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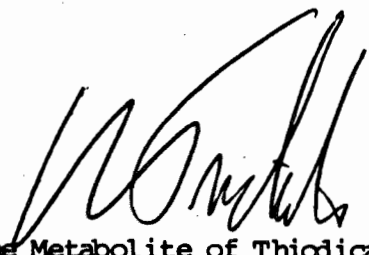
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22 JUL 1988

RCB SCIENCE INTEGRATION/DEFERRAL

TO: Theodore M. Farber, Ph.D., Chief
Toxicology Branch

FROM: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch



SUBJECT: Request for Toxicology Input on the Metabolite of Thiodicarb,
Acetonitrile.

ACTION: PP#8F3578, Thiodicarb (Iarvin®) In Or On Sweet Corn Forage and
Peppers (Acc.#403761-0, -1, -2, -3, -4; RCB #3030).

CHEMICAL NAME: Thiodicarb, dimethyl-N,N'-[thiobis[(methylimino)carbonyl-
oxy]]bis(ethanimidothioate)

PURPOSE: Request for consideration of acetonitrile as part of thiodicarb
residues in cow tissues and milk.

DUE DATE: August 31, 1988.

BACKGROUND DATA: RCB has deferred to TOX on the toxicological signifi-
cance, if any, of the acetamide and acetonitrile compounds and whether
they need to be regulated (see F. Boyd's 7/26/84 memo in connection with
PP#4F3013/ FAP#4H5421 and A. Smith's 4/11/83 memo in connection with
PP#3F2773). The problem regarding acetamide has been resolved. However,
the deferral of acetonitrile is still outstanding.

DEFERRAL: RCB continues to defer to TOX on the toxicological significance
of acetonitrile and if it needs to be regulated as part of the tolerance
expression in meat, milk, poultry and eggs. The maximum residues of aceto-
nitrile in cow tissues and milk will not exceed the following levels:
Liver (0.7 ppm), Kidney (0.05 ppm), Muscle (0.05 ppm) and Milk (0.1 ppm).

TECHNICAL CONTACT: Wei T. Chin, Ph.D., Chemist

cc: A.Rispin(HED), B.Lowery(HED), D.Edwards(PM#12), SF, PP#8F3578, W.T.Chin

FDI: P.V.Errico(7/18/88), R.D.Schmitt(7/18/88)

TS-769: RCB: CM#2, RM#2, 557-4352, W.T.Chin,wc(7/18/88)



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

22/July 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3578: Thiodicarb (Larvin®) In Or On Sweet Corn Forage and Peppers.
Evaluation of Analytical Methods and Residue Data. (Acc. #403761-0,
-1, -2, -3, -4; RCB #3030).

FROM: W. T. Chin, Ph.D., Chemist *W. T. Chin*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D. Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Dennis Edwards, Acting PM #12
Insecticide-Rodenticide Branch
Registration Division (TS-767)

and

Toxicology Branch (See Deferral)
Hazard Evaluation Division (TS-769)

The petitioner, Union Carbide Corp.; Agricultural Products Company, Inc. proposes tolerances for combined residues of the insecticide, thiodicarb, dimethyl-N,N'-[thiobis[(methyl imino)carbonyloxy]bis(ethanimidothioate), and its metabolite methomyl, S-methyl-N[(methyl carbamoyl)oxy]thioacetimidate, in or on the raw agricultural commodities sweet corn forage at 40 ppm and peppers at 5.0 ppm.

Temporary tolerances for almond nutmeat (2.0 ppm), almond hulls (50 ppm), broccoli (7.0 ppm), cabbage (7.0 ppm), cauliflower (7.0 ppm) and lettuce, head (25 ppm) have been proposed in connection with PP#6G3438.

Permanent tolerances have been established on sweet corn, grain (K+CWHR) (2.0 ppm), cottonseed (0.4 ppm) and soybeans (0.2 ppm) under 40 CFR 180.407. Feed additive tolerances are established for cottonseed hulls (0.8 ppm) and soybean hulls (0.8 ppm) under 21 CFR 561.386.

