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 No.: 1F06313

Citation: 45405114 Haughey, D.; Abdel-Baky, S. (2000) The Magnitude of BAS 510 F Residues in Strawberries: Final Report: Lab Project Number: 63910: 2000/5227: 99157 (PA/1). Unpublished study prepared by BASF Corporation. 50 p.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 strawberries. Eight strawberry trials were conducted in 1999 in US Regions 1 (1 trial; PA), 2 (1 trial; NC), 3 (1 trial; FL), 5 (1 trial; MI), 10 (3 trials; CA), and 12 (1 trial; OR). The number and location of field trials satisfy the US EPA's data requirement with respect to the geographic representation of residue data for strawberries. Three of the eight trials were conducted in US regions that are common within

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Canada, leaving a deficit of two trials required to fulfill the PMRAs zonal requirements; however, based on the magnitude of the residues observed in the various trials and the rapid dissipation of residues, the PMRA will not require additional residue trials.

At each test location, the 70% WG formulation of BAS 510 F was applied as a foliar spray five times at ~0.37 lb ai/A/application (0.41 kg ai/ha/application), with a 6- to 8-day retreatment interval, for a total rate of 1.81-1.89 lbs ai/A (2.02-2.12 kg ai/ha/season); a spray adjuvant and the ai pyraclostrobin were included in the tank mix. Mature samples were collected at a 0- or 1-day post-treatment interval. In one strawberry field trial, additional samples were collected at 7, 14, 21, and 28 days following treatment to evaluate residue decline.

Residues of BAS 510 F in/on strawberries were quantitated using a validated LC/MS/MS method (D9908), the data collection method for plant commodities. Acceptable concurrent method validation data for strawberries were included in the submission. Storage stability data (refer to the DER for MRID 45405109) are available to support the 152 day (5 month) storage interval for the samples in this study.

At the applied total rate of 1.81-1.89 lbs ai/A (2.02-2.12 kg ai/ha/season) , the range of BAS 510 F residues in/on treated mature strawberry samples was 0.16-1.16 ppm. The residue decline data for strawberries indicated that BAS 510 F residues decreased at longer post-treatment intervals with a half life of approximately 15 days and substantial dissipation of residues by approximately 30 days. Residues decreased from about 1 ppm on the day of final application to about 0.15 ppm 28 days later.

Residue data from the current submission are acceptable to fulfill US EPA crop field trial data requirements for strawberries in association with this use pattern. Although the data do not completely fulfill the PMRA's residue data requirements, based on the magnitude of the residues observed in the various trials and the rapid dissipation of the residue, the PMRA will not require additional residue trials as a condition of registration in Canada.

GLP Compliance

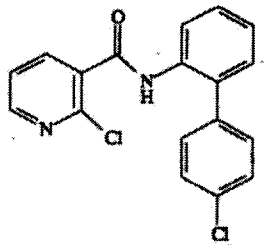
Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No GLP deviations were reported which would impact the study results or their interpretation.

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
Structure:



BAS 510 F

1.2. Trial Locations

TABLE B.1.2. Trial Numbers and Geographical Locations

Crop	Strawberries			
NAFTA Growing Regions	Submitted		Requested	
	Canada	U.S.	Canada	U.S.
1	1	1	1	1
1A				
2		1		1
3		1		1
4				
5	1	1	1	1
5A			1	
5B			1	
6				
7				
7A				
8				
9				
10		3		3
11				
12	1	1	1	1
13				
14				
15				
16				
17				
18				
19				
20				
21				
Total Trials	3	8	5	8

