicologically significant.	ORD verified 10/28/86.
CAS No. 52645-53-1	LEL= 25.0000 mg/kg	Evidence of oncogenicity in mice (liver, lung), negative rat.	EPA RFD= 0.050000			WHO last reviewed 1987; (ADI extended to 25:75 mixture).
A.I. CODE: 109701	500.00 ppm		WHO RFD 0.050000			
CFR No. 180.378	ONCO: Pending NOTE		Type: ADI			On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				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 (BONELESS)-LEAN (W/O REMOVABLE FAT)	1F2564			1.0000
53001MA	BEEF (BONELESS)-LEAN (W/O REMOVABLE 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 REMOVABLE 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 REMOVABLE 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 REMOVABLE 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
55008WA	TURKEY-FLESH(+SKIN & W/O BONES)	1F2564			0.0500
55008WG	TURKEY-FLESH(+SKIN & W/O BONES)	1F2564			0.0500
55008WC	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

10

CHEMICAL INFORMATION FOR CASWELL NUMBER 652BB

DATE: 03/14/88

PAGE: 4

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	PUBLISHED		
Permethrin	2yr feeding- rat	Decreased liver weights.	100		No data gaps.	TOX complete 9/12/86.
Caswell #652BB	NOEL= 5.0000 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	LET= 25.0000 mg/kg	Evidence of oncogenicity in mice (liver, lung),	EPA RfD= 0.050000		not considered toxicologically significant.	WHO last reviewed 1987; (ADI extended to 25:75 mixture).
A. I. CODE: 109701	500.00 ppm	negative rat.	WHO RfD 0.050000			On IRIS.
CFR No. 180.378	ONCO: Pending NOTE		Type: ADI			

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
55015BA	CHICKEN-BYPRODUCTS	1F2564			0.0500
55015IA	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			

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 03/14/88

PAGE: 4a

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	100		
Permethrin	2Yr feeding- rat	Decreased liver weights.			No data gaps.	TOX complete 9/12/86.
Caswell #652JB	NOEL= 5.0000 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, not considered toxicologically significant.	WHO last reviewed 1987; (ADI extended to 25.75 mixture).
A.I. CODE: 109701	LEL= 25.0000 mg/kg		WHO RfD 0.050000			(ADI extended to 25.75 mixture).
CFR NO. 180.378	500.00 ppm	negative rat.	Type: ADI			On IRIS.
	ONCO: Pending NOTE					
POPULATION SUBGROUP						
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	
CHILDREN (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.