CONCLUSIONS

- 1a. The metabolism of thiodicarb in plants is adequately understood for the proposed use in/on sweet corn forage and peppers. The regulated residues in the tolerance expression are the parent compound and its metabolite, methomyl.
- 1b. The metabolism of thiodicarb in animals is adequately understood. The residues requiring regulation in livestock at the present time are the parent compound and its metabolite, methomyl. RCB defers to TOX whether the residue acetonitrile should be part of the tolerance expression in meat, milk, poultry and eggs.
2. Adequate analytical methodology is available for the determination of thiodicarb and its metabolite methomyl in plants and animals in the form of methomyl oxime. This method is included in PAM II for enforcement purposes.
3. To simplify the use, the petitioner should amend the proposed use to ten applications per season with a zero-day PHI for both fresh sweet corn and its forage and raise the proposed 40 ppm tolerance for use on sweet corn forage to 300 ppm. Therefore, the petitioner should revise Section B to make the proposed use for both fresh sweet corn (K+CWHR) and its forage the same.
4. The residue data generated using formulation Larvin® brand 3.2 Thiodicarb Insecticide on peppers are considered adequate to support the proposed tolerance of 5 ppm. However, if the petitioner intends to register Larvin® brand LE Thiodicarb Insecticide on peppers, it should be specified in the proposed label and additional residue data generated using this formulation on peppers should be submitted.
5. There are no Codex or foreign tolerances established for thiodicarb in or on agricultural commodities sweet corn forage and peppers. Therefore, no compatibility questions exist with these crops.

RECOMMENDATION

At this time, RCB recommends against the proposed tolerance for combined residues of thiodicarb and its metabolite methomyl in or on the raw agricultural commodity sweet corn forage at 40 ppm because of the reason identified in Conclusions "1b" and 3. RCB recommends for the proposed tolerance for combined residues of thiodicarb and its metabolite methomyl in or on the raw agricultural commodity peppers at 5 ppm using the formulation Larvin® brand 3.2 Thiodicarb Insecticide only.

DETAILED CONSIDERATIONS

Manufacture and Formulation

The manufacturing process of thiodicarb was reviewed in detail in connection with PP#OF2413/FAP#OH5275 (see A. Smith's 1/21/81 memo). The thiodicarb product contains 96% thiodicarb. The impurities in the technical product are not likely to result in a residue problem.

A revised Confidential Statement of Formula dated 6/29/87 for Larvin® Brand 3.2 Thiodicarb Insecticide was submitted with the current petition. All inert ingredients in this formulation have been cleared for use under 40 CFR 180.1001. The 3.2 product contains 34% active ingredient as an aqueous flowable formulation.

Proposed Use on Sweet Corn

The label indicating the proposed uses on sweet corn are summarized below: The recommended dosage ranges from 0.50 to 0.75 lb a.i. (20.0 to 30.0 fluid oz.)/A. Applications are made as needed or when insect populations reach economic threshold levels. For insects attacking silks and ears, apply at 1 to 7 day intervals starting when silks first appear and continuing until silks begin to dry or infestation potential ceases. For whorl or foliage feeders, use sprays of 15 gallons or more per acre by ground equipment with solid or hollow cone nozzles directed into the plant whorl. The lower dosage rates are used for light to moderate infestations and the higher rates for heavier infestations or larger larvae. Applications may be repeated, but do not exceed a total of 7.5 lbs a.i. (or 300 fluid oz)/A/season. Do not allow livestock to graze treated field. No more than four applications (or 3.0 lbs a.i./A/season) may be made if the forage is to be used as a livestock feed. The PHI is no less than 21 days for sweet corn forage and zero day for sweet corn ears.

The proposed label described above for sweet corn is actually a modification of an established regional label. RCB concludes that the label submitted is overly complicated, inconsistent and impractical for the following reasons:

- (1) The restrictions "Fresh market only" and "Florida only" are removed from the established regional label, so that the proposed label will apply to sweet corn grown nationwide for both fresh market and processing.
- (2) The proposed use also prohibits the feeding or grazing of treated corn silage (green plant) or forage to livestock if sweet corn is treated more than four times. Because of the cultural practices and economic incentive to feed sweet corn forage/silage, RCB does not consider this restriction practical.
- (3) The petitioner also proposes a 21-day PHI for the forage and a zero-day PHI for sweet corn ears. However, a zero-day PHI for the ears should also mean a zero-day PHI for the remaining forage because this is harvest of the raw agricultural commodity. Cultural practices for sweet corn make it difficult or impractical

for farmers to maintain a 21 day PHI for treated forage while adhering to a zero-day PHI for a different part of the same plant. This label is overly complicated and impractical for a farmer to deal with.

