

US EPA ARCHIVE DOCUMENT



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

DATE: July 29, 2002

SUBJECT: Pyraclostrobin Acute and Chronic Dietary Exposure Assessments for the Section 3 Registration on Various Crops. PP#0F6139. PC code 099100. DP Barcode D284524.

FROM: Leung Cheng, Chemist
Registration Action Branch 3
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THROUGH: Jennifer Tyler, Chemist
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Dietary Exposure Science Advisory Council (DESAC)
Health Effects Division (7509C)

and

Stephen Dapson, Branch Senior Scientist
Registration Action Branch 3
Health Effects Division (7509C)

TO: William Wassell, Risk Assessor
Registration Action Branch 3
Health Effects Division (7509C)

Executive Summary

The purpose of this memorandum is to summarize the results of the dietary risk analysis for the general U.S. population and various population subgroups resulting from exposure to pyraclostrobin through food.

Tier 1 acute and chronic dietary risk analyses were conducted for all supported pyraclostrobin food uses. Dietary risk estimates are provided for the general U.S. population and various population subgroups. The dietary risk analysis concludes that for all included

commodities, the acute risk estimates are below the Agency's level of concern ($\leq 100\%$ aPAD¹) at the 95th exposure percentile for the general U.S. population ($< 1\%$ cPAD) and the females 13-50 population subgroup (41% aPAD). This analysis also concludes that the chronic risk estimates are below the Agency's level of concern ($\leq 100\%$ cPAD¹) for the general U.S. population (27% cPAD) and all population subgroups. The chronic dietary exposure estimate for the highest exposed population subgroup is 74% of the cPAD.

I. Introduction

Exposure to pesticides can occur through food, water, residential and occupational means. Risk assessment incorporates both exposure and toxicity of a given pesticide. The risk is expressed as a percentage of a dose that could be expressed as a daily or a long term dose, to pose no unreasonable adverse effects. This is called the population adjusted dose (PAD), and is expressed as %PAD. References are available on the EPA/pesticides web site which discuss the acute and chronic risk assessments in more detail: "Available Information on Assessing Exposure from Pesticides, A User's Guide", 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6, 8/20/99.

II. Toxicological Information

On July 31, 2001, the Health Effects Division's (HED) Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology database of pyraclostrobin, established reference doses (RfDs), and selected the toxicological endpoints for acute and chronic dietary, as well as occupational/residential exposure, risk assessments (HIARC report, G. Dannan, 9/13/2001). The FQPA Safety Factor for the protection of infants and children is reduced to 3x, applicable only to acute dietary exposure for females 13-50 years of age and chronic dietary exposure for all populations (FQPA report, B. Tarplee, 10/10/2001). The doses and toxicological endpoints are summarized in Table 1.

Table 1. Summary of Toxicological Endpoints for Use in Human Health Risk Assessment

| EXPOSURE SCENARIO | DOSE (mg/kg/day) | ENDPOINT | STUDY |
|--|------------------|---|---|
| Acute Dietary (Females 13-50) | NOAEL= 5 | Developmental toxicity findings of increased resorptions/litter and increased total resorptions (i.e., dams with complete litter loss) at 10 mg/kg/day (LOAEL). | Rabbit Prenatal Developmental Toxicity (MRID 45118326/45437001) |
| | UF = 100 | | |
| | FQPA=3x | | |
| Acute RfD = 0.05 mg/kg/day aPAD = 0.017 mg/kg/day | | | |

¹aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

| | | | |
|--|---|---|--|
| Acute Dietary (General Population) | NOAEL= 300 UF = 100 FQPA=1x | The systemic toxicity NOAEL of 300 mg/kg based on decreased body weight gain in males at 1000 mg/kg (LOAEL). | Rat Acute Oral Neurotoxicity (MRID 45118337) |
| | Acute RfD = 3 mg/kg/day aPAD = 3 mg/kg/day | | |
| Chronic Dietary | NOAEL = 3.4 UF = 100 FQPA=3x | Decreased body weight/gain, kidney tubular casts and atrophy in both sexes; increased incidence of liver necrosis and erosion/ulceration of the glandular stomach and forestomach in males in addition to hemolymphoreticular tumors in males and mammary adenocarcinoma in females at 9.2 mg/kg/day (LOAEL). | Rat Oral Carcinogenicity (MRID 45118331) |
| | Chronic RfD = 0.034 mg/kg/day cPAD = 0.011 mg/kg/day | | |

