



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

OCT 13 1995  
10/13/95

**MEMORANDUM**

**SUBJECT:** PP# 5F4534. **Imidacloprid on Canola.** DRES Dietary Exposure and Risk Estimates.

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

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

**TO:** D. Edwards, PM Team 19  
Registration Division (7505C)

EA. Doyle  
WJ. Brown

**Action Requested**

Provide a dietary exposure analysis for the use of imidacloprid in/on canola. The petition requests that a tolerance of 0.05 ppm be established. CBTS recommends against these proposed permanent tolerances due to outstanding data deficiencies as listed in the memo of F. Griffith (9/25/95). CBTS however, has no objections to establishing these tolerances as time-limited with a one year expiration date (See memo, F. Griffith, 9/25/95).

**Discussion**

For the purposes of this analysis, the new use on barley was upgraded to pending status.

**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).



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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.

#### **Residue Information**

The chronic exposure analysis used the existing DRES file, which incorporated only tolerances (Table 1). The 1977-78 USDA food consumption survey, which DRES estimates are based on, does not contain any consumption information estimates for canola/rape seed. BEAD (R. Griffin personal communication with R. Torla, 5/14/93) estimates 877 million pounds domestic canola production/usage for 1992/1993.

Based on the above and assuming a residue value of 1.0 ppm for rape seed (See memo, J. Wintersteen 10/17/94), DRES estimates exposure of 0.000077 mg/kg/day for the average (58.9 kg) U.S. person (See memo, Attachment A, J. Wintersteen 10/17/94). A consumption estimate based on sex, race, age, or other subgroups cannot be made from the above production/usage estimate.

Tolerances for imidacloprid are published in 40 CFR §180.472. There are no anticipated residues nor percent crop treated estimates. All uses assume 100 percent crop treated.

#### **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 | 0.016934                    | 29.7        |

##### **Proposed new Tolerances on canola:**

|                 |          |     |
|-----------------|----------|-----|
| U.S. Population | 0.000077 | 1.5 |
|-----------------|----------|-----|

Granting this tolerance would increase the TMRC as a percentage of imidacloprid's RfD by 1.5% to 16% for the general population.

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 canola 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 cause no dietary concern. In the case of canola, its contribution to the acute dietary risk cannot be calculated due to the lack of consumption data for this commodity. The acute dietary risk for the existing tolerances of imidacloprid for which there is consumption data results in a MOE of 480, which demonstrates no concern for females of child-bearing age considering the existing tolerances. DRES concludes that the risk of consuming canola at the proposed tolerance would not add significantly to the total exposure.

#### Attachments

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

## TABLE !

CHEMICAL INFORMATION FOR CASWELL NUMBER 497E DATE: 10/06/95 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: 120099<br>CFR No. 2.10 | 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) |           |
|-----------|---------------------------------------|-----------------|-----------------|-----------|
|           |                                       |                 | 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                                  | 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          |                 | 1.000000  |
| 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                | 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  |

| 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. | AD1             | UF -->100 | No data gaps.      | RfD/PR reviewed 04/22/93 |

