



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 *WBM*  
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)

```
*****
*NAME: IMIDACLOPRID
*CASWELL NO: 497E
*CAS NO: 12909-90-0 SHAUGHNESSY NO: 129099 B
*STATUS CODES:
*RDV INFO: The LD value used in this analysis is 0.01
*FILE INFO: No Tolerance Data Are Used-Without User Modifications.
*****
STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.*
A
C
MG/KG of BODY WEIGHT/DAY
AR DATA: No User Modifications*
*****
```

ESTIMATED % OF POTENTIAL<sup>1</sup> MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY

| MG/KG BODY WEIGHT/DAY | AS PERCENT OF RDV |
|-----------------------|-------------------|
|-----------------------|-------------------|

**MG/KG BODY WEIGHT/DAY**

|          |       |
|----------|-------|
| 0.000000 | 0.00  |
| 0.006399 | 63.99 |

[illegible][illegible][illegible] $-0.01 \times 5$ 

and Exposure = 0.05

**MOE = Nod + Exposure**

**MOE = 480**

|      |           |        |                   |           |        |                    |
|------|-----------|--------|-------------------|-----------|--------|--------------------|
| 497E | 01014AA10 | 1.0000 | GRAPES - FRESH    | 13005AA21 | 3.5000 | BROCCOLI           |
| 497E | 01014AA21 | 1.0000 |                   | 13005AA31 | 3.5000 | BROCCOLI           |
| 497E | 01014AA31 | 1.0000 |                   | 13005AA63 | 3.5000 | BROCCOLI           |
| 497E | 01014DA10 | 1.0000 | GRAPES - RAISINS  | 13006AA21 | 3.5000 | BRUSSEL SPROUTS    |
| 497E | 01014DA21 | 1.0000 | GRAPES - RAISINS  | 13006AA23 | 3.5000 | BRUSSEL SPROUTS    |
| 497E | 01014DA22 | 1.0000 | GRAPES - RAISINS  | 13007AA10 | 3.5000 | CABBAGE            |
| 497E | 01014JA10 | 1.0000 | GRAPES - JUICE    | 13007AA11 | 3.5000 | CABBAGE            |
| 497E | 01014JA15 | 1.0000 | GRAPES - JUICE    | 13007AA21 | 3.5000 | CABBAGE            |
| 497E | 01014JA21 | 1.0000 | GRAPES - JUICE    | 13008AA10 | 3.5000 | CAULIFLOWER        |
| 497E | 03008AA10 | 0.0500 | PECANS            | 13008AA21 | 3.5000 | CAULIFLOWER        |
| 497E | 03008AA21 | 0.0500 | PECANS            | 13009AA51 | 3.5000 | COLLARDS           |
| 497E | 03008AA22 | 0.0500 | PECANS            | 13009AA63 | 3.5000 | COLLARDS           |
| 497E | 03008AA23 | 0.0500 | PECANS            | 13010AA10 | 3.5000 | CABBAGE - CHINESE  |
| 497E | 03008AA62 | 0.0500 | PECANS            | 13010AA21 | 3.5000 | CABBAGE - CHINESE  |
| 497E | 04001AA10 | 0.5000 | APPLES - FRESH    | 13010AA63 | 3.5000 | KALE               |
| 497E | 04001AA21 | 0.5000 | APPLES - FRESH    | 13012AA21 | 3.5000 | KOHLRABI           |
| 497E | 04001AA31 | 0.5000 | APPLES - FRESH    | 13013AA10 | 3.5000 | LETTUCE - LEAFY    |
| 497E | 04001AA62 | 0.5000 | APPLES - FRESH    | 13020AA10 | 3.5000 | LETTUCE - UNSPEC   |
| 497E | 04001DA10 | 0.5000 | APPLES - DRIED    | 13021AA21 | 3.5000 | MUSTARD GREENS     |
| 497E | 04001DA22 | 0.5000 | APPLES - DRIED    | 13021AA63 | 3.5000 | MUSTARD GREENS     |
