Magnitude of the Residue OPPTS 860.1500

DACO 7.4.1

PC Code: 128008 MRID: 45405123

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 T. Drew, Chemist

Reviewer

RAB2/HED (7509C)

R. Loranger Date: 8/15/03

Richard A. Loranger Branch Senior Scientist RAB2/HED (7509C) 4 Sheremat Date: 16/7/03

Tamara Sheremata, Evaluator

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FREASHED, PMRA

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FREAS, HED, PMRA

DP Barcode: D278386

Petition:

1F06313

Citation:

45405123 Wofford, J.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F

Residues in Potato: Final Report: Lab Project Number: 64126: 2001/5000879: 2000161. Unpublished study prepared by BASF Agro Research. 63 pages.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.

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Executive Summary

BASF Corporation has submitted field trial data on potatoes. Sixteen potato trials were conducted in Regions 1 (one trial each in New Jersey and Pennsylvania), 2 (one trial in North Carolina), 3 (one trial in Florida), 5 (two trials in North Dakota and one each in Minnesota and Wisconsin), 9 (one trial in Colorado), 10 (one trial in California), and 11 (two trials each in Idaho, Oregon and Washington). The number and location of field trials satisfy the US EPA data requirement with respect to the geographic representation of residue data for potatoes.

For the PMRA, the number and location of the trials submitted does not match the guideline requirements (Dir 98-02, Table B.1.2). Six of the sixteen trials were conducted in zones which are common between the US and Canada. As the residues were consistently below the LOQ, no additional residue trials are required.

At each test location, the 70% WG formulation of BAS 510 F was applied two times as a foliar spray at approximately 0.45 lb ai/A/application (0.50 kg ai/ha/application), with a 13- to 15-day re-treatment interval, for a total rate of 0.87-0.92 lb ai/A (0.97-1.03 kg ai/ha). Mature potato tubers were harvested 29-30 days following the last application. In two trials, potato tuber samples were collected at 10, 20/21, 30, 40/41, and 49/51 days following treatment to evaluate residue decline.

An additional test plot was treated at an exaggerated rate at one test trial conducted in WA to generate RAC samples with quantifiable residues for processing. Mature potato tubers were harvested 30 days following the last of two foliar spray applications of the 70% WG formulation at approximately 2.25 lb ai/A/application (2.52 kg ai/ha), with a 14-day re-treatment interval, for a total rate of 4.50 lb ai/A (5.04 kg ai/ha) (5x the rate used in the corresponding field trials).

Residues of BAS 510 F in/on potato tubers were quantitated using a validated LC/MS/MS method (D9908, the data collection method for plant commodities). Acceptable concurrent method validation data for potatoes were included in the submission. Storage stability data (refer to the DER for MRID 45405109) are available to support the 136 day (4.5 months) storage interval for the samples in this study.

At the applied total rates of 0.87-0.92 lb ai/A (0.97-1.03 kg ai/ha) and 2.23-2.27 lb ai/A (2.50-2.54 kg ai/ha), BAS 510 F residues were below the LOQ (<0.050 ppm) in/on all treated potato tuber samples. The residue decline data for potato tubers did not demonstrate any trends in BAS 510 F residues at longer post-treatment intervals because residues were below the LOQ (<0.050 ppm) at all sampling intervals.

Residue data from the current submission are acceptable to fulfill US EPA crop field trial data requirements for potatoes. In addition, residue data from the current submission for potatoes are acceptable to fulfill crop field trial data requirements for the tuberous and corm vegetable crop subgroup (Crop Subgroup 1C). No additional residue trials are required by the PMRA.

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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:

BAS 510 F

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1.2. Trial Locations

TABLE B.1.2. T	rial Numbers ar	d Geographical	Locations	
Crop		Pota	itoes	
NAFTA Growing Regions	Subm	itted	Requ	sested
	Canada	U.S.	Canada	U.S.
1	2	2	3 ::	2
1A	. 0		4	
2		I		1
3		1		I .
4				
5	4	4	3	4
5A	0	* .	1	
5B	0		1 y z z z	No. of Society
.6				
*				
7.4	0		1	
8		·		
9	~	ı		1
10		1		1
11		6		6
12	0		1	
13				
14	0	, according to the second seco	2	^
15				
16				
17				
18				
19				
20				
21				· · ·
Total Trials	6 .	16	16	16