| FOOD CODE | FOOD NAME                                 | PETITION NUMBER | TOLERANCE (PPM) |          |
|-----------|-------------------------------------------|-----------------|-----------------|----------|
|           |                                           |                 | NEW             | PENDING  |
| 24007MA   | WHEAT-FLOUR                               | 4F4337          |                 | 0.050000 |
| 25002SA   | BEET SUGAR                                | 4F4337          |                 | 0.050000 |
| 27003OA   | COTTONSEED-OIL                            | 4F4169          |                 | 6.000000 |
| 27003WA   | COTTONSEED-MEAL                           | 4F4169          |                 | 9.000000 |
| 27017AA   | RAPE SEED                                 | 5F4534          |                 |          |
| 43058AA   | WINE AND SHERRY                           | 3F4231          | 0.050000        |          |
| 50000DB   | MILK-NON-FAT SOLIDS                       | 4F4169          |                 |          |
| 50000FA   | MILK-FAT SOLIDS                           | 4F4169          |                 |          |
| 50000SA   | MILK SUGAR (LACTOSE)                      | 4F4169          |                 |          |
| 53001BA   | BEEF-MEAT BYPRODUCTS                      | 4F4169          |                 |          |
| 53001BB   | BEEF(ORGAN MEATS)-OTHER                   | 4F4169          |                 |          |
| 53001DA   | BEEF-DRIED                                | 4F4169          |                 |          |
| 53001FA   | BEEF(BONELESS)-FAT (BEEF TALLOW)          | 4F4169          |                 |          |
| 53001KA   | BEEF(ORGAN MEATS)-KIDNEY                  | 4F4169          |                 |          |
| 53001LA   | BEEF(ORGAN MEATS)-LIVER                   | 4F4169          |                 |          |
| 53001MA   | BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)  | 4F4169          |                 |          |
| 53002BA   | GOAT-MEAT BYPRODUCTS                      | 4F4169          |                 |          |
| 53002BB   | GOAT(ORGAN MEATS)-OTHER                   | 4F4169          |                 |          |
| 53002FA   | GOAT(BONELESS)-FAT                        | 4F4169          |                 |          |
| 53002KA   | GOAT(ORGAN MEATS)-KIDNEY                  | 4F4169          |                 |          |
| 53002LA   | GOAT(ORGAN MEATS)-LIVER                   | 4F4169          |                 |          |
| 53002MA   | GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)  | 4F4169          |                 |          |
| 53003AA   | HORSE                                     | 4F4169          |                 |          |
| 53005BA   | SHEEP-MEAT BYPRODUCTS                     | 4F4169          |                 |          |
| 53005BB   | SHEEP(ORGAN MEATS)-OTHER                  | 4F4169          |                 |          |
| 53005FA   | SHEEP(BONELESS)-FAT                       | 4F4169          |                 |          |
| 53005KA   | SHEEP(ORGAN MEATS)-KIDNEY                 | 4F4169          |                 |          |
| 53005LA   | SHEEP(ORGAN MEATS)-LIVER                  | 4F4169          |                 |          |
| 53005MA   | SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT) | 4F4169          |                 |          |
| 53006BA   | PORK-MEAT BYPRODUCTS                      | 4F4169          |                 |          |
| 53006BB   | PORK(ORGAN MEATS)-OTHER                   | 4F4169          |                 |          |
| 53006FA   | PORK(BONELESS)-FAT (INCLUDING LARD)       | 4F4169          |                 |          |
| 53006KA   | PORK(ORGAN MEATS)-KIDNEY                  | 4F4169          |                 |          |
| 53006LA   | PORK(ORGAN MEATS)-LIVER                   | 4F4169          |                 |          |
| 53006MA   | PORK-LEAN                                 | 4F4169          |                 |          |
| 55008BA   | TURKEY-BYPRODUCTS                         | 3F4231          |                 |          |
| 55008LA   | TURKEY-GIBLETS (LIVER)                    | 3F4231          |                 |          |
| 55008MA   | TURKEY-FLESH(W/O SKIN, W/O BONES)         | 3F4231          |                 |          |
| 55008MB   | TURKEY-FLESH(+SKIN, W/O BONES)            | 3F4231          |                 |          |
| 55008MC   | TURKEY-UNSPECIFIED                        | 3F4231          |                 |          |

| CHEMICAL                                                                             | STUDY TYPE                                                                                                             | EFFECTS                                                                                                                 | REFERENCE DOSES                                         | DATA GAPS/COMMENTS | STATUS                   |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------|--------------------------|
| 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. | ADI UF -->100<br>OPP Rfd= 0.057000<br>EPA Rfd= 0.000000 | No data gaps.      | Rfd/PR reviewed 04/22/93 |

| FOOD CODE | FOOD NAME                               | PETITION NUMBER | TOLERANCE (PPM) |           |
|-----------|-----------------------------------------|-----------------|-----------------|-----------|
|           |                                         |                 | PENDING         | PUBLISHED |
| 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          |                 | 0.020000  |
| 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: 10/06/95

