

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JUN 11 1996

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Imidacloprid in/on Pecans
PP# 5F4480.

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: Mike Metzger, Chief *WJM*
RCAB (7509C)

Action Requested

Provide a dietary exposure analysis for the use of imidacloprid in/on pecans. The petition requests and CBTS recommends that a tolerance of 0.05 ppm be established on pecans. (See memo, F. Griffith, 6/6/95).

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 that demonstrated increased thyroid lesions in males at the next highest dose. An uncertainty factor of 100 was applied. 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, the NOEL from the rabbit developmental study. The LEL (72 mg/kg/day) was based upon decreased body weight, increased resorptions, abortions, and increased skeletal abnormalities.

Residue Information

Tolerances for imidacloprid are published in 40 CFR §180.472. For the purposes of this analysis, the new tolerance for pome fruits was upgraded to pending status. There are no anticipated residues nor percent crop treated estimates. All uses assume 100 percent crop treated.

Even though finite residues will occur in meat, milk, poultry and eggs from the feeding of imidacloprid treated RACs or their processed feed items, adequate total imidacloprid secondary tolerances have been established (See memo, F. Griffith, 6/6/95).

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	0.008187	14.4
Children (1-6 years old)	0.016934	29.7

Proposed new Tolerances on pecans:

U.S. Population	<0.000001	.000
Children (1-6 years old)	<0.000001	.001

If the new tolerances on pecans are approved:

U.S. Population	0.008187	14.4
Children (1-6 years old)	0.016934	29.7

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 from exposure to imidacloprid appears to be minimal for this petition on pecans at 0.05 ppm.

Acute Exposure:

The endpoint for acute dietary risk assessment is the NOEL (24 mg/kg/day) from the rabbit developmental toxicity study. The LEL (72 mg/kg/day) was based upon decreased body weight, and increased resorptions, abortion and increased skeletal abnormalities. Because the effects of concern are developmental in nature, the only subgroup of concern is females (13+ years old).

Generally, acute dietary margins of exposure greater than 100 tend to indicate no dietary risk concern. The MOE value of 480 demonstrates no concern for females of child-bearing age considering the proposed tolerances.

There appears to be no acute dietary concern for the proposed tolerances on pecans.

Attachments

cc: DRES; Caswell 497E; PM Team 19 ; CBTS (F. Griffith)

TABLE 4

 *NAME: IMIDACLOPRID
 *CASWELL NO: 497E CFR NO: CFR A
 *CAS NO: 12909-90-0 SHAUGHNESSY NO: 129099 B
 *STATUS CODES: C
 *RDV INFO: The LD value used in this analysis is 0.01 MG/KG of BODY WEIGHT/DAY
 *FILE INFO: No Tolerance Data Are Used--Without User Modifications.

 AR DATA: No User Modifications

-FEMALES(13+ YRS)

ESTIMATED % OF POTENTIAL		MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY																
PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV																
0	0.00	0.000000	0.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	99.85	0.006399	63.99	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

X	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
ESTIMATED %	100	73	49	34	25	18	14	11	9	7	6	2	1	0	0	0	0

TOLERANCES:
 ANTICIPATED RESIDUES:
 Exposure = RDV x X
 = 0.01 x 5
 High End Exposure = 0.05
 MOE = Noel + Exposure
 = 24 mg/kg/day + 0.05 mg/kg/day
 MOE = 480

 *RDV NO: 497E
 *CORE GRADE: A
 *SPECIES: HUMAN
 *EFF. LEV.: 100%
 *NOEL: 0.01 MG/KG
 *LD: 0.01 MG/KG
 *MOE: 480
 *FILE NO: 12909-90-0
 *STATUS: A
 *DATE: 12/15/99
 *BY: J. L. HARRIS

