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

FEB 28 1996

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of acceptability of worker exposure data submitted to support the reregistration of aldicarb

TO: Phillip Poli, PM Team 63
Special Review and Reregistration Division (7508W)

FROM: Jim Carleton, Chemist

THRU: Francis B. Suhre, Section Head
Special Review and Reregistration Section

Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

DP Barcode:	D221446
Pesticide Chemical Codes:	98301
EPA Reg. Nos.:	264-330
EPA MRID Nos.:	43852501
Review Time:	3 days
PHED:	N/A

OREB has reviewed the above referenced aldicarb worker exposure study for Subdivision U Guideline acceptability to support reregistration. The study consists of loader and applicator data collected by Rhone-Poulenc during the application of aldicarb to pecan groves in three states during 1995. The study has been found to meet all the Guideline requirements (see attached memo from Pat Wood/Tim Leighton to Al Nielsen dated 1/5/96), and may therefore be used to support reregistration.

A separate issue concerns the way in which dermal dosimeter values falling below the analytical detection limit (LOD) were estimated by the study authors. The authors quantitated these as 10% of the limit of quantitation (LOQ). Only values which fell between the LOD and the LOQ were quantitated as 50% of the LOQ. Inadequate documentation was provided to support the use of this method of quantitation. In consideration of this issue the OREB Science Peer Review committee (meeting 2/21/96) decided that as a general policy, all values less than the LOQ, including those also falling below the LOD (i.e. non-detects) should be quantitated as 50% of the LOQ. This issue is not addressed in the Subdivision U guidelines, and has no affect on the acceptability of the study to support reregistration. In future use of these data, OREB will recalculate the values in question using 50% of the LOQ.

cc: J. Carleton, OREB
Correspondence file
Chemical file

MEMORANDUM

TO: Al Nielsen EPA/OPP/OREB cc: 2994.101 file

FROM: Pat Wood/Tim Leighton

DATE: January 5, 1996

SUBJECT: Exposure of Workers Loading and Applying Temik 15G (Aldicarb) to Pecan Groves in Mississippi, Texas, and Georgia.

A study was completed in support of the registration requirements for Temik. This study was conducted in Raymond, Mississippi; Brownwood, Texas; and Albany, Georgia. This study has been submitted to satisfy the requirements specified by the U.S. Environmental Protection Agency (i.e., the Agency) under Subdivision U (Applicator Exposure Monitoring Requirements) of the Pesticide Assessment Guidelines. This study's identifying information is presented below:

Title:	Worker Loader and Applicator Exposure to Temik 15G.
Authors:	Leah Rosenheck, and Larissa L. Svhustere.
Date:	October 12, 1995
MRID No.:	438525-01
Sponsor and Performing Laboratories:	Rhone-Poulenc Ag Company 2 T.W. Alexander Drive Research Triangle Park, NC 27709
Testing Facility:	ABC Laboratories, Pan Ag Division P32380 Avenue 10 Madera, California 93638

Temik 15G (containing aldicarb) formulated as a granular product and packaged in 45 pound bags, was applied to pecan groves using a modified Tye seeder mounted to an open cab tractor. Temik 15G was applied through shank injection into the soil (orchard floor). Exposure monitoring was performed between March 28 and April 18, 1995. The objective of the study was to quantify potential exposure to aldicarb for workers loading and applying Temik 15G. Exposure was monitored for aldicarb, and also two principal by-products, aldicarb sulfoxide, and aldicarb sulfone.

Equipment used for the studies was typical for the application of Temik 15G and was practically the same for each site. A modified Tye seeder, Model 104-3404 was used in both Mississippi and Texas. Series V-7' Tye Pasture Pleaser, Model 114-5505 was used in Georgia. All seeders had 800-900 lb capacity hoppers, 4 drop hose outlets, and 4 disc openers. Each seeder was drawn by an open cab tractor at a speed of 2.76 mph (MS); 2.9 mph (TX); and 2.85 mph (GA).

