



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

MAY 1 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Thiodicarb (114501) Magnitude of the Residue and Processing Studies in Cottonseed and Soybeans. GDLN 171-4(k) and GDLN 171-4(l).
DP Barcodes: D170048, D201191; CBRS Nos. 8761 & 13472; MRID Nos.: 410191-01, 420437-01, 420437-02, 423309-01, and 423309-02; Rereg. Case No. 2675.

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Attached is a review of magnitude of the residue crop field trial and processing study data for thiodicarb in cottonseed and soybean commodities submitted by Rhone-Poulenc Ag Company. This information was reviewed by Dynamac Corporation under the supervision of CBRS/HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies. This review pertains only to crop field trial and processing studies. Additional data pertaining to analytical methods (DP Barcode D209955) and magnitude of the residue in ruminants (DP Barcode D210755) are awaiting review by CBRS. Storage stability data are being reviewed concurrently (D. Miller, 5/01/95, CBRS Nos. 13470 and 14699). Per CRMS, storage stability data for corn are due 6/30/95 and a corn magnitude of the residue study is due 1/2/96.

CBRS tentatively concludes that GDLNs 171-4(k) and (l) for soybeans are satisfied provided that the label prohibition against feeding soybean forage and hay remains in effect. The



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registrant must amend label directions for soybeans to specify a minimum retreatment interval and a maximum seasonal application rate consistent with the submitted data.

CBRS also concludes that GDLNs 171-4(k) and (l) for cotton are partially fulfilled. Data are required depicting the combined residues of thiodicarb and methomyl in/on cotton gin byproducts ginned from cotton harvested 28 days after the last of six foliar applications of thiodicarb to cotton (each at 0.9 lb ai/A). The registrant must amend its label directions for cotton to specify maximum seasonal use rates and minimum retreatment intervals, consistent with the submitted residue data.

The submitted soybean processing study is adequate. Thiodicarb residues did not concentrate in meal, oil, or soapstock, but concentrated by 3.6x in hulls and 29x in aspirated grain fractions. Based on the 3.6x concentration of residues in hulls and the established 0.2 ppm tolerance on soybeans, thiodicarb residues are unlikely to exceed the established 0.8 ppm feed additive tolerance for thiodicarb residues in soybean hulls. The registrant must propose a tolerance for thiodicarb residues in aspirated grain fractions. Based on the observed concentration factor and the established tolerance on soybeans, a 6 ppm tolerance would be appropriate for the combined residues of thiodicarb and its metabolite methomyl in aspirated grain fractions.

The submitted cottonseed processing study is adequate. CBRS concludes that thiodicarb residues in cottonseed hulls are unlikely to exceed the established 0.8 ppm feed additive tolerance in hulls. Furthermore, since the concentration factor in hulls was not significant (i.e., < 1.5), CBRS concludes that the feed additive tolerance for hulls can be deleted and residues in hulls will be covered by the rac tolerance (presently 0.4 ppm, but able to be reduced to 0.2 ppm).

If you need additional information, please advise.

Concentration Case

cc: RF, SF, List B File, Circ., Dynamac, DJM.

RDI: SHummel:4/26/95;MMetger: 4/27/95;FSuhre:4/28/95.

CSC(=N)OC(=O)N(C)SC(=O)ON=C(S)C

(CBRS No. 13472; DP Barcode D201191)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

The Thiodicarb Phase IV Review (C. Olinger, 12/10/90) required data depicting residues of thiodicarb and its metabolite methomyl in/on cotton and soybean RACs, along with data depicting the concentration of residues in cottonseed and soybean processed commodities. In response, Rhone-Poulenc Ag Company submitted cotton and soybean field trial data (1989; MRID 41019101 and 1992; MRIDs 42330901 and 42330902) and cottonseed and soybean processing studies (1991; MRID 42043701 and 42043702). These data are reviewed here to determine their adequacy in fulfilling outstanding residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to the magnitude of the residue in/on cotton and soybean RACs and processed commodities.

The qualitative nature of the residue in plants is adequately understood; the residues of concern in plants are the parent compound and its metabolite methomyl. The qualitative nature of the residues in animals is not adequately understood. Additional residue characterization and identification are required from an existing goat metabolism study.

Tolerances for residues of thiodicarb (dimethyl *N,N'*-[thiobis[[[(methylimino) carbonyl]oxy]] bis[ethanimidothioate]]) in/on soybean and cottonseed commodities are expressed in terms of the combined residues of thiodicarb and its metabolite methomyl (*S*-methyl *N*-[(methylcarbamoyl)oxy]-thioacetimadate) [40 CFR § 180.407(a) and § 186.5650]. A GLC method using sulfur specific flame photometric detection (FPD-S) is available for determining the combined residues of thiodicarb and methomyl in/on plant commodities and is listed as Method I in PAM, Vol. II (Sec. 180.407). This method has been successfully validated by the Agency using soybean meal.

Codex MRLs (Step 6) for thiodicarb are currently expressed in terms of the combined residues of thiodicarb, methomyl, and methomyl oxime and are 0.5 ppm and 0.2 ppm for cottonseeds and soybeans, respectively. Issues regarding the compatibility of the U.S. tolerances and Codex MRLs will be addressed when the reregistration eligibility decision for thiodicarb is made.