- (4) The label allows for two different number of applications: (i) Four applications if corn is to be used as forage; and (ii) ten applications if corn is not to be used as forage. RCB would consider it more reasonable for an applicator to adhere to the label if a single limit were to be placed on the number of applications.

Our calculations of potential residue levels on corn forage that can be fed to livestock (see Table 5 below) indicates that ten applications per season can be accommodated. In addition, RCB suggests a zero-day PHI for both corn grain and forage.

Proposed Use on Peppers

The proposed dosage ranges from 0.40 to 0.75 lb a.i. (16.0 to 30.0 fluid oz.)/A. Applications are made as needed. As insect populations increase and/or new plant growth is rapid, the spray interval should be shorter. Use the higher rates for heavier infestations or larger larvae and use the lower rates for light to moderate infestations. Apply in a minimum finished spray volume of 5 gallons/A by air or 20 gallons/A by ground. Do not exceed a total of 6.0 lbs a.i. (or 240 fluid oz)/A/season. The PHI for peppers is one day.

Nature of Residue in Plants

The thiodicarb metabolism studies in plants were reviewed in detail in connection with PP#OF2413, PP#9G2152, PP#3G2782, PP#3F2773 and PP#6F3417. Briefly: ¹⁴C thiodicarb was not readily translocated when applied to leaves of carrots. However, upon stem injection in corn, soybeans, wheat, cabbage and tomatoes, it is translocated and extensively degraded to naturally occurring plant constituents by volatilization as acetonitrile and carbon dioxide. Some detoxification occurs by way of conjugation/binding with plant structural components. Rapid cleavage of the N-S-N linkage results in two molecules of methomyl from one molecule of thiodicarb. Thiodicarb and methomyl comprise the majority (96-98%) of the free residue components in plants. Methomyl is degraded to methomyl oxime through sequential sulfoxidation to the sulfoxide, followed by hydrolysis. Approximately 2% of the residues are conjugated methomyl metabolites; about 10% of the residues are bound non-hydrolyzable conjugates; and the remaining residues are lost as volatiles. The results of a recent ¹⁴C-thiodicarb metabolism study on tomato plant confirmed previous conclusions that the residues of concern for thiodicarb are the parent compound, methomyl and methomyl oxime. Acetamide was not a detectable metabolite in tomato plant (see F. Boyd's 1/12/87 memo).

RCB can translate the results of the above metabolism studies to sweet corn forage and peppers.

Nature of Residue in Animals

The metabolism studies of thiodicarb in rat, cow and poultry were reviewed in detail in connection with PP#0F2413, PP#3G2782 and PP#3F2773.

Briefly: ^{14}C -thiodicarb is rapidly absorbed, metabolized and excreted by the animals. It is metabolized step-wise by thiolysis to methomyl, followed by hydrolysis to the methomyl oxime which is subsequently metabolized to acetonitrile. The acetonitrile is then metabolized to acetamide which is then hydrolyzed to acetic acid which enters the intermediary metabolism cycles of the animals. This results in the production of carbon dioxide which is expired.

Analytical Methodology

A GC procedure for the determination of thiodicarb and methomyl residues in plant and animal samples was reviewed in detail in connection with PP#6F3417. This method is included in PAM II for enforcement purposes.

Briefly: Residues of thiodicarb, methomyl and methomyl oxime are extracted with a mixture of acetone : water = 9 : 1 (v/v). Interfering coextractants are removed by a coagulation procedure. The residues are converted to methomyl oxime by caustic hydrolysis. The oxime is quantified by GC with a flame photometric detector selective for sulfur containing compounds. Data are calculated as thiodicarb equivalent. The method sensitivity is 0.04 ppm for a 25 g sample. The average recoveries are 89% for thiodicarb and 93% for methomyl at several levels over a range of 0.04 to 10 ppm. Adequate examples of gas chromatograms and sample calculations are submitted. Storage stability studies indicate that residues of thiodicarb and methomyl are stable when samples are stored at -20°C for at least six months (see PP#0F2413, Acc. #099601). Corn forage samples submitted in this petition of field residue trials were stored five to ten months at -20°C before analysis.