Five replicates of the loading and application of Temik 15G were monitored at each of the three locations for a total of 15 loading and 15 application replicates (mixer/loader monitored separately from the applicators). Each replicate included six separate dermal body part samples for a total of 90 dermal samples. The duration of each loading replicate was approximately 4 hours for which the seeder was loaded and emptied twice (once at the start and again after about 2 hours). The application replicates were monitored over a period of approximately 4 hours. The loaders handled a range of 900 lbs (61.4 kg/ai) to 1485 lbs (101 kg/ai) of Temik 15G per replicate. The application rate averaged approximately 40 lbs of product per acre (i.e., 6 lbs-ai/A).

Exposure Monitoring

Dermal exposures were monitored using whole body dosimetry (long underwear, later sectioned into arms, chest, back, and lower body), handwashes and facial and neck swipes. Long underwear (100% cotton) was worn over the subjects underwear and under the shorts, short sleeved shirt, and coveralls. The test subjects also wore protective clothing that met U.S. EPA Worker Protection Standards. This consisted of nitrile rubber gloves, rubber boots, goggles, hard hat, a dust filtering respirator, and a chemical resistant apron (loader only). Hand exposure was monitored by having each test subject wash both hands twice in detergent solution (0.01% v/v Aerosol OT 75). Face and neck exposures were monitored by wiping the face and neck with 100% cotton guaze pads wet with the detergent solution. Inhalation exposures were monitored using a tube with XAD2 resin, polyurethane foam, and glass fiber filter to collect both vapor and particulate matter. The tube was attached to a personal air pump with a flow rate of approximately 1.5 liters/minute.

Quality Assurance/Quality Control

Method Validation. The dermal residues were extracted from each matrix using methylene chloride and evaporated to dryness. Residue in the inhalation tubes were extracted with acetone and evaporated to dryness. All samples were redissolved in a water/methanol

mixture and filtered through a 45 um filter prior to analyzing by HPLC. Samples with high residues were further diluted with the water/methanol solvent so that the concentration fell within the range of the standard curve. Samples were analyzed using HPLC with a Waters 470 Fluorescence detector and a Pickering Carbamate column.

The limit of quantification (LOQ) for each chemical species in each matrix is as follows:

	LOQ (ug)
Dermal	
Arm, chest, back	1.00
Lower body	2.00
Handwash	1.00
Facial swipe	0.100
Inhalation	
OVS tube	0.05

According to the protocol, the quantitative level of detection was 1 ug/cm^2 for the dermal sample matrices and 1 ug/hr for the inhalation media. The method was validated using each matrix at a high and low spike, with at least 7 samples per spike level. Mean recoveries ranged from 72.5% to 113%. The coefficient of variation ranged from 2.6 to 10.4. The lower limit of the 95% confidence interval was over 70% for all matrices with one exception. A summary of the method validation data is presented below in Table 1.

Table 1. Method Validation Recoveries

Media	Fort. Level (ug)	No. of Reps.	% Recovery (± s.d.) Aldicarb	C.V.	% Recovery (± s.d.) Sulfoxide	C.V.	% Recovery (± s.d.) Sulfone	C.V
Inhalation Tubes	0.05	7	72.5 ± 6.2	8.6	79.6 ± 7.4	9.3	78.3 ± 7.7	9.8
	10.0	7	80.1 ± 4.7	5.9	96.3 ± 2.9	3.0	97.4 ± 3.9	4.0
Facial Swipe	0.100	7	91.2 ± 2.3	2.6	108 ± 5.9	5.5	101 ± 7.7	7.7
	50.0	7	84.0 ± 2.6	3.1	97.9 ± 3.2	3.2	99.7 ± 2.7	2.7
Hand Wash	1.00	7	87.5 ± 5.3	6.1	80.3 ± 4.5	5.6	113 ± 5.4	4.8
	300	7	93.8 ± 3.1	3.3	80.7 ± 7.2	8.9	104 ± 4.2	4.1
Dosimeters	1.0/2.0	5	81.2 ± 6.9	8.5	105 ± 10.9	10.4	110 ± 8.3	7.5
	400	2	90.3 ± 8.5	9.5	96.4 ± 9.6	10.0	109 ± 6.2	5.7

Laboratory Recovery. Laboratory control and fortification recoveries were performed for all matrices. All the control samples were less than the LOQ. For the most part, the recoveries were within EPA acceptable range of 70-120%. A summary of the recovery data is presented in Table 2.