III. Residue Information

Currently no tolerances for residues of pyraclostrobin and its acid metabolite are established under 40 CFR. RAB3 recommended the following tolerances (D272771, L. Cheng, November 28, 2001):

| | |
|---------------------------|----------|
| Almond, hulls | 1.6 ppm |
| Aspirated grain fractions | 2.5 ppm |
| Banana | 0.04 ppm |
| Barley, grain | 0.4 ppm |
| Barley, hay | 25 ppm |
| Barley, straw | 6 ppm |
| Bean, dry | 0.3 ppm |
| Beet, sugar, root | 0.2 ppm |
| Beet, sugar, tops | 8 ppm |
| Beet, sugar, dried pulp | 1 ppm |
| Berry group | 1.3 ppm |
| Citrus, dry pulp | 5.5 ppm |
| Citrus, oil | 4 ppm |
| Fruit, citrus, group | 0.7 ppm |
| Fruit, stone, group | 0.9 ppm |
| Grape | 2 ppm |
| Grape, raisin | 7 ppm |
| Grass, forage | 10 ppm |
| Grass, hay | 4.5 ppm |
| Grass, seed screenings | 27 ppm |

| | |
|--|----------|
| Grass, straw | 14 ppm |
| Nut, tree, group | 0.04 ppm |
| Peanut, nutmeat | 0.05 ppm |
| Peanut, refined oil | 0.1 ppm |
| Pistachio | 0.7 ppm |
| Radish, tops | 16 ppm |
| Rye, grain | 0.04 ppm |
| Rye, straw | 0.5 ppm |
| Strawberry | 0.4 ppm |
| Vegetable, bulb, group | 0.9 ppm |
| Vegetable, cucurbit, group | 0.5 ppm |
| Vegetable, fruiting, group | 1.4 ppm |
| Vegetable, root, except sugar beet, subgroup | 0.4 ppm |
| Vegetable, tuberous and corm, subgroup | 0.04 ppm |
| Wheat, grain | 0.2 ppm |
| Wheat, hay | 6 ppm |
| Wheat, straw | 8.5 ppm |
| Cattle*, fat | 0.1 ppm |
| Cattle*, liver | 1.5 ppm |
| Cattle*, meat | 0.1 ppm |
| Cattle*, meat byproducts, except liver | 0.2 ppm |
| Milk | 0.1 ppm |

* also to include goats, hogs, horses, and sheep

Recommended tolerances were used in the acute and chronic dietary assessments.

Percent Crop Treated Information:

Percent crop treated data were applied; these values were recommended in a BEAD memo (D278874, A. Halvorson, 4/17/2002).

Processing Information:

DEEM™ default concentration factors were used.

IV. DEEM™ Program and Consumption Information

The pyraclostrobin acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.73, which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and

within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups from the general U.S. population which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, risks estimated for these population subgroups were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

V. Results/Discussion

HED’s reference level is 100% of the PAD. That is, estimated exposures above this level are of concern, while estimated exposures at or below this level are not of concern. The DEEM analyses estimate the dietary exposure of the U.S. population and 26 population subgroups. The results reported in Tables 2 and 3 are for the U.S. Population (total), all infants (<1 year old), children 1-6, children 7-12, females 13-50, males 13-19, males 20+, and seniors 55+. The results for the other population subgroups are included in the appendices.

Results of Acute Dietary Exposure Analysis

Table 2. Results of Acute Dietary Exposure Analysis at the 95th Percentile of Exposure

| Population Subgroup | aPAD (mg/kg/day) | Exposure (mg/kg/day) | % aPAD |
|-------------------------|---------------------|-------------------------|--------|
| Females 13-50 years old | 0.017 | 0.006785 | 41 |

| Population Subgroup | aPAD (mg/kg/day) | Exposure (mg/kg/day) | % aPAD |
|-------------------------|------------------|----------------------|--------|
| U.S. Population (total) | 3 | 0.009363 | <1 |
| All Infants (< 1 year) | | 0.013661 | <1 |
| Children 1-6 years | | 0.022019 | <1 |
| Children 7-12 years | | 0.011355 | <1 |
| Males 13-19 | | 0.008302 | <1 |
| Males 20+ years | | 0.006178 | <1 |
| Seniors 55+ | | 0.005710 | <1 |

Chronic Dietary Exposure Analysis

Table 3. Results of Chronic Dietary Exposure Analysis

| Population Subgroup | cPAD (mg/kg/day) | Exposure (mg/kg/day) | % cPAD |
|-------------------------|------------------|----------------------|--------|
| U.S. Population (total) | 0.011 | 0.002958 | 27 |
| All Infants (< 1 year) | | 0.003397 | 31 |
| Children 1-6 years | | 0.008169 | 74 |
| Children 7-12 years | | 0.004546 | 41 |
| Females 13-50 | | 0.002193 | 20 |
| Males 13-19 | | 0.002806 | 26 |
| Males 20+ years | | 0.002073 | 19 |
| Seniors 55+ | | 0.002007 | 18 |

VI. Conclusions

The Tier 1 acute and chronic dietary risk assessments were conducted for all supported pyraclostrobin food uses. Dietary risk estimates are provided for the general U.S. population and various population subgroups. This analysis concludes that for all supported commodities, the acute risk estimates are below the Agency's level of concern at the 95th exposure percentile for the general U.S. population (<1% cPAD) and the females 13-50 yrs subpopulation (41% aPAD). This analysis also concludes that for all commodities, the chronic risk estimates are below the Agency's level of concern for the general U.S. population (27% cPAD) and all population subgroups. The chronic dietary exposure estimate for the highest exposed population subgroup is 74% of the cPAD.