497E	01014AA10	1.0000	GRAPES-FRESH
497E	01014AA21	1.0000	
497E	01014AA31	1.0000	
497E	01014DA10	1.0000	GRAPES-RAISINS
497E	01014DA21	1.0000	GRAPES-RAISINS
497E	01014DA22	1.0000	GRAPES-RAISINS
497E	01014JA10	1.0000	GRAPES-JUICE
497E	01014JA15	1.0000	GRAPES-JUICE
497E	01014JA21	1.0000	GRAPES-JUICE
497E	03008AA10	0.0500	PECANS
497E	03008AA21	0.0500	PECANS
497E	03008AA22	0.0500	PECANS
497E	03008AA23	0.0500	PECANS
497E	03008AA62	0.0500	PECANS
497E	04001AA10	0.5000	APPLES-FRESH
497E	04001AA21	0.5000	APPLES-FRESH
497E	04001AA31	0.5000	APPLES-FRESH
497E	04001AA62	0.5000	APPLES-FRESH
497E	04001DA10	0.5000	APPLES-DRIED
497E	04001DA22	0.5000	APPLES-DRIED
497E	04001DA62	0.5000	APPLES-DRIED
497E	04001JA15	0.5000	APPLES-JUICE
497E	04001JA31	0.5000	APPLES-JUICE
497E	06007AA10	0.2000	MANGOES
497E	06007AA21	0.2000	MANGOES
497E	08020AA21	6.0000	HOPS
497E	11001AA10	1.0000	EGGPLANT
497E	11001AA21	1.0000	EGGPLANT
497E	11001AA25	1.0000	EGGPLANT
497E	11003AA10	1.0000	PEPPERS-SWEET
497E	11003AA21	1.0000	PEPPERS-SWEET
497E	11003AB00	1.0000	CHILI PEPPERS
497E	11003AD10	1.0000	PEPPERS-OTHER
497E	11003AD21	1.0000	PEPPERS-OTHER
497E	11003AD51	1.0000	PEPPERS-OTHER
497E	11004AA10	1.0000	PIMIENTOS
497E	11004AA21	1.0000	PIMIENTOS
497E	11004AA31	1.0000	PIMIENTOS
497E	11005AA10	1.0000	TOMATOES-WHOLE
497E	11005AA21	1.0000	TOMATOES-WHOLE
497E	11005AA31	1.0000	TOMATOES-WHOLE
497E	11005JA10	1.0000	TOMATOES-JUICE
497E	11005JA21	1.0000	TOMATOES-JUICE
497E	11005RA10	3.0000	TOMATOES-PUREE
497E	11005RA21	3.0000	TOMATOES-PUREE
497E	11005RA31	3.0000	TOMATOES-PUREE
497E	11005RA32	3.0000	TOMATOES-PUREE
497E	11005RA51	3.0000	TOMATOES-PUREE
497E	11005TA21	6.0000	TOMATOES-PASTE
497E	11005TA22	6.0000	TOMATOES-PASTE
497E	11005TA31	6.0000	TOMATOES-PASTE
497E	11005UA21	1.0000	TOMATOES-CATSUP
497E	13005AA21	3.5000	BROCCOLI
497E	13005AA31	3.5000	BROCCOLI
497E	13006AA21	3.5000	BROCCOLI
497E	13006AA23	3.5000	BRUSSEL SPROUTS
497E	13007AA10	3.5000	CABBAGE
497E	13007AA11	3.5000	CABBAGE
497E	13007AA21	3.5000	CABBAGE
497E	13008AA10	3.5000	CAULIFLOWER
497E	13008AA21	3.5000	CAULIFLOWER
497E	13009AA51	3.5000	COLLARDS
497E	13009AA63	3.5000	COLLARDS
497E	13010AA10	3.5000	CABBAGE-CHINESE
497E	13010AA21	3.5000	CABBAGE-CHINESE
497E	13011AA63	3.5000	KALE
497E	13012AA21	3.5000	KOHLRABI
497E	13013AA10	3.5000	LETTUCE-LEAFY
497E	13020AA10	3.5000	LETTUCE-UNSPEC
497E	13021AA21	3.5000	MUSTARD GREENS
497E	13021AA63	3.5000	MUSTARD GREENS
497E	13045AA10	3.5000	LETTUCE-HEAD
497E	13045AA21	3.5000	LETTUCE-HEAD
497E	14013AA10	0.3000	POTATO(WH)-WHOLE
497E	14013AA21	0.3000	POTATO(WH)-WHOLE
497E	14013AA22	0.3000	POTATO(WH)-WHOLE
497E	14013AB22	0.3000	POTATO(WH)-UNSPEC
497E	14013AC21	0.3000	POTATO(WH)-PULP
497E	14013AC22	0.3000	POTATO(WH)-PULP
497E	14013AC23	0.3000	POTATO(WH)-PULP
497E	14013AC25	0.3000	POTATO(WH)-PULP
497E	14013DA10	0.3000	POTATO(WH)-DRY
497E	14013DA31	0.3000	POTATO(WH)-DRY
497E	14013HA22	0.3000	POTATO(WH)-PEEL
497E	24006AA00	0.0500	BARLEY
497E	24006AA10	0.0500	SORGHUM
497E	24007AA10	0.0500	WHEAT-ROUGH
497E	24007AA21	0.0500	WHEAT-ROUGH
497E	24007AA22	0.0500	WHEAT-ROUGH
497E	24007AA23	0.0500	WHEAT-ROUGH
497E	24007GA10	0.0500	WHEAT-GERM
497E	24007GA22	0.0500	WHEAT-GERM
497E	24007HA10	0.0500	WHEAT-GERM
497E	24007HA21	0.0500	WHEAT-BRAN
497E	24007HA22	0.0500	WHEAT-BRAN
497E	24007HA23	0.0500	WHEAT-BRAN
497E	25002SA10	0.0500	BEET SUGAR
497E	25002SA21	0.0500	BEET SUGAR
497E	25002SA22	0.0500	BEET SUGAR
497E	25002SA31	0.0500	BEET SUGAR