Table 2. Mean Laboratory Recoveries

Media	Level (ug)	No. of Reps.	% Recovery (± s.d.) Aldicarb	% Recovery (± s.d.) Sulfoxide	% Recovery (± s.d.) Sulfone
Handwash	1.0 μg/600 mL	8	87.8 ± 10.7	84.7 ± 11.0	93.8 ± 4.62
	300 μg/600 mL	8	94.9 ± 7.14	84.3 ± 12.0	105 ± 11.2
Facial Swabs	0.1	4	91.0 ± 19.4	96.3 ± 4.26	89.8 ± 12.4
	2.0	5	92.1 ± 12.4	88.0 ± 12.6	89.8 ± 12.0
Dosimeter[a]	1.0	7	77.7 ± 13.2	83.6 ± 6.62	88.3 ± 3.43
	20	6	84.3 ± 9.27	90.8 ± 12.2	98.1 ± 13.5
	400	8	86.1 ± 15.9	92.3 ± 12.0	103 ± 5.89
Inhalation OVS Tubes	0.0500	8	80 ± 11.9	75.5 ± 16.7	75.5 ± 8.82
	0.500	8	87 ± 14.4	87.7 ± 9.74	83.3 ± 11.2
	10.0	8	77.5 ± 10.2	86.7 ± 4.85	88.9 ± 5.47

[a] Registrant noted one lab recovery for dosimeters outside of the 70 to 120% range.

Field Recovery. Field controls and field fortifications were analyzed in this study. The field fortified samples were exposed for the same time period as the worker monitoring replicates. Although aldicarb was detected on two of the control samples, the registrant reported that the samples were probably contaminated during handling. Table 3 presents the field recoveries for each matrix. "The average recovery for all matrices fell within the EPA acceptable range of 50% to 120%. The average recovery ranged from 57.8% to 99.1%. When calculating average recovery [for data correction], all recoveries greater than 100% were converted to 100% to provide a conservative estimate of dissipation. The average field fortification recovery for a particular matrix was used to adjust the sample residue found on the same matrix sampled on the same day."

Table 3. Field Fortification Recoveries

Media	Level (ug)	No. of Reps.[a]	% Recovery Aldicarb	% Recovery Sulfoxide	% Recovery Sulfone
Inhalation OVS Tubes	0.2/10				
Mississippi		18	75.8 ± 3.81	NA	NA
Texas		18	77.5 ± 3.5	NA	NA
Georgia		12	79.8 ± 1.0	NA	NA
Handwash	3.0/300				
Mississippi		18	77.4 ± 3.61	75.9 ± 6.8	92.1 ± 4.5
Texas		18	77.4 ± 17.7	79.8 ± 4.5	87.6 ± 18.0
Georgia		12	79.1 ± 7.8	76.1 ± 3.2	89.9 ± 4.0
Facial	0.5/50				
Mississippi		18	80.7 ± 0.80	93.7 ± 4.5	90.3 ± 4.3
Texas		18	77.9 ± 1.7	91.3 ± 5.7	91.2 ± 3.2
Georgia		12	90.6 ± 0.35	96.2 ± 4.2	96.3 ± 3.6
Dosimeters	3.0/400				
Mississippi		18	80.9 ± 3.6	81.0 ± 1.2	89.3 ± 3.9
Texas		18	85.4 ± 9.3	80.2 ± 3.4	91.1 ± 2.7
Georgia		12	80.0 ± 1.2	80.7 ± 8.9	92.5 ± 0.8

NA = Not applicable.

