



Boscalid/7969-199/BAS 510 F/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 - Strawberry

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This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 8/31/2005). The DER has been reviewed by the HED and revised to reflect current OPP policies.

STUDY REPORT:

46588101 Jordan, J.; Jones, J. (2004) Magnitude of Pyraclostrobin (BAS 500 F) and Boscalid (BAS 510 F) Residues in Strawberries After Treatment with Pristine® (BAS 516 04 F). Lab Project Number: 2005/5000095: 202513. Unpublished study prepared by BASF Corporation. 126 p. {OPPTS 860.1500}

EXECUTIVE SUMMARY:

In three strawberry field trials conducted in CA during 2004 and 2005, a water dispersible granule (WDG) formulation containing both boscalid (25.2%) and pyraclostrobin (12.8%) was applied to strawberries as five broadcast foliar applications during fruit development at retreatment intervals (RTIs) of ~7 days. As the pyraclostrobin data are not germane to this boscalid DER, the pyraclostrobin data are not included. Four separate treatments were conducted at each field site, applying the WDG formulation at two different application rates and as either dilute or concentrate sprays. Based on the amount of product applied, the single application rate for boscalid was either 0.360-0.385 lb ai/A for a total seasonal application rate of 1.84-1.89 lb ai/A/season or 0.72-0.76 lb ai/A for a total seasonal application rate of 3.68-3.72 lb ai/A/season. The higher application rate was approximately equivalent to twice the lower rate. Applications were made with ground equipment using dilute (~150 gal/A) or concentrated (~30 gal/A) sprays. A single control and duplicate treated samples of strawberries were collected from each test plot at commercial maturity, the same day as the last treatment (0-DAT). Samples were stored frozen from collection to analysis for 12-34 days, an interval supported by available stability data.

The LC/MS/MS method (BASF Method Number D9908) used to determine residues of boscalid in/on strawberry fruit is adequate for data collection. For this method, residues are extracted with methanol:water:2 N HCl, concentrated, cleaned up by solvent partitioning and analyzed by LC/MS/MS. The LOQ is 0.05 ppm for boscalid in/on strawberries and the LOD is 0.005 ppm.

The application volume had minimal or no impact on residue levels; therefore, the data from dilute and concentrated sprays were pooled. For the lower application rate, residues in/on 12 samples of strawberry from the 0-day pre-harvest interval (PHI) were 0.86-2.36 ppm and averaged 1.54 ppm. Eight of the twelve strawberry samples in these tests had boscalid residues



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(1.24-1.98 ppm) in excess of the current 1.2 ppm tolerance for boscalid in/on strawberry. For the higher application rate, residues in/on 12 samples of strawberry from the 0-day PHI were 2.02-4.12 ppm and averaged 3.01 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

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

COMPLIANCE:

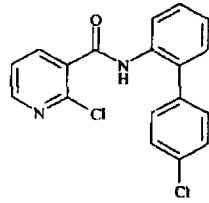
Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Boscalid is an anilide fungicide and inhibits mitochondrial respiration, inhibiting spore germination, germ tube elongation, mycelial growth, and sporulation of pathogenic fungi on the leaf surface. Permanent tolerances have been established in 40 CFR §180.589 for residues of boscalid in/on numerous plant and animal commodities, ranging from 0.02 ppm in/on eggs to 35 ppm in/on dried hops. A tolerance of 1.2 ppm has been established for strawberries. In addition, tolerances have been established for indirect or inadvertent residues of boscalid in/on numerous rotational crops, ranging from 0.05 ppm in/on undelinted cotton seed to 8.0 ppm in/on grass hay.

These supplemental strawberry field trials were conducted in response to over-tolerance residues observed in CA. As over-tolerance residues were only associated with CA, the three field trials conducted in CA are sufficient to reassess the higher tolerance on strawberries.

The nomenclature and physicochemical properties of boscalid are presented below in Tables A.1.1 and A.2.1.