CONCLUSIONS

- 1a. The submitted soybean data are adequate provided the current label prohibition against feeding soybean forage and hay remains. The available soybean data indicate that the combined residues of thiodicarb and its metabolite methomyl are unlikely to exceed the established 0.2 ppm tolerance in/on soybean seeds harvested 28 days after the last of four foliar applications of thiodicarb each at 0.75 lb ai/A.
- 1b. The registrant must amend the label directions for soybeans to specify minimum retreatment intervals and a maximum seasonal application rate consistent with the submitted data. The available data support retreatment intervals of 6 to 10 days and a maximum seasonal use rate of 3 lb ai/A/season.
- 2a. The submitted cottonseed data are adequate. The available data indicate that the combined residues of thiodicarb and its metabolite methomyl are unlikely to exceed the established 0.4 ppm tolerance in/on cottonseeds harvested 28 days after the last of six foliar applications of thiodicarb each at 0.9 lb ai/A or 28 days after the second of two foliar applications each at 0.9 lb ai/A in AZ or CA. The available data support a tolerance of as low as 0.2 ppm.
- 2b. The registrant must amend its label directions for cotton to specify maximum seasonal use rates and minimum retreatment intervals consistent with the submitted data. The available data support retreatment intervals of 7 to 10 days and a maximum seasonal use rate of 5.4 lb ai/A/season for all cotton growing regions, except AZ and CA. For AZ and CA, data indicate that a 14-day minimum retreatment is appropriate along with a maximum use rate of 1.8 lb ai/A/season.
- 2c. Data are required depicting the combined residues of thiodicarb and methomyl in/on cotton gin byproducts (formerly called gin trash) ginned from cotton harvested 28 days after the last of six foliar applications of thiodicarb to cotton each at 0.9 lb ai/A. The cotton must be harvested by commercial equipment (or a simulation thereof) to provide an adequate representation of plant residue from the ginning process. If samples are stored for more than one month prior to analysis, then storage stability data may also be required. As the registrant has already fulfilled the requirement for residue data on cottonseed, the Agency will consider allowing a reduced number of field trials representing the principal U.S. cotton growing regions. The registrant should submit a study protocol to the Agency for review.

3. The submitted soybean processing study is adequate. Thiodicarb residues did not concentrate in meal, oil, or soapstock, but concentrated by 3.6x in hulls and 29x in aspirated grain fractions. Based on the 3.6x concentration of residues in hulls and the established 0.2 ppm tolerance on soybeans, thiodicarb residues are unlikely to exceed the established 0.8 ppm feed additive tolerance for thiodicarb residues in soybean hulls. The registrant must propose a tolerance for thiodicarb residues in soybean aspirated grain fractions. Based on the observed 29x concentration factor and the 0.2 ppm tolerance on soybeans, a 6 ppm tolerance would be appropriate for the combined residues of thiodicarb and its metabolite methomyl in aspirated grain fractions.
4. The submitted cottonseed processing study is adequate. Thiodicarb residues did not concentrate in cottonseed meal, oil, or soapstock, but apparent concentration was 1.1x in cottonseed hulls. CBRs concludes that thiodicarb residues in cottonseed hulls are unlikely to exceed the established 0.8 ppm feed additive tolerance in hulls. Furthermore, since the apparent concentration factor in hulls was not significant (i.e., < 1.5), CBRs concludes that the feed additive tolerance for hulls is not needed. The feed additive tolerance can be deleted and residues in hulls will be covered by the rac tolerance (presently 0.4 ppm, but able to be reduced to 0.2 ppm--see Conclusion #2a).
5. Storage stability data to support these studies have been reviewed (D. Miller, 5/01/95, CBRs No. 13470). The cottonseed and soybean samples from the current residue studies and samples from the cottonseed and soybean processing studies were stored for short enough intervals that the residue data need not be corrected for residue declines observed in the storage stability studies (but see Conclusion #2c).

RECOMMENDATIONS

The registrant should be informed that GDLNs 171-4(k) and (l) for soybeans are satisfied provided that the label prohibition against feeding soybean forage and hay remains in effect. The registrant must amend label directions for soybeans to specify a minimum retreatment interval and the maximum seasonal application rate consistent with the residue data submitted.

The registrant should also be informed that GDLNs 171-4(k) and (l) for cotton are partially fulfilled. Data are required depicting the combined residues of thiodicarb and methomyl in/on cotton gin byproducts ginned from cotton harvested 28 days after the last of six foliar applications of thiodicarb to cotton each at 0.9 lb ai/A. The registrant must amend its label directions for cotton to specify maximum seasonal use rates and minimum retreatment intervals consistent with the data submitted. As the registrant has already fulfilled the requirement for residue data on cottonseeds, the Agency will consider allowing a reduced number of field trials representing the principal U.S. cotton growing regions. The registrant should submit a study protocol to the Agency for review.

The submitted soybean processing study is adequate. The registrant must propose a tolerance for thiodicarb residues in aspirated grain fractions. Based on the observed concentration factor and the established tolerance on soybeans, a 6 ppm tolerance would be appropriate for the combined residues of thiodicarb and its metabolite methomyl in aspirated grain fractions.

The submitted cottonseed processing study is adequate. CBRS concludes that the feed additive tolerance for hulls can be deleted and residues in hulls will be covered by the rac tolerance (presently 0.4 ppm, but able to be reduced to 0.2 ppm).

DETAILED CONSIDERATIONS

Residue Analytical Methods

In conjunction with the soybean field trial (1992; MRID 42330902), Rhone-Poulenc submitted a method description (Rhone-Poulenc SOP 90305) for the analysis of the combined residues of thiodicarb and its metabolite methomyl in/on soybean seeds, forage, hay and straw. This method is basically an updated version of Method I in PAM Vol. II. This method has been reviewed and deemed adequate by the Agency (D. Miller, 2/24/94, CBRS No. 12305).

In brief, samples are ground with dry ice and residues are extracted in acetone:water (9:1, v/v) and filtered. The acetone is removed by evaporation and the solution is coagulated for 45 min by the addition of NH_4Cl in 0.04 mM H_3PO_4 . Residues are then filtered, partitioned into methylene chloride (CH_2Cl_2), dried over sodium sulfate, and concentrated. Residues of thiodicarb and methomyl are hydrolyzed to methomyl oxime using 10% aqueous NaOH (60 C for 45 min) and the resulting hydrolysate is neutralized with HCl and saturated with NaCl. Residues are partitioned back into CH_2Cl_2 , dried over sodium sulfate, evaporated to dryness, and redissolved in acetone. Residues of methomyl oxime are quantified by GC/FPD-S and are expressed in thiodicarb equivalents. The reported method limit of quantitation is 0.04 ppm in/on soybean RACs.

For method validation, control samples were fortified with thiodicarb at the following levels: forage, 20-60 ppm; hay, 12-40 ppm; and seeds 0.04-0.12 ppm. Method validation data are presented in Table 1. Fortified control samples of forage, hay, straw and seeds were also analyzed concurrently with treated samples. The concurrent method recoveries were 67.1-119.7% and are detailed in Table 2. Of the 18-19 control samples analyzed for each commodity, apparent thiodicarb residues were nondetectable (<0.04 ppm) in/on 19 seed samples, 11 forage samples, 6 hay samples, and 16 straw samples. Apparent thiodicarb residues were 0.05-1.06 ppm in seven forage samples, 0.05-1.09 ppm in 12 hay samples, and 0.06-0.09 ppm in three straw samples.

