Image

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: May 23, 2000

MEMORANDUM

Subject: PP 9F05046/9F05051. Permanent Tolerance Petition for Use of **Thiamethoxam** on Canola, Barley, Cotton, Sorghum, Wheat, Tuberous and Corm Vegetables, Fruiting Vegetables, Cucurbit Vegetables, and Pome Fruits. **Dietary Exposure Assessment.**

DP Barcode D265606
PC Code 060109

Submission Number S558105
Case Number 290734

From: Michael Doherty, Chemist
Registration Action Branch 2
Health Effects Division (7509C)

Through: Manying Xue, Dietary Exposure SAC
Steven Knizner, Dietary Exposure SAC

Through: Richard Loranger, Branch Senior Scientist
Registration Action Branch 2
Health Effects Division (7509C)

To: G. Jeffrey Herndon, Chemist
Registration Action Branch 2
Health Effects Division (7509C)

Action Requested

Acute, chronic, and cancer dietary exposure assessments are needed to evaluate Section 3 registration requests (PP9F05046 + PP9F05051) for use of the insecticide thiamethoxam on canola, barley, cotton, sorghum, wheat, tuberous and corm vegetables, fruiting vegetables, cucurbit vegetables, and pome fruits. Thiamethoxam is a new insecticide; thus, there are no existing tolerances. Tolerance level residues should be used for the acute assessment and anticipated residues with % market share information (DP Barcode D265607, G. J. Herndon, 5/17/00) should be used for the chronic and cancer assessments.

Executive Summary

These analyses reflect Tier 1 (tolerance-level residues, 100% crop treated) acute and Tier 3 (anticipated residues, % market share estimates) chronic and cancer dietary (food only) exposure analyses for the new insecticide thiamethoxam. Acute and chronic dietary exposure estimates are below HED's level of concern. At the 95th percentile of exposure, acute dietary exposure occupies less than 8% of the acute Population-Adjusted Dose (aPAD) for all population subgroups. For chronic dietary exposure, the Tier 3 risk estimate is approximately 31% of the chronic Population-Adjusted Dose (cPAD) for non-nursing infants (<1 year); the percentage of the cPAD occupied is lower for all other population subgroups. **Estimates of dietary (food only) exposure to thiamethoxam for the requested use sites exceeds HED's level of concern for cancer risk.** For the general U.S. population, the Tier 3 estimated dietary exposure to thiamethoxam resulting from its proposed uses is 0.000052 mg/kg/day. Applying the unit risk (Q_1^*) value of 0.0377 $(mg/kg/day)^{-1}$ results in an estimated cancer risk of 2.0×10^{-6}, which is greater than HED's level of concern (generally 1×10^{-6}). Consumption of apple commodities and fruiting vegetables contributes the most to the risk estimate.

Toxicological and FQPA Considerations

On March 23, 2000, the HED's Hazard Identification Assessment Review Committee (HIARC) met to evaluate the toxicological database and select endpoints, as appropriate, for thiamethoxam risk assessment. Table 1 summarizes the findings of the HIARC as relates to dietary exposure. In meetings on April 3, 2000 and April 24, 2000, HED's FQPA Safety Factor Committee determined that for thiamethoxam the additional safety factor to account for enhanced sensitivity of infants and children should be retained at 10× for all population groups. This decision was based on a data gap in the toxicology database for thiamethoxam for a developmental neurotoxicity study and since quantitative evidence of increased susceptibility to the young following pre-/postnatal exposure to thiamethoxam is suggested in the 2-generation reproduction study in rats. Additionally, there is concern for the lack of key measurements in the 2-generation reproduction study that could further characterize the testicular effects observed in this study. On April 5, 2000, the Cancer Assessment Review Committee (CARC) met to evaluate the carcinogenic potential of thiamethoxam. The Committee classified thiamethoxam as "likely to be carcinogenic to humans" by the oral route based on the occurrence of both benign and malignant hepatocellular tumors in both sexes of mice and recommended a linear low-dose (Q_1^*) extrapolation approach for the quantification of human cancer risk based on the most potent of the liver tumors in mice.

Table 1. Summary of Dietary Toxicological Doses and Endpoints for Thiamethoxam			
Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary (General Population including Infants & Children)	NOAEL= 100 UF = 100 FQPA SF = 10	Drooped palpebral closure, lower rectal temperature, increased forelimb grip strength, decreased locomotor activity at 500 mg/kg	Acute neurotoxicity - rat
	Acute RfD = 1 mg/kg **Acute Population-Adjusted Dose = 0.1 mg/kg**		
Chronic Dietary	NOAEL = 0.6 UF = 100 FQPA SF = 10	Increased incidence and severity of tubular atrophy in testes at ≥ 1.8 mg/kg/day	2-Generation reproduction study - rat
	Chronic RfD = 0.006 mg/kg/day **Chronic Population-Adjusted Dose = 0.0006 mg/kg/day**		
Cancer	Q_1^* = 0.0377 $(mg/kg/day)^{-1}$	Benign and malignant hepatocellular tumors in both sexes of mice	18-month carcinogenicity study in Tif:MAG(SPF) mice

Residue Information

For the Tier 1 acute analysis, tolerance-level residues were used with the assumption that 100% of the requested crops would be treated. The requested tolerances range from 0.02 ppm to 0.8 ppm. A full listing of the acute residue parameters is included in Attachment 1. Due to a residue chemistry deficiency regarding the analytical method for the analysis of thiamethoxam in ruminant liver, the residue level in liver has been set higher than the proposed tolerance (0.13 ppm vs. 0.02 ppm; memo, G. J. Herndon, DP Barcode D265079, 5/8/00).