PAGE: 1

| CHEMICAL INFORMATION                                                                 |                                                                                                                        | STUDY TYPE    | EFFECTS                                                          |                            | REFERENCE DOSES              |                                | DATA GAPS/COMMENTS |                          | STATUS |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------|----------------------------|------------------------------|--------------------------------|--------------------|--------------------------|--------|
| 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. |                            | ADI                          | UF -->100                      | No data gaps.      | Rfd/PR reviewed 04/22/93 |        |
|                                                                                      |                                                                                                                        |               | No evidence of carcinogenicity in rats or mice.                  |                            | OPP Rfd= 0.057000            |                                |                    |                          |        |
|                                                                                      |                                                                                                                        |               |                                                                  |                            | EPA Rfd= 0.000000            |                                |                    |                          |        |
|                                                                                      |                                                                                                                        |               |                                                                  |                            |                              |                                |                    |                          |        |
|                                                                                      |                                                                                                                        |               |                                                                  |                            |                              |                                |                    |                          |        |
| TOTAL TMRC (MG/KG BODY WEIGHT/DAY)                                                   |                                                                                                                        |               |                                                                  |                            |                              |                                |                    |                          |        |
| POPULATION SUBGROUP                                                                  |                                                                                                                        | CURRENT TMRC* | NEW TMRC**                                                       | NEW TMRC AS PERCENT OF RFD | DIFFERENCE AS PERCENT OF RFD | EFFECT OF ANTICIPATED RESIDUES |                    | %RFD                     |        |
| U.S. POPULATION - 48 STATES                                                          |                                                                                                                        | 0.008186      | 0.008189                                                         | 14.367070                  | 0.005026                     |                                |                    |                          |        |
| U.S. POPULATION - SPRING SEASON                                                      |                                                                                                                        | 0.007785      | 0.007789                                                         | 13.664219                  | 0.005458                     |                                |                    |                          |        |
| U.S. POPULATION - SUMMER SEASON                                                      |                                                                                                                        | 0.007825      | 0.007829                                                         | 13.734228                  | 0.005302                     |                                |                    |                          |        |
| U.S. POPULATION - FALL SEASON                                                        |                                                                                                                        | 0.008559      | 0.008562                                                         | 15.020233                  | 0.004754                     |                                |                    |                          |        |
| U.S. POPULATION - WINTER SEASON                                                      |                                                                                                                        | 0.008555      | 0.008558                                                         | 15.013537                  | 0.004591                     |                                |                    |                          |        |
| NORTHEAST REGION                                                                     |                                                                                                                        | 0.008515      | 0.008519                                                         | 14.946072                  | 0.006981                     |                                |                    |                          |        |
| NORTH CENTRAL REGION                                                                 |                                                                                                                        | 0.008392      | 0.008395                                                         | 14.728439                  | 0.004826                     |                                |                    |                          |        |
| SOUTHERN REGION                                                                      |                                                                                                                        | 0.007376      | 0.007378                                                         | 12.943365                  | 0.003167                     |                                |                    |                          |        |
| WESTERN REGION                                                                       |                                                                                                                        | 0.008818      | 0.008822                                                         | 15.476839                  | 0.005909                     |                                |                    |                          |        |
| HISPANICS                                                                            |                                                                                                                        | 0.008620      | 0.008623                                                         | 15.127812                  | 0.004419                     |                                |                    |                          |        |
| NON-HISPANIC WHITES                                                                  |                                                                                                                        | 0.008311      | 0.008314                                                         | 14.586258                  | 0.005481                     |                                |                    |                          |        |
| NON-HISPANIC BLACKS                                                                  |                                                                                                                        | 0.007079      | 0.007081                                                         | 12.422396                  | 0.002333                     |                                |                    |                          |        |
| NON-HISPANIC OTHERS                                                                  |                                                                                                                        | 0.008668      | 0.008671                                                         | 15.212726                  | 0.005467                     |                                |                    |                          |        |
| NURSING INFANTS (< 1 YEAR OLD)                                                       |                                                                                                                        | 0.005513      | 0.005516                                                         | 9.677642                   | 0.006542                     |                                |                    |                          |        |
| NON-NURSING INFANTS (< 1 YEAR OLD)                                                   |                                                                                                                        | 0.014817      | 0.014824                                                         | 26.007509                  | 0.012239                     |                                |                    |                          |        |
| FEMALES (13+ YEARS, PREGNANT)                                                        |                                                                                                                        | 0.006778      | 0.006779                                                         | 11.892402                  | 0.000846                     |                                |                    |                          |        |
| FEMALES 13+ YEARS, NURSING                                                           |                                                                                                                        | 0.007715      | 0.007717                                                         | 13.538268                  | 0.003321                     |                                |                    |                          |        |
| CHILDREN (1-6 YEARS OLD)                                                             |                                                                                                                        | 0.016933      | 0.016934                                                         | 29.708784                  | 0.000996                     |                                |                    |                          |        |
| CHILDREN (7-12 YEARS OLD)                                                            |                                                                                                                        | 0.012548      | 0.012548                                                         | 22.014528                  | 0.000621                     |                                |                    |                          |        |
| MALES (13-19 YEARS OLD)                                                              |                                                                                                                        | 0.008499      | 0.008501                                                         | 14.913198                  | 0.002904                     |                                |                    |                          |        |
| FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)                                      |                                                                                                                        | 0.007187      | 0.007187                                                         | 12.609547                  | 0.001170                     |                                |                    |                          |        |
| MALES (20 YEARS AND OLDER)                                                           |                                                                                                                        | 0.006255      | 0.006263                                                         | 10.987288                  | 0.012805                     |                                |                    |                          |        |
| FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)                                      |                                                                                                                        | 0.006056      | 0.006058                                                         | 10.627449                  | 0.002714                     |                                |                    |                          |        |