| 497E | 04001DA62 | 0.5000 | APPLES - DRIED    | 13045AA10 | 3.5000 | LETTUCE - HEAD     |
| 497E | 04001JA15 | 0.5000 | APPLES - JUICE    | 13045AA21 | 3.5000 | LETTUCE - HEAD     |
| 497E | 04001JA31 | 0.5000 | APPLES - JUICE    | 14013AA10 | 0.3000 | POTATO(UH) - WHOLE |
| 497E | 06007AA10 | 0.2000 | MANGOES           | 14013AA21 | 0.3000 | POTATO(UH) - WHOLE |
| 497E | 06007AA21 | 0.2000 | MANGOES           | 14013AA22 | 0.3000 | POTATO(UH) - WHOLE |
| 497E | 08020AA21 | 6.0000 | HOPS              | 14013AB22 | 0.3000 | POTATO(UH) - UNSPE |
| 497E | 11001AA10 | 1.0000 | EGGPLANT          | 14013AC21 | 0.3000 | POTATO(UH) - PULP  |
| 497E | 11001AA21 | 1.0000 | EGGPLANT          | 14013AC22 | 0.3000 | POTATO(UH) - PULP  |
| 497E | 11001AA25 | 1.0000 | EGGPLANT          | 14013AC23 | 0.3000 | POTATO(UH) - PULP  |
| 497E | 11003AA10 | 1.0000 | PEPPERS, SWEET    | 14013AC25 | 0.3000 | POTATO(UH) - PULP  |
| 497E | 11003AA21 | 1.0000 | PEPPERS, SWEET    | 14013A10  | 0.3000 | POTATO(UH) - DRY   |
| 497E | 11003AB00 | 1.0000 | CHILI PEPPERS     | 14013A21  | 0.3000 | POTATO(UH) - DRY   |
| 497E | 11003AB00 | 1.0000 | CHILI PEPPERS     | 14013HA22 | 0.3000 | POTATO(UH) - PEEL  |
| 497E | 11003AD10 | 1.0000 | PEPPERS - OTHER   | 24001AA21 | 0.0500 | SORGHUM            |
| 497E | 11003AD21 | 1.0000 | PEPPERS - OTHER   | 24006AA00 | 0.0500 | WHEAT - ROUGH      |
| 497E | 11003AD51 | 1.0000 | PEPPERS - OTHER   | 24007AA10 | 0.0500 | WHEAT - ROUGH      |
| 497E | 11004AA10 | 1.0000 | PIMIENTOS         | 24007AA21 | 0.0500 | WHEAT - ROUGH      |
| 497E | 11004AA21 | 1.0000 | PIMIENTOS         | 24007AA23 | 0.0500 | WHEAT - ROUGH      |
| 497E | 11004AA31 | 1.0000 | PIMIENTOS         | 24007GA10 | 0.0500 | WHEAT - GERM       |
| 497E | 11005AA10 | 1.0000 | TOMATOES - WHOLE  | 24007GA22 | 0.0500 | WHEAT - GERM       |
| 497E | 11005AA21 | 1.0000 | TOMATOES - WHOLE  | 24007HA10 | 0.0500 | WHEAT - BRAN       |
| 497E | 11005AA31 | 1.0000 | TOMATOES - WHOLE  | 24007HA21 | 0.0500 | WHEAT - BRAN       |
| 497E | 11005JA10 | 1.0000 | TOMATOES - JUICE  | 24007HA22 | 0.0500 | WHEAT - BRAN       |
| 497E | 11005JA21 | 1.0000 | TOMATOES - JUICE  | 24007HA10 | 0.0500 | WHEAT - FLOUR      |
| 497E | 11005RA10 | 3.0000 | TOMATOES - PUREE  | 24007HA21 | 0.0500 | WHEAT - FLOUR      |
| 497E | 11005RA21 | 3.0000 | TOMATOES - PUREE  | 24007HA22 | 0.0500 | WHEAT - FLOUR      |
| 497E | 11005RA31 | 3.0000 | TOMATOES - PUREE  | 24007HA23 | 0.0500 | WHEAT - FLOUR      |
| 497E | 11005RA32 | 3.0000 | TOMATOES - PUREE  | 25002SA10 | 0.0500 | BEET SUGAR         |
| 497E | 11005RA51 | 3.0000 | TOMATOES - PUREE  | 25002SA21 | 0.0500 | BEET SUGAR         |
| 497E | 11005TA21 | 6.0000 | TOMATOES - PASTE  | 25002SA22 | 0.0500 | BEET SUGAR         |
| 497E | 11005TA22 | 6.0000 | TOMATOES - PASTE  | 25002SA31 | 0.0500 | BEET SUGAR         |
| 497E | 11005TA31 | 6.0000 | TOMATOES - PASTE  |           |        |                    |
| 497E | 11005UA21 | 1.0000 | TOMATOES - CATSUP |           |        |                    |

