

US EPA ARCHIVE DOCUMENT

Residue Information

Tolerances for imidacloprid are published in 40 CFR §180.472. Hops are included in this analysis as a published commodity with a 3.0 ppm tolerance. For the purposes of this analysis, the following changes were made to the DRES files: a) an increase of the hops tolerance (as per petition) from 3 to 6 ppm; b) new poultry tolerances upgraded to published status; and c) new tolerances for grapes, eggplant, peppers, tomatoes, broccoli, brussels sprouts, cabbage, cauliflower, collards, kale, kohlrabi, lettuce and mustard greens were upgraded to pending.

Residue values used and percent crop treated assumptions made in this analysis to calculate the Theoretic Maximum Residue Concentration (TMRC) and Anticipated Residue Concentration (ARC) are found in Table 1. Adequate secondary tolerances have been established at 0.1 ppm in milk, 0.3 ppm in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep, 0.02 ppm in eggs, and 0.05 ppm in meat, fat, and meat by-products of poultry (See memo, F. Griffith, 3/21/95).

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Tables 2 & 3. Summaries of the acute dietary risk for the subgroup females (13+ years) are attached as Table 4.

Chronic Exposure Analysis

Exposure from Published Uses of imidacloprid:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.002632	4.6
Children 1-6 years	0.006655	12
Non-nursing infants < 1yr	0.011718	21

Proposed new Tolerances on hops:

U.S. Population	0.000012	.02
Children 1-6 years	0.000001	.00
Non-nursing infants < 1yr		

If the new tolerances on hops are approved:

U.S. Population	0.002643	4.6
Children 1-6 years	0.006655	12
Non-nursing infants < 1yr	0.014747	26

Acute Exposure:

The DRES detailed acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 77-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of imidacloprid in the commodity supply. Since the toxicological effect to which exposure is being compared in this analysis is a developmental effect, the subgroup females (13+years) is the only appropriate group for acute dietary concern.

The Margin of Exposure (MOE) is a measure of how closely the high end exposure comes to the NOEL, the highest dose at which no effects were observed in the laboratory test. For this analysis the MOE is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). An uncertainty factor (UF) of 100 was applied to account for interspecies extrapolation and intraspecies variability. The Agency is not generally concerned unless the MOE is below 100 when based upon data generated in animal studies.

Using only the CBTS recommended tolerances, the MOE for the females 13+ subgroup is 2,500 for high end exposure. The estimated percent of potential person days on which any commodity for which imidacloprid has tolerances is consumed is ~100%.

DRES Subgroup	High End MOE (LOEL/High Exposure)	Mean MOE
Females (13+years)	2,500	>13,000

Conclusions

The chronic analysis for imidacloprid is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with imidacloprid. Even without refinements, the chronic dietary risk exposure to imidacloprid appears to be minimal for this petition on hops at 6.0 ppm and does not exceed the RfD for any of the DRES subgroups.

Generally, acute dietary margins of exposure of less than 100 tend to cause the Agency concern when endpoints from studies in animals are the basis for comparison. The MOE value of 2,500 demonstrates no concern for females of child-bearing age considering the proposed tolerances.

There appears to be no dietary concern for the tolerances on the recommended commodities found on page 1 of this memo.

Attachments

cc: DRES; Caswell 497E; RCAB; CBTS (F. Griffith); Tox I

STING TOLERANCES (PUBLISHED ONLY)
TOXICITY & MRC (F)

02532 MG/KG/DAY

TABLE 1

CHEMICAL INFORMATION FOR CASSELL NUMBER 497E

DATE: 03/29/95

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Imidacloprid Caswell #497E CAS No. 105827-78-9 A.I. CODE: 129099 CFR No.	2yr feeding- rat NOEL = 5,7000 mg/kg LEL = 16,9000 mg/kg 300.00 ppm ONCO: E (Rfd/PR Committee)	Increased incidence of mineralized particles in thyroid colloid. No evidence of carcinogenicity in rats or mice.	OPPP RFD= 0.057000 EPA RFD= 0.000000	-->100	No data gaps.	Rfd/PR reviewed 04/22/93

