



Boscalid/PC Code 128008/BASF Corporation/7969
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Banana

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STUDY REPORT:

46537101 Magnitude of BAS 510 F Residues in Bananas for Import Tolerance. BASF Study Number 179968. Unpublished study prepared by BASF Corporation, 7-21-2004, 117 p. {OPPTS 860.1500}

EXECUTIVE SUMMARY:

Field trial data have been generated for boscalid on bananas. Twelve trials were conducted on banana during the 2003-2004 growing season in Costa Rica (2 trials), Colombia (2 trials), Ecuador (2 trials), Guatemala (1 trial), Honduras (2 trials), Martinique (2 trials), and Mexico (1 trial). At each test location four broadcast foliar applications of boscalid (50% WG) were made to bananas at 0.125-0.144 lb ai/A per application. The total seasonal application rate ranged from 0.52 to 0.56 lb ai/A. The re-treatment interval was 10 to 13 days. Applications were made using ground application equipment, simulating aerial application above the plant canopy, in spray volumes of approximately 3 gallons per acre of water. An adjuvant (spray oil plus emulsifier) was added to the spray mixture for all applications. Mature banana raw agricultural commodity (RAC) samples were harvested at 0 days after the last application (DALA).

The residues of boscalid in/on banana samples (unbagged and bagged, whole fruit RAC and pulp) were quantitated using a validated LC/MS/MS method, BASF Analytical Method D9908, the data collection method for plant matrices. Acceptable concurrent method validation data for banana commodities were obtained for boscalid. The validated limit of quantitation (LOQ) was 0.05 ppm for residues of boscalid in/on banana whole fruit and pulp. The LOD was 0.005 ppm.

The field residue samples were stored frozen (<-10°C) a maximum of 4 months from harvest to analysis. The available storage stability data indicate that residues of boscalid are stable in/on a variety of frozen plant matrices for at least 12 months.

The results from these trials show that residues of boscalid ranged from <0.05 ppm to 0.18 ppm in/on 12 samples of unbagged whole bananas harvested immediately (0-day PHI) after the last of four application of boscalid (50% WG) totaling 0.52-0.56 lb ai/A/season). Boscalid residues were <0.05 ppm in/on all 12 treated bagged whole banana samples. The residues levels of boscalid in treated pulp samples, both bagged and unbagged (n=24), were <0.05 ppm (<LOQ).



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STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the banana field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the associated U.S. EPA Residue Chemistry Summary Document (D322235).

COMPLIANCE:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No GLP deviations occurred that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Boscalid is an anilide fungicide that inhibits mitochondrial respiration, thereby inhibiting spore germination, germ tube elongation, mycelial growth, and sporulation of pathogenic fungi on the leaf surface. Permanent tolerances [40 CFR §180.589(a)(1)] have been established for residues of boscalid in/on numerous plant commodities, ranging from 0.05 ppm in/on peanuts and tuberous and corm vegetables (subgroup 1C) to 35 ppm in/on dried hop cones. Separate tolerances have also been established for indirect or inadvertent residues of boscalid in rotational crops, ranging from 0.05 ppm in several commodities to 8.0 ppm in grass forage, fodder, and hay (group 17) [40 CFR §180.589(d)]. Tolerances for the combined residues of boscalid and its glucuronic acid conjugate are also established on animal commodities, ranging from 0.02 ppm in eggs to 0.35 ppm in meat byproducts of cattle, goats, horses, and sheep [40 CFR §180.589(a)(2)]. The current field trials were submitted by BASF to support the establishment of an import tolerance for bananas.

The nomenclature and physicochemical properties of boscalid are presented below in Tables A.1. and A.2.

