

BAS 510F
Lettuce (Head and Leaf)
PMRA a.i. code (CCH)

Magnitude of the Residue
OPPTS 860.1500
DACO 7.4.1

PC Code: 128008
MRID: 45405128
Submission # 2001-1027, 1036, 1043



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

Reviewers:

William Cutchin Date: 8/25/03
William Cutchin, Chemist
Reviewer
SIMB/HED (7509C)

Henri P. Bietlot Date: 8/16/03
Henri P. Bietlot, Chemist
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FREAS, HED, PMRA

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Richard A. Loranger
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RAB2/HED (7509C)

Ariff Ally Date: July 25/03
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FREAS, HED, PMRA

DP Barcode: D278386

Petition No.: 1F06313

Citation: 45405128 Haughey, D.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F Residues in Head and Leaf Lettuce: Final Report: Lab Project Number: 64114: 2001/5000051: 2000132. Unpublished study prepared by BASF Agro Research. 71 p.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 field trial data on head and leaf lettuce. Eight head lettuce trials were conducted in Regions 2 (1 trial; NC), 3 (1 trial; FL), and 10 (6 trials; AZ and CA) and eight leaf lettuce trials were conducted in Regions 2 (1 trial; NC), 3 (1 trial; FL), and 10 (6 trials; AZ and CA). The number and location of field trials are adequate for the US EPA with respect

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to the geographic representation of residue data for head and leaf lettuce. None of the submitted field trials on head and leaf lettuce were conducted in Canada.

For the head and leaf lettuce field trials, the 70% WG formulation of BAS 510 F was applied two times as a foliar spray at ~0.50 lb ai/A/application (~0.56 kg ai/ha/application), with a 9- to 11-day retreatment interval, for a total rate of 0.98-1.02 lb ai/A (1.10-1.14 kg ai/ha). Mature head lettuce (with and without wrapper leaves) and leaf lettuce were collected at a 13 to 15-day posttreatment interval. In one head lettuce and one leaf lettuce field trial, additional samples were collected at 0, 7, 21, and 28 days following treatment to evaluate residue decline.

Residues of BAS 510 F in/on head and leaf lettuce were quantitated using a validated LC/MS/MS method (D9908, the data collection method for plant commodities). Acceptable concurrent method validation data for head and leaf lettuce were included in the submission. Storage stability data (refer to the DER for MRID 45405109) are available to support the storage conditions for 184 days (6.1 months) for head lettuce and 193 days (6.3 months) for leaf lettuce.

At the applied total rate of 0.98-1.02 lb ai/A (1.10-1.14 kg ai/ha), BAS 510 F residues in/on treated samples were 0.076-6.15 ppm in/on head lettuce (with wrapper leaves), <0.05-0.95 ppm in/on head lettuce (without wrapper leaves), and 0.36-10.42 ppm for leaf lettuce. The residue decline data for head lettuce (with and without wrapper leaves) and leaf lettuce indicated that BAS 510 F residues decreased at longer posttreatment intervals.

Residue data from the current submission are acceptable to fulfill the EPA crop field trial data requirements for head and leaf lettuce.

As there is no Canadian zonal representation in these field trials, and as the trials were carried out at 2 times the Canadian label rate, the PMRA will consider a domestic registration for the use of BAS 510F on lettuce only if the registrant commits to one of the following options: Option 1, a full set of residue trials (five trials) as specified in Dir 98-02; or, Option 2, the registrant can provide two trials in each of zones 5 and 5B (for a total of 4 trials).

GLP Compliance

Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No GLP deviations were reported which would impact the study results or their interpretation.

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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

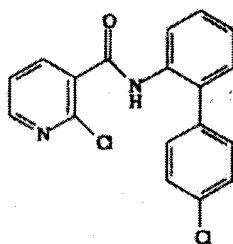
CAS Name: 3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)-

CAS Number: 188425-85-6

Company Name: BAS 510 F

Other Synonyms: BASF Registry No. 300355

Structure:



1.2. Trial Locations

TABLE B.1.2. Trial Numbers and Geographical Locations for Lettuce Field Trials												
NAFTA Growing Region	Head Lettuce				Leaf Lettuce				N/A			
	Canada		US		Canada		US		Canada		US	
	SUB	REQ	SUB	REQ	SUB	REQ	SUB	REQ	SUB	REQ	SUB	REQ
1			1	11			1	11				
1A												
2												
3			1	1			1	1				
4												
5	0	1			0	1						
5A												
5B	0	3			0	3						
6												
7												
7A												
8												
9												
10			6	6			6	6				
11												
12	0	1			0	1						
13												
14												
15												
16												
17												
18												
19												
20												
21												
Total	0	5	8	8	0	5	8	8				

¹ Either region 1 or 2 is acceptable.

