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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: July 2, 2003

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DP Barcode: D278386

Petition: 1F06313

Citation: 45405112 Versoi, P.; Adbel-Baky, S. (2000) The Magnitude of BAS 510 F Residues in Dry Bulb and Green Onions: Final Report: Lab Project Number: 2000/5207: 63894: 99171 (PA/1). Unpublished study prepared by BASF Corporation. 55 pages.

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 has also been peer-reviewed by PMRA/Canada.

Executive Summary

BASF Corporation has submitted field trial data on the representative crops, green and dry bulb onions, of the bulb vegetable crop group (Crop Group 3). Three green onion trials were conducted in Regions 6 (one trial in Texas) and 10 (two trials in California) and six dry bulb

onion trials were conducted in Regions 1 (one trial in Pennsylvania), 6 (one trial in Texas), 8 (one trial in Texas), 10 (two trials in California), and 11 (one trial in Oregon). The number and location of the field trials satisfy the US-EPA's data requirements with respect to the geographic representation of residue data for the bulb vegetable crop group. The number and location of these trials does not satisfy the data requirements of the PMRA.

At each test location, the 70% WG formulation of BAS 510 F was applied six times as a foliar spray at ~0.3 lb ai/A/application (0.336 kg ai/ha/application), with 13- to 15-day re-treatment intervals, for a total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha). Mature samples were collected at a 7-day post-treatment interval. In one dry bulb onion field trial, additional samples were collected at 0, 14, 21, and 28 days following treatment to evaluate residue decline.

At the applied total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha), the ranges of BAS 510 F residues in/on treated mature samples were: 1.06-2.94 ppm for green onions and 0.026-1.03 ppm for dry bulb onions. The residue decline data for dry bulb onion demonstrated that residues of BAS 510 F generally decreased with increasing PHIs but that the decline was not linear.

Residues of BAS 510 F in/on onions (green and dry bulb) were quantitated using a 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 186 days (6.1 month) maximum storage interval for the samples analyzed.

Residue data from the current submission are acceptable to fulfill the EPA's crop field trial data requirements for the bulb vegetable crop group (Crop Group 3). The submitted residue trials do not meet the requirements set out by the PMRA. A total of four additional residue trials in dry bulb onions (2 trial carried out in zone 5 and two trials carried out in zone 5B) and 2 additional residue trial in green onions (one trial in each of 5 and 5B) are required. It should be noted that these trials are needed to support both the use of this chemical on this crop group but also to support the residue levels resulting in rotated crops from the use of this chemical in any crop.

GLP Compliance

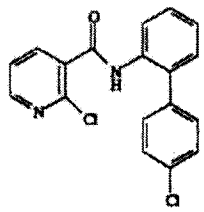
Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No GLP deviations were reported which would impact the study results or their interpretation.

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
Chemical Structure:	



1.2. Trial Locations

TABLE B.1.2. Trial Numbers and Geographical Locations

NAFTA Growing Region	Green Onions [1]				Dry Bulb Onions [1]				N/A			
	Canada		US		Canada		US		Canada		US	
	SUB	REQ	SUB	REQ[2]	SUB	REQ	SUB	REQ	SUB	REQ	SUB	REQ
1							1	1				
0.04167												
2												
3												
4												
5	0	1			0	3						
0.208333												
5B	0	1			0	2						
6			1				1	1				
7												
0.291667												
8							1	1				
9												
10			2				2	2				
11							1	1				
12												
13												
14												
15												
16												
17												
18												
19												
20												
21												
Total	0	2	3	N/A	0	5	6	6				

[1] The representative commodities for bulb vegetable crop group are green onion and dry bulb onion.
[2] OPPTS 860.1500 Table 5 does not identify specific regions for green onion field trials, however, trials were conducted for green onions in Regions 6 and 10, which together account for 72% of green onion production (OPPTS 860.1500, Table 6).

Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formulation	Application Timing	Application Rate (lb ai/A) [kg ai/ha]	Re-treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [l/ha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
Onion, green											
6	Uvalde, TX, 1999	Green onion, Texas Early White	70% WG	2 leaves	0.298-0.314 [0.334-0.352]	13-14	6	Foliar spray/ 21.8-23.0 [244-258]	1.82 [2.04]	Induce (0.25%, v:v)	Whole plant (without roots) harvested 7 days after last application (DALA).
				2 leaves							
				beginning bulbs							
				beginning bulbs							
				bulbing							
				1" bulbs							
10	Tulare, CA, 1999	Green onion, Southport White 404	70% WG	1.5" tall	0.298-0.306 [0.334-0.340]	14	6	Foliar spray/ 29.9-30.9 [335-346]	1.81 [2.03]	Latron B-1956 (4oz/100gal)	Whole plant (without roots) harvested 7 DALA.
				3-4" tall							
				3-4 leaves							
				5-6 leaves							
				6-7 leaves							
				8+ leaves							
10	Madera, CA, 1999	Green onion, K-99 Bunching	70% WG	onions emerging	0.299-0.311 [0.335-0.348]	14	6	Foliar spray/ 29.9-31.1 [335-348]	1.83 [2.05]	Latron B-1956 (6oz/100gal)	Whole plant (without roots) harvested 7 DALA.
				immature onions							
				small onions							
				medium onions							
				onions maturing							
				mature onions							

Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formulation	Application Timing	Application Rate (lb ai/A) [kg ai/ha]	Re-treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [l/ha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
Onion, dry bulb											
1	Lehigh, PA, 1999	Bulb onion, Stuttgarter	70% WG	3-7" tall	0.300-0.310 [0.336-0.347]	37635	6	Foliar spray/ 22.0-22.7 [246-254]	1.82 [2.04]	Induce (0.25%, v:v)	Bulbs harvested 7 DALA.
				6-14" tall							
				4-7 leaves							
				5-8 leaves							
				8-10 leaves							
				8-10 leaves, maturing							
6	Uvalde, TX, 1999	Bulb onion, Cimarron	70% WG	~1" diameter	0.292-0.302 [0.327-0.338]	37634	6	Foliar spray/ 21.4-22.1 [240-248]	1.79 [2.00]	Induce (0.25%, v:v)	Bulbs harvested 7 DALA.
				1" diameter							
				2-3" diameter							
				2-4" diameter							
				4" bulbs							
				mature							
8	Armstrong, TX, 1999	Bulb onion, Vega	70% WG	2-3 leaves	0.300 [0.336]	14-15	6	Foliar spray/ 22.9-24.5 [256-274]	1.80 [2.02]	Activate Plus (1pt/100gal)	Bulbs harvested 7 DALA.
				2-3 leaves							
				3-5 leaves							
				2" diameter							
				3" diameter							
				4" diameter							

Table 1.2.2. Crop and Field Trial Information.

EPA Region	Location (County, State, Year)	Crop, Variety	Formulation	Application Timing	Application Rate (lb ai/A) [kg ai/ha]	Re-treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [l/ha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
10	Tulare, CA, 1999 (decline study)	Bulb onion, Red Cerole	70% WG	~1-2" bulbs	0.299-0.302 [0.335-0.338]	14	6	Foliar spray/ 30.0-30.5 [336-342]	1.81 [2.03]	Latron B-1956 (4oz/100gal)	Bulbs harvested 0, 7, 14, 21, and 28 DALA.
				~1-2" bulbs							
				2" bulbs							
				2-3" bulbs							
				2-3" bulbs							
				mature							
10	Madera, CA, 1999	Bulb onion, Blanco Duro	70% WG	6-8" onions	0.296-0.308 [0.332-0.345]	14	6	Foliar spray/ 29.6-30.8 [332-345]	1.81 [2.03]	Latron B-1956 (6oz/100gal)	Bulbs harvested 7 DALA.
				5-8 leaves							
				small bulbs							
				medium bulbs							
				medium-large bulbs							
				large bulbs							
11	Jefferson, OR, 1999	Bulb onion, Yellow Danver	70% WG	5 leaves	0.300-0.310 [0.336-0.347]	14-15	6	Foliar spray/ 29.0-31.3 [325-351]	1.83 [2.05]	R-11 (1pt/100gal)	Bulbs harvested 7 DALA.
				8 leaves							
				12-16" tall							
				2.5-3" diameter							
				3" diameter							
				2-3" diameter							

