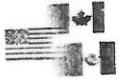


US EPA ARCHIVE DOCUMENT



Primary Evaluator Douglas Dotson, Chemist,
USEPA/OPP/HED/RAB2

Date: 2/10/04 *D. Dotson*

Reviewer William Drew, Chemist
USEPA/OPP/HED/RAB2

Date: 2/11/04 *W.D. Drew*

STUDY REPORTS:

MRID No. 45903602, Raymond C. Leonard (3/28/03) Study title: Magnitude of BAS 500 F and BAS 510 F Residues in Soybean. Lab Project Number: 140578. Unpublished study prepared by BASF Agro Research, 157 pages.

EXECUTIVE SUMMARY:

Supervised crop field trials were conducted on soybeans at seventeen sites in the United States (thirteen in Region 5 and two each in Regions 2 and 4) at a seasonal application rate of 0.5 lb a.i./A, with a pre-harvest interval of 5 days for immature seed (i.e., soybean vegetable), 14 days for forage, and 21 days for mature seed and hay. Two applications were made for a total application rate of 1.0 lb a.i./A. An LC/MS/MS method was used for residue analysis. Through analysis of fortified control samples, the method was demonstrated to be adequate for data collection. Samples were stored frozen for six months or less. Residues of boscalid have been shown to be stable in plant commodities under frozen storage conditions for up to one year. The results from these trials show that maximum residues are <0.05 ppm in mature seed, 1.3 ppm in soybean vegetable, 16 ppm in forage, 22 ppm in hay, and 2.4 ppm in aspirated grain fractions. Residue decline data were not submitted.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. There are no deficiencies. In the Field Procedures section of the field trial final report a typographical error occurred which the registrant has clarified by electronic communication to D. McNeilly (K. Akkari, 9/8/03). Field trial site number 2002218 (which is a number for a non-existent site) should be changed to 2002216 (the Quebec site).

The acceptability of this study for regulatory purposes is addressed in the U.S. EPA Residue Chemistry Summary Document (DP Barcode D290185).

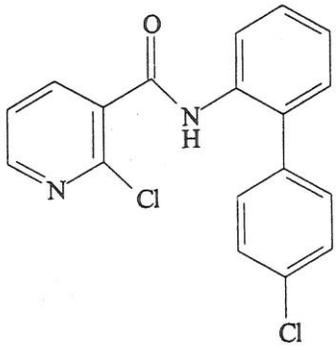


COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. The study meets the requirements of 40 CFR part 160, FIFRA Good Laboratory Practices with the following exceptions: (1) weather data were not collected in accordance with GLP standards; (2) agronomic practices (irrigation, cultural practices, etc.) and maintenance pesticide applications (past and present) were not conducted in accordance with GLP standards; and (3) the sample weights taken by the field investigator were not taken in accordance with GLP standards in that a calibrated balance was not always used for their measurement. These exceptions had no impact on the study.

A. BACKGROUND INFORMATION

The first human health risk assessment for boscalid (formerly BAS 510 F) was completed on 9/8/2003 by Y. Donovan, *et al.* (D290022). The Health Effects Division (HED) recommended in favor of the establishment of tolerances on a number of plant and animal commodities. These tolerances were published in the Federal Register Environmental Documents (July 30, 2003). Two formulated end-use products are proposed for use on soybeans: Endura™ Fungicide (EPA Reg. No. 7969-197), which contains 70% boscalid, and Pristine™ Fungicide (EPA Reg. No. 7969-199), which contains a 2:1 mixture of boscalid and pyraclostrobin as co-active ingredients (25.2%:12.8%).