Chromatograms and sample calculations were provided. The analyses were conducted by Rhone-Poulenc (Research Triangle Park, NC). The submitted method is adequate for collecting data on thiodicarb residues in/on soybean forage, hay, seed, and straw.

The above method was also utilized in a cotton field study (1989; MRID 41019101) for determining thiodicarb residues in/on cottonseed. The registrant did not present any method validation data, but concurrent method recoveries were 76-110% and are detailed in Table 2. Apparent thiodicarb residues were nondetectable (<0.04 ppm) in/on the seven control cottonseed samples analyzed in this study. Chromatograms and sample calculations were provided. The analyses were conducted by Rhone-Poulenc (Research Triangle Park, NC). The submitted method is adequate for collecting data on thiodicarb residues in/on cottonseed.

In conjunction with the other cotton field study (1992; MRID 42330901) and the soybean and cottonseed processing studies (1991; MRIDs 42043701 and 42043702), Rhone-Poulenc submitted a method description (Rhone-Poulenc SOP 90321) for the analysis of residues of thiodicarb and its metabolite methomyl in/on cotton RACs and in cottonseed and soybean processed commodities. This method was also reviewed by the Agency (D. Miller, 2/24/94, CBRS No. 12305) and deemed adequate. It is essentially the same as the method described above except for changes in the extraction solvent and the inclusion of a clean-up step using gel permeation chromatography (GPC).

Residues in cotton forage, cottonseed, soybean, and cottonseed and soybean hulls and meal are extracted in acetone:methanol (9:1, v/v), filtered, concentrated, and redissolved in acetonitrile (ACN). Residues in cottonseed and soybean oils and soapstock are extracted directly into ACN. Residues in the ACN fractions are then washed with hexane, concentrated, redissolved in CH_2Cl_2 :cyclohexane (1:1, v/v), and cleaned-up by GPC. *[Note: the GPC clean-up step was not used for forage and cottonseed samples from the cotton field study, MRID 42330901]* Residues are then concentrated and hydrolyzed to methomyl oxime using 2.5 N NaOH (60 C for 45 min). The resulting hydrolysate is neutralized with HCl and saturated with NaCl. Residues are then partitioned into CH_2Cl_2 , dried over sodium sulfate, evaporated to dryness, and redissolved in acetone. Residues of methomyl oxime are quantified by GC/FPD-S and are expressed in thiodicarb equivalents. The reported method limit of quantitation is 0.04 ppm in/on cottonseed and soybean RACs and processed commodities.

In the cotton field study, the registrant presented method validation data (Table 1) for cottonseed and fortified control samples of cottonseed were analyzed concurrently with treated samples (Table 2). Apparent thiodicarb residues were nondetectable (<0.04 ppm) in/on all control cottonseed samples. Chromatograms and sample calculations were provided. The analyses were conducted by Rhone-Poulenc (RTP, NC). The submitted method is adequate for collecting data on thiodicarb residues in/on cottonseed.

In the soybean and cottonseed processing studies, the registrant presented method validation data (Table 1) for soybeans, cottonseeds, and their processed commodities each fortified with thiodicarb at 0.04-1.0 ppm. Control samples of each commodity were also fortified with thiodicarb at 0.2 ppm and analyzed concurrently with the treated samples (Table 2). Apparent thiodicarb residues were nondetectable (<0.04 ppm) in/on all control samples of soybeans, cottonseeds, and their processed commodities. Chromatograms and sample calculations were provided. The analyses were conducted by CYAL (Morrisville, NC). The submitted method is adequate for collecting data on thiodicarb residues in/on soybean and cottonseed processed commodities.

Table 1. Recovery of thiodicarb residues from control samples of cotton and soybean commodities fortified with thiodicarb.

Crop/	Commodity	MRID	Fortification Levels (ppm)	Number of Samples	Recovery (%)
Soybean	Forage	42330902	20	1	67.8
			40	1	73.9
			60	1	79.3
	Hay		12	1	97.1
			20	2	82.5, 95.3
			28	1	79.1
			40	1	62.6
	Seeds		0.04	3	77.3-97.1
			0.08	3	79.8-89.9
			0.12	3	79.6-86.3
Soybean	Whole seeds	42043701	0.04	2	90.0, 100.0
			0.20	2	84.5, 84.0
			1.00	2	117.3, 109.2
	Hulls		0.04	2	75.0, 80.0
			0.20	2	88.5, 102.5
			1.00	2	85.9, 98.7
	Meal		0.04	2	77.5, 97.5
			0.20	2	110.0, 103.0
			1.00	2	107.2, 100.6
	Crude oil		0.04	2	82.5, 97.5
			0.20	2	88.0, 85.5
			1.00	2	92.8, 104.0
	Refined oil		0.04	2	65.0, 77.5
			0.20	2	81.0, 89.5
			1.00	2	87.5, 77.0
Soapstock	0.04	2	67.5, 85.0		
	0.20	2	77.0, 95.0		
	1.00	2	84.8, 109.5		
Cottonseeds	42330901	0.02	2	71.4, 83.1	
		0.04	2	77.2, 71.1	
		1.00	2	77.4, 78.1	
Cottonseed	Whole seeds	42043702	0.04	2	87.5, 77.5
			0.20	2	121.5, 121.0
			1.00	2	97.4, 92.0
	Meal		0.04	2	125.0, 95.0
			0.20	2	101.0, 100.0
			1.00	2	107.3, 103.3
	Hulls		0.04	2	62.5, 60.0
			0.20	2	84.5, 102.0
			1.00	2	110.2, 101.7
Cottonseed	Crude oil		0.04	2	95.0, 122.5
			0.20	2	77.5, 89.0
			1.00	2	91.5, 98.1
	Refined oil		0.04	2	77.5, 80.0
			0.20	2	78.5, 76.0
			1.00	2	90.0, 100.2
	Soapstock		0.04	2	80.0, 95.0
			0.20	2	76.5, 94.0
			1.00	2	103.3, 93.8

Table 2. Recovery of thiodicarb residues from control samples of cotton and soybean commodities fortified with thiodicarb and analyzed concurrently with treated samples.