1.3. Post-harvest Procedures

A single untreated and duplicate treated samples of green onions (whole plants without roots) and dry bulb onions were harvested from each field trial. Specific harvesting procedures were not described; however, each bulb onion sample consisted of at least 12 large bulbs or 24 small bulbs, and each green onion sample consisted of at least 24 whole plants; sample weights were ≥4.4 lbs. Additional samples of dry bulb onions were collected from the California trial (Tulare County) at various time intervals for residue decline samples. Samples were bagged and stored frozen (temperature not specified) on the day of harvest. Samples were shipped frozen within 0-22 days of harvest to BASF Agricultural Products Center (Research Triangle Park, NC) for analysis.

Table 1.3.1. Summary of Storage Conditions

Matrix	RAC	Storage Temperature (°C) at Analytical Laboratory	Duration
Onion, green	whole plant (without roots)	< -10	106-186 days (3.5-6.1 months)
Onion, dry bulb	bulb	< -10	78-170 days (2.6-5.6 months)

1.4. Analytical Methods

Samples of onion (green and dry bulb) were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plant commodities. Briefly, onion samples were extracted with methanol:water (70:30, v:v) and filtered. An aliquot of the filtrate was cleaned up using C18 solid phase extraction. Residues were eluted with dichloromethane. The eluate was evaporated and 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 0.050 ppm for the residues of BAS 510 F in/on green and bulb onions. The concurrent recovery results obtained are presented in Table 2.1 below.

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.

Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD
Onion, green	0.050, 1.0	85, 98, 102	95 ± 9
Onion, dry bulb	0.050, 1.0	76, 79, 88, 100	86 ± 11

Table 2.2. Residue Data from Crop Field Trials in Bulb Vegetables (green and dry bulb onions) with BAS 510 F.

Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
Onion, green						
Uvalde, TX, 1999	Texas Early White	whole plant (without roots)	70% WG	1.82 [2.04]	7	2.51, 2.94
Tulare, CA, 1999	Southport White 404	whole plant (without roots)	70% WG	1.81 [2.03]	7	1.84, 2.94
Madera, CA, 1999	K-99 Bunching	whole plant (without roots)	70% WG	1.83[2.05]	7	1.06, 1.19
Onion, dry bulb						
Lehigh, PA, 1999	Stuttgarter	bulbs	70% WG	1.82 [2.04]	7	0.079, 0.128
Uvalde, TX, 1999	Cimarron	bulbs	70% WG	1.79[2.00]	7	0.088, 0.100
Armstrong, TX, 1999	Vega	bulbs	70% WG	1.80[2.02]	7	0.099, 0.153
Tulare, CA, 1999 (decline study)	Red Cerole	bulbs	70% WG	1.81[2.03]	0	0.695, 0.793
					7	0.185, 0.240
					14	0.054, 0.102
					21	0.083, 0.132
					28	0.110, 0.168
Madera, CA, 1999	Blanco Duro	bulbs	70% WG	1.81[2.03]	7	0.826, 1.03
Jefferson, OR, 1999	Yellow Danver	bulbs	70% WG	1.83[2.05]	7	0.026, 0.061

Table 2.3. Summary of Residue Data from Crop Field Trials in Bulb Vegetables with BAS 510 F.