Compound	Chemical Structure
	 <p style="text-align: right;">Boscalid</p>
Common name	Boscalid
Company experimental name	BAS 510F
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 #	188425-85-6
End-use product/EP	Endura and Pristine



Parameter	Value
Melting point/range	142.8-143.8°C
pH	Unspecified
Density	1.39 g/cm ³ (powder), 1.38 g/cm ³ (crystalline)
Water solubility (20°C)	4.64 mg/L (crystalline form)
Solvent solubility (mg/L at 20°C)	Crystalline Form: Acetone: 16-20 g/100 mL Acetonitrile: 4-5 g/100 mL Methanol: 4-5 g/100 mL Ethyl Acetate: 6.7-8 g/100 mL Dichloromethane: 20-25 g/100 mL Toluene: 2-2.5 g/100 mL 1-Octanol: <1g/100 mL
Vapor pressure at 20°C	Crystalline Form: 7 x 10 ⁻⁷ Pa
Vapor pressure at 25°C	Crystalline Form: 2 x 10 ⁻⁶ Pa
Dissociation constant (pK _a)	No dissociation in water.
Octanol/water partition coefficient Log(K _{ow})	log K _{ow} of crystalline form = 2.96 (21°C)
UV/visible absorption spectrum	Unspecified

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Study Location	Soil characteristics			
	Type	%OM	pH	CEC
All Locations	Not Specified	Not Specified	Not Specified	Not Specified

The soil type, percent organic matter, pH, and cation exchange capacity were not specified for any of the sites. The registrant did not state that these values affected the use pattern in any location. With a few exceptions, rainfall and air temperatures during the duration of the study were normal. "Normal" for rainfall is defined as levels which are within 20% of the 10-year seasonal norm, and "normal" for temperature indicates that average maximum and minimum air temperatures are within 10% of the monthly norm. Rainfall levels were above normal at the Arkansas, WI site and at the Gardner, ND site. Rainfall levels were below normal at the Britton, SD site. In addition, air temperatures were above normal at the Chula, GA and Suffolk, VA sites (for month of October only), at the York NE site (for June, July, and August), and at the Quebec site (September only). Air temperatures were below normal at the Arkansas, WI and Quebec sites (May and October), and at the Gardner, ND site in May only. These conditions had no adverse effects on the study. Irrigation was done at some sites, when necessary, to ensure that the crop developed normally.

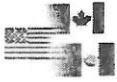


TABLE B.1.2. Study Use Pattern.								
Location (City, State)	EP ¹	Application						Tank Mix Adjuvants
		Timing	Rate, lb a.i./A (kg a.i./ha)	RTI ² (days)	Treat No.	Method	Total Rate, lb a.i./A (kg a.i./ha)	
Chula, GA	Combination of BAS 510 02 F (boscalid) and BAS 500 02 F (pyraclostrobin)	1 st application: 12 days prior to harvest of soybean vegetable. 2 nd application: 28 days prior to harvest of mature seed	0.50 lb ai/A (0.56 kg ai/ha)	7	2	Broad-cast Spray	1.0 lb ai/A (1.1 kg ai/ha)	Non-silicone spray adjuvant
Suffolk, VA								
Proctor, AR								
Newport, AR								
Arkansas, WI								
Arkansas, WI								
Webster City, IA								
Webster City, IA								
York, NE								
York, NE								
Gardner, ND								
Gardner, ND								
Britton, SD								
Britton, SD								
Carlyle, IL								
Wyoming, IL								
St-Paul d'Abbotsford, QB								

¹EP = End-use Product
² Retreatment Interval

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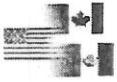


TABLE B.1.3. Trial Numbers and Geographical Locations

NAFTA Growing Region	Soybeans		
	Submitted	Requested	
		Canada	US
1			
1A			
2	2		2
3			
4	2		2
5	12		11
5A			
5B	1		0
6			
7			
7A			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	17	0	15

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B.2. Analytical Methodology

The analytical method used for data collection is BASF Analytical Method Number D9908. This method is reviewed in the DER prepared for MRID 45405027 (D278386, W. Drew, 7/2/03). Residues of boscalid are extracted from the samples with a 70:25:5 methanol/water/2N HCl mixture. An aliquot of the extract is removed and cleaned by liquid/liquid partition with cyclohexane. If necessary, a silica, solid phase extraction, micro-column was used to further clean the extract. Boscalid residues are determined by LC/MS/MS. The method was validated for the determination of boscalid residues in plant commodities through the analysis of residues in almond nutmeat, onion, and plum (D278386). Overall recoveries were acceptable in the validation study. The LOQ was determined to be 0.05 ppm for residues in plant commodities. The LOD was quoted as 5 pg/ μ L.