Crop/ Commodity	MRID	Fortification Levels (ppm)	Number of Samples *	Recovery (%)
Soybean	42330902			
Forage		4-40	12 (2)	67.1-86.6
Hay		20-60	10	77.8-119.7
Seed		0.04-0.2	11	70.5-96.1
Straw		2.8-12	11	71.0-95.0
Cotton	42330901			
Cottonseeds		0.2-1.20	11	70.8-91.4
Forage		6.9-20.8	10 (1)	65.6-80.9
Cottonseeds	41019101	0.04, 0.08	7	76-110
Soybean	42043701			
Whole seeds		0.2	1	94.0
Meal		0.2	1	119.0
Crude oil		0.2	1	88.5
Refined oil		0.2	1	96.5
Hulls		0.2	1	78.5
Soapstock		0.33	1	113.0
Grain dust		0.2	1	96.0
Cotton	42043702			
Whole seeds		0.2	1	91.0
Hulls		0.2	1	115.0
Meal		0.2	1	101.0
Crude oil		0.2	1	91.0
Refined oil		0.2	1	91.5
Soapstock		0.2	1	109.5

* Number of samples with recoveries outside of the acceptable range (70-120%) are listed parenthetically.

Storage Stability Data

The registrant stated that storage stability data (MRID 42291601) for thiodicarb residues in soybeans and soybean processed commodities (except forage and hay) have been submitted. These data have been reviewed (D. Miller, 5/01/95, CBRS No. 13470) and indicate that thiodicarb residues are stable at -15 C for at least 12 months in soybean commodities (seed, hulls, meal, crude/refined oil, and soapstock).

Samples from the soybean field trial (1992; MRID 42330902) were stored frozen (-19 to -13 C) prior to analysis for the following intervals: forage, 105-155 days; hay, 138-253 days; straw, 153-213 days; and seeds, 58-134 days. In the soybean processing study (1991; MRID 42043701), samples of whole seeds were stored frozen (0 to -20 C) 181 days and samples of aspirated grain fractions and the processed commodities were stored frozen (< 10 C) for 31-42 days prior to extraction for analysis.

The available storage stability data (D. Miller, 5/01/95, CBRS No. 13470) adequately support the submitted soybean residue data and soybean processing study. Storage stability

data were not submitted for residues in soybean forage, hay, or straw; these data are not required as long as the registrant retains the present label prohibition against feeding soybean forage and hay to livestock.

The registrant also indicated that storage stability data (MRID 42291603) for thiodicarb residues in cottonseeds and cottonseed processed commodities have been submitted. These data have been reviewed (D. Miller, 5/01/95, CBRS No. 13470) and indicate that thiodicarb residues are stable at -15 C for at least 12 months in cottonseeds and cottonseed hulls, oil, and soapstock and for at least to 3 months in cottonseed meal (the registrant did not submit any storage stability data for cotton gin trash).

Treated cottonseed samples from the earlier cotton field study (1989; MRID 41019101) were stored at -30 C for 58-132 days prior to analysis. Cottonseed samples from the later cotton field study (1992; MRID 42330901) were stored frozen at an unspecified temperature for 44-153 days prior to analysis, and cotton forage was stored frozen for 87-251 days. In the cottonseed processing study (MRID 42043702), samples of whole seeds were stored frozen for 104 days and processed commodities were stored frozen for 71-77 days prior to extraction for analysis.

The available storage stability data adequately support the submitted cottonseed residue data and the cottonseed processing study. Storage stability data for thiodicarb residues in cotton gin byproducts were not submitted. The registrant stated that cotton forage samples from the current study are being reanalyzed to provide storage stability data for forage. These data may be adequate to establish the stability of residues in cotton gin byproducts, and should be submitted to the Agency when available.

Magnitude of the Residue in Plants

Soybeans. A tolerance of 0.2 ppm has been established for the combined residues of thiodicarb and its metabolite methomyl in/on soybeans [40 CFR § 180.407 (a)].

A REF's search conducted on 5/26/94 identified three thiodicarb end-use products registered to Rhone-Poulenc for use on soybeans: a 3.2 lb/gal FIC (EPA Reg. No. 264-379) and two 80% DF formulations (EPA Reg. Nos. 264-378 and 264-530). These three end-use products are registered for foliar broadcast applications to soybeans at 0.25-0.75 lb ai/A. Applications can be made using either aerial or ground equipment in a minimum of 2 and 5 gal/A, respectively. Low volume aerial applications at 0.25-0.4 lb ai/A in a minimum of 1 gal/A are also permitted in the following states: AL, AR, DE, GA, LA, MD, MO, MS, NC, SC, and VA. The labels specify a 28-day PHI and prohibit the feeding of forage, hay, or straw to livestock. Minimum retreatment intervals and maximum seasonal use rates are not specified. The registrant must amend the use directions for soybeans to specify minimum retreatment intervals and the maximum seasonal application rate.

The Thiodicarb Phase IV Review required data depicting residues of thiodicarb in/on soybeans harvested at the established PHI following the maximum number of foliar applications applied at the maximum label rate and the minimum retreatment interval. In response, Rhone-Poulenc submitted data (1992; MRID 42330902) from 20 tests conducted in AR(2), IA(2), IL(2), IN(2), LA(2), MN(2), MO(2), MS(2), NC(1), PA(1) and VA(2) depicting thiodicarb residues in/on soybean forage, hay, straw, and seeds. Four broadcast foliar applications of thiodicarb (3.2 lb/gal FIC) each at 0.74-0.9 lb ai/A were applied to soybeans at 6- to 10-day intervals using ground equipment at 5-21 gal/A. Total application rates were 3.0 lb ai/A/season, except for one test in PA with a rate of 3.4 lb ai/A/season.

Three treated forage and hay samples were collected from each test on the day of the last application, except for tests in MN and VA in which forage was collected 7 and 3 days, respectively, after the last application. Hay samples were field-dried for 1-7 days prior to sampling. Three samples each of seeds and straw were collected from each test 27-31 days after the last application. Prior to analysis, samples were stored frozen for up to 155 days for forage, 253 days for hay, 213 days for straw, and 134 days for seed.