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
01013AA	GRAPES- FRESH	3F4231		1.000000	
01014DA	GRAPES- RAISINS	3F4231		1.000000	
01014JA	GRAPES- JUICE	3F4231		1.000000	
04001AA	APPLES- FRESH	3F4169		0.500000	0.500000
04001DA	APPLES- DRIED	3F4169		0.500000	0.500000
04001JA	APPLES- JUICE	3F4169		0.500000	
06007AA	MANGOES	4F4285		0.200000	
08020AA	HOPS	300343			3.000000
08020AA	HOPS	5E4425		3.000000	
11001AA	EGGPLANT	3F4231		1.000000	
11003AA	PEPPERS, SWEET, GARDEN	3F4231		1.000000	
11003AB	CHILI PEPPERS	3F4231		1.000000	
11003AD	PEPPERS- OTHER	3F4231		1.000000	
11004AA	PIMIENTOS	3F4231		1.000000	
11005AA	TOMATOES- WHOLE	3F4231		1.000000	
11005JA	TOMATOES- JUICE	3F4231		1.000000	
11005RA	TOMATOES- PUREE	3F4231		3.000000	
11005TA	TOMATOES- PASTE	3F4231		6.000000	
11005UA	TOMATOES- CATSUP	3F4231		1.000000	
13005AA	BROCCOLI	3F4231		3.500000	
13006AA	BRUSSEL SPROUTS	3F4231		3.500000	
13007AA	CABBAGE- GREEN AND RED	3F4231		3.500000	
13008AA	CABBAGE- GREEN AND RED	3F4231		3.500000	
13009AA	COLLARDS	3F4231		3.500000	
13010AA	CABBAGE- CHINESE/CELERY, INC. BOK CHOY	3F4231		3.500000	
13011AA	KALE	3F4231		3.500000	
13012AA	KOHLRABI	3F4231		3.500000	
13013AA	LETTUCE- LEAFY VARIETIES	3F4231		3.500000	
13013AA	LETTUCE- UNRSPECIFIED	3F4231		3.500000	
13020AA	MUSTARD GREENS	3F4231		3.500000	
13021AA	LETTUCE- HEAD VARIETIES	3F4231		3.500000	
13045AA	POTATOES(WHITE)- WHOLE	3F4169		0.300000	0.300000
14013AA	POTATOES(WHITE)- UNSPECIFIED	3F4169		0.300000	0.300000
14013AB	POTATOES(WHITE)- PEELLED	3F4169		0.300000	0.300000
14013AC	POTATOES(WHITE)- PEELLED	3F4169		0.300000	0.300000
14013DA	POTATOES(WHITE)- DRY	3F4169		0.300000	0.300000
14013HA	POTATOES(WHITE)- PEEL ONLY	3F4169		0.050000	0.050000
24006AA	SORGHUM (INCLUDING MILD)	4F4337		6.000000	6.000000
270030A	COTTONSEED- OIL	4F4169		9.000000	
270030A	COTTONSEED- MEAL	4F4169		9.000000	
43058AA	WINE AND SHERRY	3F4231		1.000000	

CHEMICAL INFORMATION FOR CASSELL NUMBER 497E

DATE: 03/29/95

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CHEMICAL Imidacloprid Caswell #497E CAS No. 105827-78-9 A.I. CODE: 129099 CFR No.	STUDY TYPE 2yr feeding- rat NOEL= 5,7000 mg/kg 100.00 ppm LEL= 16,9000 mg/kg 300.00 ppm ONCO: E (Rfd/PR Committee)	EFFECTS Increased incidence of mineralized particles in thyroid colloid. No evidence of carcinogenicity in rats or mice.	REFERENCE DOSES		DATA GAPS/COMMENTS No data gaps.	STATUS RFD/PR reviewed 04/22/93
			ADI UF -->100 OPP Rfd= 0.057000 EPA Rfd= 0.000000			