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) [l/ha]	Total Applic. Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants [metric]	Harvest Procedures
1	Montgomery, PA, 1999	Strawberry, Earliglow	70% WG	early bloom	0.36-0.37 [0.39-0.41]	7-8	5	Foliar spray/ 98.2-100.4 [918-939]	1.83 [2.05]	Induce (0.125%, v:v)	Strawberries harvested 0 days after last application (DALA).
				mid-bloom							
				late bloom fruit set							
				fruit maturing							
				early maturity							
2	Wayne, NC, 1999	Strawberry, Chandler	70% WG	bloom, immature fruit	0.37 [0.41]	7	5	Foliar spray/ 24.8-25.1 [232-235]	1.85 [2.03]	Induce (0.25%, v:v)	Strawberries harvested 0 DALA.
				flowering, immature fruit							
				flowering, immature fruit							
				immature/mature fruit							
				immature/mature fruit							
3	Alachua, FL, 1999	Strawberry, Camarosa	70% WG	flowering/ fruit	0.37-0.38 [0.41-0.43]	7	5	Foliar spray/ 39.9-40.8 [373-381]	1.86 [2.08]	X-77 (0.125%, v:v)	Strawberries harvested 0 DALA.
				flowering/ fruit							
				flowering/ fruit							
				flowering/ fruit							
				fruit production							
5	Ottawa, MI, 1999	Strawberry, Delmarvel	70% WG	early bloom	0.37 [0.41]	6-7	5	Foliar spray/ 30.1-30.8 [281-288]	1.86 [2.08]	Latron B-1956 (6oz/100gal) [37.2 g/100ha]	Strawberries harvested 0 DALA.
				½" fruit diameter							
				7/8" fruit diameter							
				1 1/8" fruit diameter							
				mature fruit							

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) [l/ha]	Total Applic. Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants [metric]	Harvest Procedures
10	San Diego, CA, 1999 (decline study)	Strawberry, Camarosa	70% WG	bloom, green fruit bloom, pink fruit bloom, red fruit mature fruit mature fruit	0.36-0.38 [0.39-0.43]	7-8	5	Foliar spray/ 48.5-51.5 [453.5-481]	1.83 [2.05]	Latron B-1956 (4oz/100gal) [25 g/100ha]	Strawberries harvested 0, 7, 14, 21, and 28 DALA.
10	Stanislaus, CA, 1999	Strawberry, Chandler	70% WG	bloom immature fruit fruiting fruiting fruiting	0.36 [0.39]	7-8	5	Foliar spray/ 97.5-98.7 [911-923]	1.81 [2.03]	Induce (0.125%, v:v)	Strawberries harvested 0 DALA.
10	Tulare, CA, 1999	Strawberry, Seascape	70% WG	fruit maturation fruit maturation fruit maturation fruit maturation maturity	0.37 [0.41]	6-7	5	Foliar spray/ 30.0-30.6 [281-286]	1.85 [2.07]	Latron B-1956 (2pt/100gal)	Strawberries harvested 0 DALA.
12	Marion, OR, 1999	Strawberry, Totem	70% WG	30% bloom 3/4-1"berries some red berries ripening mature	0.37-0.38 [0.41-0.43]	6-8	5	Foliar spray/ 50.6-51.3 [473-480]	1.89 [2.12]	Latron B-1956 (3oz/100gal) [19 g/100ha]	Strawberries harvested 1 DALA.

1.3. Post-harvest Procedures

A single untreated and duplicate treated samples of strawberries were harvested from each field trial. Specific harvesting procedures were not described; however, each strawberry sample weighed ≥2.2 lbs (> 1kg). Additional samples of strawberries were collected from the CA trial (San Diego 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 1-48 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
Strawberry	Fruit	<-10	97-152 days (3.2-5.0 months)

1.4. Analytical Methods

Samples of strawberries were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plant commodities. Briefly, strawberry 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 0.05 ppm for the residues of BAS 510 F in/on strawberries. Concurrent recoveries for a broad range of spiking levels were good (Table 2.1 below).

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.

Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD
Strawberry	0.05, 1.0, 5.0	83, 91, 93, 103	93 ± 8

Table 2.2. Residue Data from Crop Field Trials in Strawberries 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)
Montgomery, PA, 1999	Earliglow	Fruit	70% WG	1.83[2.05]	0	0.16, 0.22
Wayne, NC, 1999	Chandler	Fruit	70% WG	1.85[2.07]	0	0.54, 0.59
Alachua, FL, 1999	Camarosa	Fruit	70% WG	1.86[2.08]	0	0.53, 0.63
Ottawa, MI, 1999	Delmarvel	Fruit	70% WG	1.86[2.08]	0	0.30, 0.39
San Diego, CA, 1999 (decline study)	Camarosa	Fruit	70% WG	1.83[2.05]	0	0.83, 1.16
					7	0.61, 0.76
					14	0.46, 0.49
					21	0.18 , 0.24
					28	0.13 , 0.15
Stanislaus, CA, 1999	Chandler	Fruit	70% WG	1.81[2.03]	0	0.66, 0.90
Tulare, CA, 1999	Seascape	Fruit	70% WG	1.85[2.07]	0	0.53, 0.58
Marion, OR, 1999	Totem	Fruit	70% WG	1.89[2.12]	1	0.35, 0.42