Residue Data

Thiodicarb Residues in/on Sweet Corn Forage (Acc. #403761-1)

In accordance with the directions proposed in the label, field trials were conducted in eleven states (CA, FL, IL, IA, MI, MN, MS, NJ, NY, NC, and WA) in 1985 to determine the residues remaining in/on sweet corn forage resulting from four (4 x 0.75 lb a.i./ A/season) foliar applications of thiodicarb using Larvin[®] brand 3.2 Thiodicarb Insecticide. The average interval between applications was five days. Samples were harvested for analysis at approximately 7, 14 and 21 days after application. The established method included in PAM II was used for analysis. Results are summarized in Table 1.

Table 1. Thiodicarb Residues In/On Sweet Corn Forage (1985)
(4 x 0.75 lb a.i./A/season)

State	Thiodicarb Equivalent (ppm)								
	PHI = 7			PHI = 14			PHI = 21 days		
CA	22			ND (not detectable)			11		
CA	<0.05	<0.05	<0.05	5.8	9.9	5.4	18	13	11
FL	0.96	1.2	1.1	ND*	0.24*	0.12*	ND	ND	ND
IL	14	29	23	3.6	3.3	4.4	4.7	2.9	6.9
IA	1.3	0.78	2.2	1.0**	2.1**	2.4**	1.1	0.51	0.37
MI	2.9	4.4	7.6	<0.05	1.0	<0.05	<0.05	<0.05	<0.05
MN	0.18	<0.05	0.07	<0.05	<0.05	0.05	<0.05	0.06	<0.05
MS	13	20	12	0.45	0.32	0.28	0.21	2.3	0.19
NJ	0.18	0.29	0.16	0.11	0.05	0.07	0.06	0.21	ND
NY	0.26	0.32	0.59	0.09	0.26	0.42	0.06	0.11	0.16
NC	0.69	0.90	0.64	0.54	0.62	1.1	0.54	0.24	0.56
WA	7.3	8.3	5.4	1.0	5.2	0.87	5.1	5.2	2.9

* PHI = 16 days; ** PHI = 13 days.

The eleven states selected for these trials represent a majority of sweet corn crop grown for forage in the United States (Agri. Statistics, p. 156, 1986). These studies are reflective of the directions proposed on the label of Section B. A total of 102 samples were analyzed. Recovery of added thiodicarb varied from 62% to 102% with an average of 81%.

Data shown in Table 1 indicate that thiodicarb residues in or on sweet corn forage are all less than the proposed 40 ppm level. However, since the PHI for sweet corn ears is proposed at zero day, the residues levels for sweet corn forage at zero-day PHI must be evaluated.

According to the results of field trials conducted in 1981 and submitted in connection with PP#3F2773 (Acc. #071182), samples of sweet corn forage from 17 trials of eleven representative states (TX, NC, FL, IA, IL, MD, MN, NY, ID, WA, CA) were analyzed. Residue data of thiodicarb equivalent in/on sweet corn fractions at 0-, 4- and 7-day PHI's were extracted as summarized in Table 2.

Table 2. Thiodicarb Residues In/On Sweet Corn Fractions (1981)
(10x0.75 lb a.i./A/season)

Thiodicarb Equivalent (ppm) in Sweet Corn												
PHI	Kernel plus cobs			Kernels without cobs			Forage whole stalk, no ears			Cannery waste husks plus cobs		
0-day	<0.03	<0.03	<0.03	<0.03	<0.03	0.03	8.2	5.8	6.8	2.3	2.1	3.2
	<0.03	<0.03	<0.03	<0.03	<0.03	0.03	88	120	82	3.6	3.0	2.0
	<0.03	<0.03	<0.03	<0.03	<0.03	0.03	9.1	9.6	4.4	0.42	0.55	0.67
	<0.03	<0.03	<0.03	0.03	<0.03	0.03	18	30	21	1.8	2.6	1.9
	0.21	0.54	0.16	0.03	0.12	0.05	35	27	40	7.4	3.6	2.3
	0.08	<0.03	0.06	0.06	<0.03	0.04	4.4	7.5	6.5	2.8	5.1	5.1
	0.04	0.06	0.05	0.05	0.04	0.04	30	24	65	3.4	4.1	3.1
	0.04	<0.04	0.13	<0.04	0.04	0.06	97	110	110	5.9	5.0	3.8
	<0.04	0.09	<0.04	<0.04	0.04	<0.03	210	150	—	1.1	0.64	1.1
	<0.03	<0.03	<0.03	<0.03	<0.03	0.03	90	57	50	0.56	0.93	0.69
0.31	1.3	1.5	0.05	0.06	0.22	90	130	100	17	21	12	
<0.03	<0.03	<0.03	0.04	0.08	0.03	84	120	97	14	5.0	4.2	
4-day	no data			no data			260	110	—	no data		
7-day	0.11	0.06	-	no data			1.8	2.8	9.6	no data		
	0.23	0.38	0.25				9.7	113	4.4			
							12	9.4	11			
							29	23	24			
							5.2	5.4	3.7			
							8.9	13	8.8			
							17	11	18			
							2.5	3.1	3.			
							110	76	140			
							150	180	46			
							66	62	130			
							140	87	110			
							120	92	120			