Table 4. Summary of Dietary Exposure and Risk for Pyraclostrobin

| Population Subgroup | Acute Dietary | | Chronic Dietary | | |
|-------------------------|------------------------------|--------|------------------------------|--------|--------|
| | Dietary Exposure (mg/kg/day) | % aPAD | Dietary Exposure (mg/kg/day) | % cPAD | Cancer |
| U.S. Population (total) | 0.009363 | <1 | 0.002958 | 27 | NA |
| All Infants (< 1 year) | 0.013661 | <1 | 0.003397 | 31 | |
| Children 1-6 years | 0.022019 | <1 | 0.008169 | 74 | |
| Children 7-12 years | 0.011355 | <1 | 0.004546 | 41 | |
| Females 13-50 | 0.006785 | 41 | 0.002193 | 20 | |
| Males 13-19 | 0.008302 | <1 | 0.002806 | 26 | |
| Males 20+ years | 0.006178 | <1 | 0.002073 | 19 | |
| Seniors 55+ | 0.005710 | <1 | 0.002007 | 18 | |

VII. List of Attachments

1. Acute Exposure Analysis
2. Chronic Exposure Analysis
3. Values for Acute and Chronic Analyses
4. BEAD memo dated 4/17/2002

cc:RAB3 Reading F, Cheng

RD/I:DESAC:7/29/2002:SDapson:7/25/2002

7509C:RAB3:LCheng:CM#2:RM810A:3rab/variouscrops.dmr

ATTACHMENT 1

U.S. Environmental Protection Agency
 DEEM ACUTE Analysis for PYRACLOSTROBIN
 Residue file: pyraclo4.rs7
 Analysis Date: 07-26-2002/14:03:59
 NOEL (Acute) = 5.000000 mg/kg body-wt/day
 Daily totals for food and foodform consumption used.
 Run Comment: ""

Ver. 7.76
 (1989-92 data)
 Adjustment factor #2 used.
 Residue file dated: 07-26-2002/13:52:06/8

=====

Summary calculations (per capita):

| | 95th Percentile | | | 99th Percentile | | | 99.9th Percentile | | |
|--------------------------------------|-----------------|--------|-----|-----------------|--------|-----|-------------------|--------|-----|
| | Exposure | % aRfD | MOE | Exposure | % aRfD | MOE | Exposure | % aRfD | MOE |
| Females 13+ (preg/not nursing): | 0.005838 | 34.96 | 856 | 0.009896 | 59.26 | 505 | 0.017652 | 105.70 | 283 |
| Females 13+ (nursing): | 0.009361 | 56.05 | 534 | 0.017980 | 107.67 | 278 | 0.051107 | 306.03 | 97 |
| Females 13-19 (not preg or nursing): | 0.008413 | 50.38 | 594 | 0.015257 | 91.36 | 327 | 0.025127 | 150.46 | 198 |
| Females 20+ (not preg or nursing): | 0.005926 | 35.48 | 843 | 0.011555 | 69.19 | 432 | 0.021559 | 129.09 | 231 |
| Females 13-50 yrs: | 0.006785 | 40.63 | 736 | 0.013554 | 81.16 | 368 | 0.022957 | 137.47 | 217 |

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U.S. Environmental Protection Agency
 DEEM ACUTE Analysis for PYRACLOSTROBIN (1989-92 data)
 Residue file: pyraclo4.rs7 Adjustment factor #2 used.
 Analysis Date: 07-26-2002/14:03:59 Residue file dated: 07-26-2002/13:52:06/8
 NOEL (Acute) = 5.000000 mg/kg body-wt/day
 Acute Reference Dose (aRfD) = 0.016700 mg/kg body-wt/day
 Daily totals for food and foodform consumption used.
 Run Comment: ""

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| Females 13-50 yrs | Daily Exposure Analysis (mg/kg body-weight/day) | |
|------------------------|--|----------|
| ----- | per Capita | per User |
| Mean | 0.002193 | 0.002197 |
| Standard Deviation | 0.002582 | 0.002583 |
| Standard Error of mean | 0.000025 | 0.000025 |
| Margin of Exposure | 2,280 | 2,275 |
| Percent of aRfD | 13.13 | 13.16 |