Compound	
Common name	Boscalid

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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	MAI water dispersible granular formulation (WDG) containing 25.2 %boscalid and 12.8% pyraclostrobin. (Pristine® Fungicide; EPA Reg. No. 7969-199).

Parameter	Value	Reference
Melting point	143.4-143.6°C (TGAI)	D278385, M. Nelson, 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

Weather conditions were reported to be normal (Table B.1.1); no further details were provided. No unusual conditions that would affect the integrity of the study were reported. Rainfall was supplemented with irrigation as needed. Five plots were established at each test site, including a control plot, and four treated plots using either a 1x or 2x application rate with dilute or concentrate spray volumes (Table B.1.2).

Trial Identification (City, State, Year)	Soil characteristics				Meteorological data ¹	
	Type	%OM	pH	CEC	Overall total monthly rainfall range (inches)	Overall average monthly temperature range (°C)
Monterey, CA, 2004	Loam	NA = Not Applicable			Normal (0.00-0.08)	Normal (47.7-66.8)
Ventura Co. CA, 2004	Loam	NA			Normal (0.00-0.01)	Normal (49.4-76.4)
Tulare, CA, 2005	loam	NA			Normal (1.58-2.11)	Normal (42.28-79.58)

¹Detailed meteorological data were not provided.

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TABLE B.1.2. Study Use Pattern on Strawberry.

Location (City, State) Year	Application of WDG Formulation containing 25.2% Boscalid (B) ¹							
	EP ¹	Method ² ; Timing	Volume ³ (gal/A)	Single Rate (lb ai/A) ⁴	No. of Appl.	RTI (days)	Total Rate (lb ai/A) ⁴	Tank Mix Adjuvants ⁵
Monterey, CA, 2004	12.8% WDG	Broadcast foliar; beginning 28 days prior to normal harvest	30-32	0.36-0.39	5	7	1.89	Bond®
			149-158	0.36-0.39	5	7	1.86	Bond®
			30-32	0.73-0.76	5	7	3.72	Bond®
			148-154	0.72-0.75	5	7	3.70	Bond®
Ventura Co, CA, 2004	12.8% WDG	Broadcast foliar; beginning 28 days prior to normal harvest	30-31	0.36-0.37	5	6-8	1.84	Bond®
			149-159	0.36-0.38	5	6-8	1.86	Bond®
			30-32	0.72-0.76	5	6-8	3.70	Bond®
			149-157	0.72-0.75	5	6-8	3.68	Bond®
Tulare, CA 2005	12.8% WDG	Broadcast foliar; beginning 28 days prior to normal harvest	32	0.37	5	6-8	1.85	Bond®
			151-154	0.37	5	6-8	1.85	Bond®
			32	0.73-0.74	5	6-8	3.69	Bond®
			151-156	0.74-0.76	5	6-8	3.72	Bond®

- ¹ EP = End-use Product. The EP is a WDG containing 25.2% boscalid and 12.8% pyraclostrobin.
- ² The applications were made using ground equipment.
- ³ Sprays were applied as either a dilute or concentrated spray volume.
- ⁴ The 1x target application rate for the WDG formulation is 0.36 lb ai/A/application of boscalid for 1.8 lb ai/A/season.
- ⁵ Bond®, a commercial non-silicone based adjuvant, was applied according to the label on the adjuvant.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Region ¹	Strawberry		
	Submitted	Requested	
		Canada	US
1	--	NA	--
2	--	NA	--
3	--	NA	--
4	--	NA	--
5	--	NA	--
6	--	NA	--
7	--	NA	--
8	--	NA	--
9	--	NA	--
10	3	NA	3 ²
11	--	NA	--
12	--	NA	--
13	--	NA	--
Total	3	NA	3

- ¹ Regions 14-21 and 1A, 5A, 5B, and 7A were not included as the proposed use is for the US only.
 - ² As over-tolerance residues were observed only in CA, only supplemental residue data from CA are required.
- NA = not applicable.