TABLE A.1. Nomenclature of Boscalid	
Compound	
Common name	Boscalid
Company experimental names	BAS 510 F
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 products/EP	50% Wettable Granule, Cantus Fungicide, Banastar Fungicide



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Parameter	Value	Reference
Melting point	143.4-143.6°C (TGAI)	D278385, M. Neilson, 8/15/03
pH (23°C)	5.5 (1% solution)	
Density	1.394g/cm ³ (TGAI)	
Water solubility (20°C)	4.64 mg/L (PAI)	
Solvent solubility (g/100 mL at 20°C)	PAI: 16-20 in acetone; 4-5 in acetonitrile; 4-5 in methanol; 6.7-8 in ethylacetate; 20-25 in dichloromethane; 2-2.5 in toluene; <1 in 1-octanol	
Vapour pressure at 20°C	7 x 10 ⁻⁹ hPa (PAI)	
Dissociation constant (pK _a)	Does not dissociate in water.	
Octanol/water partition coefficient at 21°C Log(K _{ow})	2.96 (PAI)	
UV/visible absorption spectrum	Not available	

TGAI: technical grade active ingredient

PAI: pure active ingredient

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Trial Identification (City, State, Year)	Soil characteristics				Meteorological data ¹	
	Type	%OM	pH	CEC	Overall total monthly rainfall range (inches)	Overall monthly temperature range (°C)
Limon, Costa Rica/2004 RCN 2003149	ND		ND		Normal	Normal
Limon, Costa Rica/2004 RCN 2003150	ND		ND		Normal	Normal
Guayas, Ecuador/2004 RCN 2003151	ND		ND		Rainfall was below normal (supplemented with irrigation)	Normal
Guayas, Ecuador/2004 RCN 2003152	ND		ND		Rainfall was below normal (supplemented with irrigation)	Normal
Magdalena, Colombia/2004 RCN 2003153	ND		ND		Normal	Avg. minimum air temps. were above normal
Magdalena, Colombia/2004 RCN 2003154	ND		ND		Normal	Avg. minimum air temps. were above normal
Cortes, Honduras/2003 RCN 2003155	ND		ND		Rainfall was below normal	Avg. min. and max. air temps. were below normal
Cortes, Honduras/2003 RCN 2003156	ND		ND		Rainfall was below normal	Avg. min. and max. air temps. were below normal
Tiquisate, Guatemala/2004 RCN 2003157	ND		ND		Normal	Normal
Tapachula, Mexico/2004 RCN 2003158	ND		ND		Rainfall was below normal (supplemented with irrigation)	Normal



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Trial Identification (City, State, Year)	Soil characteristics				Meteorological data ¹	
	Type	%OM	pH	CEC	Overall total monthly rainfall range (inches)	Overall monthly temperature range (°C)
Martinique, F.W. Indies/2004 RCN 2003159	ND		ND		Normal	Normal
Martinique, F.W. Indies/2004 RCN 2003160	ND		ND		Normal	Normal

¹ Detailed meteorological data were not provided.

The test crop was grown and maintained according to typical agricultural practices for the geographical regions. The banana varieties included Williams, Giant Cavendish, Gran Enano, Ecuatoriano, Gran Nane, and Cavendish. The actual temperature and rainfall recordings were generally within average historical values for the residue study period, with minor exceptions. Irrigation was used to supplement as needed. There were no meteorological abnormalities (i.e., unusual circumstances such as drought or hurricane) that occurred during the conduct of the study.

One treated plot and one untreated control plot were established at each test site. Four broadcast foliar applications of boscalid (50% WG) were made to the treated plots at 0.12-0.14 lb ai/A, for a total application rate of 0.50-0.58 lb ai/A. The retreatment intervals between applications were 6-8 days. The applications were initiated 30-35 days prior to normal harvest and the retreatment intervals were 10-13 days. The applications were made using ground equipment simulating aerial application by positioning the sprayer nozzels above the plant canopy, in a spray volume of approximately 3 gallons of water. Aerial application is the predominant application method used for banana fungicides. Applications included a spray oil (rate, 0.8 gallons/A) and emulsifier in the spray mixture as spray additives. Mature banana RAC samples (whole fruit) were harvested at 0 DALA.

The conditions at each test site are summarized in Table B.1.2. and the trial locations are given in Table B.1.3.