Percent of Person-Days that are User-Days = 99.80%

Estimated percentile of user-days falling below calculated exposure
 in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

| Perc. | Exposure | % aRfD | MOE | Perc. | Exposure | % aRfD | MOE |
|-------|----------|--------|--------|-------|----------|--------|-------|
| 10.00 | 0.000333 | 1.99 | 15,018 | 90.00 | 0.004656 | 27.88 | 1,073 |
| 20.00 | 0.000600 | 3.59 | 8,335 | 95.00 | 0.006790 | 40.66 | 736 |
| 30.00 | 0.000855 | 5.12 | 5,846 | 97.50 | 0.009100 | 54.49 | 549 |
| 40.00 | 0.001106 | 6.62 | 4,519 | 99.00 | 0.013556 | 81.17 | 368 |
| 50.00 | 0.001416 | 8.48 | 3,531 | 99.50 | 0.015710 | 94.07 | 318 |
| 60.00 | 0.001817 | 10.88 | 2,751 | 99.75 | 0.018305 | 109.61 | 273 |
| 70.00 | 0.002380 | 14.25 | 2,101 | 99.90 | 0.022958 | 137.47 | 217 |
| 80.00 | 0.003203 | 19.18 | 1,560 | | | | |

Estimated percentile of per-capita days falling below calculated exposure
 in mg/kg body-wt/day with Margin of Exposure (MOE) and Percent of aRfD

| Perc. | Exposure | % aRfD | MOE | Perc. | Exposure | % aRfD | MOE |
|-------|----------|--------|--------|-------|----------|--------|-------|
| 10.00 | 0.000328 | 1.96 | 15,257 | 90.00 | 0.004653 | 27.86 | 1,074 |
| 20.00 | 0.000596 | 3.57 | 8,392 | 95.00 | 0.006785 | 40.63 | 736 |
| 30.00 | 0.000852 | 5.10 | 5,871 | 97.50 | 0.009092 | 54.44 | 549 |
| 40.00 | 0.001102 | 6.60 | 4,535 | 99.00 | 0.013554 | 81.16 | 368 |
| 50.00 | 0.001413 | 8.46 | 3,538 | 99.50 | 0.015705 | 94.04 | 318 |
| 60.00 | 0.001814 | 10.86 | 2,756 | 99.75 | 0.018303 | 109.60 | 273 |
| 70.00 | 0.002375 | 14.22 | 2,104 | 99.90 | 0.022957 | 137.47 | 217 |
| 80.00 | 0.003192 | 19.11 | 1,566 | | | | |

U.S. Environmental Protection Agency
 DEEM ACUTE Analysis for PYRACLOSTROBIN
 Residue file: pyraclo4.rs7
 Analysis Date: 07-26-2002/13:59:45
 NOEL (Acute) = 5.000000 mg/kg body-wt/day
 Daily totals for food and foodform consumption used.
 Run Comment: ""

Ver. 7.76
 (1989-92 data)
 Adjustment factor #2 used.
 Residue file dated: 07-26-2002/13:52:06/8

Summary calculations (per capita):

| | 95th Percentile | | | 99th Percentile | | | 99.9th Percentile | | |
|----------------------------------|-----------------|--------|----------|-----------------|--------|----------|-------------------|--------|-----|
| | Exposure | % aRfD | MOE | Exposure | % aRfD | MOE | Exposure | % aRfD | MOE |
| U.S. Population: | | | | | | | | | |
| 0.009363 | 0.31 | 534 | 0.018908 | 0.63 | 264 | 0.042802 | 1.43 | 116 | |
| All infants: | | | | | | | | | |
| 0.013661 | 0.46 | 366 | 0.030404 | 1.01 | 164 | 0.052932 | 1.76 | 94 | |
| Nursing infants (<1 yr old): | | | | | | | | | |
| 0.005551 | 0.19 | 900 | 0.030478 | 1.02 | 164 | 0.052950 | 1.76 | 94 | |
| Non-nursing infants (<1 yr old): | | | | | | | | | |
| 0.015190 | 0.51 | 329 | 0.026702 | 0.89 | 187 | 0.036320 | 1.21 | 137 | |
| Children 1-6 yrs: | | | | | | | | | |
| 0.022019 | 0.73 | 227 | 0.042806 | 1.43 | 116 | 0.115859 | 3.86 | 43 | |
| Children 7-12 yrs: | | | | | | | | | |
| 0.011355 | 0.38 | 440 | 0.020366 | 0.68 | 245 | 0.035011 | 1.17 | 142 | |
| Males 13-19 yrs: | | | | | | | | | |
| 0.008302 | 0.28 | 602 | 0.013491 | 0.45 | 370 | 0.017578 | 0.59 | 284 | |
| Males 20+ yrs: | | | | | | | | | |
| 0.006178 | 0.21 | 809 | 0.011017 | 0.37 | 453 | 0.017598 | 0.59 | 284 | |
| Seniors 55+: | | | | | | | | | |
| 0.005710 | 0.19 | 875 | 0.010036 | 0.33 | 498 | 0.016189 | 0.54 | 308 | |
| Pacific: | | | | | | | | | |
| 0.009652 | 0.32 | 518 | 0.020575 | 0.69 | 243 | 0.082441 | 2.75 | 60 | |