C. RESULTS AND DISCUSSION

The results of the residue analyses are given in Tables C.3.1 through C.3.5. Residues in mature soybean seed were below the LOQ of 0.05 ppm in all samples. In soybean vegetable (referred to as immature seed by the registrant), residues were below the LOQ (0.05 ppm) in 25 out of 34 samples. The highest residue found was 1.29 ppm. Two samples of aspirated grain fractions were prepared and analyzed. Residues were 0.71 and 2.42 ppm. Residues were considerably higher in forage and hay. In forage, residues ranged up to 16 ppm, and in hay, residues ranged up to 21 ppm. Weather conditions were typical during the field trials. The registrant reported that the minor variations from the norm did not affect the field trials. As a result, the field trial values are adequate for tolerance-setting purposes. Adequate numbers of field trials were performed, and geographic representation of the field trials is adequate. Seventeen field trials were performed whereas only fifteen are required when a crop group tolerance is being requested. Tolerances have been established for Crop Subgroups 6A, 6B, and 6C. The human health risk assessment which includes these subgroups was completed on 9/8/03 (Memo, PP#1F6313, D290022, Y. Donovan). Residue decline data for soybeans were not submitted.

The analytical method used for data collection is BASF Analytical Method Number D9908. This method is suitable for data collection. Mature seed, soybean vegetable, forage, and hay were fortified at both the LOQ (0.05 ppm) and at 1.0 ppm. Forage and hay were also fortified at 50 ppm. Recoveries in the various matrices ranged as follows: mature seed (78% to 104%), soybean vegetable (74% to 83%), forage (81% to 125%), and hay (86% to 116%). Mean recoveries ranged from 78% to 99%. Standard deviations as a percentage of the mean ranged from 4% to 19%. The method LOD was reported to be 0.1 ng/mL. A sample calibration curve showed good detector linearity (correlation coefficient of 0.998).

The registrant submitted a storage stability study which was performed to investigate the frozen storage stability of boscalid residues in sugar beet root, cabbage, canola seed, pea, peach, wheat forage, wheat grain, and wheat straw. Fortified commodities were stored at -20°C for 12 months.

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Residues were measured after 0, 1, 3, 6, and 12 months of storage. This study has been reviewed, and a DER has been prepared (MRID 45405109, D278386, M. Nelson, 7/2/03). Residues of boscalid were stable for up to 12 months of frozen storage in all commodities. In the soybean field trial studies, no commodity was stored for more than 6 months in any trial. The results of the storage stability study support the storage periods used in the soybean field trials.

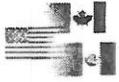
TABLE C.1. Summary of Concurrent Recoveries of Boscalid from Soybean Commodities.

Matrix	Analyte	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
Mature Seed	Boscalid	0.05	3	92.2, 78.2, 95.6	88.7 ± 9.2
		1.0	3	104.4, 91.2, 94.2	96.6 ± 6.9
Soybean Vegetable		0.05	3	74.4, 77.0, 82.8	78.1 ± 4.3
		1.0	3	81.6, 76.0, 82.8	80.1 ± 3.6
Forage		0.05	4	125.2, 81.0, 91.6, 101.8	99.9 ± 18.9
		1.0	3	83.0, 96.0, 100.4	93.1 ± 9.1
		50.0	1	87.2	87.2
Hay		0.05	3	115.8, 90.4, 91.8	99.3 ± 14.3
		1.0	2	101.6, 86.4	94.0 ± 10.8
		50.0	1	91.8	91.8

TABLE C.2. Summary of Storage Conditions

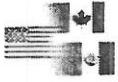
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (months)	Limit of Demonstrated Storage Stability (months)
Mature Seed	-10°C	4	12
Soybean Vegetable	-10°C	5	12
Forage	-10°C	6	12
Hay	-10°C	5	12

