Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRID: 45405116

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:

Tamara Sheremata, Evaluator

William T. Drew, Chemist

Peer reviewer

Reviewer

RAB2/HED (7509C)

REAS, HED, PMRA

MOR Date: 8 Richard A. Lorander

Branch Senior Scientist

Ariff AM Section Head

RAB2/HED (7509C)

FREAS, HED, PMRA

DP Barcode: D278386

Petition:

1F06313

Citation:

45405116 Versoi, P.; Abdel-Baky, S. (2001) The Magnitude of BAS 510 F Residues in Canola: Final Report: Lab Project Number: 58645: 2001/5000048:

2000110 (ND/5). Unpublished study prepared by BASF Agro Research. 69

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 data evaluation record (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 canola seed. A total of 16 canola seed trials were conducted in the U.S. and Canada. Four U.S. canola seed trials were conducted in Regions 5 (one trial each in MN and ND), 7 (one trial in ND) and 11 (one trial in ID). Twelve Canadian canola seed trials were conducted in Region 14 in Alberta (six trials), Saskatchewan (two trials) and Manitoba (four trials). The number and location of field trials conducted for canola seed are in accordance with the study design approved by the US-EPA and BASF Corporation on 2/23/00 for a reduction in the number of canola test sites needed for a NAFTA registration. The Food Residue Exposure Assessment Section of the Health Evaluation Division (FREAS, HED) of PMRA/Canada concurred with the revised distribution and locations of the crop field trials (noted in References).

At each test location, the 70% WG formulation of BAS 510 F was applied two times as a foliar spray at approximately 0.4 lb ai/A/application (0.5 kg ai/ha/application) with a 4- to 7-day retreatment interval, for a total rate of 0.75-0.82 lb ai/A (0.84-0.92 kg ai/ha). Mature canola plants were cut 19-23 days following the last application and dried in the field for 0-9 days prior to collection of canola seed. In two trials, canola seed samples were collected at 0, 10, 20/21, 29/30, and 40 days following treatment to evaluate residue decline.

At the applied total rate of 0.75-0.82 lb ai/A (0.84-0.92 kg ai/ha), the range of BAS 510 F residues in/on treated mature canola seed samples was 0.136-3.42 ppm. The residue decline data for canola seed indicated that BAS 510 F generally did not increase with longer post-treatment intervals.

At four of the test trials, in ND (one trial), MN (one trial) and Manitoba (two trials), an additional test plot was treated at a higher rate. Mature canola plants were cut 20-22 days following the last of two foliar spray applications of the 70% BAS 510 F WG formulation at approximately 1.2 lb ai/A/application (1.3 kg ai/ha), with a 5- to 6-day retreatment interval, for a total rate of 2.38-2.43 lb ai/A (2.67-2.72 kg ai/ha). The range of BAS 510 F residues in/on treated canola seed samples was 0.575-5.10 ppm. Canola seed obtained from these field trials were also used in a processing study; refer to the processed canola seed DER reviewing MRID 45405124 for details of the study.

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

Storage stability data (refer to the DER for MRID 45405109) are available to support the 147 days (4.8 months) storage interval for the samples in this study.

Residue data from the current submission are acceptable to fulfill crop field trial data requirements for canola seed.

It is noted that crop field trial residue data for sunflower seed were also submitted by BASF (see DER of MRID 45623407). A new Oilseed crop group (Crop Group 20) will likely be established by EPA to harmonize with PMRA/Canada's Crop Group 20. The representative commodities for this crop group are rapeseed (canola varieties only) and sunflower, seed. The maximum residues from the sunflower crop field trial studies were 0.539 ppm and, as stated above, 3.42 ppm for canola seed. These maximum residues vary by more than a factor of 5x, thus rendering a crop group tolerance for the Oilseed crop group inappropriate.

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

3 of 14

1.2. Trial Locations

Crop		Canol	a (sed)	
NAFTA Growing Regions	Submitte	P	Reque	sted
	Canada	U.S.	Canada¹	U.S.¹
1	2.			-
IA .				
2				1 3
3				
4				
3		2	1	2
5A				
5B				
6				
7		1		2
7.4	^ ·			
8				
9	3			
10 .			į.	
11	1	1	l e	3
12				**************************************
13				
14	12	12	14	*
15				
16				
17				
18		•		
19				
20				
21				
Total Trials	· 16	16	16.	8

As per US EPA Residue Chemistry Test Guidelines, OPPTS 860.1500, Table 5.