The chronic and cancer dietary exposure analyses are refined to a Tier-3 level, incorporating chronic anticipated residues and projected % market share information (memo, G. J. Herndon, DP Barcode D265607, 5/17/00). The complete listing of the input parameters for the chronic and cancer analyses is given in Attachment 2.

Consumption Data

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For this acute dietary risk assessment, the entire distribution of single day food consumption events is combined with a single residue level (deterministic analysis) to obtain a distribution of exposure in mg/kg/day. For chronic and cancer dietary risk assessments, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

Results and Discussion

Acute Analysis. The acute dietary (food only) risk estimate associated with thiamethoxam use on the subject-listed commodities is below HED's level of concern. The Tier 1 analysis estimates that at the 95th percentile of exposure, less than 8% of the aPAD will be occupied for all of the DEEM™ population subgroups. HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups 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 subpopulations were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years). The per-capita exposure estimates at the 95th, 99th, and 99.9th percentiles of exposure for representative population subgroups are shown in Table 2; the results for all population subgroups are included as Attachment 3. The assumptions that went into this analysis are highly conservative and result in overestimates of exposure. Use of more refined assessment techniques (e.g., probabilistic analysis) would result in lower estimates of exposure.

Table 2. Acute Dietary (Food Only) Tier 1 Exposure and Risk Estimates for Thiamethoxam.

Population Subgroup[a]	aPAD, mg/kg	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure, mg/kg	% aPAD[b]	Exposure, mg/kg	% aPAD[b]	Exposure, mg/kg	% aPAD[b]
U.S. pop - all seasons:	0.1	0.002837	3	0.006202	6	0.012772	13
All infants (<1 year):	0.1	0.007793	8	0.013123	13	0.029155	29
Children (1-6 years):	0.1	0.007037	7	0.012337	12	0.028265	28
Children (7-12 years):	0.1	0.003782	4	0.006434	6	0.008564	9
Females (13-50 years):	0.1	0.001737	2	0.003038	3	0.005112	5

[a] Population subgroups shown include the U.S. general population, those of infants, children, and women of child-bearing age, and other populations whose exposure exceeds that of the U.S. general population at the 95th percentile of exposure.

[b] % aPAD = Exposure (mg/kg) ÷ aPAD (mg/kg) × 100

Chronic Analysis. The chronic dietary (food only) risk estimates associated with thiamethoxam use on the subject-listed commodities are below HED's level of concern. The Tier 3 analysis estimates that exposure to the most highly exposed population subgroup (non-nursing infants < 1 year) will be 0.00018 mg/kg/day. This is approximately 30% of the cPAD. Exposure estimates and associated risk estimate, as % cPAD, are shown in Table 3 for representative population subgroups. A complete listing of chronic exposure estimates for all DEEM™ population subgroups is included as Attachment 4.

Table 3. Chronic Dietary (Food Only) Tier 3 Exposure and Risk Estimates for Thiamethoxam.			
Population Subgroup[1]	cPAD, mg/kg/day[2]	Exposure, mg/kg/day	% cPAD
U.S. Population (total)	0.0006	0.000052	9
All infants (< 1 year)	0.0006	0.000153	26
Children 1-6 yrs	0.0006	0.000158	26
Children 7-12 yrs	0.0006	0.000082	14
Females 13-50 yrs	0.0006	0.000034	6

[1] Population subgroups shown include the U.S. general population, those of infants, children, and women of child-bearing age, and other, representative populations whose exposure exceeds that of the U.S. general population.

[2] % cPAD = Exposure (mg/kg) ÷ cPAD (mg/kg) × 100

Cancer. The dietary (food only) cancer risk estimate associated with the requested uses for thiamethoxam is above HED's level of concern (generally 1×10^{-6}). The Tier 3 analysis estimates that exposure to the U.S. general population will be 0.000052 mg/kg/day. Applying the unit risk (Q_1^*) value of 0.0377 $(mg/kg/day)^{-1}$ results in an estimated cancer risk of 2.0×10^{-6} (Attachment 5). Consumption of apple commodities and fruiting vegetables lead to the greatest contribution to this risk estimate. A complete listing of exposure contributions for each commodity is given in Attachment 5. This risk estimate is fairly refined, incorporating both anticipated residues and percent of market share data into the analysis. Further refinement, in the form of market basket surveys or other monitoring data (e.g., USDA's Pesticide Data Program) may further reduce the estimated exposure, resulting in a lower cancer risk estimate for thiamethoxam.