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 53001B821 0.3000 BEEF-OTH ORGAN  
497E 53001B851 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 53002B800 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 53005B821 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 53006B821 0.3000 PORK-OTH ORGAN  
497E 53006B826 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 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 INFORMATION FOR CASWELL NUMBER 497E

DATE: 06/10/96

PAGE: 1

| CHEMICAL                                                                             | STUDY TYPE                                                                                                             | EFFECTS                                                                                                                 | REFERENCE DOSES                        |        | DATA GAPS/COMMENTS | STATUS                   |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------|--------------------|--------------------------|
|                                                                                      |                                                                                                                        |                                                                                                                         | ADI                                    | UF     |                    |                          |
| Imidacloprid<br>Caswell #497E<br>CAS No. 105827-78-9<br>A.I. CODE: 129099<br>CFR No. | 2yr feeding- rat<br>NOEL= 5.7000 mg/kg<br>100.00 ppm<br>LEL= 16.9000 mg/kg<br>300.00 ppm<br>ONCO: E (Rfd/PR Committee) | Increased incidence of mineralized particles in thyroid colloid.<br><br>No evidence of carcinogenicity in rats or mice. | OPP Rfd= 0.057000<br>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  |
| 03008AA   | PECANS                                | 5F4480          | 0.050000 |                 |           |
| 04001AA   | APPLES-FRESH                          | 3F4169          |          |                 | 0.500000  |
| 04001AA   | APPLES-FRESH                          | 5F4600          |          | 0.100000        |           |
| 04001DA   | APPLES-DRIED                          | 3F4169          |          |                 | 0.500000  |
| 04001DA   | APPLES-DRIED                          | 5F4600          |          | 0.100000        |           |
| 04001JA   | APPLES-JUICE                          | 3F4169          |          |                 | 0.500000  |
| 04001JA   | APPLES-JUICE                          | 5F4600          |          | 0.100000        |           |
| 04002AA   | CRABAPPLES                            | 5F4600          |          | 0.600000        |           |
| 04003AA   | PEARS-FRESH                           | 5F4600          |          | 0.600000        |           |
| 04003DA   | PEARS-DRIED                           | 5F4600          |          | 0.600000        |           |
| 04004AA   | QUINCES                               | 5F4600          |          | 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   | 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  |
| 13014AA   | DANDELION                             | 5F4522          |          | 3.500000        |           |
| 13015AA   | ENDIVE, CURLEY AND ESCAROLE           | 5F4522          |          | 3.500000        |           |
| 13017AA   | CRESS, GARDEN, FIELD                  | 5F4522          |          |                 | 3.500000  |
| 13020AA   | LETTUCE-UNSPECIFIED                   | 3F4231          |          |                 | 3.500000  |
| 13021AA   | MUSTARD GREENS                        | 3F4231          |          |                 | 3.500000  |

# CHEMICAL INFORMATION FOR CASWELL NUMBER 497E

DATE: 06/10/96

PAGE: 2

STATUS

DATA GAPS/COMMENTS

REFERENCE DOSES

EFFECTS

STUDY TYPE

CHEMICAL

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

RfD/PR reviewed 04/22/93

TOLERANCE (PPM)

PETITION NUMBER

FOOD CODE FOOD NAME

|         |                                          | NEW    | 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  |
| 24007NA | WHEAT-FLOUR                              | 4F4337 |         | 0.050000  |
| 25002SA | BEEF SUGAR                               | 4F4337 |         | 6.000000  |
| 270030A | COTTONSEED-OIL                           | 4F4169 |         | 9.000000  |
| 27003VA | COTTONSEED-MEAL                          | 4F4169 |         |           |
| 27017AA | RAPE SEED                                | 5F4534 |         | 0.050000  |
| 43058AA | WINE AND SHERRY                          | 3F4231 |         |           |
| 500000B | MILK-NON-FAT SOLIDS                      | 4F4169 |         | 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 INFORMATION FOR CASWELL NUMBER 497E

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| CHEMICAL                                                                             | STUDY TYPE                                                                                                             | EFFECTS                                                                                                                 | REFERENCE DOSES                        |        | DATA GAPS/COMMENTS | STATUS                   |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------|--------------------|--------------------------|
|                                                                                      |                                                                                                                        |                                                                                                                         | ADI                                    | UF     |                    |                          |
| Imidacloprid<br>Caswell #497E<br>CAS No. 105827-78-9<br>A.I. CODE: 129099<br>CFR No. | 2yr feeding- rat<br>NOEL= 5.7000 mg/kg<br>100.00 ppm<br>LEL= 16.9000 mg/kg<br>300.00 ppm<br>ONCO: E (Rfd/PR Committee) | Increased incidence of mineralized particles in thyroid colloid.<br><br>No evidence of carcinogenicity in rats or mice. | OPP Rfd= 0.057000<br>EPA Rfd= 0.000000 | -->100 | No data gaps.      | Rfd/PR reviewed 04/22/93 |

| FOOD CODE | FOOD NAME                                | PETITION NUMBER | TOLERANCE (PPM) |                   |
|-----------|------------------------------------------|-----------------|-----------------|-------------------|
|           |                                          |                 | NEW             | PENDING 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          |                 | 0.050000          |
| 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

DATE: 06/10/96

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| CHEMICAL INFORMATION                                                                 | STUDY TYPE                                                                                                             | EFFECTS                                                                                                                 | REFERENCE DOSES                        |        | DATA GAPS/COMMENTS | STATUS                   |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------|--------------------|--------------------------|
|                                                                                      |                                                                                                                        |                                                                                                                         | ADI                                    | UF     |                    |                          |
| Imidacloprid<br>Caswell #497E<br>CAS No. 105827-78-9<br>A.I. CODE: 129099<br>CFR No. | 2yr feeding- rat<br>NOEL= 5.7000 mg/kg<br>100.00 ppm<br>LEL= 16.9000 mg/kg<br>300.00 ppm<br>ONCO: E (RfD/PR Committee) | Increased incidence of mineralized particles in thyroid colloid.<br><br>No evidence of carcinogenicity in rats or mice. | OPP RfD= 0.057000<br>EPA RfD= 0.000000 | -->100 | No data gaps.      | RfD/PR reviewed 04/22/93 |

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

\*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: 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. |