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ATTACHMENT 2

U.S. Environmental Protection Agency Ver. 7.76
 DEEM Chronic analysis for PYRACLOSTROBIN (1989-92 data)
 Residue file name: C:\deem\pyraclostrobin\pyraclo4.rs7
 Adjustment factor #2 used.
 Analysis Date 07-26-2002/13:54:23 Residue file dated: 07-26-2002/13:52:06/8
 Reference dose (Rfd, Chronic) = .011 mg/kg bw/day

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 Total exposure by population subgroup
 =====

| Population Subgroup | Total Exposure | |
|-------------------------------------|-------------------|----------------|
| | mg/kg body wt/day | Percent of Rfd |
| U.S. Population (total) | 0.002958 | 26.9% |
| U.S. Population (spring season) | 0.002874 | 26.1% |
| U.S. Population (summer season) | 0.002993 | 27.2% |
| U.S. Population (autumn season) | 0.003123 | 28.4% |
| U.S. Population (winter season) | 0.002828 | 25.7% |
| Northeast region | 0.003109 | 28.3% |
| Midwest region | 0.002991 | 27.2% |
| Southern region | 0.002738 | 24.9% |
| Western region | 0.003139 | 28.5% |
| Hispanics | 0.003056 | 27.8% |
| Non-hispanic whites | 0.002971 | 27.0% |
| Non-hispanic blacks | 0.002719 | 24.7% |
| Non-hisp/non-white/non-black | 0.003385 | 30.8% |
| All infants (< 1 year) | 0.003397 | 30.9% |
| Nursing infants | 0.001617 | 14.7% |
| Non-nursing infants | 0.004146 | 37.7% |
| Children 1-6 yrs | 0.008169 | 74.3% |
| Children 7-12 yrs | 0.004546 | 41.3% |
| Females 13-19 (not preg or nursing) | 0.002657 | 24.2% |
| Females 20+ (not preg or nursing) | 0.002025 | 18.4% |
| Females 13-50 yrs | 0.002193 | 19.9% |
| Females 13+ (preg/not nursing) | 0.002409 | 21.9% |
| Females 13+ (nursing) | 0.003342 | 30.4% |
| Males 13-19 yrs | 0.002806 | 25.5% |
| Males 20+ yrs | 0.002073 | 18.8% |
| Seniors 55+ | 0.002007 | 18.2% |
| Pacific Region | 0.003171 | 28.8% |

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ATTACHMENT 3

Filename: C:\deem\pyraclostrobin\pyraclo4.rs7 Chemical: Pyraclostrobin
 RfD(Chronic): .011 mg/kg bw/day NOEL(Chronic): 3.4 mg/kg bw/day
 RfD(Acute): 3 mg/kg bw/day NOEL(Acute): 5 mg/kg bw/day
 Date created/last modified: 07-26-2002/13:52:06/8 Program ver. 7.76

