

BAS 510 F
Radish (Root and Tops)
PMRA a.i. code (CCH)

Magnitude of the Residue
OPPTS 860.1500
DACO 7.4.1

PC Code: 128008
MRID: 45623402
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:

W. T. Drew Date: 8/29/03
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DP Barcode: D281841 and D297173

Petition: 1F06313

Citations: 45623402 Haughey, D.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F Residues in Radishes: Final Report: Lab Project Number: 2001/5002572: 66694. Unpublished study prepared by BASF Agro Research. 50 pages.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 radishes. Five trials were conducted during the 2001 growing season in Regions 1 (one trial in Pennsylvania), 3 (two trials in Florida), 5 (one trial in Minnesota) and 10 (one trial in CA). The number and location of field trials satisfy the

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US EPA's data requirement with respect to the number and geographic representation of residue data for radishes as per US EPA Residue Test Chemistry Guidelines, OPPTS GLN 860.1500. The submitted field trial studies do not fully address the PMRA's residue data requirements (Dir 98-02) for radishes. Two additional trials carried out in zone 5B are required as a condition of full domestic registration in Canada. 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.

Radish roots and tops were harvested 0, 3, 6-7, and 10 days following the last of three foliar spray applications of the 70% wettable granule (WG) formulation at ~0.34 lb ai/A/application (~0.38 kg ai/ha/application), with a 6- to 8-day re-treatment interval, for a total rate of 1.02-1.07 lb ai/A (1.14-1.20 kg ai/ha/application). Applications were made using ground equipment in a spray volume of 17.4-37.1 gal/A (194.9-415.5 L/ha) of water with a spray adjuvant added.

Residues of BAS 510 F in/on radish roots and tops were quantitated using a validated LC/MS/MS method (D9908, the data collection method for plant commodities). Acceptable concurrent method validation data for radish roots and tops were included in the submission.

Storage stability data (refer to the DER for MRID 45405109) are available to support the 188-day (6.2 month) maximum storage interval for the samples in this study.

Residues of BAS 510 F in/on treated radish tops were 20.7-61.4 ppm, 2.65-43.9 ppm, 1.65-10.5 ppm, and 0.800-7.78 ppm in/on samples harvested at the 0-, 3-, 6- or 7-, and 10-day PHIs, respectively.

Residues of BAS 510 F in/on treated radish roots were 0.058-0.605 ppm, 0.063-0.463 ppm, <0.050-0.225 ppm, and <0.050-0.157 ppm in/on samples harvested at the 0-, 3-, 6- or 7-, and 10-day pre-harvest intervals (PHIs), respectively.

Residue data from the current submission are acceptable to fulfill US EPA crop field trial data requirements for radishes. In addition, residue data for radish roots from the current submission for radishes, in conjunction with the submission of satisfactory residue data for carrot roots (see DER for MRID 454051113), are acceptable to fulfill US EPA crop field trial data requirements for the root vegetable, except sugar beet, crop subgroup (**Crop Subgroup 1B** - the representative commodities of which are radish and carrot). [Note: Radish tops (leaves) are in Crop Group 2.]

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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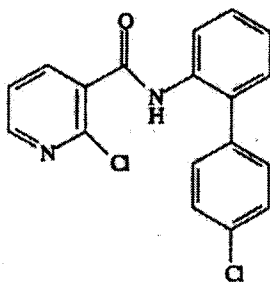
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1. Materials and Methods

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
Chemical Structure:



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1.2. Trial Locations

Crop	Potatoes			
	Submitted		Requested	
	Canada	U.S.	Canada	U.S.
1		1		1
1A				
2				
3		2		2
4				
5	1	1	1	1
5A				
5B	0		2	
6				
7				
7A				
8				
9				
10		1		1
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
Total Trials	1	5	3	5

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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
Radish											
1	Lehigh, PA, 2001	Radish; Altaglobe	70% WG	Second true leaves Bulb formation Normal harvest	0.348-0.360 [0.390-0.403]	6	3	Foliar spray/ 35.8-37.1 [401.0-415.5]	1.07 [1.20]	Penetrator Plus	Radish roots and tops harvested 0, 3, 7, and 10 days after last application (DALA).
3	Seminole, FL, 2001	Radish; Early Scarlet Globe	70% WG	14 days to harvest 7 days to harvest At harvest	0.338-0.340 [0.379-0.381]	7	3	Foliar spray/ 29.9-30.0 [334.9-336.0]	1.02 [1.14]	Triangle D-W Surfactant	Radish roots and tops harvested 0, 3, 7, and 10 DALA.
3	Martin, FL, 2001	Radish; Red Silk	70% WG	2-4 true leaves 1/4" root diameter Mature radishes	0.340-0.342 [0.381-0.383]	37444	3	Foliar spray/ 30.2-33.9 [338.2-379.7]	1.02 [1.14]	Unifilm B	Radish roots and tops harvested 0, 3, 6, and 10 DALA.
5	Freebom, MN, 2001	Radish; White Icicle	70% WG	Vegetative Root growth Mature radish	0.340 [0.381]	7	3	Foliar spray/ 17.4-18.1 [194.9-202.7]	1.02 [1.14]	Crop Oil Plus	Radish roots and tops harvested 0, 3, 7, and 10 DALA.
10	Tulare, CA, 2001	Radish; White Icicle	70% WG	Tuber sizing Tuber sizing Mature radishes	0.337-0.347 [0.377-0.389]	7	3	Foliar spray/ 30.21-34.66 [338.4-388.2]	1.03 [1.15]	Latron B-1956	Radish roots and tops harvested 0, 3, 7, and 10 DALA.