497E 27003QA18 6.0000 COTTONSEED-OIL
 497E 27003QA18 9.0000 COTTONSEED-MEAL
 497E 43058AA10 1.0000 WINE AND SHERRY
 497E 43058AA21 1.0000 WINE AND SHERRY
 497E 50000B810 0.1000 MILK-NON-FAT SOL
 497E 50000B821 0.1000 MILK-NON-FAT SOL
 497E 50000B851 0.1000 MILK-NON-FAT SOL
 497E 50000FA10 0.1000 MILK-FAT SOLIDS
 497E 50000FA21 0.1000 MILK-FAT SOLIDS
 497E 50000FA51 0.1000 MILK-FAT SOLIDS
 497E 50000SA21 0.1000 MILK SUG (LACT)
 497E 50000SA51 0.1000 MILK SUG (LACT)
 497E 53001BA21 0.3000 BEEF-MEAT BYP
 497E 53001BA26 0.3000 BEEF-MEAT BYP
 497E 53001BB21 0.3000 BEEF-OTH ORGAN
 497E 53001BB51 0.3000 BEEF-OTH ORGAN
 497E 53001DA21 0.3000 BEEF-DRIED
 497E 53001FA10 0.3000 BEEF-FAT
 497E 53001FA21 0.3000 BEEF-FAT
 497E 53001FA22 0.3000 BEEF-FAT
 497E 53001FA23 0.3000 BEEF-FAT
 497E 53001FA24 0.3000 BEEF-FAT
 497E 53001FA25 0.3000 BEEF-FAT
 497E 53001KA21 0.3000 BEEF-KIDNEY
 497E 53001LA25 0.3000 BEEF-LIVER
 497E 53001LA31 0.3000 BEEF-LIVER
 497E 53001MA10 0.3000 BEEF-LEAN
 497E 53001MA21 0.3000 BEEF-LEAN
 497E 53001MA22 0.3000 BEEF-LEAN
 497E 53001MA23 0.3000 BEEF-LEAN
 497E 53001MA24 0.3000 BEEF-LEAN
 497E 53002BA00 0.3000 GOAT-MEAT BYP
 497E 53002BB00 0.3000 GOAT-OTH ORGAN
 497E 53002FA23 0.3000 GOAT-FAT
 497E 53002FA25 0.3000 GOAT-FAT
 497E 53002KA00 0.3000 GOAT-KIDNEY
 497E 53002LA00 0.3000 GOAT-LIVER
 497E 53002MA23 0.3000 GOAT-LEAN
 497E 53002MA25 0.3000 GOAT-LEAN
 497E 53003AA00 0.3000 HORSE
 497E 53005BA21 0.3000 SHEEP-MEAT BYP
 497E 53005BB21 0.3000 SHEEP-OTH ORGAN
 497E 53005FA21 0.3000 SHEEP-FAT
 497E 53005KA21 0.3000 SHEEP-KIDNEY
 497E 53005LA00 0.3000 SHEEP-LIVER
 497E 53005MA21 0.3000 SHEEP-LEAN
 497E 53005MA31 0.3000 SHEEP-LEAN
 497E 53005BA21 0.3000 PORK-MEAT BYP
 497E 53006BB21 0.3000 PORK-OTH ORGAN
 497E 53006BB26 0.3000 PORK-OTH ORGAN
 497E 53006FA10 0.3000 PORK-FAT
 497E 53006FA21 0.3000 PORK-FAT