| Food Code | Crop Grp | Food Name | Def Res (ppm) | Adj.Factors | |
|-----------|----------|----------------------------|---------------|-------------|-------|
| | | | | #1 | #2 |
| 1 | 13A | Blackberries | 1.300000 | 1.000 | 0.240 |
| 2 | 13A | Boysenberries | 1.300000 | 1.000 | 0.240 |
| 3 | 13A | Dewberries | 1.300000 | 1.000 | 0.240 |
| 4 | 13A | Loganberries | 1.300000 | 1.000 | 0.240 |
| 5 | 13A | Raspberries | 1.300000 | 1.000 | 0.240 |
| 6 | 13A | Youngberries | 1.300000 | 1.000 | 0.240 |
| 7 | 13B | Blueberries | 1.300000 | 1.000 | 0.240 |
| 10 | 13B | Currants | 1.300000 | 1.000 | 0.240 |
| 11 | 13B | Elderberries | 1.300000 | 1.000 | 0.240 |
| 12 | 13B | Gooseberries | 1.300000 | 1.000 | 0.240 |
| 13 | 0 | Grapes | 2.000000 | 1.000 | 0.290 |
| 14 | 0 | Grapes-raisins | 7.000000 | 4.300 | 0.290 |
| 15 | 0 | Grapes-juice | 2.000000 | 1.000 | 0.290 |
| 16 | 13B | Huckleberries | 1.300000 | 1.000 | 0.240 |
| 17 | 0 | Strawberries | 0.400000 | 1.000 | 0.240 |
| 20 | 10 | Citrus citron | 0.700000 | 1.000 | 0.400 |
| 22 | 10 | Grapefruit-peeled fruit | 0.700000 | 1.000 | 0.400 |
| 23 | 10 | Grapefruit-juice | 0.700000 | 1.000 | 0.400 |
| 24 | 10 | Kumquats | 0.700000 | 1.000 | 0.400 |
| 26 | 10 | Lemons-peeled fruit | 0.700000 | 1.000 | 0.400 |
| 27 | 10 | Lemons-peel | 0.700000 | 1.000 | 0.400 |
| 28 | 10 | Lemons-juice | 0.700000 | 1.000 | 0.400 |
| 30 | 10 | Limes-peeled fruit | 0.700000 | 1.000 | 0.400 |
| 31 | 10 | Limes-peel | 0.700000 | 1.000 | 0.400 |
| 32 | 10 | Limes-juice | 0.700000 | 1.000 | 0.400 |
| 33 | 10 | Oranges-juice-concentrate | 0.700000 | 3.700 | 0.400 |
| 34 | 10 | Oranges-peeled fruit | 0.700000 | 1.000 | 0.400 |
| 35 | 10 | Oranges-peel | 0.700000 | 1.000 | 0.400 |
| 36 | 10 | Oranges-juice | 0.700000 | 1.000 | 0.400 |
| 37 | 10 | Tangelos | 0.700000 | 1.000 | 0.400 |
| 38 | 10 | Tangerines | 0.700000 | 1.000 | 0.400 |
| 39 | 10 | Tangerines-juice | 0.700000 | 1.000 | 0.400 |
| 40 | 14 | Almonds | 0.040000 | 1.000 | 0.150 |
| 41 | 14 | Brazil nuts | 0.040000 | 1.000 | 0.150 |
| 42 | 14 | Cashews | 0.040000 | 1.000 | 0.150 |
| 43 | 14 | Chestnuts | 0.040000 | 1.000 | 0.150 |
| 44 | 14 | Filberts (hazelnuts) | 0.040000 | 1.000 | 0.150 |
| 45 | 14 | Hickory nuts | 0.040000 | 1.000 | 0.150 |
| 46 | 14 | Macadamia nuts (bush nuts) | 0.040000 | 1.000 | 0.150 |
| 47 | 14 | Pecans | 0.040000 | 1.000 | 0.150 |
| 48 | 14 | Walnuts | 0.040000 | 1.000 | 0.150 |
| 49 | 14 | Butter nuts | 0.040000 | 1.000 | 0.150 |
| 50 | 0 | Pistachio nuts | 0.700000 | 1.000 | 0.150 |
| 51 | 14 | Beechnuts | 0.040000 | 1.000 | 0.150 |
| 59 | 12 | Apricots | 0.900000 | 1.000 | 0.250 |
| 60 | 12 | Apricots-dried | 0.900000 | 6.000 | 0.250 |
| 61 | 12 | Cherries | 0.900000 | 1.000 | 0.250 |
| 62 | 12 | Cherries-dried | 0.900000 | 4.000 | 0.250 |
| 63 | 12 | Cherries-juice | 0.900000 | 1.500 | 0.250 |
| 64 | 12 | Nectarines | 0.900000 | 1.000 | 0.250 |
| 65 | 12 | Peaches | 0.900000 | 1.000 | 0.250 |
| 66 | 12 | Peaches-dried | 0.900000 | 7.000 | 0.250 |
| 67 | 12 | Plums (damsons) | 0.900000 | 1.000 | 0.250 |
| 68 | 12 | Plums-prunes (dried) | 0.900000 | 1.000 | 0.250 |
| 69 | 12 | Plums/prune-juice | 0.900000 | 1.400 | 0.250 |
| 72 | 0 | Bananas | 0.040000 | 1.000 | 1.000 |
| 73 | 0 | Bananas-dried | 0.040000 | 3.900 | 1.000 |
| 94 | 0 | Plantains-ripe | 0.040000 | 1.000 | 1.000 |
| 124 | 1CD | Ginger | 0.040000 | 1.000 | 1.000 |