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BAS 510 F
Potato (Tuber)
PMRA a.i. code (CCH)

BAS 510 F
OPPTS 860.1500
OPPTS 860.1500

PC Code: 128008 MRID: 45405123 Submission #2001-1027, 1036, 1043

Table 1	Table 1.2.2. Crop and Field Trial Information.	old Trial In	formation.								
EPA Region	EPA Location Region (County, State, Year)	Crop: Variety	Formu- lation	Application Timing	Application Rate (lb ai/A) [kg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Appliation. Volume (GPA) [L/ha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
-	Lehigh, PA, 2000	Potato, Andover	70% WG	70% WG Growth stage 15, 4-12" height Early bloom, 18-24" height	0.457-0.464 [0.512- 0.520]	51	2	Foliar spray/ 35.6-36.1 [398.7-404.3]	0.921	X-77 (80z/100 gal) [(0.59 g/L]	Potatoes harvested 30 days after last application (DALA).
_	Hunterdon, NJ, 2000 (decline study)	Potato, Reba	70% WG	Early tuber bulk, 24-30" height Tuber bulk, 15-18" height	0.448-0.464 [0.502- 0.520]	13	2	Foliar spray/ 31.5-32.5 [352.8-364.0]	0.912	Agridex (0.125%, v.v)	Potatoes harvested 10, 21, 30, 41, and 49 days DALA.
2	Wake, NC, 2000	Potato, Atlantic	70% WG	Plants 18" tall, flowering Plants 13" tall, post bloom	0.452-0.453 [0.506- 0.507]	. 14	2	Foliar spray/ 30.2 [338.2]	0.905	Induce (0.25%, v:v)	Potatoes harvested 30 days DALA.
.3	Seminole, FL, 2000	Potato, Red Pontiac	70% WG	Plants 14" tall Plants 16" tall	0.450-0.454 [0.504- 0.509]	SI ·		Foliar spray/ 30.0-30.3. [336.0-339.4]	0.904	Diamond R Activator (1pv/100gal) [1.48 mL/L]	Potatoes harvested 29 days DALA.
٧.	Grand Forks, ND, 2000	Potato, Atlantic	70% WG	Plants 18-20" tall, BBCH 34 Plants 18-20" tall, tuber bulk, BBCH 45	0.447-0.457	14	2	Foliar spray/ 19.9-20.3 [222.9-227.4]	0.903 [1.01]	Bond (0.25%, v:v)	Potatoes harvested 30 days DALA.

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BAS 510 F Potato (Tuber) PMRA a.i. code (CCH)

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Table I	Table 1.2.2. Crop and Field Trial Information.	old Trial In	formation.								
EPA Region	Location (County, State, Year)	Crop; Variety	Formal Intion	Application Timing	Application Rate (Ib ai/A) [kg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Appliation. Volume (GPA) [L/ha]	Total Application Rate (1b ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
w	Steele, ND, 2000	Potato, Atlantic	70% WG	Plants 18-20" tall, tuber bulk, BBCH 34 Plants 22-24" tall, tuber bulk, BBCH 45	0.439-0.447 [0.492- 0.501]	14	2	Foliar spray/ 19.5-19.8 [218.4-221.8]	0.886 [0.992]	Bond (0.25%, v.v)	Potatoes harvested 30 days DALA.
~	Pepin, WI, 2000	Potato, Russet Burbank	70% WG	Plants 20" tail, late bloom Plants 20" tall, post bloom	0.455-0.459 [0.510- 0.514]	13	2	Foliar spray/ 20.2-20.4 [226.2-228.5]	0.914	Latron CS-7 (24oz/100gal) [1.78 g/L]	Potatoes harvested 29 days DALA.
v	Wabasha, MN, 2000	Potato, Atlantic Newleaf	70% WG	Plants 22", late bloom Plants 12" tall, vine recumbence	0.450-0.459 [0.504- 0.514]	13	2	Foliar spray/ 20.0-20.4 [224.0-228.5]	0:909	Latron CS-7 (24oz/100gal) 1.78 g/L.]	Potatoes harvested 30 days DALA.
0	Custer, CO, 2000	Potato, Norkotah	70% WG	Plants 20" tall, 3-4 ounce tubers Plants 20" tall, tuber bulking	0.448-0.456 [0.502- 0.511]	4	2	Foliar spray/ 24.8-25.2 [277.8-282.4]	0.904	Activate Plus (0.25%, v.v)	Potatoes harvested 30 days DALA.
2	Tulare, CA, 2000 (decline study)	Potato, Russet	70% WG	Plants 12-14" tall, bloom Plants 12-14" tall, post bloom	0.449-0.450	15	64	Foliar spray/ 30.4 [340.5]	0.898	Non-ionic surfactant (4oz/100gal) [0.30 g/L]	Potatoes harvested 10, 20, 30, 40, and 51 days DALA.