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Location (City, State)	Region	Soybean Variety	Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)
Chula, GA	2	NK RR S73-Z5	Mature Seed	1.01	21	<0.05	<0.05
Suffolk, VA	2	NK S53Q7 7B-1001		1.02		<0.05	<0.05
Proctor, AR	4	AG4403		1.00		<0.05	<0.05
Newport, AR	4	AG5603		1.00		<0.05	<0.05
Arkansas, WI	5	BR2099RR		1.00		<0.05	<0.05
Arkansas, WI	5	BR2099RR		1.01		<0.05	<0.05
Webster City, IA	5	SG2531RR		1.03		<0.05	<0.05
Webster City, IA	5	SG2533RR		1.02		<0.05	<0.05
York, NE	5	Asgrow A2553		1.00		<0.05	<0.05
York, NE	5	Asgrow 2703		1.00		<0.05	<0.05
Gardner, ND	5	Mycogen 5007		1.01		<0.05	<0.05
Gardner, ND	5	Mycogen 5007		1.01		<0.05	<0.05
Britton, SD	5	CropOland RT0583		1.00		<0.05	<0.05
Britton, SD	5	CropOland RT0583		1.00		<0.05	<0.05
Carlyle, IL	5	B-T 441 CR		1.00		<0.05	<0.05
Wyoming, IL	5	Asgrow Ag3302		1.01		<0.05	<0.05
St-Paul d'Abbotsford, QB	5b	DKB07-51	0.95	<0.05	<0.05		

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Location (City, State)	Region	Soybean Variety	Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)
Chula, GA	2	NK RR S73-Z5	Soybean Vegetable (Green)	1.01	5	<0.05	<0.05
Suffolk, VA	2	NK S53Q7 7B-1001		1.02		0.06	<0.05
Proctor, AR	4	AG4403		1.00		1.07	1.29
Newport, AR	4	AG5603		1.00		<0.05	0.05
Arkansas, WI	5	BR2099RR		1.00		0.07	0.08
Arkansas, WI	5	BR2099RR		1.01		0.08	0.31
Webster City, IA	5	SG2531RR		1.03		<0.05	<0.05
Webster City, IA	5	SG2533RR		1.02		<0.05	<0.05
York, NE	5	Asgrow A2553		1.00		<0.05	<0.05
York, NE	5	Asgrow 2703		1.00		0.13	<0.05
Gardner, ND	5	Mycogen 5007		1.01		<0.05	<0.05
Gardner, ND	5	Mycogen 5007		1.01		<0.05	<0.05
Britton, SD	5	CropOland RT0583		1.00		<0.05	<0.05
Britton, SD	5	CropOland RT0583		1.00		<0.05	<0.05
Carlyle, IL	5	B-T 441 CR		1.00		<0.05	<0.05
Wyoming, IL	5	Asgrow Ag3302		1.01		<0.05	<0.05
St-Paul d'Abbotsford, QB	5b	DKB07-51		0.95		<0.05	<0.05

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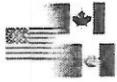


TABLE C.3.3. Residue Data from Crop Field Trials with Boscalid.							
Location (City, State)	Region	Soybean Variety	Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)
Chula, GA	2	NK RR S73- Z5	Forage	1.01	14	3.99	4.62
Suffolk, VA	2	NK S53Q7 7B-1001		1.02		5.88	3.08
Proctor, AR	4	AG4403		1.00		16.3	15.7
Newport, AR	4	AG5603		1.00		3.36	2.59
Arkansas, WI	5	BR2099RR		1.00		1.73	1.51
Arkansas, WI	5	BR2099RR		1.01		6.42	6.76
Webster City, IA	5	SG2531RR		1.03		5.30	5.33
Webster City, IA	5	SG2533RR		1.02		0.27	2.08
York, NE	5	Asgrow A2553		1.00		6.46	6.88
York, NE	5	Asgrow 2703		1.00		9.40	6.47
Gardner, ND	5	Mycogen 5007		1.01		5.25	5.60
Gardner, ND	5	Mycogen 5007		1.01		8.00	9.40
Britton, SD	5	CropOland RT0583		1.00		6.38	3.07
Britton, SD	5	CropOland RT0583		1.00		10.35	6.15
Carlyle, IL	5	B-T 441 CR		1.00		3.11	2.98
Wyoming, IL	5	Asgrow Ag3302		1.01		3.64	3.61
St-Paul d'Abbotsford, QB	5b	DKB07-51	0.95	4.81	4.43		

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TABLE C.3.4. Residue Data from Crop Field Trials with Boscalid.