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|-----|-----|--------------------------------|-----------|-------|-------|
| 137 | 1CD | Turmeric | 0.040000 | 1.000 | 1.000 |
| 139 | 8 | Paprika | 1.400000 | 1.000 | 1.000 |
| 141 | 9A | Melons-cantaloupes-juice | 0.500000 | 1.000 | 0.090 |
| 142 | 9A | Melons-cantaloupes-pulp | 0.500000 | 1.000 | 0.090 |
| 143 | 9A | Casabas | 0.500000 | 1.000 | 0.090 |
| 144 | 9A | Crenshaws | 0.500000 | 1.000 | 0.090 |
| 145 | 9A | Melons-honeydew | 0.500000 | 1.000 | 0.090 |
| 146 | 9A | Melons-persian | 0.500000 | 1.000 | 0.090 |
| 147 | 9A | Watermelon | 0.500000 | 1.000 | 0.090 |
| 148 | 9B | Cucumbers | 0.500000 | 1.000 | 0.090 |
| 149 | 9B | Pumpkin | 0.500000 | 1.000 | 0.090 |
| 150 | 9B | Squash-summer | 0.500000 | 1.000 | 0.090 |
| 151 | 9B | Squash-winter | 0.500000 | 1.000 | 0.090 |
| 152 | 9B | Bitter melon | 0.500000 | 1.000 | 0.090 |
| 154 | 8 | Eggplant | 1.400000 | 1.000 | 0.170 |
| 155 | 8 | Peppers-sweet(garden) | 1.400000 | 1.000 | 0.170 |
| 156 | 8 | Peppers-chilli incl jalapeno | 1.400000 | 1.000 | 0.170 |
| 157 | 8 | Peppers-other | 1.400000 | 1.000 | 0.170 |
| 158 | 8 | Pimientos | 1.400000 | 1.000 | 0.170 |
| 159 | 8 | Tomatoes-whole | 1.400000 | 1.000 | 0.540 |
| 160 | 8 | Tomatoes-juice | 1.400000 | 1.500 | 0.540 |
| 161 | 8 | Tomatoes-puree | 1.400000 | 1.000 | 0.540 |
| 162 | 8 | Tomatoes-paste | 1.400000 | 5.400 | 0.540 |
| 163 | 8 | Tomatoes-catsup | 1.400000 | 2.500 | 0.540 |
| 164 | 8 | Groundcherries | 1.400000 | 1.000 | 0.540 |
| 195 | 0 | Grapes-leaves | 2.000000 | 1.000 | 0.290 |
| 201 | 1CD | Taro-root | 0.040000 | 1.000 | 0.560 |
| 202 | 3 | Garlic | 0.900000 | 1.000 | 0.230 |
| 203 | 1CD | Artichokes-jerusalem | 0.040000 | 1.000 | 0.560 |
| 204 | 3 | Leeks | 0.900000 | 1.000 | 0.230 |
| 205 | 3 | Onions-dry-bulb (cipollini) | 0.900000 | 1.000 | 0.230 |
| 206 | 3 | Onions-dehydrated or dried | 0.900000 | 9.000 | 0.230 |
| 207 | 1C | Potatoes/white-whole | 0.040000 | 1.000 | 0.330 |
| 208 | 1C | Potatoes/white-unspecified | 0.040000 | 1.000 | 0.330 |
| 209 | 1C | Potatoes/white-peeled | 0.040000 | 1.000 | 0.330 |
| 210 | 1C | Potatoes/white-dry | 0.040000 | 1.000 | 0.330 |
| 211 | 1C | Potatoes/white-peel only | 0.040000 | 1.000 | 0.330 |
| 213 | 2 | Radishes-tops | 16.000000 | 1.000 | 1.000 |
| 217 | 3 | Shallots | 0.900000 | 1.000 | 0.230 |
| 218 | 1CD | Sweet potatoes (incl yams) | 0.040000 | 1.000 | 0.560 |
| 221 | 1CD | Yambean tuber (jicama) | 0.040000 | 1.000 | 0.560 |
| 222 | 1CD | Cassava (yuca blanca) | 0.040000 | 1.000 | 0.560 |
| 224 | 1CD | Yautia (tannier) | 0.040000 | 1.000 | 0.560 |
| 227 | 6C | Beans-dry-great northern | 0.300000 | 1.000 | 0.250 |
| 228 | 6C | Beans-dry-kidney | 0.300000 | 1.000 | 0.250 |
| 229 | 6C | Beans-dry-lima | 0.300000 | 1.000 | 0.250 |
| 230 | 6C | Beans-dry-navy (pea) | 0.300000 | 1.000 | 0.250 |
| 231 | 6C | Beans-dry-other | 0.300000 | 1.000 | 0.250 |
| 232 | 6C | Beans-dry-pinto | 0.300000 | 1.000 | 0.250 |
| 249 | 6C | Beans-dry-broadbeans | 0.300000 | 1.000 | 0.250 |
| 251 | 6C | Beans-dry-pigeon beans | 0.300000 | 1.000 | 0.250 |
| 256 | 0 | Beans-dry-hyacinth | 0.300000 | 1.000 | 0.250 |
| 258 | 6C | Beans-dry-blackeye peas/cowpea | 0.300000 | 1.000 | 0.250 |
| 259 | 6C | Beans-dry-garbanzo/chick pea | 0.300000 | 1.000 | 0.250 |
| 262 | 3 | Onions-green | 0.900000 | 1.000 | 0.230 |
| 265 | 15 | Barley | 0.400000 | 1.000 | 0.010 |
| 272 | 15 | Rye-rough | 0.040000 | 1.000 | 0.010 |
| 273 | 15 | Rye-germ | 0.040000 | 1.000 | 0.010 |
| 274 | 15 | Rye-flour | 0.040000 | 1.000 | 0.010 |
| 276 | 15 | Wheat-rough | 0.200000 | 1.000 | 0.010 |
| 277 | 15 | Wheat-germ | 0.200000 | 1.000 | 0.010 |
| 278 | 15 | Wheat-bran | 0.200000 | 1.000 | 0.010 |
| 279 | 15 | Wheat-flour | 0.200000 | 1.000 | 0.010 |
| 282 | 1A | Sugar-beet | 0.200000 | 1.000 | 0.250 |
| 293 | 0 | Peanuts-oil | 0.100000 | 1.000 | 0.270 |
| 315 | 0 | Grapes-wine and sherry | 2.000000 | 1.000 | 0.290 |
| 318 | D | Milk-nonfat solids | 0.100000 | 1.000 | 1.000 |
| 319 | D | Milk-fat solids | 0.100000 | 1.000 | 1.000 |
| 320 | D | Milk sugar (lactose) | 0.100000 | 1.000 | 1.000 |
| 321 | M | Beef-meat byproducts | 0.200000 | 1.000 | 1.000 |