Data shown in Table 2 indicate that with ten applications and at 0-, 4- and 7-day PHI's, the residue levels of thiodicarb equivalent have reached as high as 210, 260 and 180 ppm, respectively. However, our calculations of potential residue levels on corn forage that can be fed to livestock (see Table 5 below) indicates that ten applications per season can be accommodated with a 0-day PHI. In addition, to simplify the label instructions, RCB suggests a zero-day PHI for both fresh sweet corn and its forage.

RCB has previously concluded that if the established thiodicarb use on sweet corn is ever expanded to include uses other than "Florida only" and "fresh market only", the corn forage and fodder tolerance levels will need to be raised to 300 ppm (see A. Smith's 4/11/83 memo in connection with PP#4F3050 and M. P. Firestone's 1/2/85 memo in connection with PP#3F2773).

RCB, therefore, suggests that the proposed 40 ppm be raised to 300 ppm in or on fresh sweet corn and its forage. This would require the petitioner to revise Section B to allow ten applications per season for both fresh sweet corn (K+CWHR) and its forage.

Thiodicarb Residues in/on Peppers (Acc. #403761-2)

Four field trials were conducted in eight states (CA, FL, IA, MI, MS, NJ, NC, and TX) in 1985 to determine the residues remaining in or on peppers resulting from six (6x1.0 lb a.i./A/season) applications of thiodicarb. Two kinds of commercial peppers were tested: Hot peppers (Long Red Cayenne, Italian Wax and Jalapeno) and sweet peppers (Yolo Wonder, Jupiter, Lady bell and Cali. Wonder). Two formulations were used in these trials: (1) Larvin® Brand 3.2 Thiodicarb Insecticide and (2) Larvin® Brand LE Thiodicarb Insecticide. The average interval between applications is six days. Samples were harvested one day after application for residue analyses using the established method included in PAM II. Results are summarized in Table 3.

Table 3. Thiodicarb Residues In/On Peppers (1985)
(6 x 1.0 lb a.i./A/season, PHI = 1 day)

State	Thiodicarb Equivalent (ppm)						Weather Condition
	Larvin® Brand 3.2			Larvin® Brand LE			
CA	1.9	2.1	0.72	1.4	1.4	-	Normal
	3.1	2.7	2.6				
	1.5	1.4	1.1				
FL	0.45	0.95	0.65				Normal
IA	0.35	0.21	0.34	1.3	0.50	0.79	Normal to dry
	4.3	4.4	4.3				
	0.79	0.41	0.41				
MI	0.29	0.34	0.19				Drier than normal
MS	0.62	0.74	0.88	1.1	0.94	0.43	Hot and dry, irrigated 0.6 in. on 4/19 7 6/5
	0.80	0.62	0.53				
	0.55	0.77	0.67				
NJ	ND	0.21	0.17				>3 in. heavy rain after last application
	0.15	0.15	0.16				
NC	0.80	0.46	0.48	0.36	0.49	0.67	Heavy rain between 7/24 and final harvest
	2.3	1.8	2.1				
	0.25	0.22	0.32				
TX	0.83	0.61	0.64				Variable

The eight states selected for these trials represent a majority of peppers grown as a commercial crop in the United States (Agri. Statistics, p.179, 1977). These trials are reflective of the directions proposed on the label of Section B. Totally 62 samples were analyzed. Recovery of added thiodicarb varied from 62% to 101% with an average of 85%. The means and standard deviations of the results were 1.0 + 1.0 ppm. The thiodicarb residue equivalent ranges from non-detectable to 4.4 ppm. Rain fall and irrigation slightly reduced residue levels. In all cases, thiodicarb residue levels are less than the proposed 5 ppm tolerance. RCB, therefore, concludes that the residue data submitted on peppers are adequate.