1.3. Post-harvest Procedures

A single untreated and duplicate treated samples of radish roots and tops were harvested from each field trial at each sampling interval. Specific harvesting procedures were not described; however, each root sample consisted of at least 12 large radishes or 24 small radishes and weighed a minimum of 4.4 lbs (2.0 kg), and each top sample was collected from 12 different plants and weighed at least 2.2 lbs (1.0 kg). Samples were bagged and stored frozen (temperature not specified) on the day of harvest. Samples were shipped frozen within 4-31 days of harvest to BASF Agro Research (Research Triangle Park, NC) for analysis. Radish root and top samples were analyzed within 4 days of extraction.

Table 1.3.1. Summary of Storage Conditions			
Matrix	RAC	Storage Temperature (°C) (Analytical Laboratory)	Duration
Radish	Roots (RAC)	< -10	81-188 days (2.7-6.3 months)
	Tops (RAC)		

1.4. Analytical Methods

Samples of radish roots and tops 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). 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, if necessary, subjected to further cleanup through a silica gel micro-column; residues were eluted with ethyl acetate in dichloromethane. The cyclohexane aliquot or eluate following silica gel cleanup was then evaporated to dryness and residues were redissolved in methanol:4 mM ammonium formate and 0.1% formic acid buffer solution (8:2, v:v) 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 radish roots and tops. Concurrent recoveries for a broad range of spiking levels are summarized below (Table 2.1).

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.			
Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery \pm SD (%)
Radish roots	0.050, 1.00	76, 82, 82, 82, 84, 84, 86, 91, 99, 116	88 \pm 12
Radish tops	0.050-80.0	75, 79, 90, 94, 106, 106, 106, 108, 108, 154 ¹	97 \pm 13

¹ Determined to be an outlier due to contamination in the control sample; therefore, this recovery value was not included in the mean calculation.

Table 2.2. Residue Data from Crop Field Trials in Radishes 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)
Radish Roots						
Lehigh, PA, 2001	Radish; Altaglobe	Roots	70% WG	1.07 [1.20]	0	0.596, 0.605
					3	0.427, 0.463
					7	0.197, 0.225
					10	0.153, 0.157
Seminole, FL, 2001	Radish; Early Scarlett Globe	Roots	70% WG	1.02 [1.14]	0	0.384, 0.402
					3	0.246, 0.338
					7	0.143, 0.180
					10	0.117, 0.121
Martin, FL, 2001	Radish; Red Silk	Roots	70% WG	1.02 [1.14]	0	0.147, 0.195
					3	0.203, 0.213
					6	0.118, 0.124
					10	0.074, 0.092
Freeborn, MN, 2001	Radish; White Icicle	Roots	70% WG	1.02 [1.14]	0	0.058, 0.076
					3	0.123, 0.154
					7	<0.050, <0.050
					10	<0.050, <0.050
Tulare, CA, 2001	Radish; White Icicle	Roots	70% WG	1.03 [1.15]	0	0.100, 0.118
					3	0.063, 0.108
					7	0.083, 0.086
					10	<0.050, 0.063
Radish Tops						
Lehigh, PA, 2001	Radish; Altaglobe	Tops	70% WG	1.07 [1.20]	0	22.8, 24.5
					3	2.63, 2.72
					7	1.65, 1.67
					10	0.80, 0.92
Seminole, FL, 2001	Radish; Early Scarlett Globe	Tops	70% WG	1.02 [1.14]	0	48.3, 61.4
					3	31.1, 43.9
					7	4.19, 4.39
					10	1.11, 1.37
Martin, FL, 2001	Radish; Red Silk	Tops	70% WG	1.02 [1.14]	0	26.2, 33.0
					3	5.79, 6.46
					6	4.08, 4.87
					10	2.33, 2.99

Location (County, State, Year)	Crop; Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
Freeborn, MN, 2001	Radish; White Icicle	Tops	70% WG	1.02 [1.14]	0	20.7, 20.7
					3	7.11, 8.51
					7	6.41, 7.69
					10	2.81, 4.47
Tulare, CA, 2001	Radish; White Icicle	Tops	70% WG	1.03 [1.15]	0	24.4, 25.8
					3	11.2, 13.8
					7	10.5, 10.5
					10	6.56, 7.78