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Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formul.	Applic. Timing	Applic. Rate (lb ai/ha) [kg ai/ha]	Retreat. Intervals (days)	No. of Applies.	Applic. Method/ Applic. Volume (GPA)	Total Applic. Rate (lb ai/ha) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
Lettuce, head											
2	Wake, NC, 2000	Lettuce, Crisp Head	70% WG	plants 4-6" tall, very early heading	0.502-0.506 [0.562-0.567]	10	2	Foliar spray/ 30.1-30.3	1.008 [1.13]	Surfac 820 (1pt/100gal)	Head lettuce (with and without wrapper leaves) harvested 15 days after last application (DALA).
3	Seminole, FL, 2000	Lettuce, Great Lakes	70% WG	plants 10" tall plants 12" tall	0.50-0.51 [0.56-0.57]	10	2	Foliar spray/ 29.7-30.8	1.01 [1.13]	Diamond R Activator (1pt/100gal)	Head lettuce (with and without wrapper leaves) harvested 13 DALA.
10	Tulare, CA, 2000 (decline study)	Lettuce, Bayview	70% WG	plants ~8" tall, softball size heads plants ~8" tall, melon size heads	0.49-0.502 [0.55-0.56]	10	2	Foliar spray/ 29.3-30.2	0.992 [1.11]	Latron B-1956 (4-6oz/100gal)	Head lettuce (with and without wrapper leaves) harvested 0, 7, 14, 21, and 28 DALA.
10	Madera, CA, 2000	Lettuce, Empire	70% WG	plants 4-6" tall, 4-6 true leaves plants 5-6" tall, small heads	0.4939-0.496 [0.553-0.555]	10	2	Foliar spray/ 39.5-39.7	0.9899 [1.11]	Latron B-1956 (3oz/100gal)	Head lettuce (with and without wrapper leaves) harvested 14 DALA.
10	San Diego, CA, 2000	Lettuce, Salinas, MI	70% WG	plants 6-12" tall, heads 3-6" diameter plants 6-12" tall, heads 6-8" diameter	0.489-0.494 [0.548-0.553]	9	2	Foliar spray/ 39.2-39.5	0.983 [1.10]	Silwett L-77 (6oz/100gal)	Head lettuce (with and without wrapper leaves) harvested 14 DALA.

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Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formul.	Applic. Timing	Applic. Rate (lb ai/A) [kg ai/ha]	Retreat. Intervals (days)	No. of Applics.	Applic. Method/ Applic. Volume (GPA)	Total Applic. Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
10	San Joaquin, CA, 2000	Lettuce, Great Lakes	70% WG	plants 4-8" tall plants 6-8" tall	0.485-0.501 [0.543-0.561]	10	2	Foliar spray/ 48.5-50.1	0.986 [1.10]	Silwett L-77 (6oz/100gal)	Head lettuce (with and without wrapper leaves) harvested 14 DALA.
10	Pinal, AZ, 2000	Lettuce, Green Lightning	70% WG	plants 1' tall, 50-70% final size plants 12-14" tall, 60-80% final size	0.495-0.515 [0.554-0.577]	9	2	Foliar spray/ 29.7-30.9	1.01 [1.13]	Induce (0.25%, v:v)	Head lettuce (with and without wrapper leaves) harvested 14 DALA.
10	Pinal, AZ, 2000	Lettuce, Diamond	70% WG	plants 5-6" tall, 5th true leaf open plants 8" tall, 14" diameter small head	0.482-0.5245 [0.539-0.587]	10	2	Foliar spray/ 28.9-31.5	1.01 [1.13]	Induce (0.25%, v:v)	Head lettuce (with and without wrapper leaves) harvested 14 DALA.
Lettuce, leaf											
2	Wake, NC, 2000	Lettuce, Salad Bowl	70% WG	plants 3-4" tall, early growth plants 4-6" tall	0.499-0.505 [0.559-0.566]	11	2	Foliar spray/ 29.9-30.3	1.0037 [1.12]	Surfac 820 (1pt/100gal)	Leaf lettuce harvested 14 DALA.
3	Seminole, FL, 2000	Lettuce, Bibb	70% WG	plants 7" tall plants 7-9" tall	0.48-0.52 [0.54-0.58]	10	2	Foliar spray/ 29.0-31.0	1.00 [1.12]	Diamond R Activator (1pt/100gal)	Leaf lettuce harvested 14 DALA.
10	Tulare, CA, 2000 (decline study)	Lettuce, New Red Fire	70% WG	plants 4" tall, ~8 leaves plants 8" tall, ~10 leaves	0.500-0.503 [0.559-0.563]	10	2	Foliar spray/ 30.2-30.3	1.00 [1.12]	Latron B-1956 (4oz/100gal)	Leaf lettuce harvested 0, 7, 14, 21, and 28 DALA.