RCB concludes that the residue data generated using the formulation Larvin® brand 3.2 Thiodicarb Insecticide are adequate for the proposed use of thiodicarb in/on the raw agricultural commodity peppers. However, the formulation Larvin® brand LE Thiodicarb Insecticide was not recommended in the proposed label for use on peppers. If the petitioner intends to recommend the LE formulation for peppers, it should be specified in the label and more residue data are needed. A Confidential Statement of Formula for the LE formulation should be submitted using EPA Form 8570-4 (Rev. 2-85) and the differences between these two formulations should be adequately explained.

Meat, Milk, Poultry and Eggs

Sweet corn forage and peppers are not considered poultry feed items. Sweet corn grain, forage, silage and fodder, however, are important feed items for other livestock. A cattle feeding study (Acc. #099600) was previously reviewed in detail in connections with PP#0F2413/FAP0H5275 (see M. P. Firstone's 9/24/84 memo).

Briefly: Lactating cows were fed with acetyl-1-¹⁴C-thiodicarb daily for 21 days at dietary levels equivalent to 0.1, 10, 30 and 100 ppm. Analysis for thiodicarb residues showed no carbamate residues in milk and tissues; i.e., no thiodicarb, methomyl, methomyl metholol, and methomyl oxime sulfoxide. However, activity in the form of acetonitrile was detected in milk at levels of 0.001, 0.051, 0.263 and 0.814 ppm, respectively; with trace amounts (<0.01 ppm) of acetamide were found in milk only at the 100 ppm level. In addition, measurable levels of acetamide and acetonitrile were detected in tissues as shown in Table 4.

Table 4. ¹⁴C-Thiodocarb Equivalent Residues in Cow Tissues

Tissue Feeding level (ppm)	Liver			Kidney			Muscle		
	10	30	100	10	30	100	10	30	100
Acetamide	0.143	0.166	0.677	0.005	0.044	0.061	-	0.007	0.040
Acetonitrile	0.002	0.014	0.625	0.002	0.013	0.036	-	0.004	0.047

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The following exposure analysis is based on the assumption that a tolerance for thiodicarb residues in/on sweet corn forage is revised to 300 ppm and at 0-day PHI.

Table 5. An Exposure Analysis* for Livestock with Sweet Corn Forage

Feeding Items	Tolerance (ppm)	% of Livestock Diet		Exposure to Livestock Diet	
		Beef	Dairy	Beef	Dairy (ppm)
Sweet Corn Forage	300*	25	10	75.00	30.00
Cottonseed, Hull	0.8	25	20	0.20	0.16
Wheat grain	1.0**	50	50	0.50	0.50
Sum		100	80	75.70	30.66

* RCB's recommended tolerance for sweet corn forage at 300 ppm and at zero-day PHI.

** Tolerance established for methomyl under 40 CFR 180.253.

Data shown in Table 5 indicate that sweet corn forage at the suggested zero-day PHI and 300 ppm tolerance level may lead to a maximum exposure of thiodicarb residues of 75.70 and 30.66 ppm to beef and dairy livestock, respectively. According to the results of the above feeding study, no carbamate residues are expected in milk and tissues at this maximum level; but measurable levels of acetamide and acetonitrile are expected to be detected in tissues and milk.