The combined residues of thiodicarb and methomyl were determined by Rhone-Poulenc using the GC/FPD-S method described above. Residues are presented in Table 3 and are not corrected for concurrent method recoveries. The combined residues of thiodicarb and its metabolite methomyl were 8.6-51.2 ppm in/on 51 forage samples harvested on the day of the last application and 4.73-162.7 ppm in/on 57 hay samples harvested 0 to 11 days after the last application. By approximately 28 days after the last application, thiodicarb residues were <0.04-0.15 ppm and <0.04-3.43 ppm in/on 57 samples each of seeds and straw, respectively.

Geographic representation is adequate. The tests states of AR (4.7%), IA (16.9%), IL (18.5%), IN (8.9%), LA (2.3%), MN (9.3%), MO (6.5%), MS (2.1%), NC (1.7%), PA (0.6%) and VA (0.9%) accounted for over 70% of the 1990 U.S. production of soybeans [Source: *Agricultural Statistics, 1991, p. 121*]

The submitted soybean data are adequate provided the label prohibition against feeding of forage and hay is retained; if the registrant wishes to remove from the label this prohibition, then acceptable storage stability data for residues in soybean forage and hay must be submitted. The available data indicate that the combined residues of thiodicarb and its metabolite methomyl are unlikely to exceed the established 0.2 ppm tolerance in/on soybean seeds harvested 28 days after the last of four foliar applications of thiodicarb each at 0.75 lb ai/A. Provided that label prohibitions against the feeding of forage and hay to livestock is retained, tolerances for thiodicarb residues in/on soybean forage and hay will not be necessary.

Cotton. A tolerance of 0.4 ppm has been established for the combined residues of thiodicarb and its metabolite methomyl in/on cottonseed [40 CFR §180.407 (a)].

Table 3. Combined residues of thiodicarb and its metabolite methomyl in/on soybean forage, hay, straw and grain following four foliar applications of thiodicarb (3.2 lb/gal FIC) at $\approx 1\times$ the maximum label rate (MRID 42330902).

Commodity	State	Application information				PHI (days)	Residues (ppm) ^a
		Single Rate (lb ai/A)	Total Rate (lb ai/A/year)	Volume (GPA)	Interval (days)		
Soybean forage	AR	0.75	3.0	5-6	7	0	19.1-24.0
		0.75	3.0	15	6-7	0	20.9-25.8
	IA	0.75	3.0	20	7-8	0	17.2-22.5
		0.75	3.0	20	7-8	0	11.9-25.6
	IL	0.75	3.0	20	6-7	0	37.6-51.2
		0.73-0.90	NR ^b	5	7-10	0	23.0-24.3
	IN	0.75	3.0	20-21	7	0	15.8-21.8
		0.75	3.0	20-21	7	0	27.8-40.0
	LA	0.75	3.0	5	6-8	0	8.6-16.0
		0.75	3.0	10	7-8	0	23.2-29.6
	MN	0.70-0.81	3.0	17-18	6-8	7	3.5-4.0
		0.75	3.0	10	7	0	25.3-28.3
	MO	0.75	3.0	20	7	0	19.5-22.5
		0.75-0.76	3.0	20	7	0	16.3-29.6
	MS	0.75	3.0	7	6-7	0	22.2-27.4
	NC	0.75	3.0	9	7-9	0	13.4-22.0
	PA	0.81-0.89	3.4	14	7	0	19.8-35.7
	VA	0.75	3.0	5	6-7	0	10.6-23.2
		0.75	3.0	5-7	7-8	3	8.4-20.5
Soybean hay	AR	0.75	3.0	5-6	7	5	50.2-85.0
		0.75	3.0	15	6-7	0	25.0-41.8
	IA	0.75	3.0	20	7-8	7	16.5-34.9
		0.75	3.0	20	7-8	7	20.3-78.9
	IL	0.75	3.0	20	6-7	7	36.8-49.7
		0.73-0.90	NR	5	7-10	3	27.2-31.1
	IN	0.75	3.0	20-21	7	0	31.9-65.9
		0.75	3.0	20-21	7	0	50.2-145.2
	LA	0.75	3.0	5	6-8	0	43.9-75.0
		0.75	3.0	10	7-8	7	151.9-162.7
	MN	0.70-0.81	3.0	17-18	6-8	11	4.73-7.19
		0.75	3.0	10	7	0	21.2-37.6
	MO	0.75	3.0	20	7	4	12.3-25.7
		0.75-0.76	3.0	20	7	4	10.5-22.6
	MS	0.75	3.0	15-16	6-9	2	45.2-50.8
	NC	0.75	3.0	9	7-9	5	61.4-134.4
	PA	0.81-0.89	3.4	14	7	1	19.1-23.8
	VA	0.75	3.0	5-7	7-8	3	13.1-25.3

Table 3. (continued).

Commodity	State	Application information				PHI (days)	Residues (ppm) ^a
		Single Rate (lb ai/A)	Total Rate (lb ai/A/year)	Volume (GPA)	Interval (days)		
Soybean straw	AR	0.75	3.0	5-6	7	28	0.65-1.61
		0.75	3.0	15	6-7	28	<0.04-0.06
	IA	0.75	3.0	20	7-8	28	0.20-0.28
		0.75	3.0	20	7-8	28	0.30-1.00
	IL	0.75	3.0	20	6-7	28	0.18-0.69
		0.73-0.90	NR	5	7-10	28	0.20-0.42
	IN	0.75	3.0	20-21	7	28	<0.04-0.06
		0.75	3.0	20-21	7	31	0.05-0.13
	LA	0.75	3.0	5	6-8	28	0.1-0.82
		0.75	3.0	10	7-8	28	≤0.04
	MN	0.70-0.81	3.0	17-18	6-8	28	<0.04-0.09
		0.75	3.0	10	7	28	0.19-0.51
	MO	0.75	3.0	20	7	28	0.20-0.23
		0.75-0.76	3.0	20	7	28	0.22-0.33
	MS	0.75	3.0	7	6-7	27	0.27-2.36
		0.75	3.0	15-16	6-9	29	0.23-1.97
	NC	0.75	3.0	9	7-9	28	0.07-0.13
	PA	0.81-0.89	3.4	14	7	27	<0.04-0.08
	VA	0.75	3.0	5-7	7-8	28	1.95-3.43
Soybean seeds	AR	0.75	3.0	5-6	7	28	0.05-0.06
		0.75	3.0	15	6-7	28	<0.04
	IA	0.75	3.0	20	7-8	28	<0.04
		0.75	3.0	20	7-8	28	<0.04
	IL	0.75	3.0	20	6-7	28	<0.04
		0.73-0.90	NR	5	7-10	28	<0.04
	IN	0.75	3.0	20-21	7	28	<0.04
		0.75	3.0	20-21	7	31	<0.04
	LA	0.75	3.0	5	6-8	28	<0.04
		0.75	3.0	10	7-8	28	<0.04
	MN	0.70-0.81	3.0	17-18	6-8	28	<0.04
		0.75	3.0	10	7	28	<0.04
	MO	0.75	3.0	20	7	28	<0.04
		0.75-0.76	3.0	20	7	28	<0.04
	MS	0.75	3.0	7	6-7	27	<0.04
	NC	0.75	3.0	15-16	6-9	29	<0.04
		0.75	3.0	9	7-9	28	<0.04
	PA	0.81-0.89	3.4	14	7	27	0.06-0.15
	VA	0.75	3.0	5-7	7-8	28	<0.04