| | | | | | |
|-----|-----|--------------------------------|----------|--------|-------|
| 323 | M | Beef-dried | 0.100000 | 1.920 | 1.000 |
| 324 | M | Beef-fat w/o bones | 0.100000 | 1.000 | 1.000 |
| 326 | M | Beef-liver | 1.500000 | 1.000 | 1.000 |
| 327 | M | Beef-lean (fat/free) w/o bones | 0.100000 | 1.000 | 1.000 |
| 328 | M | Goat-meat byproducts | 0.200000 | 1.000 | 1.000 |
| 330 | M | Goat-fat w/o bone | 0.100000 | 1.000 | 1.000 |
| 332 | M | Goat-liver | 1.500000 | 1.000 | 1.000 |
| 333 | M | Goat-lean (fat/free) w/o bone | 0.100000 | 1.000 | 1.000 |
| 334 | M | Horsemeat | 0.100000 | 1.000 | 1.000 |
| 336 | M | Sheep-meat byproducts | 0.200000 | 1.000 | 1.000 |
| 338 | M | Sheep-fat w/o bone | 0.100000 | 1.000 | 1.000 |
| 340 | M | Sheep-liver | 1.500000 | 1.000 | 1.000 |
| 341 | M | Sheep-lean (fat free) w/o bone | 0.100000 | 1.000 | 1.000 |
| 342 | M | Pork-meat byproducts | 0.200000 | 1.000 | 1.000 |
| 344 | M | Pork-fat w/o bone | 0.100000 | 1.000 | 1.000 |
| 346 | M | Pork-liver | 1.500000 | 1.000 | 1.000 |
| 347 | M | Pork-lean (fat free) w/o bone | 0.100000 | 1.000 | 1.000 |
| 378 | O | Bananas-juice | 0.040000 | 1.000 | 1.000 |
| 379 | 1A | Sugar-beet-molasses | 0.200000 | 1.000 | 0.250 |
| 380 | 13A | Blackberries-juice | 1.500000 | 1.000 | 0.240 |
| 386 | 9B | Christophine | 0.500000 | 1.000 | 0.090 |
| 392 | O | Grapes-juice-concentrate | 2.000000 | 3.000 | 0.290 |
| 397 | 9B | Okra/chinese (luffa) | 0.500000 | 1.000 | 0.090 |
| 398 | D | Milk-based water | 0.100000 | 1.000 | 1.000 |
| 402 | 12 | Peaches-juice | 0.900000 | 1.000 | 0.250 |
| 403 | O | Peanuts-butter | 0.050000 | 1.890 | 0.260 |
| 410 | 12 | Apricot juice | 0.900000 | 1.000 | 0.250 |
| 415 | 9B | Squash-spaghetti | 0.500000 | 1.000 | 0.090 |
| 416 | O | Strawberries-juice | 0.400000 | 1.000 | 0.240 |
| 420 | 10 | Tangerines-juice-concentrate | 0.700000 | 3.200 | 0.400 |
| 423 | 8 | Tomatoes-dried | 1.400000 | 14.300 | 0.540 |
| 431 | 14 | Walnut oil | 0.040000 | 1.000 | 0.150 |
| 436 | 9A | Watermelon-juice | 0.500000 | 1.000 | 0.090 |
| 437 | 15 | Wheat-germ oil | 0.200000 | 1.000 | 0.010 |
| 439 | 9B | Wintermelon | 0.500000 | 1.000 | 0.090 |
| 441 | 10 | Grapefruit-juice-concentrate | 0.700000 | 3.930 | 0.400 |
| 442 | 10 | Lemons-juice-concentrate | 0.700000 | 5.700 | 0.400 |
| 443 | 10 | Limes-juice-concentrate | 0.700000 | 3.000 | 0.400 |
| 448 | 10 | Grapefruit peel | 0.700000 | 1.000 | 0.400 |
| 480 | O | Plantains-green | 0.040000 | 1.000 | 1.000 |
| 481 | O | Plantains-dried | 0.040000 | 3.900 | 1.000 |
| 497 | 9B | Balsam pear | 0.500000 | 1.000 | 0.090 |
| 940 | O | Peanuts-hulled | 0.050000 | 1.000 | 0.270 |

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Pages 16 through 21 are not included in this copy.

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- Description of quality control procedures.
- Identity of the source of product ingredients.
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- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
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