Commodity	Total Application Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)				
			Minimum	Maximum	HAFT	Mean [Median]	Std. Dev.
Radish roots	1.02-1.07	0	0.058	0.605	0.601	0.268 (0.212)	0.212
		3	0.063	0.463	0.445	0.234 (0.208)	0.136
		37413	<0.050	0.225	0.211	0.126 (0.121)	0.061
		10	<0.050	0.157	0.155	0.093 (0.083)	0.042
Radish tops	1.02-1.07	0	20.7	61.4	54.9	30.79 (25.15)	13.5
		3	2.65	43.9	37.5	13.33 (7.81)	13.5
		37413	1.65	10.5	10.5	5.60 (4.63)	3.17
		10	0.8	7.78	7.17	3.11 (2.57)	2.44

3. Discussion

3.1. Methods

In studies conducted in 2001, radish roots and tops were harvested 0, 3, 6-7, and 10 days following the last of three foliar spray applications of the 70% WG formulation at approximately 0.34 lb ai/A/application (0.38 kg ai/ha/application), with a 6- to 8-day re-treatment interval, for a

total rate of 1.02-1.07 lb ai/A (1.14-1.20 kg ai/ha). Applications were made using ground equipment in a spray volume of 17.4-37.1 gal/A (194.9-415.5 L/ha) of water with a spray adjuvant added.

Five radish trials were conducted in Regions 1 (one trial in Pennsylvania), 3 (two trials in Florida), 5 (one trial in Minnesota) and 10 (one trial in CA). For the EPA, the number and location of field trials conducted for radishes are in accordance with the guidance requirements (US EPA Residue Test Chemistry Guidelines, OPPTS 860.1500, Tables 1 and 5). For the PMRA, the number and location of the trials submitted does not match the guideline requirements (Dir 98-02, see Table 1.2). Two additional trials carried out in zone 5B are required.

Residues of BAS 510 F in/on radish roots and tops were quantitated using LC/MS/MS method D9908, the data collection method for plant commodities.

Maximum storage intervals of crop samples from harvest to analysis were 188 days (6.2 months) for radish roots and tops. 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 radish field trials.

3.2. Results

In radish roots, residues of BAS 510 F were 0.058-0.605 ppm, 0.063-0.463 ppm, <0.050-0.225 ppm, and <0.050-0.157 ppm in/on samples harvested 0, 3, 6-7, and 10 days, respectively, following the last of three foliar spray applications of the 70% WG formulation at 0.337-0.360 lb ai/A/application (0.377-0.403 kg ai/ha/application), for a total rate of 1.02-1.07 lb ai/A (1.14-1.20 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on 20 samples of untreated radish roots. Residue decline information obtained for radish roots from the five trials was pooled. Analysis of this data set indicates that BAS 510 F residues in radishes decline in a linear fashion. Using average values for each PHI, the residue decline data fits the linear equation $y = -0.019x + 0.2726$ with a correlation coefficient (r^2) of 0.9526. The equation predicts a half life of approximately 8 days and complete dissipation of the residues in radish roots by approximately 15 days.

In radish tops, residues of BAS 510 F were 20.7-61.4 ppm, 2.65-43.9 ppm, 1.65-10.5 ppm, and 0.800-7.78 ppm in/on samples harvested 0, 3, 6-7, and 10 days, respectively, following the last of three foliar spray applications of the 70% WG formulation at 0.337-0.360 lb ai/A/application (0.377-0.403 kg ai/ha/application), for a total rate of 1.02-1.07 lb ai/A (1.14-1.20 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on 20 samples of untreated radish tops. The residue decline data for radish tops indicate that residues of BAS 510 F significantly decreased at the 3-day PHI and generally continued to decrease at longer post-treatment intervals. Residue decline information obtained for radish tops from five trials was pooled. Analysis of this data set indicates that BAS 510 F residues in radishes decline in a linear fashion. Using average values for each PHI, the residue decline data fits the linear equation $y = -2.6693x + 26.216$ with a correlation coefficient (r^2) of 0.8543. The equation predicts a half

life of approximately 5 days and complete dissipation of the residues in radish tops by approximately 10 days. However, we note that residues up to 7.8 ppm remained after 10 days.

Aside from above-normal rainfall at the Minnesota and one of the Florida trial sites, and below-normal rainfall at the Pennsylvania trial site, no abnormal weather, environmental conditions or agricultural practices were noted during the radish field trials. Irrigation was used to supplement rainfall at all of the radish field trials except the trial in Minnesota.

Residue data from the current submission are acceptable to fulfill US EPA crop field trial data requirements for radishes. In addition, residue data for radish roots from the current submission for radishes (in conjunction with submission of satisfactory residue data for carrots; see DER for MRID 45405113 are acceptable to fulfill crop field trial data requirements for the root vegetable, except sugar beet, crop subgroup (Crop Subgroup 1B - representative commodities are radish and carrot). [Note: Radish tops (leaves) are in crop group 2.]

Although the zonal requirements for Canada have not been fully met for radishes, sufficient data are available to support a temporary domestic registration in Canada, pending submission of two additional trials on radishes to be carried out in zone 5B.

4. Deficiencies

None for a US registration.

The submitted field trial studies do not fully address the PMRA's residue data requirements (Dir 98-02) for radishes. Two additional trials carried out in zone 5B are required as a condition of full domestic 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 pages.