^a Residues are expressed in thiodicarb equivalent and are not corrected for concurrent method recoveries.
^b NR = not reported.

A REF's search conducted on 5/26/94 identified three thiodicarb end-use products registered to Rhone-Poulenc for use on cotton: a 3.2 lb/gal FIC (EPA Reg. No. 264-379) and two 80% DF formulations (EPA Reg. Nos. 264-378 and 264-530). These three end-use products are registered for multiple foliar broadcast applications at 3- to 7-day intervals to cotton at 0.125-0.9 lb ai/A. Thiodicarb can be applied using either aerial or ground equipment in a minimum of 2 and 5 gal/A, respectively. The labels specify a 28-day PHI and prohibit the grazing of livestock in treated fields¹. In AZ, applications must be made prior to boll opening and the seasonal use rate may not exceed 1.8 lb ai/A/year; these restrictions are also listed for CA on one of the 80% DF labels (EPA Reg. No. 264-530). The registrant should amend the use directions for cotton to specify the maximum seasonal use rates and PHIs for all cotton growing regions consistent with the residue data submitted.

The Thiodicarb Phase IV Review required data depicting residues of thiodicarb in/on cottonseed harvested at the established PHI following the maximum number of foliar applications applied at the maximum label rate and the minimum retreatment interval. In response, Rhone-Poulenc submitted data (1992; MRID 42330901) from 14 tests conducted in AR(2), GA(2), LA(2), MS(2), OK(2) and TX(4) depicting thiodicarb residues in/on cotton forage and cottonseeds. Six broadcast foliar applications of thiodicarb (3.2 lb/gal FIC) each at \approx 0.9 lb ai/A were applied to cotton at approximately 10-day intervals using ground and aerial equipment at 5-15 gal/A and 2 gal/A, respectively. Total application rates were approximately 5.4 lb ai/A/season.

Three treated forage samples were collected from each test on the day of the last application and three treated cottonseed samples were collected from each test 28 days later. Prior to analysis, forage samples were stored frozen for up to 251 days and cottonseed samples were stored frozen for up to 153 days (since cotton forage is no longer regulated as a livestock feed, no tolerances are necessary).

Thiodicarb residues were determined by Rhone-Poulenc using the GC/FPD-S method described above. Thiodicarb residues in/on cotton forage and seed are presented in Table 4 and are not corrected for concurrent method recoveries. The combined residues of thiodicarb and its metabolite methomyl were 14.7-193.6 ppm in/on 42 forage samples harvested on the day of the last application and <0.04-0.10 ppm in/on 42 cottonseed samples harvested 28 days after the last of six applications of thiodicarb each at 0.9 lb ai/A.

Rhone-Poulenc also submitted data (1989; MRID 41019101) from seven tests conducted in AZ(2) and CA(5) depicting thiodicarb residues in/on cottonseed harvested 33-46 days following the last of two foliar applications of thiodicarb (3.2 lb/gal FIC) each at either 0.6 or 0.9 lb ai/A. The applications were made using either ground (10-20 gal/A) or aerial (5

¹ CBRS notes that since cotton forage is no longer regulated as a livestock feed, this explicit label prohibition is no longer necessary.

gal/A) equipment at 4-28 day retreatment intervals. Total application rates were 1.2 lb ai/A/season for the two tests in AZ and 1.8 lb ai/A/season for the five tests in CA. Three treated cottonseed samples were collected from each test 33-46 days after the second application. Cottonseed samples were stored at -30 C for up to 132 days prior to analysis.

Thiodicarb residues were determined by Rhone-Poulenc using the GC/FPD-S method described above for the soybean field study. Residues are presented in Table 5 and are not corrected for concurrent method recoveries. The combined residues of thiodicarb and its metabolite methomyl were <0.04-0.13 ppm in/on 21 cottonseed samples.

Geographic representation is adequate. The tests states of AR (7%), AZ (6.5%), CA (18%), GA (2.6%), LA (7.6%), MS (11.9%), OK (2.4%), and TX (32.6%) accounted for >80% of the 1990 U.S. production of cotton [Source: *Agricultural Statistics, 1991, p. 63*]

The submitted cottonseed data are adequate. The available data indicate that the combined residues of thiodicarb and its metabolite methomyl are unlikely to exceed the established 0.4 ppm tolerance in/on cottonseed harvested 28 days after the last of six foliar applications of thiodicarb each at 0.9 lb ai/A or 28 days after the second of two foliar applications each at 0.9 lb ai/A in AZ or CA. Based on this information, the tolerance could be reduced to 0.2 ppm².

Data are required depicting the combined residues of thiodicarb and methomyl in/on cotton gin byproducts ginned from cotton harvested 28 days after the last of six foliar applications of thiodicarb to cotton each at 0.9 lb ai/A. The cotton must be harvested by commercial equipment (or a simulation thereof) to provide an adequate representation of plant residue from the ginning process. If samples are stored for more than one month prior to analysis, storage stability data may be required. As the registrant has already fulfilled the requirement for residue data on cottonseed, the Agency will consider allowing a reduced number of field trials representing the principal cotton growing regions. The registrant should propose to the Agency a series of field trials to determine residue levels of thiodicarb in cotton gin byproducts.