List of Attachments:

Attachment 1. Input parameters for DEEM™ acute analyses.
Attachment 2. Input parameters for DEEM™ chronic and cancer analyses.
Attachment 3. Tier 1 Acute DEEM™ analysis results.
Attachment 4. Tier 3 Chronic DEEM™ analysis results.
Attachment 5. Estimates of commodity exposure contributions and cancer risk.

cc: M. Doherty, RAB2 Reading File, L. Richardson (CEB1)

Attachment 1 – Input Parameters for Tier 1 Acute DEEM™ Analysis

Filename: C:\My Documents\Chemistry Reviews\DEEM Runs\Thiamethoxam\060109a.RS7
Chemical: Thiamethoxam
RfD(Chronic): .006 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): 1 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day Q*= .0377
Date created/last modified: 05-23-2000/08:49:06/8 Program ver. 7.075

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
301	O	Canola oil (rape seed oil)	0.020000	1.000	1.000	
291	O	Cottonseed-meal	0.050000	1.000	1.000	
290	O	Cottonseed-oil	0.020000	1.000	1.000	
323	M	Beef-dried	0.020000	1.920	1.000	
325	M	Beef-kidney	0.020000	1.000	1.000	
327	M	Beef-lean (fat/free) w/o bones	0.020000	1.000	1.000	
326	M	Beef-liver	0.130000	1.000	1.000	
321	M	Beef-meat byproducts	0.020000	1.000	1.000	
322	M	Beef-other organ meats	0.020000	1.000	1.000	
331	M	Goat-kidney	0.020000	1.000	1.000	
333	M	Goat-lean (fat/free) w/o bone	0.020000	1.000	1.000	
332	M	Goat-liver	0.130000	1.000	1.000	
328	M	Goat-meat byproducts	0.020000	1.000	1.000	
329	M	Goat-other organ meats	0.020000	1.000	1.000	
334	M	Horsemeat	0.020000	1.000	1.000	
339	M	Sheep-kidney	0.020000	1.000	1.000	
341	M	Sheep-lean (fat free) w/o bone	0.020000	1.000	1.000	
340	M	Sheep-liver	0.130000	1.000	1.000	
336	M	Sheep-meat byproducts	0.020000	1.000	1.000	
337	M	Sheep-other organ meats	0.020000	1.000	1.000	
429	M	Veal-dried	0.020000	1.920	1.000	
426	M	Veal-kidney	0.020000	1.000	1.000	
425	M	Veal-lean (fat free) w/o bones	0.020000	1.000	1.000	
427	M	Veal-liver	0.130000	1.000	1.000	
430	M	Veal-meat byproducts	0.020000	1.000	1.000	
428	M	Veal-other organ meats	0.020000	1.000	1.000	
398	D	Milk-based water	0.020000	1.000	1.000	
319	D	Milk-fat solids	0.020000	1.000	1.000	
318	D	Milk-nonfat solids	0.020000	1.000	1.000	
320	D	Milk sugar (lactose)	0.020000	1.000	1.000	
203	1CD	Artichokes-jerusalem	0.020000	1.000	1.000	
222	1CD	Cassava (yuca blanca)	0.020000	1.000	1.000	
124	1CD	Ginger	0.020000	1.000	1.000	
210	1C	Potatoes/white-dry	0.020000	6.500	1.000	
209	1C	Potatoes/white-peeled	0.020000	1.000	1.000	
211	1C	Potatoes/white-peel only	0.020000	1.000	1.000	
208	1C	Potatoes/white-unspecified	0.020000	1.000	1.000	
207	1C	Potatoes/white-whole	0.020000	1.000	1.000	
218	1CD	Sweet potatoes (incl yams)	0.020000	1.000	1.000	
201	1CD	Taro-root	0.020000	1.000	1.000	
137	1CD	Turmeric	0.020000	1.000	1.000	
221	1CD	Yam-bean tuber (jicama)	0.020000	1.000	1.000	
224	1CD	Yautia (tanier)	0.020000	1.000	1.000	
154	8	Eggplant	0.250000	1.000	1.000	
164	8	Groundcherries	0.250000	1.000	1.000	
139	8	Paprika	0.250000	1.000	1.000	
156	8	Peppers-chilli incl jalapeno	0.250000	1.000	1.000	