Location (City, State), Year	EP	Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	No. of Appl.	RTI (days)	Total Rate (lb ai/A)	Tank Mix Adjuvants
Limon, Costa Rica, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 31 days before harvest Appl. 2. 21 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	10-11	0.54	Spray oil (Prorex) + emulsifier (NP-7)
Limon, Costa Rica, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 32 days before harvest Appl. 2. 21 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13	4	10-11	0.54	Spray oil (Prorex) + emulsifier (NP-7)

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TABLE B.1.2. Study Use Pattern on Bananas

Location (City, State), Year	EP	Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	No. of Appl.	RTI (days)	Total Rate (lb ai/A)	Tank Mix Adjuvants
Guayas, Ecuador, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 33 days before harvest Appl. 2. 22 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	11	0.55	Spray oil (Banole) + emulsifier (Triton X-45)
Guayas, Ecuador, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 33 days before harvest Appl. 2. 21 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	2-3	0.12-0.13	4	11-12	0.52	Spray oil (Banole) + emulsifier (Triton X-45)
Magdalena, Colombia, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 35 days before harvest Appl. 2. 23 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13	4	11-12	0.53	Spray oil (Banole) + emulsifier (Triton X-45)
Magdalena, Colombia, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 35 days before harvest Appl. 2. 23 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13	4	11-12	0.53	Spray oil (Banole) + emulsifier (Triton X-45)
Cortes, Honduras, 2003	50% WG	Broadcast foliar, air (simulated) Appl. 1. 31 days before harvest Appl. 2. 21 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	10-11	0.52	Spray oil (Banole) - emulsifier (Triton NP-7)
Cortes, Honduras, 2003	50% WG	Broadcast foliar, air (simulated) Appl. 1. 31 days before harvest Appl. 2. 21 days before harvest Appl. 3. 11 days before harvest Appl. 4. At harvest, mature fruit	3	0.13	4	10-11	0.52	Spray oil (Banole) + emulsifier (Triton NP-7)
Tiquisate, Guatemala, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 30 days before harvest Appl. 2. 20 days before harvest Appl. 3. 10 days before harvest Appl. 4. At harvest, mature fruit	3	0.14	4	10	0.56	Spray oil (Spraytex) + emulsifier (NP-7)
Tapachula, Mexico, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 31 days before harvest Appl. 2. 20 days before harvest Appl. 3. 10 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	10-11	0.55	Spray oil (Spraytex) + emulsifier (NP-7)
Martinique, French W. Indies, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 32 days before harvest Appl. 2. 21 days before harvest Appl. 3. 10 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	11-13	0.55	Spray oil (Spraytex M) + emulsifier
Martinique, French W. Indies, 2004	50% WG	Broadcast foliar, air (simulated) Appl. 1. 31 days before harvest Appl. 2. 21 days before harvest Appl. 3. 10 days before harvest Appl. 4. At harvest, mature fruit	3	0.13-0.14	4	10-13	0.55	Spray oil (Spraytex M) + emulsifier



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Country ^b	Banana		
	Submitted	Requested ^a	
		Canada	US
Ecuador (26%)	2	Not Specified	Not Specified
Costa Rica (25%)	2	Not Specified	Not Specified
Colombia (16%)	2	Not Specified	Not Specified
Honduras (13%)	2	Not Specified	Not Specified
Guatemala (11%)	1	Not Specified	Not Specified
Mexico (7%)	1	Not Specified	Not Specified
Martinique ^c (<1%)	2	Not Specified	Not Specified
Total	12		

- a For a tolerance on imported banana, 12 trials distributed among the countries that account for >5% of the amount imported into the United States are required (Federal Register, Volume 65, No. 106, Thursday, June 1, 2000, Notices)
- b The quantity imported into the US is shown in parentheses below each country (1991-1995 average). The countries in which trials were conducted in this study collectively represent >98% of all bananas imported into the US.
- c Site in Martinique (French West Indies) selected by the registrant to support European import tolerance requirements.

B.2. Sample Handling and Preparation

Banana RAC samples were collected on the date of the last application (0-day PHI). One sample was collected from the untreated plot at each site and two independent samples (one bagged and one unbagged) were collected from each treated plot at each site. Each sample consisted of at least 24 bananas and was collected without bias from at least six bunches and from several locations within each bunch.

The samples were held in temporary storage at the field facilities at ambient temperatures until shipment. The samples were shipped 0-1 days after harvest by express courier under ambient conditions to the analytical laboratory, BASF Agro Research (Research Triangle Park, NC), and arrived there within 2-4 days of harvest. Upon arrival at BASF, a portion of each sample (≥ 12 bananas) was peeled to produce a pulp fraction, and another portion (≥ 12 bananas) was selected for whole fruit analysis. The samples were homogenized (Hobart meat grinder) with dry ice to a consistency appropriate for analysis. The samples were then placed in plastic bags and stored frozen at $< -10^{\circ}\text{C}$ until the time of analysis.