RCB's Deferrals To TOX Regarding Acetamide and Acetonitrile

RCB has deferred to TOX on the toxicological significance, if any, of the acetamide and acetonitrile compounds and whether they need to be regulated (see F. Boyd's 7/26/84 memo in connection with PP#4F30L3/4H5421 and A. Smith's 4/11/83 memo in connection with PP#3F2773). TOX's response is summarized below:

- (1) Acetamide: TOX indicated that they cannot answer this deferral because adequate residue data were not available (see Alan C. Katz's 1/18/85 memo). According to the final rule published in the Federal Register of 10/10/85 (V. 50, p. 41341), however, the Agency has waived the requirement of a regulatory analytical method for analysis of acetamide in milk and eggs for thiodicarb residues. The Agency concurred with the petitioner in that acetamide is ubiquitous in milk and eggs based upon data from the Analytical Chemistry Section, COB, HUD, EPA (see the 8/20/85 memo of D. Wright, Jr.). Levels of acetamide, based on the petitioner's submitted data, ranged from 275 to 500 ppb (average 400 ppb) in milk, and from 75 to 350 ppb (averaged 170 ppb) in eggs. Although the Agency values were lower, the ubiquitous nature of acetamide in milk and eggs was consistent with the petitioner's observations. Based upon the above estimated levels of acetamide that might be observed if the proposed tolerances in this petition (PP#8F3578) are established, the estimated increase in level of acetamide would be well below the ubiquitous levels of acetamide levels of acetamide measured in milk and eggs.

According to Agency estimations using FDA guidelines (see Federal Register, 7/3/85, V. 150, p. 27455), the maximum allowable level for acetamide residues in beef liver

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liver is 1530 ppb which is much higher than the estimated residue from thiodicarb use in/on sweet corn forage. In addition, the Agency has found that the petitioner's method for detection of acetamide residues in beef (and poultry) liver is adequate to detect acetamide residues (method sensitivity: 770 ppb for beef liver and 400 ppb for poultry liver). RCB concludes that the acetamide problem in milk and eggs has been resolved.

- (2) Acetonitrile: However, RCB's deferral to TOX on the toxicological significance of acetonitrile is still outstanding. The residue data of acetonitrile determined in the cattle feeding study (Acc. #099600) discussed above are summarized in Table 6. Based on these data and the exposure data shown in Table 5 (75.7 ppm for beef and 30.66 ppm for dairy), the maximum residue levels of acetonitrile in cow tissues and milk were estimated and are shown in Table 6 below:

Table 6. Acetonitrile Residues in Cow Tissues and Milk

Feeding level (ppm)	Acetonitrile Determined (ppm)			
	Liver	Kidney	Muscle	Milk
10	0.002	0.002	-	0.051
30	0.014	0.013	0.004	0.026
100	0.625	0.036	0.047	0.081
Estimated maximum acetonitrile (ppm)	0.7*	0.05*	0.05*	0.1**

- * Estimated for 75.70 ppm feeding level.
- ** Estimated for 30.66 ppm feeding level.

RCB continues to defer to TOX on the toxicological significance of acetonitrile and if it needs to be regulated as part of the tolerance expression in meat, milk, poultry and eggs.

Other Considerations

An International Tolerance Sheet is attached. There are no Codex or foreign tolerances established for thiodicarb in or on the agricultural commodities peppers and sweet corn forage. Therefore, no compatibility questions exist with these crops.

Attachment: Codex Sheet

cc: R.F., S.F., Circu., PM#12, W.T.Chin, PP#8F3578, TOX, EAB, EEB, and PMSD-ISB.
RDI: P.V.Errico(7/18/88), R.D.Schmitt(7/18/88)
TS-769: RCB: CM#2, RM#12, 557-4352, W.T.Chin, wc(7/18/88)

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Thiodicarb

CODEX NO. 154

J. Jones
12/8/87

CODEX STATUS:

No Codex Proposal
Step 6 or above

PROPOSED U.S. TOLERANCES:

Petition No. 8F3578

RCB Reviewer W. T. Chin

Residue: Thiodicarb + metabolite Methomyl

Residue (if Step 8): ^{Thiodicarb} Sum of methomyl
and methomyl hydroxythioacetimidate
("methyl oxime"), expressed as thiodicarb *

Crop(s) Limit
 (mg/kg)

Maise fodder
Maise forage

50 (fresh
wt.)

50 (fresh
wt.)

Crop(s) Limit
 (mg/kg)

Sweet Corn Forage *40.0*

Peppers *5.0*

CANADIAN LIMITS:

No Canadian limit

Residue: _____

MEXICAN LIMITS:

No Mexican limit

Residue: _____

Crop(s) Limit
 (mg/kg)

Crop(s) Limit
 (mg/kg)

NOTES:
* The U.S. has proposed deletion of the "oxime" to Codex and ^{that} is under consideration.

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