157	8	Peppers-other	0.250000	1.000	1.000
155	8	Peppers-sweet(garden)	0.250000	1.000	1.000
158	8	Pimientos	0.250000	1.000	1.000
163	8	Tomatoes-catsup	0.800000	1.000	1.000
423	8	Tomatoes-dried	0.250000	14.300	1.000
160	8	Tomatoes-juice	0.250000	1.000	1.000
162	8	Tomatoes-paste	0.800000	1.000	1.000
161	8	Tomatoes-puree	0.250000	1.000	1.000
159	8	Tomatoes-whole	0.250000	1.000	1.000
497	9B	Balsam pear	0.200000	1.000	1.000
152	9B	Bitter melon	0.200000	1.000	1.000
143	9A	Casabas	0.200000	1.000	1.000
386	9B	Christophine	0.200000	1.000	1.000
144	9A	Crenshaws	0.200000	1.000	1.000
148	9B	Cucumbers	0.200000	1.000	1.000
141	9A	Melons-cantaloupes-juice	0.200000	1.000	1.000
142	9A	Melons-cantaloupes-pulp	0.200000	1.000	1.000
145	9A	Melons-honeydew	0.200000	1.000	1.000
146	9A	Melons-persian	0.200000	1.000	1.000
397	9B	Okra/chinese (luffa)	0.200000	1.000	1.000
149	9B	Pumpkin	0.200000	1.000	1.000
150	9B	Squash-summer	0.200000	1.000	1.000
415	9B	Squash-spaghetti	0.200000	1.000	1.000
151	9B	Squash-winter	0.200000	1.000	1.000
147	9A	Watermelon	0.200000	1.000	1.000
436	9A	Watermelon-juice	0.200000	1.000	1.000
439	9B	Wintermelon	0.200000	1.000	1.000
52	11	Apples	0.200000	1.000	1.000
53	11	Apples-dried	0.200000	8.000	1.000
54	11	Apples-juice/cider	0.200000	1.300	1.000
377	11	Apples-juice-concentrate	0.200000	3.900	1.000
55	11	Crabapples	0.200000	1.000	1.000
81	11	Loquats	0.200000	1.000	1.000
56	11	Pears	0.200000	1.000	1.000
57	11	Pears-dried	0.200000	6.250	1.000
404	11	Pears-juice	0.200000	1.000	1.000
58	11	Quinces	0.200000	1.000	1.000
265	15	Barley	0.020000	1.000	1.000
275	15	Sorghum (including milo)	0.020000	1.000	1.000
278	15	Wheat-bran	0.020000	1.000	1.000
279	15	Wheat-flour	0.020000	1.000	1.000
277	15	Wheat-germ	0.020000	1.000	1.000
437	15	Wheat-germ oil	0.020000	1.000	1.000
276	15	Wheat-rough	0.020000	1.000	1.000

Attachment 2 – Input Parameters for Chronic and Cancer Tier 3 DEEM™ Analyses

Filename: C:\My Documents\Chemistry Reviews\DEEM Runs\Thiamethoxam\060109.rs7
Chemical: Thiamethoxam
RfD(Chronic): .006 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): 1 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day Q*= .0377
Date created/last modified: 05-23-2000/08:48:35/8 Program ver. 7.075

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
301	O	Canola oil (rape seed oil)	0.010000	1.000	1.000	
291	O	Cottonseed-meal	0.016000	0.150	0.210	
290	O	Cottonseed-oil	0.016000	0.100	0.210	
323	M	Beef-dried	0.000043	1.920	1.000	
325	M	Beef-kidney	0.000032	1.000	1.000	
327	M	Beef-lean (fat/free) w/o bones	0.000043	1.000	1.000	
326	M	Beef-liver	0.001800	1.000	1.000	
321	M	Beef-meat byproducts	0.000032	1.000	1.000	
322	M	Beef-other organ meats	0.000032	1.000	1.000	
331	M	Goat-kidney	0.000032	1.000	1.000	
333	M	Goat-lean (fat/free) w/o bone	0.000043	1.000	1.000	
332	M	Goat-liver	0.001800	1.000	1.000	
328	M	Goat-meat byproducts	0.000032	1.000	1.000	
329	M	Goat-other organ meats	0.000032	1.000	1.000	
334	M	Horsemeat	0.000043	1.000	1.000	
339	M	Sheep-kidney	0.000032	1.000	1.000	
341	M	Sheep-lean (fat free) w/o bone	0.000043	1.000	1.000	
340	M	Sheep-liver	0.001800	1.000	1.000	
336	M	Sheep-meat byproducts	0.000032	1.000	1.000	
337	M	Sheep-other organ meats	0.000032	1.000	1.000	
429	M	Veal-dried	0.000043	1.920	1.000	
426	M	Veal-kidney	0.000032	1.000	1.000	
425	M	Veal-lean (fat free) w/o bones	0.000043	1.000	1.000	
427	M	Veal-liver	0.001800	1.000	1.000	
430	M	Veal-meat byproducts	0.000032	1.000	1.000	
428	M	Veal-other organ meats	0.000032	1.000	1.000	
398	D	Milk-based water	0.000098	1.000	1.000	
319	D	Milk-fat solids	0.000098	1.000	1.000	
318	D	Milk-nonfat solids	0.000098	1.000	1.000	
320	D	Milk sugar (lactose)	0.000098	1.000	1.000	
203	1CD	Artichokes-jerusalem	0.010000	1.000	1.000	
222	1CD	Cassava (yuca blanca)	0.010000	1.000	1.000	
124	1CD	Ginger	0.010000	1.000	1.000	
210	1C	Potatoes/white-dry	0.010000	1.900	0.260	
209	1C	Potatoes/white-peeled	0.010000	1.000	0.260	
211	1C	Potatoes/white-peel only	0.010000	1.000	0.260	
208	1C	Potatoes/white-unspecified	0.010000	1.000	0.260	
207	1C	Potatoes/white-whole	0.010000	1.000	0.260	
218	1CD	Sweet potatoes (incl yams)	0.010000	1.000	1.000	
201	1CD	Taro-root	0.010000	1.000	1.000	
137	1CD	Turmeric	0.010000	1.000	1.000	
221	1CD	Yam-bean tuber (jicama)	0.010000	1.000	1.000	
224	1CD	Yautia (tanier)	0.010000	1.000	1.000	
154	8	Eggplant	0.072000	1.000	0.210	
164	8	Groundcherries	0.052000	1.000	0.210	
139	8	Paprika	0.072000	1.000	0.210	
156	8	Peppers-chilli incl jalapeno	0.074000	1.000	0.210	