Location (City, State)	Region	Soybean Variety	Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)
Chula, GA	2	NK RR S73-Z5	Hay	1.01	21	1.07	1.50
Suffolk, VA	2	NK S53Q7 7B-1001		1.02		2.67	1.88
Proctor, AR	4	AG4403		1.00		4.64	4.45
Newport, AR	4	AG5603		1.00		1.99	2.24
Arkansas, WI	5	BR2099RR		1.00		3.45	0.07
Arkansas, WI	5	BR2099RR		1.01		2.77	2.79
Webster City, IA	5	SG2531RR		1.03		4.36	5.21
Webster City, IA	5	SG2533RR		1.02		2.22	1.76
York, NE	5	Asgrow A2553		1.00		20.9	21.6
York, NE	5	Asgrow 2703		1.00		1.11	1.65
Gardner, ND	5	Mycogen 5007		1.01		8.61	4.85
Gardner, ND	5	Mycogen 5007		1.01		7.68	6.47
Britton, SD	5	CropOland RT0583		1.00		7.80	7.75
Britton, SD	5	CropOland RT0583		1.00		10.95	11.60
Carlyle, IL	5	B-T 441 CR		1.00		5.05	5.60
Wyoming, IL	5	Asgrow Ag3302		1.01		7.25	7.35
St-Paul d'Abbotsford, QB	5b	DKB07-51	0.95	3.59	3.55		

TABLE C.3.5. Residue Data from Crop Field Trials with Boscalid.

Location (City, State)	Region	Soybean Variety	Commodity	Total Rate (lbs ai/A)	PHI (days)	Residues 1 (ppm)	Residues 2 (ppm)
York, NE	5	Asgrow 2703	Aspirated Grain Fractions	1.00	21	2.42	0.71

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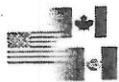


TABLE C.4. Summary of Residue Data from Crop Field Trials with Boscalid.

Commodity	Total Applic. Rate, lb a.i./A (kg a.i./ha)	PHI (days)	Analyte	Residue Levels (ppm)					
				n	Min.	Max.	HAFT*	Mean	Std. Dev.
Mature Seed	1.0 lb ai/A (1.1 kg ai/ha)	21	Boscalid	34	<0.05	<0.05	<0.05	<0.05	0
Soybean Vegetable		5		34	<0.05	1.29	1.18	0.11	0.28
Forage		14		34	0.27	16.3	16.0	5.6	3.5
Hay		21		34	0.07	21.6	21.3	5.5	4.9
AGF		21		2	0.71	2.42	1.57	1.57	-

* HAFT = Highest Average Field Trial.

D. CONCLUSION

The soybean field trials have been performed in accordance with the OPPTS Series 860 Residue Chemistry Test Guidelines. The total application rate was 1.0 lb a.i./acre. The PHIs were 5 days for soybean vegetable, 14 days for forage, and 21 days for forage and hay. Adequate numbers of field trials were performed in the major soybean-growing regions of the country. There were no adverse weather conditions which would affect the results of the study. The analytical method has been demonstrated to be adequate for data collection. Residues of boscalid have been shown to be stable over the storage periods used in the study. Residues in mature soybean seed were below the LOQ of 0.05 ppm in all samples. In soybean vegetable, residues were below the LOQ (0.05 ppm) in 25 out of 34 samples. The highest residue found was 1.29 ppm. Two samples of aspirated grain fractions were prepared and analyzed. Residues were 0.71 and 2.42 ppm. Residues were considerably higher in forage and hay. In forage, residues ranged up to 16 ppm, and in hay, residues ranged up to 21 ppm.

E. REFERENCES

Human Health Risk Assessment for New Fungicide BAS 510 F (Common Name: Boscalid) – Proposal for Tolerances for Residues in/on Numerous Crops and Livestock Commodities, PP# 1F6313, D290022, Y. Donovan, 9/8/03.

Residue Analytical Methods DER, Plant Commodities, BAS 510 F, PP# 1F6313, D278386, W. Drew, 7/2/2003.

Storage Stability Data DER, Plant Commodities, BAS 510 F, PP# 1F6313, D278386, M. Nelson, 7/2/2003.

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