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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

Reviewers:

Maxie Jo Nelson Date: 9.2.03
Maxie Jo Nelson, Chemist
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[Signature] Date: July 16/03
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[Signature] Date: July 25/03
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DP Barcode: D281841 and D297173

Petition No.: 1F06313

Citation: 45623413 Jordan, J. (2002) Cotton Field Rotational Crop Study for BAS 510F:
Lab Project Number: 2002/5002425. Unpublished study prepared by BASF
Corporation. 51 p.

Sponsor: BASF Corporation

Background

The information contained herein was compiled by Dynamac Corporation (20440 Century Boulevard, Suite 100, Germantown MD 20874), contractor, under the supervision of RAB2/HED. This DER has undergone secondary review by RAB2, and reflects current HED and Office of Pesticide Programs (OPP) policies. This DER was also peer-reviewed by PMRA.

Executive Summary

BASF Corporation has submitted the results of an extended field rotational crop study on cotton. Nine trials were conducted in Regions 2 (1 trial; NC), 4 (2 trials; AR and MS), 6 (1 trial; OK), 8 (3 trials; TX), and 10 (2 trials; CA). Geographical representation of cotton data is adequate.

At each field trial, three applications of the 70% wettable granule (WG) formulation were made to the bare soil surface. The first application was made at ~0.72 lb ai/A (0.81 kg ai/ha) followed by two applications at 0.55 lb ai/A/application (0.62 kg ai/ha), with 6- to 9-day retreatment intervals, for a total rate of 1.81-1.83 lb ai/A (2.03-2.05 kg ai/ha). Cotton was planted onto the treated soil as a rotational crop 13-15 days following the last application of the test formulation. Cotton plants were allowed to mature according to good agricultural practices. At maturity, samples of the cottonseed and cotton gin byproducts were collected by hand (3 trials; cottonseed only), picker (3 trials), or stripper (3 trials), and analyzed for residues of BAS 510 F using LC/MS/MS Method D9908. Concurrent method recovery data indicate that the LC/MS/MS method is adequate for data collection.

Samples of cottonseed and cotton gin byproducts were held in frozen storage for 80-112 days prior to extraction, and were analyzed within 0-2 days of extraction. Adequate storage stability data (refer to the DER for MRID 45405109) are available to support the storage conditions and intervals of samples from the submitted rotational crop field trials on cottonseed.

In rotational crops planted 13-15 days following the last application of the 70% WG formulation to bare soil for a total rate of 1.81-1.83 lb ai/A (2.03-2.05 kg ai/ha), residues of BAS 510 F were <0.05 ppm in/on cottonseed and <0.05-0.20 ppm in/on cotton gin byproducts grown in treated soil.

The residue data in the current submission are considered acceptable to fulfill the registration requirement for an extensive field rotational crop study on cotton.

GLP Compliance

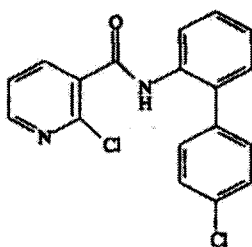
Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No deviations from regulatory requirements were cited.

1. Materials and Methods

1.1. Test Substance

Active Ingredient

Common Name: Nicobifen (ISO, proposed)
IUPAC Name: 2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
CAS Name: 3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)-
CAS Number: 188425-85-6
Company Name: BAS 510 F
Other Synonyms: BASF Registry No. 300355
Structure:



BAS 510 F

1.2. Trial Information

Cotton	Growing Region													Total Number of Trials
	1	2	3	4	5	6	7	8	9	10	11	12	13	
Submitted	-	1	-	2	-	1	-	3	-	2	-	-	-	9
Requested ^{1,2}	-	1	-	3/2	-	1	-	4/3	-	3/2	-	-	-	12/9

¹ When two entries are provided, the second entry represents a 25 percent reduction in the number of trials due to the pesticidal use resulting in no quantifiable residues.

² For cotton gin byproducts, at least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials.

BAS 510 F
Cotton
PMRA a.i. code (CCH)