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
500000B	MILK-NON-FAT SOLIDS	4F4169			0.100000
50000FA	MILK-FAT SOLIDS	4F4169			0.100000
50000SA	MILK SUGAR (LACTOSE)	4F4169			0.100000
53001BA	BEEF-MEAT BYPRODUCTS	4F4169			0.300000
53001BB	BEEF(ORGAN MEATS)-OTHER	4F4169			0.300000
53001DA	BEEF-DRIED	4F4169			0.300000
53001FA	BEEF(BOHELESS)-FAT (BEEF TALLOW)	4F4169			0.300000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53001LA	BEEF(ORGAN MEATS)-LIVER	4F4169			0.300000
53001MA	BEEF(BOHELESS)-LEAN (W/O REMOVABLE FAT)	4F4169			0.300000
53002BA	GOAT-MEAT BYPRODUCTS	4F4169			0.300000
53002BB	GOAT(ORGAN MEATS)-OTHER	4F4169			0.300000
53002FA	GOAT(BOHELESS)-FAT	4F4169			0.300000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53002LA	GOAT(ORGAN MEATS)-LIVER	4F4169			0.300000
53002MA	GOAT(BOHELESS)-LEAN (W/O REMOVABLE FAT)	4F4169			0.300000
53003AA	HORSE	4F4169			0.300000
53003BA	SHEEP-MEAT BYPRODUCTS	4F4169			0.300000
53003BB	SHEEP(ORGAN MEATS)-OTHER	4F4169			0.300000
53003FA	SHEEP(BOHELESS)-FAT	4F4169			0.300000
53003KA	SHEEP(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53003LA	SHEEP(ORGAN MEATS)-LIVER	4F4169			0.300000
53003MA	SHEEP(BOHELESS)-LEAN (W/O REMOVABLE FAT)	4F4169			0.300000
53006BA	PORK-MEAT BYPRODUCTS	4F4169			0.300000
53006BB	PORK(ORGAN MEATS)-OTHER	4F4169			0.300000
53006FA	PORK(BOHELESS)-FAT (INCLUDING LARD)	4F4169			0.300000
53006KA	PORK(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53006LA	PORK(ORGAN MEATS)-LIVER	4F4169			0.300000
53006MA	PORK-LEAN	4F4169			0.300000
55008BA	TURKEY-BYPRODUCTS	3F4231			0.050000
55008BLA	TURKEY-GIBLETS (LIVER)	3F4231			0.050000
55008BLB	TURKEY-FLESH(W/O SKIN, W/O BONES)	3F4231			0.050000
55008MA	TURKEY-FLESH(+SKIN, W/O BONES)	3F4231			0.050000
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	3F4231			0.050000
55008MC	TURKEY-UNSPECIFIED	3F4231			0.050000
55013BA	POULTRY, OTHER-BYPRODUCTS	3F4231			0.050000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	3F4231			0.050000
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	3F4231			0.020000
55014AA	EGGS-WHOLE	3F4231			0.020000
55014AB	EGGS-WHITE ONLY	3F4231			0.020000
55014AC	EGGS-YOLK ONLY	3F4231			0.020000

CHEMICAL INFORMATION FOR CASWELL NUMBER 497E

DATE: 03/29/95

PAGE: 3

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Imidacloprid Caswell #497E CAS No. 105827-78-9 A.I. CODE: 129099 CFR No.	2yr feeding- rat NOEL= 5.7000 mg/kg LEL= 16.9000 mg/kg 300.00 ppm ONCO: E (Rfd/PR Committee)	Increased incidence of mineralized particles in thyroid colloid. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.057000 EPA RfD= 0.000000	No data gaps.	Rfd/PR reviewed 04/22/93

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
55015BA	CHICKEN-BYPRODUCTS	3F4231		0.050000		
55015LA	CHICKEN-GIBLETS(LIVER)	3F4231		0.050000		
55015MA	CHICKEN-FLESH(U/O SKIN,U/O BONES)	3F4231		0.050000		
55015MB	CHICKEN-FLESH(+SKIN,U/O BONES)	3F4231		0.050000		