497E 53006FA23 0.3000 PORK-FAT
 497E 53006FA25 0.3000 PORK-FAT
 497E 53006FA26 0.3000 PORK-FAT
 497E 53006KA21 0.3000 PORK-KIDNEY
 497E 53006LA21 0.3000 PORK-LIVER
 497E 53006LA25 0.3000 PORK-LIVER
 497E 53006MA21 0.3000 PORK-LEAN
 497E 53006MA25 0.3000 PORK-LEAN
 497E 53006MA26 0.3000 PORK-LEAN
 497E 55008BA21 0.0500 TURKEY-BYP
 497E 55008BA26 0.0500 TURKEY-BYP
 497E 55008LA21 0.0500 TURKEY ORGAN
 497E 55008LA25 0.0500 TURKEY ORGAN
 497E 55008MA21 0.0500 TURKEY W/O SKIN
 497E 55008MA31 0.0500 TURKEY W/O SKIN
 497E 55008MA62 0.0500 TURKEY W/O SKIN
 497E 55008MB21 0.0500 TURKEY+SKIN
 497E 55008MB25 0.0500 TURKEY+SKIN
 497E 55008MC21 0.0500 TURKEY-UNSPEC
 497E 55013BA00 0.0500 POULTRY, OTH-BYP
 497E 55013LA25 0.0500 POULTRY, ORGAN
 497E 55013MA21 0.0500 POULTRY, OTHER
 497E 55014AA10 0.0200 EGGS-WHOLE
 497E 55014AA21 0.0200 EGGS-WHOLE
 497E 55014AA22 0.0200 EGGS-WHOLE
 497E 55014AA23 0.0200 EGGS-WHOLE
 497E 55014AA25 0.0200 EGGS-WHOLE
 497E 55014AB10 0.0200 EGGS-WHITE ONLY
 497E 55014AB21 0.0200 EGGS-WHITE ONLY
 497E 55014AB22 0.0200 EGGS-WHITE ONLY
 497E 55014AB62 0.0200 EGGS-WHITE ONLY
 497E 55014AB81 0.0200 EGGS-WHITE ONLY
 497E 55014AC10 0.0200 EGGS-YOLK ONLY
 497E 55014AC21 0.0200 EGGS-YOLK ONLY
 497E 55014AC25 0.0200 EGGS-YOLK ONLY
 497E 55014AC31 0.0200 EGGS-YOLK ONLY
 497E 55015BA00 0.0500 CHICKEN-BYP
 497E 55015LA21 0.0500 CHICKEN-ORGAN
 497E 55015LA25 0.0500 CHICKEN-ORGAN
 497E 55015LA26 0.0500 CHICKEN-ORGAN
 497E 55015MA21 0.0500 CHICKEN-W/O SKIN
 497E 55015MA22 0.0500 CHICKEN-W/O SKIN
 497E 55015MA25 0.0500 CHICKEN-W/O SKIN
 497E 55015MA31 0.0500 CHICKEN-W/O SKIN
 497E 55015MA53 0.0500 CHICKEN-W/O SKIN
 497E 55015MB21 0.0500 CHICKEN+SKIN
 497E 55015MB25 0.0500 CHICKEN+SKIN

TABLE 1

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 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
01013AA	GRAPES-FRESH	3F4231				1.000000
01014DA	GRAPES-RAISINS	3F4231				1.000000
01014JA	GRAPES-JUICE	3F4231				1.000000
03008AA	PECANS	5F4480				0.500000
04001AA	APPLES-FRESH	3F4169	0.050000			0.500000
04001AA	APPLES-FRESH	5F4600		0.100000		0.500000
04001DA	APPLES-DRIED	3F4169		0.100000		0.500000
04001DA	APPLES-DRIED	5F4600		0.100000		0.500000
04001JA	APPLES-JUICE	3F4169		0.100000		0.500000
04001JA	APPLES-JUICE	5F4600		0.600000		0.600000
04002AA	CRABAPPLES	5F4600		0.600000		0.600000
04003AA	PEARS-FRESH	5F4600		0.600000		0.600000
04003DA	PEARS-DRIED	5F4600		0.600000		0.600000
04004AA	QUINCES	5F4600		0.600000		0.600000
06007AA	MANGOES	4F4285				0.200000
08020AA	HOPS	5E4425				6.000000
11001AA	EGGPLANT	3F4231				1.000000
11003AA	PEPPERS,SWEET,GARDEN	3F4231				1.000000
11003AB	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
13014AA	DANDELION	5F4522		3.500000		3.500000
13015AA	ENDIVE,CURLEY AND ESCAROLE	5F4522		3.500000		3.500000
13017AA	CRESS,GARDEN,FIELD	5F4522		3.500000		3.500000
13020AA	LETTUCE-UNSPECIFIED	3F4231				3.500000
13021AA	MUSTARD GREENS	3F4231				3.500000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
13022AA	PARSLEY	5F4522		3.500000		
13024AA	SPINACH	5F4522		3.500000		
13039AA	CRESS,UPLAND	5F4522		3.500000		
13045AA	LETTUCE-HEAD VARIETIES	3F4231		3.500000		
14013AA	POTATOES(WHITE)-WHOLE	3F4169		0.300000		
14013AB	POTATOES(WHITE)-UNSPECIFIED	3F4169		0.300000		
14013AC	POTATOES(WHITE)-PEELED	3F4169		0.300000		
14013DA	POTATOES(WHITE)-DRY	3F4169		0.300000		
14013HA	POTATOES(WHITE)-PEEL ONLY	3F4169		0.300000		
24001AA	BARLEY	4F4337		0.050000		
24006AA	SORGHUM (INCLUDING MILO)	4F4337		0.050000		
24007AA	WHEAT-ROUGH	4F4337		0.050000		
24007GA	WHEAT-GERM	4F4337		0.050000		
24007HA	WHEAT-BRAN	4F4337		0.050000		
24007WA	WHEAT-FLOUR	4F4337		0.050000		
25002SA	BEEF SUGAR	4F4337		0.050000		
270030A	COTTONSEED-OIL	4F4169		6.000000		
27003WA	COTTONSEED-MEAL	4F4169		9.000000		
27017AA	RAPE SEED	4F4169		0.050000		
43058AA	WINE AND SHERRY	5F4534		0.050000		
50000DB	MILK-WON-FAT SOLIDS	3F4231		1.000000		
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		