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Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formul.	Applic. Timing	Applic. Rate (lb ai/A) [kg ai/ha]	Retreat. Intervals (days)	No. of Applics.	Applic. Method/ Applic. Volume (GPA)	Total Applic. Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
10	Madera, CA, 2000	Lettuce, Waldmans Green	70% WG	plants 4-6" tall, >10 leaves	0.489-0.497 [0.548-0.557]	10	2	Foliar spray/ 29.4-29.8	0.986 [1.10]	Latron B-1956 (5oz/100gal)	Leaf lettuce harvested 14 DALA.
				plants 6-8" tall, >10 leaves							
				plants 10-12" tall, mature							
10	San Diego, CA, 2000	Lettuce, Red Salad Bowl	70% WG	plants 6-9" tall, midgrowth	0.490-0.508 [0.549-0.569]	9	2	Foliar spray/ 39.2-40.7	0.998 [1.12]	Silwett L-77 (6oz/100gal)	Leaf lettuce harvested 14 DALA.
				plants 10-12" tall, mature							
				plants 4-5" tall							
10	San Joaquin, CA, 2000	Lettuce, Waldmann's Green	70% WG	plants 2" tall, 4-5 leaves	0.485-0.505 [0.543-0.566]	10	2	Foliar spray/ 48.5-50.6	0.99 [1.11]	Silwett L-77 (6oz/100gal)	Leaf lettuce harvested 14 DALA.
				plants 4-5" tall							
				plants 15-18" tall, 50-70% final size							
10	Pinal, AZ, 2000	Lettuce, Paris Island	70% WG	plants 12-14" tall, 60-80% final size	0.493-0.513 [0.566-0.574]	9	2	Foliar spray/ 29.6-30.8	1.01 [1.13]	Induce (0.25%, v:v)	Leaf lettuce harvested 14 DALA.
				plants 2" tall, 4-5 leaf stage							
				plants 4" tall, 14-16 leaf stage							
10	Yuma, AZ, 2000	Lettuce, Shining Star	70% WG	plants 2" tall, 4-5 leaf stage	0.494-0.524 [0.533-0.587]	10	2	Foliar spray/ 29.7-31.5	1.02 [1.14]	Induce (0.25%, v:v)	Leaf lettuce harvested 14 DALA.
				plants 4" tall, 14-16 leaf stage							
				plants 4" tall, 14-16 leaf stage							

1.3. Post-harvest Procedures

A single untreated and duplicate treated samples each of head lettuce (with and without wrapper leaves) and leaf lettuce were harvested from each field trial. Specific harvesting procedures were not described; however, each lettuce sample weighed ≥ 2.2 lbs (≥ 1 kg) and decomposed or withered leaves were removed from the leaf lettuce samples. Additional samples of head lettuce (with and without wrapper leaves) and leaf lettuce were collected from the CA trials (Tulare County) at various time intervals for residue decline samples. At the 28-day interval of the decline study, only one treated sample each of head lettuce (with and without wrapper leaves) was collected because a hard frost had destroyed much of the crop. Samples were bagged and stored frozen (temperature not specified) on the day of harvest. Samples were shipped frozen within 0-50 days of harvest to BASF Agricultural Products Center (Research Triangle Park, NC) for analysis.