²As per PMRA Dir 98-02, Residue Chemistry Guidelines, Section 9, Table 2.

³ The petitioner stated these trial numbers and geographic distribution were agreed upon for the Canola NAFTA Project in a meeting between the Agency and BASF Corporation on 2/23/00. These sites were also approved by PMRA according to correspondence with BASF dated 6/27/00.

Magnitude of the Residue OPPTS 860.1500 DACO 74.1

PC Code: 128008 MRID: 45405116 Submission #2001-1027, 1036, 1043

IET	Table 1.2.2. Crop and Field Trial Information.	rmation.								
Crop, Re	<u> </u>	Formu- lation	Application Timing	Application Rate (1b ai/A) [khg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [L/ha]	Total Application Rate (1b ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
Canola, 70% Golden Ready	<u>ڳ</u>	70% WG	Plants 40" tall, flowering, beginning pod-fill	0.397-040 [0.444- 0.449]	\$	2	Foliar spray/ 19.9-20.1 [223-225]	0.798 [0.895]	R-Way Crop Oil Concentrate	Canola seed harvested 22 days after last application (DALA).
			Plants 32" tall (lodging), end- bloom, pods filling	1.20	^	0	Foliar spray/ 20.0 [224]	2.40 [2.70]	(190A)	Canola seed harvested 22 DALA.
Carrola, 70%	<u>5</u>	70% WG	Plants 46-48" (all, 10% full-sized pod	0.372-0.380 (0.417-	5	2	Foliar spray/ 18.6-19.0	0.752 (0.842]	Prime Oil (1%, v.v)	Canola seed harvested 0, 10, 21, 30, and 40
			Plants 48-52" tall, 20-30% full-sized pod	0.426]			[208-213]	*		DALA, and field dried for 0-9 days.
Canola, 70% Hyola 401	70%	70% WG	Plants 40" tall, flowering	0.399-0.400 [0.447- 0.448]	9	2	Foliar spray/ 19.9-20.0 [223-224]	0.799	17% Crop Oil, Class (1qt/A)	Canola seed harvested 21 DALA and field dried for 5 days.
			Plants 40" tall, end of bloom	1.20-1.21 [1.34-1.36]	9	2	Foliar spray/ 19.9-20.1 [223-225]	2.41		
Canola, 70% Phoenix	70%	70% WG	Plants 44" tall, 30% of pods ripe	0.400	v	2	Foliar spray/ 19.6-20.5	0.800	Agri-dex (1qt/A)	Canola seed harvested 0, 10, 20, 29, and 40
			Plants 44" tall, 30% of pods ripe				[220-230]	. :		DALA, and field dried for 0-6 days.
Canola, L.O 709 3235	6	70% WG	Plants 31-32" tall, 95% bloom	0.395-0.396 [0.442.	v	7	Foliar spray/ 10.6	0.791	Assist Oil Concentrate	Canola seed harvested 22 DALA and field
	ı		Plants 31-32" tall, end of bloom	0.4444			6		(1%, v.v)	dried for 7 days.

Canola (Seed)
PMRA a.i. code (CCH) **BAS 510 F**

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRJD: 45405116 Submission #2001-1027, 1036, 1043