[a] Recoveries averaged over 3 days of sampling for Mississippi and Texas sites; and over 2 days for Georgia (calculated by Versar from data presented in the study report). Half the number of replicates were done at each fortification level.

Storage Stability. Storage stability was also analyzed during this study. Two samples at each fortification level were analyzed for each selected day. The data were corrected for the average spike recovery for each analyte on each day. If the average spike recovery was >100%, the sample recoveries were not corrected. These instances were noted in the study. The stability data are presented in Table 4.

Results

The amount of aldicarb, aldicarb sulfoxide, and aldicarb sulfone found for each replicate are presented in Tables 5, 6, and 7. The data are presented for both dermal and inhalation exposures.

Table 4. Storage Stability

Media	Level (ug)	Day	No. of Reps.	Percent Recovery		
				Aldicarb	Sulfoxide	Sulfone
OVS Tubes	0.5	0	2	93.65	99.9	93.5
		1	2	97.6	96.85	92.9
		7	2	114	116	116.5
		15	2	103.5	104	102
		31	2	100	99.45	98.85
Facial Swipes	1	0	2	94.3	86.85	91
		2	2	105.55	120	88.05
		7	2	104.05	105	108
		21	2	130.5	131.5	122.5
		37	2	94.3	94.05	91.3
		67	2	91.2	97.05	96.5
Handwash	10	0	2	90.15	91.4	100.4
		1	2	109.5	105.5	110
		7	2	87	93.5	104
		14	2	83.65	95.15	98.4
		30	2	64.35	72.45	99.95
		44	2	100.15	98.8	99.95
		61	2	43.7	94.4	115
Dosimeter	10	0	2	123	98.4	104.5
		1	2	91.3	94.55	96.6
		7	2	89.85	75.3	79.3
		14	2	96.95	99.45	104.85
		30	2	122	102.45	97.7
		60	2	83.85	80.8	86.5
		95	2	95.7	97.2	114

Calculated by Versar from data presented in the study report.

Table 5. Total Dermal Exposure from Temik to Loaders

Reps.	µg/Rep			µg/kg ai		
	Aldicarb[a]	Sulfone[b]	Sulfoxide[c]	Aldicarb[a]	Sulfone[b]	Sulfoxide[c]
1	21.0	0.650	5.96	0.208	0.00644	0.0590
2	76.8	14.2	20.5	0.835	0.154	0.223
3	64.7	2.21	10.5	1.05	0.0360	0.171
4	25.0	0.610	7.44	0.272	0.00663	0.0809
5	26.6	3.11	9.48	0.289	0.0383	0.103
6	12.4	10.0	15.9	0.168	0.0316	0.216
7	7.70	2.58	2.25	0.0930	0.0312	0.0272
8	7.89	6.02	10.3	0.117	0.8923	0.153
9	3.45	1.01	7.53	0.0489	0.0143	0.107
10	8.27	3.30	15.5	0.112	0.0448	0.211
11	17.8	2.65	9.10	0.207	0.0308	0.106
12	26.7	2.65	5.32	0.311	0.0308	0.0619
13	44.9	3.27	16.5	0.488	0.0355	0.179
14	31.1	2.96	2.02	0.338	0.0322	0.0220
15	21.1	2.99	1.45	0.229	0.0325	0.0158
Geometric Mean	19.4	2.76	7.31	0.234	0.0333	0.0883
				Geometric Mean (µg/lb ai) 0.106	Geometric Mean (µg/lb ai) 0.015	Geometric Mean (µg/lb ai) 0.040

Recoveries less than the LOQ and greater than LOD are reported as 50% of the LOQ; 10% LOQ was used when no peak was detected.

[a] 38 of 90 samples were <LOQ, 11 of 90 samples were <LOD.
[b] 79 of 90 samples were <LOQ, 47 of 90 samples were <LOD.
[c] 56 of 90 samples were <LOQ, 20 of 90 samples were <LOD.