157	8	Peppers-other	0.072000	1.000	0.210
155	8	Peppers-sweet(garden)	0.072000	1.000	0.210
158	8	Pimientos	0.074000	1.000	0.210
163	8	Tomatoes-catsup	0.052000	3.800	0.210
423	8	Tomatoes-dried	0.052000	14.300	0.210
160	8	Tomatoes-juice	0.052000	1.000	0.210
162	8	Tomatoes-paste	0.052000	3.800	0.210
161	8	Tomatoes-puree	0.052000	1.700	0.210
159	8	Tomatoes-whole	0.052000	1.000	0.210
497	9B	Balsam pear	0.045000	1.000	0.440
152	9B	Bitter melon	0.045000	1.000	0.440
143	9A	Casabas	0.045000	1.000	0.440
386	9B	Christophine	0.045000	1.000	0.440
144	9A	Crenshaws	0.045000	1.000	0.440
148	9B	Cucumbers	0.038000	1.000	0.440
141	9A	Melons-cantaloupes-juice	0.045000	1.000	0.440
142	9A	Melons-cantaloupes-pulp	0.045000	1.000	0.440
145	9A	Melons-honeydew	0.045000	1.000	0.440
146	9A	Melons-persian	0.045000	1.000	0.440
397	9B	Okra/chinese (luffa)	0.045000	1.000	0.440
149	9B	Pumpkin	0.046000	1.000	0.440
150	9B	Squash-summer	0.046000	1.000	0.440
415	9B	Squash-spaghetti	0.046000	1.000	0.440
151	9B	Squash-winter	0.046000	1.000	0.440
147	9A	Watermelon	0.045000	1.000	0.440
436	9A	Watermelon-juice	0.045000	1.000	0.440
439	9B	Wintermelon	0.045000	1.000	0.440
52	11	Apples	0.057000	1.000	0.530
53	11	Apples-dried	0.057000	8.000	0.530
54	11	Apples-juice/cider	0.057000	0.750	0.530
377	11	Apples-juice-concentrate	0.057000	2.250	0.530
55	11	Crabapples	0.057000	1.000	0.530
81	11	Loquats	0.054000	1.000	0.530
56	11	Pears	0.054000	1.000	0.180
57	11	Pears-dried	0.054000	6.250	0.180
404	11	Pears-juice	0.054000	0.750	0.180
58	11	Quinces	0.054000	1.000	0.530
265	15	Barley	0.010000	1.000	1.000
275	15	Sorghum (including milo)	0.010000	1.000	0.120
278	15	Wheat-bran	0.010000	1.000	0.020
279	15	Wheat-flour	0.010000	1.000	0.020
277	15	Wheat-germ	0.010000	1.000	0.020
437	15	Wheat-germ oil	0.010000	1.000	0.020
276	15	Wheat-rough	0.010000	1.000	0.020

Attachment 3 – Summary of Acute Tier 1 DEEM™ Results

U.S. Environmental Protection Agency Ver. 7.075
DEEM ACUTE analysis for THIAMETHOXAM (1989-92 data)
Residue file: 060109a.RS7 Adjustment factor #2 NOT used.
Analysis Date: 05-23-2000/08:54:48 Residue file dated: 05-23-2000/08:49:06/8
Daily totals for food and foodform consumption used.
Run Comment: "The aRfD of 0.1 mg/kg/day is actually the acute population-adjus ted dose"

Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.002837	2.84	0.006202	6.20	0.012772	12.77
U.S. Population (spring season):	0.002605	2.61	0.005675	5.67	0.011811	11.81
U.S. Population (summer season):	0.002837	2.84	0.005916	5.92	0.015515	15.51
U.S. Population (autumn season):	0.003279	3.28	0.006713	6.71	0.013293	13.29
U.S. Population (winter season):	0.002696	2.70	0.006053	6.05	0.010856	10.86
Northeast region:	0.003140	3.14	0.006763	6.76	0.013945	13.95
Midwest region:	0.002780	2.78	0.005650	5.65	0.012113	12.11
Southern region:	0.002705	2.71	0.006421	6.42	0.011595	11.60
Western region:	0.002655	2.66	0.006292	6.29	0.013987	13.99
Hispanics:	0.002897	2.90	0.006116	6.12	0.008649	8.65
Non-hispanic whites:	0.002829	2.83	0.006359	6.36	0.013299	13.30
Non-hispanic blacks:	0.002752	2.75	0.005335	5.34	0.009520	9.52
Non-hisp/non-white/non-black:	0.003398	3.40	0.005653	5.65	0.008287	8.29
All infants:	0.007793	7.79	0.013123	13.12	0.029155	29.15
Nursing infants (<1 yr old):	0.004380	4.38	0.028890	28.89	0.043157	43.16
Non-nursing infants (<1 yr old):	0.007865	7.87	0.011551	11.55	0.016448	16.45
Children 1-6 yrs:	0.007037	7.04	0.012337	12.34	0.028265	28.26
Children 7-12 yrs:	0.003782	3.78	0.006434	6.43	0.008564	8.56
Females 13+ (preg/not nursing):	0.002083	2.08	0.003040	3.04	0.007003	7.00