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Table 1.	Table 1.2.2. Crop and Field Trial Information.	eld Trial In	formation.								
EPA Region	Location (County, State, Year)	Crop; Variety	Formu- lation	Application Timing	Application Rate (1b ai/A) [kg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Appliation. Volume (GPA) [L/ha]	Total Application Rate (lb ai/A)	Tank Mix Adjuvants	Harvest Procedures
****	Jefferson, OR, 2000	Potato, Russet Norkotah	70% WG	Growth stage 77, crop height 24" Growth stage 85, crop height 24"	0.456-0.458 [0.511- 0.513]	*	2	Foliar spray/ 18.1-18.2 [202.7-203.8]	0.913 [1.02]	Non-ionic surfactant (4oz/100gal) [0.30 g/L]	Potatoes harvested 30 days DALA.
	Payette, ID, 2000	Potato, Russet Burbank	70% WG	Plants 22" tall, tuber bulking Plants 22" tall, tuber bulking	0.424-0.444 [0.475- 0.497]	14	2	Foliar spray/ 28.2-29.6 [315.8-331.5]	0.868	Wilbur-Ellis R-11 (1pv/100gal) [1.48 mL/L]	Potatoes harvested 30 days DALA.
-	Washington, ID, 2000	Potato, Russet Burbank	0% %0/	Plants 22" tall, tuber bulking Plants 18" tall, maturation	0.440-0.450 [0.493- 0.504]	14	2	Foliar spray/ 29.7-30.0 [332.6-336.0]	0.890	Wilbur-Ellis R-11 (1pt/100gal) [1.48 mL/L]	Potatoes har vested 30 days DALA.
	Grant, W.A. 2000	Potato, Newleaf Plus	70% WG	Plants 33" height, BBCH 75 Plants 32" height, BBCH 75	0.450 [0.504] 2.23-2.27 [2.50-2.54]	4 4	8 8	Foliar spray/ 20.0-20.2 [224.0-226.2] Foliar spray/ 19.9-20.2 [222.9-226.2]	0.900 [1.01] 4.50 [5.04]	Latron B1956 (16oz/100gal) [1.19 g/L]	Potatoes harvested 30 days DALA.
****	Jefferson, OR, 2000	Potato, Norchip	70% WG	24" tall, bloom, 2" diameter tubers 24" tall, post bloom, 2.5".	0.447-0.458 [0.501- 0.513]	13	7	Foliar spray/ 19.4-22.2 [217.3-248.6]	0.906	Wilbur-Ellis R-11 (0.25%, v.v)	Potatoes harvested 29 DALA.

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Table I.	Table 1.2.2. Crop and Field Trial Information.	eld Trial In	formation.									
EPA Region	Location (County, State, Year)	Crop; Variety	Formu- lation	Formu- Application Timing Application lation Rate (1b ai/A) [kg ai/ha]	Application Rate (1b ai/A) [kg ai/ha]	Re- treatment Intervals (days)	Re- Number of reatment Applications Intervals (days)	Application Method/ Appliation. Volume (GPA) [L/ha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures	
# **	Grant, WA, 2000	Potato, Newleaf Plus	70% WG	Potato, 70% WG Plants 33" tall, Newleaf bulking Plus 60% tuber mass	0.450-0.452 [0.504- 0.506]	14	~	Foliar spray/ 20.2-20.7 [226.2-231.8]	Z06'0	Latron B1956 (160z/100gal) [1.19 g/L]	Potatoes harvested 30 days DALA.	