B.3. Analytical Methodology

Samples of banana whole fruit and pulp were analyzed for residues of boscalid using BASF Analytical Method Number D9908 (Refer to the DER for MRID 45405027). The method detects parent boscalid, which has been determined to be the residue of concern based on plant metabolism studies. A brief description of the methodology used to analyze the samples follows.



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Samples of banana pulp and whole fruit were extracted with methanol:water:2 N HCl (70:25:5, v/v/v) using a Polytron homogenizer. The extract was centrifuged, and an aliquot of the supernatant was removed and cleaned up by liquid/liquid partitioning in a solution of cyclohexane and 1N HCl saturated with NaCl (5:1, v/v). An aliquot of the cyclohexane phase was taken, evaporated to dryness, and re-dissolved in 80:20 methanol:buffer solution (99.9% of 4 mM ammonium formate in water and 0.1% formic acid) for analysis by LC/MS/MS. The method uses external standards. The performance of the detection instrument was evaluated during each analytical set. The correlation coefficients of the calibration curves were >0.99.

The method LOD was 0.005 ppm and the validated LOQ was 0.05 ppm for residues of boscalid in/on banana fruit and pulp.

C. RESULTS AND DISCUSSION

The number and geographic representation of the almond field trials are adequate for a tolerance on imported bananas.

The LC/MS/MS method (BASF Method Number D9908) used to determine residues of boscalid in/on banana fruit and pulp is adequate for data collection. Acceptable concurrent method validation data for banana fruit and pulp were obtained. Concurrent recoveries of boscalid fortified in control whole fruit and pulp samples at 0.05 and 5.0 ppm were 76-118% (n=4) and 87-109% (n=6). Apparent residues of boscalid were below the LOQ of 0.05 ppm in/on all banana fruit and pulp control samples (n=12 each). No interferences were noted in control samples. Recoveries were not corrected, as apparent residues were non-detectable in the associated controls. The concurrent recoveries are presented in Table C.1. Adequate sample calculations and chromatograms were provided.

Samples were stored frozen from collection to analysis for a maximum of 4 months (Table C.2). Storage stability data are available on representative plant commodities indicating that boscalid is stable in frozen storage for at least 12 months (D278385, M. Nelson, 8/15/03). These data will support the current banana field trials.

Analyte	Banana Matrix	Spiking Level (mg/kg)	Sample size	Recoveries (%)	Mean Recovery ± SD
Boscalid	Whole fruit	0.05	2	118, 92	105
		5.0	2	107, 76	92
		Total	4	76-118	98±18
	Pulp	0.05	3	103, 101, 109	104±4
		5.0	3	93, 96, 87	92±5
		Total	6	87-109	98±8



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TABLE C.2 Summary of Freezer Storage Conditions

Matrix	Storage Temp. (°C)	Actual Storage Duration (months)	Limit of Demonstrated Storage Stability (months) ¹
Banana, fruit	Ambient (field/shipping) ^a	4	12
Banana, pulp	<-10°C (in laboratory)	4	

^a All samples were held fresh at the test site and were later shipped (within 0-1 days of collection) under ambient conditions by express courier to the analytical laboratory (BASF), where they arrived within 2-4 days of harvest and were promptly placed in frozen storage. The Agency has previously indicated that bananas spend time in transit at ambient temperatures as a part of normal import into the U.S.; therefore, storage stability data are not required to cover the time in transit for banana samples.