U.S. Environmental Protection Agency Ver. 7.075
DEEM ACUTE analysis for THIAMETHOXAM (1989-92 data)
Residue file: 060109a.RS7 Adjustment factor #2 NOT used.
Analysis Date: 05-23-2000/08:54:48 Residue file dated: 05-23-2000/08:49:06/8
Daily totals for food and foodform consumption used.
Run Comment: "The aRfD of 0.1 mg/kg/day is actually the acute population-adjus ted dose"

Summary calculations:

	95th Percentile Exposure	95th Percentile % aRfD	99th Percentile Exposure	99th Percentile % aRfD	99.9th Percentile Exposure	99.9th Percentile % aRfD
Females 13+ (nursing):	0.002645	2.64	0.005085	5.09	0.007317	7.32
Females 13-19 (not preg or nursing):	0.002328	2.33	0.003616	3.62	0.005737	5.74
Females 20+ (not preg or nursing):	0.001547	1.55	0.002760	2.76	0.004557	4.56
Females 13-50 yrs:	0.001737	1.74	0.003038	3.04	0.005125	5.12
Males 13-19 yrs:	0.002024	2.02	0.003359	3.36	0.005614	5.61
Males 20+ yrs:	0.001611	1.61	0.002697	2.70	0.004238	4.24
Seniors 55+:	0.001475	1.47	0.002523	2.52	0.003956	3.96
Pacific:	0.002640	2.64	0.005798	5.80	0.013806	13.81

Attachment 4 – Results of the Chronic Tier 3 DEEM™ Analysis

U.S. Environmental Protection Agency Ver. 7.075
DEEM Chronic analysis for THIAMETHOXAM (1989-92 data)
Residue file name: C:\My Documents\Chemistry Reviews\DEEM Runs\Thiamethoxam\060109.rs7
Adjustment factor #2 used.
Analysis Date 05-23-2000/08:50:51 Residue file dated: 05-23-2000/08:48:35/8
Reference dose (RfD, Chronic) = .0006 mg/kg bw/day
COMMENT 1: The RfD of 0.0006 mg/kg/day is actually the chronic population-adjusted dose.

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000052	8.7%
U.S. Population (spring season)	0.000048	8.0%
U.S. Population (summer season)	0.000053	8.8%
U.S. Population (autumn season)	0.000058	9.7%
U.S. Population (winter season)	0.000050	8.3%
Northeast region	0.000059	9.8%
Midwest region	0.000051	8.4%
Southern region	0.000049	8.1%
Western region	0.000054	9.0%
Hispanics	0.000051	8.5%
Non-hispanic whites	0.000054	8.9%
Non-hispanic blacks	0.000044	7.3%
Non-hisp/non-white/non-black	0.000058	9.6%
All infants (< 1 year)	0.000153	25.5%
Nursing infants	0.000081	13.5%
Non-nursing infants	0.000183	30.5%
Children 1-6 yrs	0.000158	26.3%
Children 7-12 yrs	0.000082	13.6%
Females 13-19 (not preg or nursing)	0.000037	6.1%
Females 20+ (not preg or nursing)	0.000033	5.5%
Females 13-50 yrs	0.000034	5.7%
Females 13+ (preg/not nursing)	0.000047	7.9%
Females 13+ (nursing)	0.000063	10.4%
Males 13-19 yrs	0.000038	6.4%
Males 20+ yrs	0.000034	5.7%
Seniors 55+	0.000034	5.7%
Pacific Region	0.000054	9.0%

Attachment 5 – Tier 3 Commodity Contributions for the Cancer Risk to the U.S. Population

U.S. Environmental Protection Agency Ver. 7.075
DEEM Chronic analysis for THIAMETHOXAM (1989-92 data)
Residue file name: C:\My Documents\Chemistry Reviews\DEEM Runs\Thiamethoxam\060109.rs7
Adjustment factor #2 used.
Analysis Date 05-23-2000/08:51:10 Residue file dated: 05-23-2000/08:48:35/8
Q* = 0.0377

Complete commodity contribution analysis for
U.S. Population (total)

Crop Group = (O) Other

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis mg/kg body wt/day	Lifetime risk (Q*= .0377)
Cottonseed-oil	0.016000	0.100	0.210	0.0000000	3.28E-10
Cottonseed-meal	0.016000	0.150	0.210	0.0000000	5.70E-14
Canola oil (rape seed oil)	0.010000	1.000	1.000	0.0000000	1.71E-09
Crop group subtotal				0.0000001	2.04E-09