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1.3. Post-harvest Procedures

A single untreated and duplicate treated samples of mature potato tubers were harvested 29-30 days following the last application from each field trial; each sample consisted of at least 24 tubers or 12 large tubers. Additional samples of potato tubers were collected from the California and New Jersey trials at various time intervals for residue decline samples. In addition, a bulk-sized sample (weighing at least 170 lbs, or 76.9 kg) of potato tubers was collected from the Washington (Grant County) trial treated at an exaggerated rate to generate samples for processing. All samples of potato tubers (except the bulk samples) were bagged and stored frozen (temperature not specified) on the day of collection. Field samples were shipped frozen within 0-44 days of harvest to BASF Agro Research (Research Triangle Park, NC) for analysis. RAC and bulk-sized samples of potato tubers treated at an exaggerated rate were shipped on the day of harvest under ambient conditions to BASF Agro Research and Englar Food Laboratories, Inc. (Moses Lake, WA), respectively, and placed in frozen storage until a determination was made that processing was not needed.

Table 1.3.1. Sur	nmary of Storage Co	nditions	
Matrix	RAC	Storage Temperature (°C) (Analytical Laboratory)	Duration
Potato	Tuber	<-10	11-136 days (0.4-4.5 months)

1.4. Analytical Methods

Samples of potato tubers were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plants. Briefly, samples of potato tubers 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 buffer 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 potato tubers. Concurrent recoveries for a range of spiking levels are summarized below (Table 2.1).

2. Results

Table 2.1. Sum	mary of Concurrent Ar	nalytical Method Validation.	
Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD (%)
Potato, tuber	0.050, 1.00	74, 82, 83, 85, 88, 88, 89, 91, 93, 94, 95, 99, 102, 107	91 ± 9

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Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm
Lehigh, PA, 2000	Andover	Tuber	70% WG	0.921 [1.03]	30	<0.050, <0.05
Hunterdon, NJ, 2000	Reba	Tuber	70% WG	0.912	10	<0.050, <0.05
(Decline study)	P.,			[1.02]	21	<0.050, <0.05
					30	<0.050, <0.05
					41	<0.050, <0.05
					49	<0.050, <0.05
Wake, NC, 2000	Atlantic	Tuber	70% WG	0.9 05 [1.01]	30	<0.050, <0.05
Seminole, FL, 2000	Red Pontiac	Tuber	70% WG	0.904 [1.01]	29	<0.050, <0.05
Grand Forks, ND, 2000	Atlantic	Tuber	70% WG	0.903 [1.01]	30	<0.050, <0.05
Steele, ND, 2000	Atlantic	Tuber	70% WG	0.886 [0.992]	30	<0.050, <0.05
Pepin, WI, 2000	Russet Burbank	Tuber	70% WG	0.914 [1.02]	29	<0.050, <0.05
Wabasha, MN, 2000	Atlantic Newleaf	Tuber	70% WG	0.909 [1.02]	30	<0.050, <0.05
Custer, CO, 2000	Norkotah	Tuber	70% WG	0.904 [1.01]	30	<0.050, <0.05
Tulare, CA, 2000	Russet	Tuber	70% WG	0.898	10	<0.050, <0.05
(Decline study)	۳.			[1.01]	20	<0.050, <0.05
	, s .				30	<0.050, <0.05
		₩ ,5₩ ¹			40	<0.050, <0.05
					51	<0.050, <0.05
Jefferson, OR, 2000	Russet Norkotah	Tuber	70% WG	0.913 [1.01]	30	<0.050, <0.05
Payette, ID, 2000	Russet Burbank	Tuber	70% WG	0.868 [0.972]	30	<0.050, <0.05
Washington, ID, 2000	Russet Burbank	Tuber	70% WG	0.890 [0.997]	30	<0.050, <0.05
Grant, WA, 2000	Newleaf Plus	Tuber	70% WG	0.900 [1.01]	30	<0.050, <0.05
				4.50 [5.04]	30	<0.050, <0.03

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Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
Jefferson, OR, 2000	Norchip	Tuber	70% WG	0.906 [1.02]	29	<0.050, <0.050
Grant, WA, 2000	Newleaf Plus	Tuber	70% WG	0.902	30	<0.050, <0.050

Commodity	Total Application	РН		Resid	ue Levels (j	opm)	
٠.	Rate (lb si/A)	(days)	Minimum	Maximum	HAFT	Mean [Median]	Std. Dev.
Potato tuber	0.868-0.921	29-30	<0.050	<0.050	<0.050	<0.050 [<0.050]	0.0
	4.50	30	<0.050	<0.050	<0.050	<0.050 [<0.050]	0.0

3. Discussion

3.1. Methods

Mature potato tubers were harvested 29-30 days following the last of two foliar spray applications of the 70% WG formulation at approximately 0.45 lb ai/A/application (0.50 kg ai/ha/application), with a 13- to 15-day retreatment interval, for a total rate of 0.87-0.92 lb ai/A (0.97-1.03 kg ai/ha). Applications were made using ground equipment in 18.1-36.1 gal/A (202.7-404.3 L/ha) of water with a spray adjuvant added. In two trials (California and New Jersey), potato tuber samples were collected at 10, 20/21, 30, 40/41, and 49/51 days following treatment to evaluate residue decline.