TABLE C.3.a. Boscalid Residues in Banana Whole Fruit

Trial ID/Year City, Country	Banana Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Boscalid Residues (ppm)	
					Bagged	Unbagged
RCN2003149/2004 Limon, Costa Rica	Williams	Whole Fruit	0.54	0	<0.05	0.05
RCN2003150/2004 Limon, Costa Rica	Williams	Whole Fruit	0.54	0	<0.05	0.10
Guayas, Ecuador/2004 RCN2003151	Cavendish	Whole Fruit	0.55	0	<0.05	<0.05
Guayas, Ecuador/2004 RCN2003152	Cavendish	Whole Fruit	0.52	0	<0.05	0.10
Magdalena, Colombia/2004 RCN2003153	Gran Enano	Whole Fruit	0.53	0	<0.05	<0.05
Magdalena, Colombia/2004 RCN2003154	Gran Enano	Whole Fruit	0.53	0	<0.05	0.18
Cortes, Honduras/2003 RCN2003155	Ecuadoriano	Whole Fruit	0.52	0	<0.05	<0.05
Cortes, Honduras/2003 RCN2003156	Ecuadoriano	Whole Fruit	0.52	0	<0.05	0.07
Tiquisate, Guatemala/2004 RCN2003157	Gran Nane	Whole Fruit	0.56	0	<0.05	0.09
Tapachula, Mexico/2004 RCN2003158	Gran Nane	Whole Fruit	0.55	0	<0.05	0.11
Martinique, French W. Indies RCN2003159	Cavendish	Whole Fruit	0.55	0	<0.05	0.07
Martinique, French W. Indies RCN2003160	Cavendish	Whole Fruit	0.55	0	<0.05	<0.05

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TABLE C.3.b. Boscalid Residues in Banana Pulp

Trial ID/Year City, Country	Banana Variety	Matrix	Total Rate (lb ai/A)	PHI (days)	Boscalid Residues (ppm)	
					Bagged	Unbagged
RCN2003149/2004 Limon, Costa Rica	Williams	Pulp	0.54	0	<0.05	<0.05
RCN2003150/2004 Limon, Costa Rica	Williams	Pulp	0.54	0	<0.05	<0.05
Guayas, Ecuador/2004 RCN2003151	Cavendish	Pulp	0.55	0	<0.05	<0.05
Guayas, Ecuador/2004 RCN2003152	Cavendish	Pulp	0.52	0	<0.05	<0.05
Magdalena, Colombia/2004 RCN2003153	Gran Enano	Pulp	0.53	0	<0.05	<0.05
Magdalena, Colombia/2004 RCN2003154	Gran Enano	Pulp	0.53	0	<0.05	<0.05
Cortes, Honduras/2003 RCN2003155	Ecuadoriano	Pulp	0.52	0	<0.05	<0.05
Cortes, Honduras/2003 RCN2003156	Ecuadoriano	Pulp	0.52	0	<0.05	<0.05
Tiquisate, Guatemala/2004 RCN2003157	Gran Nane	Pulp	0.56	0	<0.05	<0.05
Tapachula, Mexico/2004 RCN2003158	Gran Nane	Pulp	0.55	0	<0.05	<0.05
Martinique, French W. Indies RCN2003159	Cavendish	Pulp	0.55	0	<0.05	<0.05
Martinique, French W. Indies RCN2003160	Cavendish	Pulp	0.55	0	<0.05	<0.05

TABLE C.4. Summary of Residue Data for Bananas (Whole Fruit)

Commodity	Total Rate (lb a.i./A)	PHI (days)	Boscalid Residue Levels (ppm)						
			n	Min.	Max.	HAFT ¹	Median (STMdR ²)	Mean (STMR ²)	Std. Dev.
Whole Fruit (bagged)	0.52-0.56	0	12	<0.05	<0.05	<0.05	<0.05	<0.05	0
Whole Fruit (Unbagged)			12	<0.05	0.18	0.18	0.07	0.08	0.04
Whole Fruit (Both)			24	<0.05	0.18	0.18	<0.05	0.07	0.03
Pulp	0.52-0.56	0	24	<0.05	<0.05	<0.05	<0.05	<0.05	0

¹ HAFT = Highest Average Field Trial.

² STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

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D. CONCLUSION

The banana field trial data are adequate and reflect the use of four applications of boscalid (50%WG) at 0.12-0.14 lb ai/A/application, for a total of 0.52-0.56 lb ai/A/season. The data support a 0-day PHI. In whole fruit, maximum boscalid residues were 0.18 ppm. In pulp, residues were below the LOQ of 0.05 ppm in all samples.

E. REFERENCES

PP#0F06313. BAS 510 F (Common Name: Boscalid), New Fungicide Active Ingredient. Residue Chemistry Summary Document, D278385, M. Nelson, 8/15/03

F. DOCUMENT TRACKING

Petition Number: 5E6933
DP Barcode: D316787
PC Code: 128008

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