Field Accumulation in Rotational Crops
OPPTS 860.1900
DACO 7.4.4

PC Code: 128008
MRID: 45623413
Submission # 001-1027, 1036, 1043

Table 1.2.2. Rotational Crop Trial Information

Location (County, State, Year)	EPA Region	Formulation	Applic. Rate (lb ai/A) ¹ [kg ai/ha]	Tank Mix Adjuvants	Rotated Crop; Variety	PBI (days)	Harvest Procedures		
							Method	Matrix	DAP ²
Wake, NC, 2001	2	70% WG	0.7224 + 0.553 + 0.541 = 1.82 [2.03]	None	Cotton; DP 5415-RR	14	Hand	cottonseed	150
Crittenden, AR, 2001	4	70% WG	0.7220 + 0.5512 + 0.5515 = 1.82 [2.04]	None	Cotton; ST4793R	14	Picker	cottonseed gin byproducts	155 155
Washington, MS, 2001	4	70% WG	0.7114 + 0.5512 + 0.5498 = 1.81 [2.03]	None	Cotton; Suregrow 125 Br	14	Picker	cottonseed gin byproducts	154 154
Caddo, OK, 2001	6	70% WG	0.7216 + 0.5457 + 0.5537 = 1.82 [2.04]	None	Cotton; Paymaster 2280 BG RR	14	Stripper	cottonseed gin byproducts	162 162
Armstrong, TX, 2001	8	70% WG	0.7232 + 0.5549 + 0.5520 = 1.83 [2.05]	None	Cotton; PM2200RR	14	Hand	cottonseed	154
Lamb, TX, 2001	8	70% WG	0.721 + 0.555 + 0.554 = 1.83 [2.05]	None	Cotton; PM 2326 BG/RR	13	Stripper	cottonseed gin byproducts	154 154
Hockley, TX, 2001	8	70% WG	0.72 + 0.5571 + 0.5512 = 1.83 [2.04]	None	Cotton; PM 2326 BG/RR	15	Stripper	cottonseed gin byproducts	161 161
Tulare, CA, 2001	10	70% WG	0.727 + 0.55 + 0.5495 = 1.83 [2.04]	None	Cotton; DP 6207 Acala	14	Picker	cottonseed gin byproducts	161 161
King, CA, 2001	10	70% WG	0.7226 + 0.553 + 0.5512 = 1.83268 [2.04]	None	Cotton; PhytoGen 57	14	Hand	cottonseed	157

¹ Three sequential broadcast applications were made directly to the soil, with 6- to 9-day retreatment intervals. Applications were made using ground equipment in 9.9-30.22 gal/A of water.

² Represents the number of days after planting (DAP) rotational crop samples were harvested

Note: The soil at the trial sites was loamy sand, silt loam, clay loam, and sandy loam. Information was provided pertaining to soil composition, pH, OM and percent water holding; no unusual characteristics were reported.

A single untreated and duplicate treated samples of cottonseed were harvested from each field trial at normal maturity, 150-162 days after planting (DAP), by hand or mechanically (stripper or mechanical picker). Undelinted cottonseeds were collected from all 9 test sites. Cotton gin byproducts were collected from 6 test sites; three sites harvested by stripper and 3 sites harvested by picker. Sampling procedures and sample weights were not otherwise specified.

1.3. Post-harvest Procedures

Samples of cottonseed and cotton gin byproducts were frozen (temperature not specified) on the day of harvest. Samples were then shipped frozen to BASF (Research Triangle Park, NC) for analysis. Samples were held in frozen storage for 80-112 days prior to extraction, and were analyzed within 0-2 days of extraction. Adequate storage stability data (refer to the DER for MRID 45405109) are available to support the storage conditions and intervals of samples from the submitted rotational crop field trials on cottonseed.

Matrix	RAC or Extract	Storage Temperature (°C)	Duration
Cotton	Seed	<-10 C	80-112 days (2.6-3.7 months)
	Gin byproducts		88-106 days (2.9-3.5 months)

1.4. Analytical Methods

Samples of rotated cotton commodities (cottonseed and cotton gin byproducts) were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plants. Briefly, samples were extracted with methanol:water:2N HCl (70:25:5, v:v:v) and filtered. An aliquot of the filtrate was cleaned-up using liquid:liquid partitioning with saturated NaCl and cyclohexane. An aliquot of the cyclohexane phase was further cleaned-up using silica gel solid phase extraction (SPE); residues were eluted from the silica gel SPE with 4% ethyl acetate in dichloromethane (DCM). The eluate was evaporated to dryness and dissolved in LC/MS/MS mobile phase for analysis. Refer to the DER for MRID 45405027 for a complete description of the quantitation procedures. The validated limit of quantitation (LOQ) was <0.05 ppm for residues of BAS 510 F in/on rotated cottonseed and cotton gin byproducts.

2. Results

Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD
Cottonseed	0.05, 1.0	76, 80, 82, 86, 88, 94	84 ± 6
Cotton gin byproducts	0.05, 1.0	74, 84	79

Table 2.2. Residue Data from Rotational Crop Trials with BAS 510 F, 70% WG formulation, Applied to the Soil for a Total Rate of 1.81-1.83 lb ai/A.