\*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: 10/06/95

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. |
| NO NEW TOLERANCES ARE IN THE FILE.       |          |               |
| OTHER PENDING TOLERANCES EXCLUDING THE   |          |               |
| CURRENT NEW PETITION HAVE A TMRC OF:     | 0.000003 | MG/KG/DAY     |
| THIS TMRC WILL OCCUPY                    | 0.005    | % OF THE ADI. |
| IF ALL PENDING TOLERANCES (INCLUDING THE |          |               |
| CURRENT NEW PETITION) ARE GRANTED        |          |               |
| THE RESULTANT TMRC WILL BE:              | 0.008190 | MG/KG/DAY     |
| THE TOTAL TMRC WILL OCCUPY               | 14.367   | % 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. |
| NO NEW TOLERANCES ARE IN THE FILE.       |          |               |
| OTHER PENDING TOLERANCES EXCLUDING THE   |          |               |
| CURRENT NEW PETITION HAVE A TMRC OF:     | 0.000001 | MG/KG/DAY     |
| THIS TMRC WILL OCCUPY                    | 0.001    | % OF THE ADI. |
| IF ALL PENDING TOLERANCES (INCLUDING THE |          |               |
| CURRENT NEW PETITION) ARE GRANTED        |          |               |
| THE RESULTANT TMRC WILL BE:              | 0.016935 | MG/KG/DAY     |
| THE TOTAL TMRC WILL OCCUPY               | 29.709   | % OF THE ADI. |

TABLE 4

1 DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 15:12 Friday, October 6, 1995 43

\*\*\*\*\*  
 \*NAME: INIDACLOPRID  
 \*CASWELL NO: 497E CFR NO: CFR  
 \*CAS NO: 12909-90-0 SHAUGHNESSY NO: 129099 B  
 \*STATUS CODES: A  
 \*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\*\*\*\*\*  
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-FEMALES(13+ YRS)

| ESTIMATED % OF POTENTIAL                                                                        |  |  |  |  |  |  |  |  |  | MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY |  |  |  |  |                   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   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| PERSON DAYS THAT ARE USER-DAYS                                                                  |  |  |  |  |  |  |  |  |  | MG/KG BODY WEIGHT/DAY                        |  |  |  |  | AS PERCENT OF RDV |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   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| TOLERANCES:                                                                                     |  |  |  |  |  |  |  |  |  | 0.00                                         |  |  |  |  | 0.00              |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   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| ANTICIPATED RESIDUES:                                                                           |  |  |  |  |  |  |  |  |  | 99.85                                        |  |  |  |  | 63.67             |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   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| ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X= |  |  |  |  |  |  |  |  |  | 0                                            |  |  |  |  | 20                |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |     |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |    |  |  |  |  |    |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   |  |  |  |  |   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| TOLERANCES:                                                                                     |  |  |  |  |  |  |  |  |  | 0                                            |  |  |  |  | 0                 |  |  |  |  | 0  |  |  |  |  | 0  |  |  |  |  | 0 |  |  |  |  | 0   |  |  |  |  | 0   |  |  |  |  | 0   |  |  |  |  | 0   |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0  |  |  |  |  | 0  |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 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 | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  | 0 |  |  |  |  |

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

Mean MOE = NOEL + Mean  
 = 24 + 0.006337  
 = >3,700