TABLE 2
TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 03/29/95

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Imidacloprid Caswell #497E CAS No. 105827-78-9 A.I. CODE: 129099 CFR No.	2yr feeding - rat NOEL= 5.7000 mg/kg 100.00 ppm LEL= 16.9000 mg/kg 300.00 ppm ONCO: E (Rfd/PR Committee)	Increased incidence of mineralized particles in thyroid colloid. No evidence of carcinogenicity in rats or mice.	Opp RfD= 0.057000 EPA RfD= 0.000000	No data gaps.	Rfd/PR reviewed 04/22/93	
POPULATION SUBGROUP						
U.S. POPULATION - 48 STATES	0.002631	0.008099	14.209154	9.593240		
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)						
U.S. POPULATION - SPRING SEASON	0.002468	0.007700	13.508718	9.179433		
U.S. POPULATION - SUMMER SEASON	0.002535	0.007740	13.578412	9.130546		
U.S. POPULATION - FALL SEASON	0.002781	0.008470	14.859261	9.980784		
U.S. POPULATION - WINTER SEASON	0.002736	0.008467	14.854167	10.053851		
NORTHEAST REGION						
NORTH CENTRAL REGION	0.002760	0.008426	14.782172	9.940133		
SOUTHERN REGION	0.002698	0.008301	14.563830	9.830533		
WESTERN REGION	0.002372	0.007291	12.791993	8.629763		
	0.002801	0.008736	15.325465	10.410582		
HISPANICS						
NON-HISPANIC WHITES	0.003096	0.008537	14.977821	9.546453		
NON-HISPANIC BLACKS	0.002642	0.008222	14.425288	9.790779		
NON-HISPANIC OTHERS	0.002324	0.006999	12.279626	8.202982		
	0.002718	0.008585	15.062230	10.293246		
NURSING INFANTS (< 1 YEAR OLD)						
NON-NURSING INFANTS (< 1 YEAR OLD)	0.004866	0.005485	9.623265	1.085839		
FEMALES (13+ YEARS, PREGNANT)	0.011718	0.014746	25.870911	5.313479		
FEMALES (13+ YEARS, NURSING)	0.001814	0.006715	11.780782	8.598193		
CHILDREN (1-6 YEARS OLD)	0.002172	0.007638	13.399537	9.589472		
CHILDREN (7-12 YEARS OLD)	0.006655	0.016735	29.359284	17.683961		
MALES (13-19 YEARS OLD)	0.004088	0.012404	21.760947	14.589793		
MALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.002710	0.008397	14.731632	9.976493		
FEMALES (20 YEARS AND OLDER)	0.002181	0.007107	12.467749	8.640956		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.001821	0.006188	10.856200	7.661346		
	0.001562	0.005999	10.525363	7.784332		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Imidacloprid
CASWELL #497E

DATE: 04/07/95

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.002632 4.616	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	0.000012 0.020	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.002643 4.636	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.005457 9.574	MG/KG/DAY % OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE: THE TOTAL TMRC WILL OCCUPY	0.008100 14.209	MG/KG/DAY % OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.011718 20.557	MG/KG/DAY % OF THE ADI.
NO NEW TOLERANCES ARE IN THE FILE.		
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.003029 5.313	MG/KG/DAY % OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE: THE TOTAL TMRC WILL OCCUPY	0.014747 25.871	MG/KG/DAY % OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.006655 11.675	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	<0.000001 0.000	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.006655 11.675	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.010080 17.684	MG/KG/DAY % OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE: THE TOTAL TMRC WILL OCCUPY	0.016735 29.359	MG/KG/DAY % OF THE ADI.

TABLE 4

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:41 Tuesday, April 4, 1995 22

 *NAME: IMIDACLOPRID *****
 *CASWELL NO: 497E CFR NO: CFR A STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 *CAS NO: 12909-90-0 SHAUGHNESSY NO: 129099 B C *****
 *STATUS CODES: *****
 *RDV INFO: The LD value used in this analysis is 0.0024 MG/KG of BODY WEIGHT/DAY
 FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

 -FEMALES(13+ YRS) *****

ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY															
TOLERANCES:	0.00	0.000000	0.00																
ANTICIPATED RESIDUES:	99.78	0.001732	72.16																
ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20		
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
ANTICIPATED RESIDUES:	100	91	71	51	34	22	14	9	6	4	3	1	0	0	0	0	0		

Exposure = RDV x X
 = 0.0024 x 4
 High End Exposure = 0.0096
 MOE = Noel + Exposure
 = 24 mg/kg/day + 0.0096 mg/kg/day
 MOE = 2500
 Mean MOE = NOEL + Mean
 = 24 + 0.001732
 = >13,000