An additional plot in the Washington field trial (Grant County) was treated at an exaggerated rate to generate RAC samples with quantifiable residues for processing. Mature potato tubers were harvested 30 days following the last of two foliar spray applications of the 70% WG formulation at approximately 2.25 lb ai/A/application (2.82 kg ai/ha), with a 14-day retreatment interval, for a total rate of 4.50 lb ai/A (5.04 kg ai/ha) (5x the rate used in the corresponding field trials). Applications were made using ground equipment in 19.9-20.2 gal/A (222.9-226.2 L/ha) of water with a spray adjuvant added.

Sixteen potato trials were conducted in Regions 1 (one trial each in New Jersey and Pennsylvania), 2 (one trial in North Carolina), 3 (one trial in Florida), 5 (two trials in North Dakota and one each in Minnesota and Wisconsin), 9 (one trial in Colorado), 10 (one trial in California), and 11 (two trials each in Idaho, Oregon and Washington). For the EPA, the

number and location of field trials conducted for potatoes 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, Table B.1.2). Six of the sixteen trials were conducted in zones which are common between the US and Canada. Four additional trials will be required by the PMRA as a condition of registration. These additional trials must be carried out in zones 1 (one trial), 1A (two trials) and 14 (one trial).

Residues of BAS 510 F in/on potato tubers were quantitated using LC/MS/MS method D9908, the data collection method for plant commodities.

The maximum storage interval from harvest to analysis was 136 days (4.5 months) for potato tubers. Adequate storage stability data in five matrices (refer to the DER for MRID 45405109) are available to support the storage conditions and intervals of samples from the submitted potato field trials.

3.2. Results

Residues of BAS 510 F were below the LOQ (<0.050 ppm) in/on all potato tuber samples harvested 29-30 days following the last of two foliar spray applications of the 70% WG formulation at 0.42-0.46 lb ai/A/application (0.47-0.52 kg ai/ha/application), with a 13- to 15-day retreatment interval, for a total rate of 0.87-0.92 lb ai/A (0.97-1.03 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on 17 samples of untreated potato tubers. The residue decline data for potato tubers did not demonstrate any trends in BAS 510 F residues at longer posttreatment intervals because residues were below the LOQ (<0.050 ppm) at all sampling intervals.

In addition, residues of BAS 510 F were below the LOQ (<0.050 ppm) in/on all potato tuber samples harvested 30 days following the last of two foliar spray applications of the 70% WG formulation at an exaggerated rate (2.23-2.27 lb ai/A/application, or 2.50-2.54 kg ai/ha/application) with a 14-day retreatment interval, for a total rate of 4.50 lb ai/A (5.05 kg ai/ha) (5x the rate used in the corresponding field trials).

There was above-normal rainfall at the North Dakota, Wisconsin, Minnesota and one of the Oregon trial sites. There was below-normal rainfall at the North Carolina and Washington trial sites. Above-normal temperatures occurred at the Wisconsin and Minnesota trial sites. Aside from these cases, no abnormal weather, environmental conditions or agricultural practices were noted during the potato field trials. Irrigation was used to supplement rainfall at all of the potato field trials except the trials in Minnesota, North Dakota and one of the Idaho trials.

Residue data from the current submission are acceptable to fulfill crop field trial data requirements for potatoes for US EPA. In addition, residue data from the current submission for

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potatoes are acceptable to fulfill crop field trial data requirements for the tuberous and corm vegetable crop subgroup (Crop Subgroup 1C).

Six of the sixteen trials were conducted in zones which are common between the US and Canada. Four additional trials will be required by the PMRA as a condition of registration. These additional trials must be carried out in zones 1 (one trial), 1A (two trials) and 14 (one trial).

4. Deficiencies

None for a US registration.

Four additional Canadian field trials are required by PMRA as a condition of 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.