Table 1.3.1. Summary of Storage Conditions			
Matrix	RAC or Extract	Storage Temperature (°C) (Analytical Laboratory)	Duration
Lettuce, head	head with and without wrapper leaves	<-10	11-184 days (0.4-6.1 months)
Lettuce, leaf	leaves	<-10	12-193 days (0.4-6.3 months)

1.4. Analytical Methods

Samples of head lettuce (with and without wrapper leaves) and leaf lettuce were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plants. Briefly, lettuce samples were extracted with methanol:water:2N HCl (70:25:5, v:v:v) using Polytron homogenization. An aliquot of the extract was subjected to liquid/liquid partitioning with saturated sodium chloride and cyclohexane. An aliquot of the cyclohexane phase was collected and evaporated to dryness. Residues were redissolved in ammonium formate:formic acid for analysis by LC/MS/MS; refer to the DER for MRID 45405027 for a complete description of the quantitation procedures. The limit of detection (LOD) was 0.025 ppm, and the validated limit of quantitation (LOQ) was 0.05 ppm for the residues of BAS 510 F in/on head and leaf lettuce. The concurrent recoveries obtained are presented in Table 2.1.

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.			
Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery $\pm$ SD
Lettuce, head	0.05, 1.00, 20.00	79, 80, 81, 83, 84, 85, 87, 87, 91, 92	84.9 $\pm$ 4.4
Lettuce, leaf	0.05, 1.00, 20.00	78, 80, 81, 84, 84, 97	84.0 $\pm$ 6.8

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Table 2.2. Residue Data from Crop Field Trials in Lettuce (Head and Leaf) with BAS 510 F.

Location (County, State, Year)	Crop Variety	Commodity	Formul.	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
Head Lettuce						
Wake, NC, 2000	Crisp Head	head with wrapper leaves	70% WG	1.01 [1.13]	15	1.67, 1.86
Seminole, FL, 2000	Great Lakes	head with wrapper leaves	70% WG	1.01 [1.13]	13	2.56, 2.89
Tulare, CA, 2000 (decline study)	Bayview	head with wrapper leaves	70% WG	0.992 [1.11]	0	5.00, 6.69
					7	0.303, 0.500
					14	0.076, 0.144
					21	0.055, 0.075
					28	<0.05
Madera, CA, 2000	Empire	head with wrapper leaves	70% WG	0.990 [1.11]	14	0.868, 1.092
San Diego, CA, 2000	Salinas, MI	head with wrapper leaves	70% WG	0.983 [1.10]	14	2.54, 2.81
San Joaquin, CA, 2000	Great Lakes	head with wrapper leaves	70% WG	0.986 [1.10]	14	4.68, 6.15
Pinal, AZ, 2000	Green Lightning	head with wrapper leaves	70% WG	1.0104 [1.13]	14	2.75, 3.61
Pinal, AZ, 2000	Diamond	head with wrapper leaves	70% WG	1.01 [1.13]	14	2.82, 2.23
Wake, NC, 2000	Crisp Head	head without wrapper leaves	70% WG	1.01 [1.13]	15	0.921, 0.935
Seminole, FL, 2000	Great Lakes	head without wrapper leaves	70% WG	1.01 [1.13]	13	0.29, 0.55
Tulare, CA, 2000 (decline study)	Bayview	head without wrapper leaves	70% WG	0.992 [1.11]	0	0.308, 0.326
					7	0.079, 0.087
					14	<0.05, <0.05
					21	<0.05, <0.05
					28	<0.05
Madera, CA, 2000	Empire	head without wrapper leaves	70% WG	0.990 [1.11]	14	0.078, 0.254
San Diego, CA, 2000	Salinas, MI	head without wrapper leaves	70% WG	0.983 [1.10]	14	0.27, 0.54
San Joaquin, CA, 2000	Great Lakes	head without wrapper leaves	70% WG	0.986 [1.10]	14	<0.05, <0.05
Pinal, AZ, 2000	Green Lightning	head without wrapper leaves	70% WG	1.01 [1.13]	14	0.48, 0.95