Location (County, State, Year)	Crop; Variety	Commodity	Plant-Back Interval (days)	BAS 510 F Residues (ppm)
Wake, NC, 2001	Cotton; DP 5415-RR	cottonseed	14	<0.05, <0.05
Crittenden, AR, 2001	Cotton; ST4793R	cottonseed	14	<0.05, <0.05
		gin byproducts		<0.05, <0.05
Washington, MS, 2001	Cotton; Suregrow 125 Br	cottonseed	14	<0.05, <0.05 ¹
		gin byproducts		<0.05, <0.05
Caddo, OK, 2001	Cotton; Paymaster 2280 BG RR	cottonseed	14	<0.05, <0.05
		gin byproducts		<0.05, <0.05
Armstrong, TX, 2001	Cotton; PM2200RR	cottonseed	14	<0.05, <0.05
Lamb, TX, 2001	Cotton; PM 2326 BG/RR	cottonseed	13	<0.05, <0.05
		gin byproducts		<0.05, <0.05
Hockley, TX, 2001	Cotton; PM 2326 BG/RR	cottonseed	15	<0.05, <0.05 ²
		gin byproducts		<0.05, <0.05
Tulare, CA, 2001	Cotton; DP 6207 Acala	cottonseed	14	<0.05, <0.05
		gin byproducts		0.14, 0.198
King, CA, 2001	Cotton; Phytogen 57	cottonseed	14	<0.05, <0.05

¹ The original analyses of the replicate samples did not agree (<0.05 and 0.089 ppm). The petitioner indicated that the initial analysis showed an interference or contamination of the sample. Subsequent duplicate analyses resulted in non-quantifiable residues (<0.05 ppm) which are reported here.

² The original analyses of the replicate samples did not agree (<0.05 and 0.455 ppm). The petitioner indicated that the initial analysis showed an interference or contamination of the sample. Subsequent duplicate analyses resulted in inconsistent results (<0.05 ppm and 0.173 ppm) and the petitioner decided to redo the sample in four replicates. Subsequent quadruplicate analyses resulted in non-quantifiable residues (<0.05 ppm) which are reported here.

Table 2.3. Summary of Residue Data from Rotational Crop Trials with BAS 510 F Applied to the Soil.

Commodity	Total Applic. Rate (lb ai/A)	Plant-Back Interval (days)	Residue Levels (ppm)			
			Maximum	HAFT	Mean	Std. Dev.
Cottonseed	1.81-1.83	13-15	<0.05	<0.05	<0.05	0.0
Cotton gin byproducts	1.81-1.83	13-15	0.198	0.169	0.070	0.048

Apparent residues of BAS 510 F in all untreated samples of cottonseed and cotton gin byproducts were below the method LOQ (<0.05 ppm).

3. Discussion

3.1. Methods

Nine field trials were conducted in Regions 2 (1 trial; NC), 4 (2 trials; AR and MS), 6 (1 trial; OK), 8 (3 trials; TX), and 10 (2 trials; CA) on cotton as a rotational crop. OPPTS 860.1900 requires that the same number of trials for primary tolerances be conducted on crops for which inadvertent or indirect (rotational crop) tolerances would be required. The geographical representation and number of field trials as required by OPPTS 860.1500 (Table 5) for cottonseed is adequate in this instance, since all residues in cottonseed were below the method LOQ (<0.05 ppm).

At each field trial, three sequential applications of the 70% WG formulation were made to the bare soil surface. The first application was made at -0.72 lb ai/A (0.81 kg ai/ha) followed by two applications at 0.55 lb ai/A/application (0.62 kg ai/ha/application), with 6- to 9-day retreatment intervals, for a total rate of 1.81-1.83 lb ai/A. Applications were made using ground equipment in 9.9-30.22 gal/A (111-338 l/ha) of water. The rotational crop cotton was planted 13-15 days following the last application to the soil and allowed to grow to normal maturity.

Weather conditions during the course of the rotational crop field trials on cotton were reported as normal temperatures at all trials; above normal rainfall at the MS trial; below normal rainfall at the NC, OK, and TX trials; and no irrigation at the NC, AR, and MS trials.

Samples of cottonseed and cotton gin byproducts were collected by hand (3 trials; cottonseed only), picker (3 trials), or stripper (3 trials); stored frozen (< -10 C) pending analysis; and, analyzed for residues of BAS 510 F using LC/MS/MS Method D9908. Concurrent method recovery data included in this submission indicate that the LC/MS/MS method is adequate for data collection.

The maximum storage intervals from harvest-to-analysis were 106 days (3.7 months) for cottonseed and 112 days (3.5 months) for cotton gin byproducts. Adequate storage stability data (refer to the 860.1380 DER for MRID 45405109) are available which demonstrate that residues of BAS 510F are stable for up to 12 months in/on various crop commodities, including rape seed and wheat grain, forage, and straw. The available storage stability data support the storage conditions and intervals of the rotated cottonseed and cotton gin byproducts samples.

3.2. Results

Cotton was planted as a rotational crop 13-15 days following the last application of the 70% WG formulation to bare soil for a total rate of 1.81-1.83 lb ai/A (2.03-2.05 kg ai/ha). Inadvertent residues of BAS 510 F were <0.05 ppm in/on cottonseed and <0.05-0.20 ppm in/on cotton gin byproducts.

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4. Deficiencies

None.

5. References

45672101 Wofford, J.; et al (2002) A Summary of Weather Conditions for BAS 510 F Field Residue Studies Conducted from 1999-2001 Data: BASF Registration Document Number: 2002/5002878. Unpublished study prepared by BASF Agro Research. 24 p.