Magnitude of the Residue in Processed Commodities

Soybeans. A tolerance of 0.8 ppm has been established for the combined residues of thiodicarb and its metabolite methomyl in/on soybean hulls [40 CFR §186.5650]. No food additive tolerances have been established for thiodicarb residues.

² The original tolerance of 0.4 ppm was based on a study using a total application rate of 8 lbs ai/A (8 applications of 1 lb ai/A) and a 6 day PHI (memo from A. Smith to F. Sanders, dated 12/19/79, PP# 9G2152)

Table 4. Combined residues of thiodicarb and its metabolite methomyl in/on cotton forage and cottonseed following six foliar applications of thiodicarb (3.2 lb/gal FIC) at $\approx 1\times$ the maximum label rate (MRID 42330901).

Commodity	State	Type	Application information				PHI (days)	Residues (ppm) *
			Single Rate (lb ai/A)	Total Rate (lb ai/A/year)	Volume (GPA)	Interval (days)		
Cotton forage	AR	Ground	0.9	5.40	5.1-6.0	7-10	0	37.5-57.6
		Aerial	0.9	5.40	2.3-2.7	10	0	33.0-34.1
	GA	Ground	0.91-0.94	5.54	5.0-5.1	10	0	27.1-98.2
		Aerial	0.9	5.40	2.0	10	0	23.2-28.8
	LA	Ground	0.88-0.9	5.32	5.1-5.2	11-17	0	32.5-47.1
		Aerial	0.93	5.58	2.0	7-18	0	73.1-126.5
	MS	Ground	0.88-0.92	5.40	14.7-15.3	7-16	0	28.4-32.1
		Aerial	0.9	5.40	1.9-2.0	8-13	0	81.6-116.5
	OK	Ground	0.85-0.99	5.47	5.5-6.2	10-14	0	24.5-30.7
		Aerial	0.83-0.97	5.35	1.8-2.1	6-12	0	14.7-31.9
	TX	Ground	0.87-0.95	5.49	5.0	9-15	0	47.9-97.5
			0.88-0.92	5.39	4.9-5.1	7-12	0	168.7-193.6
		Aerial	0.9	5.40	2.2-2.4	9-14	0	21.7-26.2
			0.88-0.92	5.39	2.1-2.3	7-12	0	91.1-106.8
Cottonseeds	AR	Ground	0.9	5.40	5.1-6.0	7-10	28	<0.04
		Aerial	0.9	5.40	2.3-2.7	10	28	0.04-0.10
	GA	Ground	0.91-0.94	5.54	5.0-5.1	10	28	0.07-0.10
		Aerial	0.9	5.40	2.0	10	28	<0.04
	LA	Ground	0.88-0.9	5.32	5.1-5.2	11-17	28	<0.04
		Aerial	0.93	5.58	2.0	7-18	28	<0.04
	MS	Ground	0.88-0.92	5.40	14.7-15.3	7-16	28	<0.04
		Aerial	0.9	5.40	1.9-2.0	8-13	27	<0.04
	OK	Ground	0.85-0.99	5.47	5.5-6.2	10-14	28	<0.04
		Aerial	0.83-0.97	5.35	1.8-2.1	6-12	28	<0.04
	TX	Ground	0.87-0.95	5.49	5.0	9-15	28	<0.04
			0.88-0.92	5.39	4.9-5.1	7-12	28	<0.04
		Aerial	0.9	5.40	2.2-2.4	9-14	28	<0.04
			0.88-0.92	5.39	2.1-2.3	7-12	28	<0.04-0.09

* Residues are expressed in thiodicarb equivalent and are not corrected for concurrent method recoveries.

Table 5. Combined residues of thiodicarb and its metabolite methomyl in/on cottonseeds following two foliar applications of thiodicarb (3.2 lb/gal FIC) at $\approx 1\times$ the maximum label rate (MRID 41019101).

Commodity	State	Type	Application information				PHI (days)	Residues (ppm) ^a
			Single Rate (lb ai/A)	Total Rate (lb ai/A/year)	Volume (GPA)	Interval (days)		
Cottonseed	AZ	Ground	0.6	1.2	NR ^b	28	44	≤ 0.04
		Aerial	0.6	1.2	5	28	44	< 0.04
	CA	Ground	0.9	1.8	20	14	46	< 0.04
		Ground	0.9	1.8	10	15	45	< 0.04
		Ground	0.9	1.8	10	15	45	$< 0.04-0.05$
		Aerial	0.9	1.8	5	14	46	< 0.04
		Aerial	0.9	1.8	5	4	33	0.05-0.13

^a Residues are expressed in thiodicarb equivalent and are not corrected for concurrent method recoveries.

^b NR = not reported.

In response to the Thiodicarb Phase IV Review, Rhone-Poulenc submitted data (1991; MRID 42043701) from a test conducted in IL depicting residues of thiodicarb in/on soybeans and soybean processed commodities. Four foliar applications of thiodicarb (3.2 lb/gal FIC) were applied to soybeans at 3.75 lb ai/A (5x) at 7-day intervals for a total application rate of 15.0 lb ai/A/season. Applications were made using ground equipment at 5 gal/A. One composited treated and control sample was harvested 29 days after the last application, frozen, and shipped via freezer truck to Rhone-Poulenc. The frozen samples were subsequently shipped to the Food Protein R&D Center at Texas A&M for processing. The soybeans were cleaned by aspiration and screening to yield whole seeds and an aspirated grain fraction. Whole seeds were processed into hulls, meal, crude and refined oil, and soapstock using simulated commercial practices. The processed commodities and soybean samples were frozen and shipped to Rhone-Poulenc. Prior to extraction for analysis, samples of whole seeds were stored frozen storage for 181 days and samples of aspirated grain fractions and the processed commodities were stored frozen for 31-42 days. Two subsamples of each treated commodity were analyzed. Samples analyses were conducted by CYAL using the GC/FPD-S method discussed above.

Thiodicarb residues were nondetectable (< 0.04 ppm) in one control sample of each commodity. Thiodicarb residues in treated fractions are presented in Table 6. Thiodicarb residues did not concentrate in meal, oil, and soapstock, but concentrated by 3.6x in hulls and by 29x in aspirated grain fractions.