6

Table 1.2.2.		Crop and Field Trial Information	mation.								
EPA Region	Location (County, State, Year)	Crop. Variety	Formu- lation	Application Timing	Application Rate (Ib ai/A) [khg 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
-	Fairview, AB, Canada, 2000	Canola, LG 3235	70% WG	Plants 33-34" tall, 95% bloom	0.399-0.410 [0.447-	5	ы	Foliar spray/ 10.7-11.1	0.809 (0.906)	Assist Oil Concentrate	Canola seed harvested 22 DALA and field
				Plants 29-30" tail (lodging), end of bloom	0.459]			[120-124]		(1%, v:v)	dried for 7 days.
7	Leduc, AB, Canada, 2000	Canola, Agassiz	70% WG	Plants 49-50" tall, 70% full-sized pods	0.400-0.402 [0.448-	4	2	Foliar spray/ II.9	0.802 [0.898]	Merge Surfactant	Canola seed harvested 22 DALA and field
		· .		Plants 49-50" tall, nearly all pods full-	0.450]		-	3		m.L/ha)	dried for 7 days.
7	Wctaskiwin.	Canola.	70% WG	Plants 19-48" (all	0.390-0.404	5	3	Foliar spraw	0 704	Kerros	Comple poor harvested
	AB, Canada, 2000	Agassiz		(lodging), 50% full- sized pods	[0.437- 0.453]			11.4-12.0	(0.889)	Surfacturat (865	23 DALA and field dried for 6 days.
				Plants 31-32" tall (lodging), 60% full-						Application #2 only	
4	Lacombe, AB,	Canola, LG	70% WG	Plants 39-40" tall,	0.400-0.413	S	22	Foliar spray/	0.812		Canola seed harvested
				Plants 35-36" tall	0.463]			[239-248]			dried for 7 days.
				(lodging), pods beginning to ripen							
7	Red Decr, AB, Canada, 2000	Canola, LG 3235	70% WG	Plants 29-30" tall, 70% full-sized pods	0.394-0.402	6	2	Foliar spray/ 21.1-21.5	0.796	Ag-Surf (0.1%, v:v)	Canola seed harvested 20 DALA and field
				Plants 17-18" tall	0.450)			[236-241]			dried for 7 days.
				(lodging), pods beginning to ripen		š.					

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

e Residue 1500 4.1 Submissio

PC Code: 128008 MRID: 45405116 Submission #2001-1027, 1036, 1043

Table	Table 1.2.2. Crop and Field Trial Information.	eld Trial Info	rmation.			1 200					
EPA Region	EPA Location Region (County, State, Year)	Crop, Variety	Formu- lation	Application Timing	Application Rate (Ib ai/A) [khg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [L/ha]	Total Application Rate (Ib ai/A)	Tank Mix Adjuvants	Harvest Procedures
*	County 401, SK, Canada, 2000	Canola, 45A71	70% WG	Plants 43-47" tall, flowering full to nearly complete Plants 43-47" tall, end-bloom to 30% full-sized pods	0.395-0.399 [0.442- 0.447]	9	2	Foliar spray/ 11.6-11.7 [130-131]	0.794 [0.889]	Merge Surfactant (IL/ha)	Canola seed harvested 22 DALA and field dried for 6 days.
*	County 463, SK, Canada, 2000	Canola, 46A76	70% WG	Plants 57" tall, flowering full to nearly complete Plants 57" tall, 50-70% full-sized pods	0.400-0.410 [0.448- 0.459]	L	2	Foliar spray/ 11.9-12.0 [133-134]	0.810 [0.907]	Merge Surfactant (1L/ha)	Canola seed harvested 20 DALA and field dried for 6 days.
*	Whitewater, MB, Canada, 2000	Canola, Canterra 1867RR	70% WG	Plants 43.44" tall, 30% full-sized pods Plants 43.44" tall, 50% full-sized pods	0.395-0.399 [0.442- 0.447] 1.18-1.20 [1.32-1.34]	v v	2 2	Foliar spray/ 21.1-21.3 [236-239] Foliar spray/ 21.0-21.4 [235-240]	0.794 [0.889] 2.38 [2.67]	Assist Oil Concentrate (1%, v:v)	Canola seed harvested 21 DALA and field dried for 7 days.
*	Morton, MB, Canada, 2000	Canola, LG3235	70% WG	Plants 33-34" tall, 30% full-sized pods Plants 31-32" tall (lodging), 50% full-sized pods	0.401-0.404 [0.449- 0.453]	ĸ	.03	Foliar spray/ 21.4-21.6 [240-242]	0.805	Assist Oil Concentrate (1%, v:v)	Canola seed harvested 21 DALA and field dried for 4 days

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRID: 45405116 Submission #2001-1027, 1036, 1043