Crop Group = (M) Meat

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis mg/kg body wt/day	Lifetime risk (Q*= .0377)
Beef-meat byproducts	0.000032	1.000	1.000	0.0000000	1.20E-11
Beef-other organ meats	0.000032	1.000	1.000	0.0000000	4.49E-12
Beef-dried	0.000043	1.920	1.000	no exposure	
Beef-kidney	0.000032	1.000	1.000	0.0000000	1.69E-14
Beef-liver	0.001800	1.000	1.000	0.0000000	3.01E-10
Beef-lean (fat/free) w/o bon	0.000043	1.000	1.000	0.0000000	1.23E-09
Goat-meat byproducts	0.000032	1.000	1.000	no exposure	
Goat-other organ meats	0.000032	1.000	1.000	no exposure	
Goat-kidney	0.000032	1.000	1.000	no exposure	
Goat-liver	0.001800	1.000	1.000	no exposure	
Goat-lean (fat/free) w/o bon	0.000043	1.000	1.000	0.0000000	1.30E-14
Horsemeat	0.000043	1.000	1.000	no exposure	
Sheep-meat byproducts	0.000032	1.000	1.000	no exposure	
Sheep-other organ meats	0.000032	1.000	1.000	no exposure	
Sheep-kidney	0.000032	1.000	1.000	no exposure	
Sheep-liver	0.001800	1.000	1.000	no exposure	
Sheep-lean (fat free) w/o bo	0.000043	1.000	1.000	0.0000000	1.32E-11
Veal-lean (fat free) w/o bon	0.000043	1.000	1.000	0.0000000	1.49E-11
Veal-kidney	0.000032	1.000	1.000	no exposure	
Veal-liver	0.001800	1.000	1.000	no exposure	
Veal-other organ meats	0.000032	1.000	1.000	no exposure	
Veal-dried	0.000043	1.920	1.000	no exposure	
Veal-meat byproducts	0.000032	1.000	1.000	no exposure	
Crop group subtotal				0.0000000	1.58E-09

1

Crop Group = (D) Dairy Products

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Milk-nonfat solids	0.000098	1.000	1.000	0.0000000	1.54E-09
Milk-fat solids	0.000098	1.000	1.000	0.0000000	1.19E-09
Milk sugar (lactose)	0.000098	1.000	1.000	0.0000000	1.51E-09
Milk-based water	0.000098	1.000	1.000	0.0000006	2.22E-08
Crop group subtotal				0.0000007	2.65E-08

Crop Group = (1) Root and Tuber Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Potatoes/white-whole	0.010000	1.000	0.260	0.0000003	1.26E-08
Potatoes/white-unspecified	0.010000	1.000	0.260	no exposure	
Potatoes/white-peeled	0.010000	1.000	0.260	0.0000020	7.35E-08
Potatoes/white-dry	0.010000	1.900	0.260	0.0000000	1.57E-09
Potatoes/white-peel only	0.010000	1.000	0.260	0.0000000	7.23E-11
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (tanier)	0.010000	1.000	1.000	no exposure	
Crop group subtotal				0.0000026	9.93E-08

Crop Group = (1C) Tuberous and Corm Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Potatoes/white-whole	0.010000	1.000	0.260	0.0000003	1.26E-08
Potatoes/white-unspecified	0.010000	1.000	0.260	no exposure	
Potatoes/white-peeled	0.010000	1.000	0.260	0.0000020	7.35E-08
Potatoes/white-dry	0.010000	1.900	0.260	0.0000000	1.57E-09
Potatoes/white-peel only	0.010000	1.000	0.260	0.0000000	7.23E-11
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10

Crop Group = (1C) Tuberous and Corm Vegetables (continued)

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (tanier)	0.010000	1.000	1.000	no exposure	
Crop group subtotal				0.0000026	9.93E-08

Crop Group = (1D) Tuberous/Corm Vegetables (exc sugar beet)

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Ginger	0.010000	1.000	1.000	0.0000000	5.73E-11
Turmeric	0.010000	1.000	1.000	0.0000000	7.69E-11
Taro-root	0.010000	1.000	1.000	0.0000000	3.62E-10
Artichokes-jerusalem	0.010000	1.000	1.000	no exposure	
Sweet potatoes (incl yams)	0.010000	1.000	1.000	0.0000003	1.03E-08
Yam-bean tuber (jicama)	0.010000	1.000	1.000	0.0000000	1.49E-10
Cassava (yuca blanca)	0.010000	1.000	1.000	0.0000000	5.52E-10
Yautia (tanier)	0.010000	1.000	1.000	no exposure	
Crop group subtotal				0.0000003	1.15E-08

Crop Group = (8) Fruiting Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Paprika	0.072000	1.000	0.210	0.0000000	1.25E-10
Eggplant	0.072000	1.000	0.210	0.0000000	1.75E-09
Peppers-sweet(garden)	0.072000	1.000	0.210	0.0000002	6.39E-09
Peppers-chilli incl jalapeno	0.074000	1.000	0.210	0.0000006	2.24E-08
Peppers-other	0.072000	1.000	0.210	no exposure	
Pimientos	0.074000	1.000	0.210	0.0000000	1.08E-09
Tomatoes-whole	0.052000	1.000	0.210	0.0000045	1.71E-07
Tomatoes-juice	0.052000	1.000	0.210	0.0000004	1.65E-08
Tomatoes-puree	0.052000	1.700	0.210	0.0000037	1.40E-07
Tomatoes-paste	0.052000	3.800	0.210	0.0000049	1.85E-07
Tomatoes-catsup	0.052000	3.800	0.210	0.0000020	7.70E-08
Groundcherries	0.052000	1.000	0.210	no exposure	
Tomatoes-dried	0.052000	14.300	0.210	0.0000000	1.18E-11
Crop group subtotal				0.0000165	6.22E-07

