



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

APR 10 1995

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Imidacloprid in/on Hops.  
PP# 5E4425.

FROM: Brian Steinwand *BS*  
Dietary Risk Evaluation Section  
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head *E. A. Doyle*  
Dietary Risk Evaluation Section  
SAB/Health Effects Division

TO: H. Jamerson/D. Edwards, PM Team 43 & 19 *W. B. Smith*  
Registration Division (7505C)

Action Requested

Provide a dietary exposure analysis for the use of imidacloprid in/on hops. The petition requests and CBTS recommends that a tolerance of 6.0 ppm be established on hops; a time limited tolerance on hops which expires on June 28, 1996 has already been established (See memo, F. Griffith, 3/21/95).

Discussion

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.057 mg/kg bwt/day, based on a NOEL of 100 ppm (5.70 mg/kg bwt/day) from a two year rat feeding study with an uncertainty factor of 100 that demonstrated increased thyroid lesions in males as an endpoint. The HED RfD Peer review Committee also classified imidacloprid as a Group E carcinogen (G. Ghali memo, 11/10/93).

An acute dietary assessment is required by the Toxicology Endpoint Selection Document for imidacloprid (M. Ottley & K. Baetcke memo, 4/18/94). The endpoint for acute dietary risk assessment is 24 mg/kg/day from the rabbit developmental study. The LEL (72 mg/kg/day) was based upon decreased body weight, increased resorptions, abortions, and increased skeletal abnormalities.



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## 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 ( $\text{NOEL/exposure} = \text{MOE}$ ). 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  $\approx 100\%$ .

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**

STUDY TOLERANCES (PUBLISHED ONLY)  
TREAT IN A MRC DFI

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

Imidacloprid CASSELL #497E ACTION CAS No. 105827-78-9 A.I. CODE: 129099 CFR No.	2yr feeding- rat NOEL= 5,7000 mg/kg LEL= 100.00 ppm 16,9000 mg/kg 300.00 ppm	Increased incidence of mineralized particles in thyroid colloid. No evidence of carcinog- enicity in rats or mice.	ADI OPR RfD= 0.057000 EPA RfD= 0.000000	No data gaps.	RfD/PR reviewed 04/22/93
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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		
04001DA	APPLES-DRIED	3F4169		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	CAULIFLOWER	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		
13020AA	LETTUCE-UNSPECIFIED	3F4231		3.500000		
13021AA	MUSTARD GREENS	3F4231		3.500000		
13045AA	LETTUCE-HEAD VARIETIES	3F4169		0.300000		
14013AA	POTATOES(WHITE)-WHOLE	3F4169		0.300000		
14013AB	POTATOES(WHITE)-UNSPECIFIED	3F4169		0.300000		
14013AC	POTATOES(WHITE)-PEELED	3F4169		0.300000		
14013DA	POTATOES(WHITE)-PEEL ONLY	3F4169		0.300000		
14013HA	POTATOES(WHITE)-PEEL ONLY	3F4169		0.300000		
24006AA	SORGHUM (INCLUDING MILO)	4F4337		0.050000		
270030A	COTTONSEED-OIL	4F4169		6.000000		
270030A	COTTONSEED-MEAL	4F4169		9.000000		
43058AA	WINE AND SHERRY	3F4231		1.000000		

## CHEMICAL INFORMATION FOR CASSELL NUMBER 497E

DATE: 03/29/95

PAGE: 2

CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Imidacloprid Cassell #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 carcinog- enicity 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		TOLERANCE (PPM)	
		NUMBER	NEW	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(BONELESS)-FAT (BEEF TALLOW)	4F4169			0.300000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53001LA	BEEF(ORGAN MEATS)-LIVER	4F4169			0.300000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F4169			0.300000
53002BA	GOAT-MEAT BYPRODUCTS	4F4169			0.300000
53002BB	GOAT(ORGAN MEATS)-OTHER	4F4169			0.300000
53002FA	GOAT(BONELESS)-FAT	4F4169			0.300000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53002LA	GOAT(ORGAN MEATS)-LIVER	4F4169			0.300000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F4169			0.300000
53003AA	HORSE	4F4169			0.300000
53005BA	SHEEP-MEAT BYPRODUCTS	4F4169			0.300000
53005BB	SHEEP(ORGAN MEATS)-OTHER	4F4169			0.300000
53005FA	SHEEP(BONELESS)-FAT	4F4169			0.300000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	4F4169			0.300000
53005LA	SHEEP(ORGAN MEATS)-LIVER	4F4169			0.300000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F4169			0.300000
53006BA	PORK-MEAT BYPRODUCTS	4F4169			0.300000
53006BB	PORK(ORGAN MEATS)-OTHER	4F4169			0.300000
53006FA	PORK(BONELESS)-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
55008LA	TURKEY-GIBLETS (LIVER)	3F4231			0.050000
55008MA	TURKEY-FLESH(W/O 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 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 carcinog- enicity 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(W/O SKIN,W/O BONES)	3F4231			0.050000
55015MB	CHICKEN-FLESH(+SKIN,W/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			
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 carcinog- enicity in rats or mice.		ADI UF -->100 OPP RfD= 0.057000 EPA RfD= 0.000000		No data gaps.		RfD/PR reviewed 04/22/93			
POPULATION SUBGROUP		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	
												XRFD	
U.S. POPULATION - 48 STATES		0.002631		0.008099		14.209154		9.593240					
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		0.002760		0.008426		14.782172		9.940133					
NORTH CENTRAL REGION		0.002698		0.008301		14.563830		9.830533					
SOUTHERN REGION		0.002372		0.007291		12.791993		8.629763					
WESTERN REGION		0.002801		0.008736		15.325465		10.410582					
HISPANICS		0.003096		0.008537		14.977821		9.546453					
NON-HISPANIC WHITES		0.002642		0.008222		14.425288		9.790779					
NON-HISPANIC BLACKS		0.002324		0.006999		12.279626		8.202982					
NON-HISPANIC OTHERS		0.002718		0.008585		15.062230		10.293246					
NURSING INFANTS (< 1 YEAR OLD)		0.004866		0.005485		9.623265		1.085839					
NON-NURSING INFANTS (< 1 YEAR OLD)		0.011718		0.014746		25.870911		5.313479					
FEMALES (13+ YEARS, PREGNANT)		0.001814		0.006715		11.780782		8.598193					
FEMALES 13+ YEARS, NURSING		0.002172		0.007638		13.399537		9.589472					
CHILDREN (1-6 YEARS OLD)		0.006655		0.016735		29.359284		17.683961					
CHILDREN (7-12 YEARS OLD)		0.004088		0.012404		21.760947		14.589793					
MALES (13-19 YEARS OLD)		0.002710		0.008397		14.731632		9.976493					
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.002181		0.007107		12.467749		8.640936					
MALES (20 YEARS AND OLDER)		0.001821		0.006188		10.856200		7.661346					
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		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:	0.002632	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	4.616	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000012	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.020	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.002643	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	4.636	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.005457	MG/KG/DAY
THIS TMRC WILL OCCUPY	9.574	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.008100	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	14.209	% OF THE ADI.

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

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

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

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

TABLE 4

10:41 Tuesday, April 4, 1995 22

DOC. NO. \*

18

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AB DATA: No User Modifications\*

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