Table I.	Table 1.2.2. Crop and Field Trial Information.	dd Trial Info	rmation.								
Region	Location (County, State,	Crop, Variety		Application Timing	Application Rate	Re- treatment	Number of Applications	Application Method/	Total Application	Tank Mix Adjuvants	Harvest Procedures
	Year)				(lb ai/A) [khg ai/ha]	Intervals (days)		Application Volume (GPA) [L/ha]	Rate (Ib ai/A) [kg ai/ha]		
*	Minto, MB, Canada, 2000	Quest Quest	70% WG	Plants 42-44" tall, 50% full-sized pods	0.400-0.420 [0.448- 0.470]	6	2	Foliar spray/ 11.8-12.3 [132-138]	0.820 [0.898]	Merge Surfactant (117ha)	Canola seed harvested 19-20 DALA and field dried for 5-6
				Plants 40" tall 1.21-1.22 (lodging), nearly all [1.36-1.37] pods full-sized	1.21-1.22 [1.36-1.37]	6	2	Foliar spray/ 11.9-12.0 [133-134]	2.43 [2.72]		days
7	North Cypress, MB, Canada,	Canola, 45A51	70% WG	Plants 41-46" tall, 50% full-sized pods	0.400 [0.448]	7	2	Foliar spray/	0.800 [0.896]	Merge Surfactant	Canola seed harvested 19 DALA and field
	288			Plants 36" tall				(L)	Market State Control	(III)	dried for 6 days.
				(lodging), nearly all				\		·	
				pods full-sized							

1.3. Post-harvest Procedures

Canola plants were cut 19-23 days following the last application and dried in the field for 0-9 days prior to collection of canola seed. A single untreated and duplicate treated samples of canola seed were harvested from each field trial; each sample weighed at least 1.1 lbs (0.5 kg). Additional samples of canola seed were collected from the North Dakota (Grand Forks County) and Idaho (Jerome County) trials at various time intervals for residue decline samples. In addition, one or two bulk-sized samples of canola seed were collected at four trials treated at exaggerated rates to generate samples for processing. A single subsample was collected from each bulk-sized sample to obtain canola seed for a preliminary analysis to determine the need for a processing study. All samples of canola seed were bagged and stored frozen (temperature not specified) on the day of collection. Field samples were shipped frozen, within 2-52 days of harvest.

Table 1.3.1. Sun	nmary of Storage Co	nditions	
Matrix	RAC	Storage Temperature (°C). (Analytical Laboratory)	Duration
Canola	Seed	<-10	32-147 days (1.1-4.8 months)

1.4. Analytical Methods

Samples of canola seed were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plant commodities. Briefly, canola seed 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 and cleaned up further using silica gel solid phase extraction (SPE); residues were eluted from the silica gel SPE with 4% ethyl acetate in dichloromethane. The eluate was evaporated to dryness and re-dissolved 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 canola seed. Concurrent recoveries for a broad range of spiking levels are summarized below (Table 2.1).

2. Results

Table 2.1. Sun	nmary of Concurrent An	alytical Method Validation.	
Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD (%)
Canola seed	0.050-10.0	60, 71, 74, 78, 78, 79, 83, 84, 88, 98, 99, 100	83 ± 12

Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI ¹ (days)	BAS 510 F residues (ppm
Grand Forks, ND,	Quantum	Seed	70% WG	0.752	0 (0)	1.61, 1.62
2000 (decline study)				[0.842]	10 (6)	0.626, 1.34
(,			\$ 4 h	* ***	21 (9)	0.360, 0.696
	'				30 (5)	1.05, 1.08
	N				40 (0)	0.746, 1.09
McHenry, ND, 2000	Hyola 401	Seed	70% WG	0.799 [0.895]	21 (5)	0.701, 0.882
Jerome, ID,	Phoenix	Seed	70% WG	0.800	0 (6)	1.23, 1.34
2000 (decline study)	*			[0.896]	10 (0)	0.427, 0.445
			a g		20 (0)	0.447, 0.551
					29 (0)	0.451, 0.462
•	Ĺ				40 (0)	0.171, 0.221
Fairview, AB, Canada, 2000	LG 3235	Seed	70% WG	0.791 [0.886]	22 (7)	0.136, 0.215
Fairview, AB, Canada, 2000	LG 3235	Seed	70% WG	0,809 [0,906]	22 (7)	0.190, 0.200
Leduc, AB, Canada, 2000	Agassiz	Seed	70% WG	0.802 [0.898]	22 (7)	0.551, 0.698
Wetaskiwin, AB, Canada, 2000	Agassiz	Seed	70% WG	0.794 [0.889]	23 (6)	2.99, 3.42
Lacombe, AB, Canada, 2000	LG 3235	Seed	70% WG	0.812 [0.909]	21 (7)	0.236, 0.358
Red Decr, AB, Canada, 2000	LG 3235	Seed	70% WG	0.796 [0. 8 92]	20 (7)	1.27, 2.58
County 401, SK, Canada, 2000	45A71	Seed	70% WG	0.794 [0.889]	22 (6)	0.775, 1.23
County 463, SK, Canada, 2000	46A76	Seed	70% WG	0.810 [0. 907]	20 (6)	0.747, 0.756
Whitewater, MB, Canada, 2000	Canterra 1867RR	Seed	70% WG	0.794 [0.889]	21 (7)	0.850, 1.74
Morton, MB, Canada, 2000	LG3235	Seed	70% WG	0.805 [0.902]	21 (4)	3.12, 3.13
Minto, MB, Canada, 2000	Quest	Seed	70% WG	0.820 [0.918]	19 (6)	0.188, 0.436