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

Commodity	Total Applic. Rate (lb ai/A) [kg ai/ha]	PHI (days)	Residue Levels (ppm)				
			Minimum	Maximum	HAFT	Mean [median]	Std. Dev.
Strawberry	1.81-1.89 [2.03-2.12]	0-1	0.16	1.16	1.00	0.55 [0.535]	0.26

3. Discussion

3.1. Methods

Strawberries were harvested on the day or one day following the last of five foliar spray applications of the 70% WG formulation at ~0.37 lb ai/A/application (0.41kg ai/ha/application), with a 6- to 8-day retreatment interval, for a total rate of 1.81-1.89 lb ai/A (2.02-2.03 kg ai/ha/season). Applications were made using ground equipment in a spray volume of 24.8-100.4 gal/A (54.6-221 l/ha) of water with a spray adjuvant added. Another experimental active ingredient (BAS 500 F; pyraclostrobin) was included as part of the tank mix; data for the BAS 500 F active ingredient were submitted separately. In one trial (San Diego County, CA), additional strawberry samples were collected at 7, 14, 21, and 28 days following treatment to evaluate residue decline.

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Eight strawberry trials were conducted in Regions 1 (PA, 1 trial), 2 (NC, 1 trial), 3 (FL,1 trial), 5 (MI, 1 trial), 10 (CA, 3 trials), and 12 (OR, 1 trial). For the EPA, the number and location of field trials conducted for strawberries are in accordance with the guidance requirements (OPPTS 860.1500, Tables 1 and 5). For the PMRA, the number and trial location of the trials submitted does not match the guideline requirements (Dir 98-02, see Table 1.2).

During the course of the field trials, rainfall was reported as normal in the PA, MI, OR, and two of the CA trials, and below normal in the NC, FL, and one of the CA trials. Irrigation (sprinkler, drip, or furrow) occurred in all trials. Temperatures were reported as normal in all trials except PA, where it was above normal.

Residues of BAS 510 F in/on strawberries were quantitated using LC/MS/MS method D9908, the data collection method for plant commodities. Adequate concurrent method validation data for strawberries were included in the submission.

The maximum storage interval from harvest-to-analysis was 152 days (5 months) for strawberries. Adequate storage stability data in five diverse matrices (refer to the DER for MRID 45405109) are available to support the storage conditions and intervals of samples from the submitted strawberry field trials.

3.2. Results

Residues of BAS 510 F were 0.16-1.16 ppm in/on strawberry samples harvested on the day or one day following the last of five foliar spray applications of the 70% WG formulation (BAS 516 02 F) at 0.36-0.38 lb ai/A/application (0.40-0.43 kg ai/ha/application) with a 6- to 8-day retreatment interval, for a total rate of 1.81-1.89 lb ai/A (2.03-2.12 kg ai/ha/season). Apparent residues of BAS 510 F were less than the method LOQ (<0.05 ppm) in/on eight samples of untreated strawberries. Residue decline information obtained in California indicated that the residues of BAS 510 in strawberries decline in a linear fashion. The residue decline data fits the linear equation $y = -0.0312x + 0.938$ with a correlation coefficient (r^2)of 0.9673. The equation predicts a half life of approximately 15 days and complete dissipation of the residues by approximately 30 days. However, residues were still 0.13-0.15 ppm 28 days after the final application.

Residue data from the current submission are acceptable to fulfill US EPA crop field trial data requirements for strawberries in association with the proposed use pattern. Although the data do not completely fulfill the PMRA's residue data requirements, based on the magnitude of the residues observed in the various trials and the rapid dissipation of the residue, the PMRA will not require additional residue trials as a condition of registration in Canada.

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 Ago Research. 24 pages.