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 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)	PUBLISHED
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		0.050000	
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

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 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

POPULATION SUBGROUP	TOTAL THRC (MG/KG BODY WEIGHT/DAY)		NEW THRC**	NEW THRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT THRC*	NEW THRC**				ARC	%RFD
U.S. POPULATION - 48 STATES	0.008186	0.008514	0.008514	14.936168	0.574125		
U.S. POPULATION - SPRING SEASON	0.007785	0.008093	0.008093	14.198891	0.540130		
U.S. POPULATION - SUMMER SEASON	0.007825	0.008112	0.008112	14.231872	0.502946		
U.S. POPULATION - FALL SEASON	0.008559	0.008915	0.008915	15.640881	0.625402		
U.S. POPULATION - WINTER SEASON	0.008555	0.008912	0.008912	15.634489	0.625544		
NORTHEAST REGION	0.008515	0.008930	0.008930	15.666049	0.726958		
NORTH CENTRAL REGION	0.008392	0.008669	0.008669	15.208216	0.484604		
SOUTHERN REGION	0.007376	0.007654	0.007654	13.427367	0.487168		
WESTERN REGION	0.008818	0.009187	0.009187	16.117544	0.646614		
HISPANICS	0.008620	0.008925	0.008925	15.657418	0.534025		
NON-HISPANIC WHITES	0.008311	0.008630	0.008630	15.140518	0.559740		
NON-HISPANIC BLACKS	0.007079	0.007456	0.007456	13.080195	0.660132		
NON-HISPANIC OTHERS	0.008668	0.009101	0.009101	15.966418	0.759158		
NURSING INFANTS (< 1 YEAR OLD)	0.005513	0.006970	0.006970	12.227395	2.556295		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.014817	0.017228	0.017228	30.224154	4.228884		
FEMALES (13+ YEARS, PREGNANT)	0.006778	0.006925	0.006925	12.149911	0.258354		
FEMALES 13+ YEARS, NURSING	0.007715	0.008224	0.008224	14.427340	0.892393		
CHILDREN (1-6 YEARS OLD)	0.016933	0.017587	0.017587	30.853518	1.145730		
CHILDREN (7-12 YEARS OLD)	0.012548	0.013000	0.013000	22.807107	0.793200		
MALES (13-19 YEARS OLD)	0.008499	0.008749	0.008749	15.349116	0.438821		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.007187	0.007383	0.007383	12.952560	0.344182		
MALES (20 YEARS AND OLDER)	0.006255	0.006487	0.006487	11.381389	0.406907		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURSING)	0.006056	0.006300	0.006300	11.052777	0.428042		

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

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Imidacloprid
CASWELL #497E

DATE: 06/10/96

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.008187	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	14.362	% 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:	0.008187	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	14.362	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000328	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.574	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.008514	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	14.936	% OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.016934	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	29.708	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	<0.000001	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.001	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.016934	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	29.709	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000653	MG/KG/DAY
THIS TMRC WILL OCCUPY	1.145	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.017587	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	30.854	% OF THE ADI.