PC Code: 128008

Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm
North Cypress, MB, Canada, 2000	45A51	Seed	70% WG	0.800 [0.896]	19 (6)	0.302, 0.338
Ottertail, MN, 2000	Golden Ready	Seed	70% WG	0.798 [0.894]	22 (0)	0.923, 0.968
		Exaggerate	d Rate Studies			
McHenry, ND, 2000	Hyola 401	Seed	70% WG	2.41 [2.70]	21 (5)	0.575
Whitewater, MB, Canada, 2000	Canterra 1867RR	Seed	70% WG	2.38 [2.67]	21 (7)	5.10
Minto, MB, Canada, 2000	Quest	Seed	70% WG	2.43 [2.72]	20 (5)	1.96
Ottertail, MN, 2000	Golden Ready	Seed	70% WG	2.40 [2.69]	22 (0)	2.15

¹ The first number represents the number of days after the last application when canola was cut; the number in parentheses represents the number of days plants were dried in the field prior to collection.

Commodity	Total	PHI	·v	Resid	ie Levels (j	opm)	*.
	Application Rate (lb ai/A)	(days)	Minimum	Maximum	HAFT	Mean [median]	Std. Dev
Canola seed	0.752-0.820	19-23	0.136	3.42	3.20	1.07 [0.752]	1.02
	2.38-2.43	20-22	0.575	5.10	5.10	2,45 [2.06]	1.90

3. Discussion

3.1. Methods

Mature canola plants were cut 19-23 days following the last of two foliar spray applications of the 70% WG formulation at approximately 0.4 lb ai/A/application (0.5 kg ai/ha/application), with a 4- to 7-day re-treatment interval, for a total rate of 0.75-0.82 lb ai/A (0.84-0.92 kg ai/ha). Applications were made using ground equipment in 10.6-22.10 gal/A (119-112 L/ha) of water with a spray adjuvant added. Canola plants were allowed to dry in the field 0-9 days prior to collection of canola seed. In two trials (Grand Forks, ND and Jerome, ID), canola seed samples

were collected at 0, 10, 20/21, 29/30, and 40 days following treatment to evaluate residue decline.

At four of the test trials, in North Dakota (one trial), Minnesota (one trial), and Manitoba (two trials), an additional test plot was treated at an exaggerated rate. Mature canola plants were cut 20-22 days following the last of two foliar spray applications of the 70% BAS 510 F WG formulation at approximately 1.2 lb ai/A/application (1.3 kg ai/ha), with a 5- to 6-day retreatment interval, for a total rate of 2.38-2.43 lb ai/A (2.67-2.72 kg ai/ha). Applications were made using ground equipment in 11.9-21.4 gal/A (133-240 L/ha) of water with a spray adjuvant added. It was noted that the 70% BAS 510 F WG formulation used in the exaggerated rate field trials also contained another experimental active ingredient (BAS 505 F) as part of the tank-mix; data for the BAS 505 F active ingredient were not reported in the study because these data were generated solely for the purpose of registration in Europe. Canola seed obtained from these field trials were also used in a processing study; refer to the processed canola seed DER reviewing MRID 45405124 for details of the study.