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Table 2.2. Residue Data from Crop Field Trials in Lettuce (Head and Leaf) with BAS 510 F.						
Location (County, State, Year)	Crop Variety	Commodity	Formul.	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
Pinal, AZ, 2000	Diamond	head without wrapper leaves	70% WG	1.01 [1.13]	14	0.211, 0.316
Leaf Lettuce						
Wake, NC, 2000	Salad Bowl	leaves	70% WG	1.00 [1.10]	14	8.69, 10.4
Seminole, FL, 2000	Bibb	leaves	70% WG	1.00 [1.12]	14	0.36, 1.12
Tulare, CA, 2000 (decline study)	New Red Fire	leaves	70% WG	1.00 [1.12]	0	15.6, 18.5
					7	7.78, 12.43
					14	1.61, 1.65
					21	0.31, 0.35
					28	<0.05, 0.11
Madera, CA, 2000	Waldmans Green	leaves	70% WG	0.986 [1.10]	14	4.85, 5.42
San Diego, CA, 2000	Red Salad Bowl	leaves	70% WG	0.998 [1.12]	14	1.44, 1.76
San Joaquin, CA, 2000	Waldmann's Green	leaves	70% WG	0.99 [1.11]	14	1.76, 2.06
Pinal, AZ, 2000	Paris Island	leaves	70% WG	1.005 [1.13]	14	4.28, 5.45
Yuma, AZ, 2000	Shining Star	leaves	70% WG	1.02 [1.14]	14	9.34, 9.38

Table 2.3. Summary of Residue Data from Crop Field Trials in Lettuce with BAS 510 F.							
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)				
			Minimum	Maximum	HAPT	Mean [median]	Std. Dev.
Head lettuce (with wrapper leaves)	0.983-1.01	37635	0.076	6.15	5.42	2.42 [2.55]	1.57
Head lettuce (without wrapper leaves)	0.983-1.01	37635	<0.05	0.95	0.928	0.375 [0.28]	0.325
Leaf lettuce	0.986-1.02	14	0.36	10.4	9.56	4.35 [3.17]	3.43

3. Discussion

3.1. Methods

Head lettuce (with and without wrapper leaves) and leaf lettuce were harvested 13-15 days following the last of two foliar spray applications of the 70% WG formulation at ~0.50 lb ai/A/application (~0.56 kg ai/ha/application) with a 9- to 11-day retreatment interval, for a total rate of 0.98-1.02 lb ai/A (1.10-1.14 kg ai/ha). Applications were made using ground equipment in a spray volume of 28.9-50.56 gal/A (324-567 l/ha) of water with a spray adjuvant added. In two trials (one each head and leaf lettuce in Tulare County, CA), additional head and leaf lettuce samples were collected at 0, 7, 21, and 28 days following treatment to evaluate residue decline.

Eight head lettuce trials were conducted in Regions 2 (1 trial), 3 (1 trial), and 10 (6 trials) and eight leaf lettuce trials were conducted in Regions 2 (1 trial), 3 (1 trial), and 10 (6 trials). Geographic representation of residue data for lettuce (head and leaf) is adequate. The number and location of field trials conducted for lettuce (head and leaf) are in accordance with the US EPA guidance requirements (OPPTS 860.1500, Tables 1 and 5). As there is no zonal representation (Canadian field trials), the PMRA data requirements were not met.

Residues of BAS 510 F in/on head and leaf lettuce were quantitated using validated LC/MS/MS method (D9908, the data collection method for plant commodities). Storage stability data (refer to the DER for MRID 45405109) are available to support the 184 days (6.1 months) for head lettuce and 193 days (6.3 months) for leaf lettuce storage interval in these studies.

3.2. Results

Residues of BAS 510 F were 0.076-6.15 ppm in/on head lettuce with wrapper leaves, <0.05-0.95 ppm in/on head lettuce without wrapper leaves, and 0.36-10.42 ppm in/on leaf lettuce samples harvested 13-15 days following the last of two foliar spray applications of the 70% WG formulation at 0.48-0.5245 lb ai/A/application (0.54-0.59 kg ai/ha/application), with a 9- to 11-day retreatment interval, for a total rate of 0.98-1.02 lb ai/A (1.10-1.14 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.05 ppm) in/on eight samples each of untreated head lettuce, with and without wrapper leaves, and leaf lettuce. The residue decline data for head lettuce (with and without wrapper leaves) and leaf lettuce indicated that BAS 510 F residues decreased at longer posttreatment intervals.

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4. Deficiencies

None for a US registration.

As there is no Canadian zonal representation among these field trials, and as the trials were carried out at 2 times the Canadian label rate, the PMRA will consider a domestic registration for the use of BAS 510 on lettuce only if the registrant commits to one of the following options: Option 1, a full set of residue trials (five trials) as specified in Dir 98-02; or, Option 2, the registrant can provide two trials in each of zones 5 and 5B (for a total of 4 trials).

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.