Commodity	Total Application Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)				
			Minimum	Maximum	HAFT	Mean (median)	Std. Dev.
Onion, green	1.81-1.83	7	1.06	2.94	2.72	2.08 (2.18)	0.841
Onion, dry bulb	1.79-1.83	7	0.026	1.03	0.929	0.251 (0.114)	0.325

3. Discussion

3.1. Methods

Bulb and green onions were harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at ~0.3 lb ai/A/application (0.336 kg ai/ha/application), with 13- to 15-day retreatment intervals, for a total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha). Applications were made using ground equipment in a spray volume of 21.4-31.3 gal/A (240-351 l/ha) of water with a spray adjuvant added. In one trial (Tulare County, CA), additional dry bulb onion samples were collected at 0, 7, 14, 21, and 28 days following treatment to evaluate residue decline. It was noted that the 70% BAS 510 F WG formulation used in the field trials also contained another experimental active ingredient (BAS 500 F; pyraclostrobin) as part of the tank-mix. Data for the BAS 500 F active ingredient were submitted separately.

Three green onion trials were conducted in Regions 6 (one trial) and 10 (two trials) and six dry bulb onion trials were conducted in Regions 1 (one trial), 6 (one trial), 8 (one trial), 10 (two trials), and 11 (one trial). The number and location of field trials conducted for green and dry bulb onions are in accordance with the EPA's guidance requirements (OPPTS 860.1500, Tables 2, 5, and 6). The number and location of the trials does not satisfy the PMRA data requirements (Dir 98-02). A total of four additional residue trials in dry bulb onions (2 trial carried out in zone 5 and two trials carried out in zone 5B) and 2 additional residue trial in green onions (one trial in each of 5 and 5B) are required. It should be noted that these trials are needed to support both the use of this chemical on this crop group but also to support the residue levels resulting in rotated crops from the use of this chemical in any crop.

Residues of BAS 510 F in/on onions (green and dry bulb) were quantitated using a validated LC/MS/MS method D9908, the data collection method for plant commodities. Storage stability data (refer to the DER for MRID 45405109) in five diverse matrices are available to support the storage conditions and intervals of samples from the submitted onion field trials.

3.2. Results

In green onions, residues of BAS 510 F were 1.06-2.94 ppm in/on samples harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at 0.298-0.314 lb ai/A/application (0.334-0.352 kg ai/ha/application), for a total rate of 1.81-1.83 lb ai/A (2.03-2.05 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on three samples of untreated green onions. Aside from below-normal rainfall at the Texas trial site and one of the California trial sites, no abnormal weather, environmental conditions or agricultural practices were noted during the green onion field trials. Irrigation was employed at all of the green onion field trials.

In dry bulb onions, residues of BAS 510 F were 0.026-1.03 ppm in/on samples harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at 0.292-0.310 lb ai/A/application (0.327 0.347 kg ai/ha/application), for a total rate of 1.79-1.83 lb ai/A (2.00-2.05

kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on six samples of untreated dry bulb onion. The residue decline data for dry bulb onion demonstrated that residues of BAS 510 F generally declined with longer posttreatment intervals. Aside from above-normal temperatures at the Pennsylvania trial site, and below-normal rainfall at one Texas trial site and one California trial site, no abnormal weather, environmental conditions or agricultural practices were noted during the dry bulb onion field trials. Irrigation was employed at all of the dry bulb onion field trials.

Residue data from the current submission are acceptable to fulfill the EPA's crop field trial data requirements for the bulb vegetable crop group (Crop Group 3). The submitted residue trials do not meet the requirements set out by the PMRA. A total of five additional trials (3 trials carried out in zone 5 and two trials carried out in zone 5B) will be needed to support a full registration.

4. Deficiencies

None for US registration. The submitted residue trials do not meet the requirements set out by the PMRA. A total of five additional trials (3 trials carried out in zone 5 and two trials carried out in zone 5B) will be needed to support a full registration in Canada.

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.