Table 6. Total Dermal Exposure from Temik to Applicators

Reps.	µg/Rep			µg/kg ai		
	Aldicarb[a]	Sulfone[b]	Sulfoxide[c]	Aldicarb[a]	Sulfone[b]	Sulfoxide[c]
1	14.5	4.69	5.97	0.147	0.0476	0.0606
2	3.15	5.21	4.89	0.0578	0.0956	0.0897
3	13.3	2.61	2.98	0.136	0.0267	0.0305
4	2.21	0.610	4.26	0.0238	0.00658	0.0460
5	11.6	0.610	6.55	0.119	0.00626	0.0672
6	11.5	2.61	9.01	0.164	0.0372	0.128
7	1.45	1.05	4.78	0.0220	0.0160	0.0726
8	4.17	1.05	7.95	0.0594	0.0150	0.113
9	9.00	9.91	11.0	0.115	0.126	0.140
10	5.06	2.21	7.30	0.734	0.0321	0.160
11	5.94	3.41	4.98	0.0665	0.0382	0.0558
12	3.30	1.01	8.01	0.0375	0.0115	0.0910
13	5.82	1.81	4.07	0.0686	0.0213	0.0479
14	2.42	5.66	2.25	0.0279	0.0654	0.0260
15	1.05	7.05	1.05	0.0109	0.0734	0.0109
Geometric Mean	4.75	2.35	4.94	0.0584	0.0289	0.0607
				Geometric Mean (µg/lb ai) 0.027	Geometric Mean (µg/lb ai) 0.013	Geometric Mean (µg/lb ai) 0.028

Recoveries less than the LOQ and greater than LOD are reported as 50% of the LOQ; 10% LOQ was used when no peak was detected.

[a] 56 of 90 samples were <LOQ, 15 of 90 samples were <LOD.
[b] 83 of 90 samples were <LOQ, 55 of 90 samples were <LOD.
[c] 79 of 90 samples were <LOQ, 27 of 90 samples were <LOD.

Table 7. Inhalation Exposure to Aldicarb[a] to Loaders and Applicators

Reps.	µg/Rep		µg/kg ai	
	Loaders[b]	Applicators[c]	Loaders[b]	Applicators[c]
1	0.252	0.232	0.0482	0.0455
2	0.224	0.0100	0.0471	0.00355
3	2.00	0.228	0.630	0.0451
4	0.381	0.0100	0.0801	0.00209
5	1.25	0.177	0.263	0.0351
6	0.344	0.216	0.0904	0.00595
7	0.234	0.0100	0.0546	0.00315
8	0.0301	0.0100	0.0092	0.00275
9	0.167	0.0100	0.0419	0.0264
10	0.0367	0.0100	0.0103	0.00281
11	0.0780	0.559	0.0176	0.0121
12	0.166	0.0788	0.0374	0.0185
13	0.393	0.0458	0.0826	0.0112
14	0.159	0.00200	0.0334	0.000419
15	0.0100	0.198	0.00210	0.0427
Geometric Mean	0.179	0.048	0.0421	0.00994
			Geometric Mean (µg/lb ai) 0.019	Geometric Mean (µg/lb ai) 0.005

[a] Aldicarb + Aldicarb Sulfoxide + Aldicarb Sulfone
[b] 14 of 30 samples were <LOQ.
[c] 22 of 30 samples were <LOQ.

Note: Results showed no breakthrough. All levels for OVS tubes were <LOQ.

Compliance with sections 230-236 of Subdivision U of the Pesticide Assessment Guidelines (U.S. EPA, 1986) is discussed below. The list describes on an item-by-item basis, compliance with major points of Subdivision U. All review/analysis of this study with regard to the specific Temik 15G (aldicarb pesticide) label requirements are based on the EPA Reg No. 264-330.