A total of 16 canola seed trials were conducted in the U.S. and Canada. Four U.S. canola seed trials were conducted in Regions 5 (one trial each in Minnesota and North Dakota), 7 (one trial in North Dakota) and 11 (one trial in Idaho). Twelve Canadian canola seed trials were all conducted in Region 14 in Alberta (six trials), Saskatchewan (two trials) and Manitoba (four trials). The petitioner proposed a reduction in the number of canola test sites needed for a NAFTA registration at a meeting between EPA and BASF Corporation on 2/23/00. According to a correspondence dated 2/29/00 regarding trial number and geographic distribution, the petitioner indicated that the US-EPA accepted the following proposal for the canola NAFTA project: a total of 16 trials conducted in Region 5 (two trials), 7 (one trial), 11 (one trial) and 14 (12 trials). The Food Residue Exposure Assessment Section of the Health Evaluation Division (FREAS, HED) of PMRA/Canada concurred with the revised distribution and locations of the crop field trials (noted in References). Geographic representation of residue data for canola seed is acceptable. The number and location of field trials conducted for canola seed are in accordance with the study design approved by the US-EPA and PMRA/Canada.

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

The maximum storage interval of canola seed samples from harvest to analysis was 147 days (4.8 months). 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 canola seed field trials.

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRID: 45405116 Submission #2001-1027, 1036, 1043

3.2. Results

Residues of BAS 510 F were 0.136-3.42 ppm in/on canola seed samples cut 19-23 days and dried 0-9 days following the last of two foliar spray applications of the 70% WG formulation at 0.37-0.42 lb ai/A/application (0.47 kg ai/ha/application) with a 4- to 7-day retreatment interval, for a total rate of 0.75-0.82 lb ai/A (0.84-0.92 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on 16 samples of untreated canola seed. Residue decline data for the two sites (Grand Forks, ND and Jerome, ID) were pooled, and BAS 510F residues appeared to decline in a linear fashion. The average residue decline data were loosely fit to the linear equation y = -0.0176x + 1.154 with a correlation coefficient (r^2) of 0.5418. This equation predicts a half life of 33 days and complete dissipation of the residues by approximately 66 days.

Rainfall was reported as above normal at one of the North Dakota, four of the Alberta and all of the Manitoba field trial sites. Temperatures were reported as below normal at two of the Alberta trial sites. Aside from these instances, no abnormal weather, environmental conditions or agricultural practices were noted during the potato field trials. Irrigation was not used to supplement rainfall at any of the canola field trials except the Idaho trial, which utilized sprinklers.

Residues of BAS 510 F were 0.575-5.10 ppm in/on canola seed samples cut 20-22 days and dried 0-9 days following the last of two foliar spray applications of the 70% WG formulation at an exaggerated rate (1.17-1.22 lb ai/A/application, or 1.31-1.37 kg ai/ha/application), with a 5- to 6-day retreatment interval, for a total rate of 2.38-2.43 lb ai/A (2.67-2.72 ka ai/ha).

Residue data from the current submission are acceptable to fulfill crop field trial data requirements for canola seed. In addition, it was noted that crop field trial residue data for sunflower seed were submitted by BASF in support of the petition for a BAS 510 F tolerance in/on sunflower seed. A new Oilseed crop group (Crop Group 20) will likely be established by EPA to harmonize with PMRA/Canada's Crop Group 20. The representative commodities for this crop group are rapeseed (canola varieties only) and sunflower, seed. The maximum residues from these studies were 0.539 ppm for sunflower seed and 3.42 ppm for canola seed. These maximum residues vary by more than a factor of 5x, thus rendering a crop group tolerance for the Oilseed crop group inappropriate.

4. Deficiencies

None.

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRID: 45405116 Submission #2001-1027, 1036, 1043

5. References

Meeting between BASF and EPA of 2/23/00, regarding BASF proposal for modification of canola crop field trial requirements. EPA agreed to revision in number (reduced from 22 to 16) and distribution (trial in Region 2 dropped) of required crop field trials for BAS 510 F in/on canola, seed; documented in BASF internal correspondence, dated 2/29/00. PMRA/Canada concurred with proposed revisions, as documented in PMRA/Canada correspondence to BASF, dated 6/27/00.

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.