The submitted soybean processing study is adequate. Thiodicarb residues did not concentrate in meal, oil, or soapstock, but concentrated by 3.6x in hulls and 29x in aspirated grain fractions. Based on the 3.6x concentration of residues in hulls and the established 0.2 ppm tolerance on soybeans, thiodicarb residues are unlikely to exceed the established 0.8 ppm feed additive tolerance for thiodicarb residues in soybean hulls. The registrant must propose

a tolerance for thiodicarb residues in aspirated grain fractions. Based on the observed concentration factor and the established tolerance on soybeans, a 6 ppm tolerance would be appropriate for the combined residues of thiodicarb and its metabolite methomyl in aspirated grain fractions.

Table 6. Combined residues of thiodicarb and its metabolite methomyl in/on soybeans and soybean processed commodities following four foliar applications of thiodicarb 5x the maximum label rate (MRID 42043701).

Commodity	Residues (ppm) ^a	Concentration factor ^b
Soybeans	0.043, 0.042 (0.043)	N/A
Hulls	0.145, 0.166 (0.156)	3.6
Meal	<0.04, <0.04 (<0.04)	—
Crude oil	<0.04, <0.04 (<0.04)	—
Refined oil	<0.04, <0.04 (<0.04)	—
Soapstock	<0.04, 0.04 (<0.04)	—
Aspirated grain fractions	1.096, 1.379 (1.238)	28.8

^a Residues are expressed in thiodicarb equivalent and are not corrected for concurrent method recoveries. Values in parentheses are the average of the duplicate subsamples.

^b Concentration factors were calculated using the average residue values.

Cotton. A tolerance of 0.8 ppm has been established for the combined residues of thiodicarb and its metabolite methomyl in/on cottonseed hulls [40 CFR §186.5650]. No food additive tolerances have been established for thiodicarb residues.

In response to the Thiodicarb Phase IV Review, Rhone-Poulenc submitted data (1991; MRID 42043702) from a test conducted in TX depicting residues of thiodicarb in/on cottonseeds and cottonseed processed commodities. Six foliar applications of thiodicarb (3.2 lb/gal FIC) were applied to cotton at 4.5 lb ai/A (5x) at 7- to 11-day intervals for a total application rate of 27.0 lb ai/A/season. Applications were made using ground equipment at ≈5 gal/A. One treated and control cotton sample was harvested 28 days after the last application and was ginned 7 days later. After 4 days of unfrozen storage, the ginned cottonseed was shipped to the Food Protein R&D Center at Texas A&M and placed in frozen storage until processing. Cottonseeds were processed into hulls, meal, crude and refined oil, and soapstock using simulated commercial practices. The processed commodities and cottonseeds were frozen and shipped to Rhone-Poulenc. Prior to extraction for analysis, cottonseeds were stored frozen for 104 days and processed commodities were stored frozen for 71-77 days. Two subsamples of each treated commodity were analyzed. Samples analyses were conducted by CYAL using the GC/FPD-S method discussed above.

Thiodicarb residues were nondetectable (<0.04 ppm) in control samples of each commodity. Thiodicarb residues in treated fractions are presented in Table 7.

The submitted cottonseed processing study is adequate. Thiodicarb residues did not concentrate in cottonseed meal, oil, or soapstock, but concentrated by 1.1x in cottonseed hulls. CBRS concludes that thiodicarb residues in cottonseed hulls are unlikely to exceed the established 0.8 ppm feed additive tolerance in hulls. Furthermore, since the concentration factor in hulls was not significant (i.e., < 1.5), CBRS concludes that the feed additive tolerance for hulls is not needed. The tolerance can be deleted and residues in hulls will be covered by the rac tolerance (presently 0.4 ppm, but able to be reduced to 0.2 ppm).

Table 7. Combined residues of thiodicarb and its metabolite methomyl in/on cottonseeds and cottonseed processed commodities following six foliar applications of thiodicarb 5x the maximum label rate.

Commodity	Residues (ppm) ^a	Concentration factor ^b
Cottonseeds	0.184, 0.215 (0.200)	N/A
Hulls	0.217, 0.228 (0.223)	1.1
Meal	0.054, <0.04 (0.047)	0.26
Crude oil	<0.04, <0.04 (<0.04)	—
Refined oil	<0.04, <0.04 (<0.04)	—
Soapstock	0.060, 0.064 (0.062)	0.31

^a Residues are expressed in thiodicarb equivalent and are not corrected for concurrent method recoveries. Values in parentheses are the average of the duplicate subsamples.

^b Concentration factors were calculated using the average residues.

AGENCY MEMORANDA

CBRS NO.: 12305
DP Barcode: D193543
Subject: Thiodicarb. Recovery/Validation Data for Analytical Methodology used in Plant Commodities.
From: D. Miller
To: B. Adler
Date: 2/24/94
MRID(s): 42381303

MASTER RECORD IDENTIFICATION NUMBERS

The citations for the MRID documents referred to in this review are presented below.

41019101 Hunt, T. (1989) Thiodicarb Insecticide Residue Report: CA/AZ Cotton: Project No. 804R10. Unpublished study prepared by Rhone-Poulenc Ag Co. 21 p.

42043701 Lee, R. (1991) Magnitude of Thiodicarb Residues on Soybeans and Processed Commodities After Ground Applications of LARVIN 3.2 brand Thiodicarb Insecticide/Ovicide: Study No. USA90L01. Unpublished study prepared by Rhone-Poulenc Ag Co. and CYAL. 112 p.

42043702 Lee, R. (1991) Magnitude of Thiodicarb Residues on Cottonseed and Processed Commodities After Ground Applications of LARVIN 3.2 brand Thiodicarb Insecticide/Ovicide: Study No. USA90L82. Unpublished study prepared by Rhone-Poulenc Ag Co. and CYAL. 132 p.

42330901 Lee, R. (1992) Magnitude of Thiodicarb Residues on Cotton Raw Agricultural Commodities After Ground and Aerial Applications of LARVIN 3.2 brand Thiodicarb Insecticide/Ovicide: Study No. USA91L82. Unpublished study prepared by Rhone-Poulenc Ag Co. 318 p.

42330902 Bird, R.; Coffery, J.; Lee, R. (1992) Magnitude of Thiodicarb Residues on Soybean Raw Agricultural Commodities After Ground Applications of LARVIN 3.2 brand Thiodicarb Insecticide/Ovicide: Study No. USA91L30. Unpublished study prepared by Rhone-Poulenc Ag Co. and Environmental Technologies Institute, Inc. 286 p.