Crop Group = (9) Curcurbit Vegetables

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Melons-cantaloupes-juice	0.045000	1.000	0.440	no exposure	
Melons-cantaloupes-pulp	0.045000	1.000	0.440	0.0000012	4.45E-08
Casabas	0.045000	1.000	0.440	0.0000000	1.71E-10
Crenshaws	0.045000	1.000	0.440	no exposure	
Melons-honeydew	0.045000	1.000	0.440	0.0000002	6.56E-09
Melons-persian	0.045000	1.000	0.440	no exposure	
Watermelon	0.045000	1.000	0.440	0.0000014	5.24E-08
Cucumbers	0.038000	1.000	0.440	0.0000012	4.56E-08
Pumpkin	0.046000	1.000	0.440	0.0000001	4.00E-09
Squash-summer	0.046000	1.000	0.440	0.0000008	3.02E-08
Squash-winter	0.046000	1.000	0.440	0.0000004	1.46E-08
Bitter melon	0.045000	1.000	0.440	0.0000000	2.02E-11
Christophine	0.045000	1.000	0.440	no exposure	
Okra/chinese (luffa)	0.045000	1.000	0.440	no exposure	
Squash-spaghetti	0.046000	1.000	0.440	no exposure	
Watermelon-juice	0.045000	1.000	0.440	no exposure	
Wintermelon	0.045000	1.000	0.440	no exposure	
Balsam pear	0.045000	1.000	0.440	no exposure	
Crop group subtotal				0.0000053	1.98E-07

Crop Group = (9A) Melons

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Melons-cantaloupes-juice	0.045000	1.000	0.440	no exposure	
Melons-cantaloupes-pulp	0.045000	1.000	0.440	0.0000012	4.45E-08
Casabas	0.045000	1.000	0.440	0.0000000	1.71E-10
Crenshaws	0.045000	1.000	0.440	no exposure	
Melons-honeydew	0.045000	1.000	0.440	0.0000002	6.56E-09
Melons-persian	0.045000	1.000	0.440	no exposure	
Watermelon	0.045000	1.000	0.440	0.0000014	5.24E-08
Watermelon-juice	0.045000	1.000	0.440	no exposure	
Crop group subtotal				0.0000027	1.04E-07

Crop Group = (9B) Squash/Cucumbers

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Cucumbers	0.038000	1.000	0.440	0.0000012	4.56E-08
Pumpkin	0.046000	1.000	0.440	0.0000001	4.00E-09
Squash-summer	0.046000	1.000	0.440	0.0000008	3.02E-08
Squash-winter	0.046000	1.000	0.440	0.0000004	1.46E-08
Bitter melon	0.045000	1.000	0.440	0.0000000	2.02E-11
Christophine	0.045000	1.000	0.440	no exposure	
Okra/chinese (luffa)	0.045000	1.000	0.440	no exposure	
Squash-spaghetti	0.046000	1.000	0.440	no exposure	
Wintermelon	0.045000	1.000	0.440	no exposure	
Balsam pear	0.045000	1.000	0.440	no exposure	
Crop group subtotal				0.0000025	9.45E-08

Crop Group = (11) Pome Fruits

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Apples	0.057000	1.000	0.530	0.0000133	5.03E-07
Apples-dried	0.057000	8.000	0.530	0.0000004	1.48E-08
Apples-juice/cider	0.057000	0.750	0.530	0.0000098	3.69E-07
Crabapples	0.057000	1.000	0.530	no exposure	
Pears	0.054000	1.000	0.180	0.0000008	2.85E-08
Pears-dried	0.054000	6.250	0.180	0.0000000	1.33E-09
Quinces	0.054000	1.000	0.530	no exposure	
Loquats	0.054000	1.000	0.530	no exposure	
Apples-juice-concentrate	0.057000	2.250	0.530	0.0000014	5.40E-08
Pears-juice	0.054000	0.750	0.180	0.0000002	8.23E-09
Crop group subtotal				0.0000260	9.79E-07

Crop Group = (15) Cereal Grains

Food name	Residue (ppm)	Adjustment Factors		Exposure analysis: mg/kg body wt/day	Exposure analysis: Lifetime risk (Q*= .0377)
Barley	0.010000	1.000	1.000	0.0000009	3.34E-08
Sorghum (including milo)	0.010000	1.000	0.120	no exposure	
Wheat-rough	0.010000	1.000	0.020	0.0000000	5.15E-10
Wheat-germ	0.010000	1.000	0.020	0.0000000	2.18E-11
Wheat-bran	0.010000	1.000	0.020	0.0000000	1.99E-10
Wheat-flour	0.010000	1.000	0.020	0.0000003	1.04E-08
Wheat-germ oil	0.010000	1.000	0.020	0.0000000	4.67E-13
Crop group subtotal				0.0000012	4.45E-08
Population subgroup total				0.0000523	1.97E-06