- *Typical end use product of active ingredient tested.* This criterion was met. The highest label use rate is for Temik 15G is for pecans at 40 pounds of formulated product per acre (6.0 lbs active ingredient/acre). The label (pending) recommends the product for the control of aphids, mites, and nematodes on pecan trees. Recommended application is soil injection.

- *End use product handled and applied using recommended equipment, application rates, and typical work practices.* This criterion was met. Exposures as result of loading and application were monitored for this study. The study used the label recommended equipment and typical work practices during loading (product was granular, mixing not required) and application. The application rate for this study was 6.0 lb ai/A. The study was performed in late spring between bud break as recommended by the label.

- *For outdoor exposure monitoring at least five replicates at each of at least three sites for each job function with the exception of pilots. Pilots should have at least three replicates at each of at least three sites.* This criterion was met. Fifteen replicates were conducted for this study, 5 at each of three sites. The three sites were in different states: Smith's Pecans, Raymond Mississippi; Mockingbird Hills Farm, Albany, Georgia; and Pecan Bayou Farm, Brownwood, Texas.

- *Monitoring period is sufficient to collect measurable residues but not excessive so that residue loss occurs.* This criterion was met. The exposure period for loaders ranged from 19 to 57 minutes for a total of two loading events and approximately 4 hours for applicators. The applicators drove the tractor and remotely lifted the seeder when turning rows. Incidental exposures were noted in the study appendix.

- *Dermal and/or inhalation exposure monitored by validated methodologies. Biological monitoring is consistent with and supported by pharmacokinetic data accepted by the Agency.* This criterion was met. Dermal exposure was measured using full body dosimetry and facial swipes; hand exposure was monitored using handwash, and inhalation exposure was monitored using personal air-sampling pumps attached to OSHA Versatile Sampler (OVS) tubes. No biological monitoring data were conducted.

- *Quantity of active ingredient handled and duration of monitoring period reported for each replicate.* This criterion was met. The quantity of active ingredient

handled (900 lbs) 61.4 kg ai to (1485 lbs) 101 kg ai per replicate and the loading and application duration of each monitoring period (19 to 57 minutes and approximately 4 hours) was reported in the study.

- *Clothing worn by each study participant and location of dosimeters reported.* This criterion was met. A description of the participants' clothing and the location of dosimeters were reported. [Note: the label specifies chemical resistant footwear plus socks and chemical resistant headgear for overhead exposure. It was not clear in the study if the rubber boots and hard hats worn by the test subjects were chemical resistant. It was noted that the work clothing met the specifications of U.S. EPA Worker Protection Standards. The label also specifies a dust/mist filtering respirator (MSHA/NIOSH D/M approval number prefix TC-21C). Verification of use of this specific respirator was not found in the study.]

- *Quantitative level of detection (LOD) is at least 1 ug/cm^2.* This criterion was met. The LOQ was 1 μg per body part and 0.05 μg for inhalation.

- *Storage of samples consistent with storage stability data.* This criterion was met as the fortified matrices samples were stored for up to 2-3 months.

- *Efficiency of extraction in laboratory provided as mean plus or minus one standard deviation. Lower 95 percent confidence limit is not less than 70 percent based on a minimum of seven replications per fortification level or prior Agency approval of extraction methodology provided.* This criterion was met, as the method validation results are acceptable.

- *At least one field fortification sample per worker per monitoring period per fortification level for each matrix. At least one filed blank per worker per monitoring period for each matrix.* This criterion was met. A total of 48 field recovery samples per matrix (2 fortification levels) were performed (12 to 18 replications per fortification level per matrix per site).

- *When collecting urine for biological monitoring, collection should involve 24 hour urine samples. A minimum of one baseline, pre-exposure 24 hour sample must be collected for the day of application and for sufficient days post application as determined by the excretion profile of the pesticide.* This criterion does not apply to this study.

Conclusion

This study has been submitted to satisfy the requirements specified by the U.S. EPA under Subdivision U of the Pesticide Assessment Guidelines. No significant issues have been noted.

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