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B.2. Sample Handling and Preparation

Strawberries were harvested at commercial maturity, the same day as the last application (0-DAT). A single control and duplicate treated strawberry (≥ 2 lbs each) samples were collected from each test and immediately placed in coolers with dry ice, then placed in frozen storage at the test facility within 8.5 hours. Samples were stored frozen for 3-5 days, then shipped by FedEx to the analytical laboratory, BASF Agro Research, RTP, NC, and stored frozen ($< -10^{\circ}\text{C}$) prior to analysis. Samples were stored frozen from collection to analysis for up to 34 days.

B.3. Analytical Methodology

Residues of boscalid were determined using a single LC/MS/MS method (BASF Method Number D9908). Method D9908 was validated in conjunction with a previous boscalid petition (D278385, M. Nelson, 8/15/03) and deemed acceptable for data collection. A brief description of the method follows.

Residues are extracted with methanol:water:2 N HCl (70:25:5, v/v/v), concentrated, cleaned up by partitioning into cyclohexane. Residues are then concentrated, redissolved in a methanol:buffer solution (99.9% 4 mM ammonium formate in water and 0.1% formic acid) (80:20, v/v) and analyzed by LC/MS/MS, using external standards. For quantitation, the product/daughter ion for the transition m/z 343 to 307 is measured. The LOQ is 0.05 ppm for boscalid in/on strawberries and the LOD is 0.005 ppm.

In conjunction with the current field trials, duplicate control samples of strawberries were fortified with boscalid at 0.05 and 2.0 ppm. The samples were analyzed concurrently with the field samples.

C. RESULTS AND DISCUSSION

The number and geographic representation of the strawberry field trials are adequate. These supplemental strawberry field trials were conducted in response to over-tolerance residues observed in CA. As over-tolerance residues were only associated with CA, the three field trials conducted in CA are sufficient to reassess the higher tolerance on strawberries.

In three strawberry field trials conducted during 2004 and 2005, a WDG formulation containing 25.2% boscalid and 12.8% pyraclostrobin was applied as five broadcast foliar applications to strawberries during fruit development at RTIs of 6-8 days. Based on the amount of product applied, the single application rate for boscalid was 0.360-0.385 lb ai/A/application, for a total of 1.84-1.89 lb ai/A/season, or 0.72-0.76 lb ai/A/application for a total of 3.68-3.72 lb ai/A/season. Applications were made with ground equipment using dilute (~150 gal/A) or concentrated (~30 gal/A) sprays. A single control and duplicate treated samples of strawberries were collected from each test at commercial maturity, on the day of the final application (0-DAT).



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The LC/MS/MS method (BASF Method Number D9908) used to determine residues of boscalid in/on strawberry fruit is adequate for data collection. Average concurrent recoveries were 94% with a standard deviation of 16% for boscalid (Table C.1). Apparent residues of boscalid were <LOD in/on all control samples. The LOQ is 0.05 ppm for boscalid in/on strawberries and the LOD is 0.005 ppm. Adequate sample calculations and chromatograms were provided.

Samples were stored frozen from collection to analysis for ≤34 days (Table C.2). Storage stability data are available on representative plant commodities indicating that boscalid is stable for at least 12 months (D278385, M. Nelson, 8/15/03). These data will support the current strawberry field trials.

TABLE C.1 Summary of Concurrent Recoveries of Boscalid from Strawberries using LC/MS/MS Method D9908.

Analyte	Strawberry Matrix	Spiking Level (mg/kg)	Sample size	Recoveries (%)	Mean Recovery ± SD (%)
Boscalid (BAS 510 F)	Fruit	0.05	4	85, 98, 93, 122	94 ± 16
		2.0	4	84, 97, 69, 104	

TABLE C.2 Summary of Boscalid Freezer Storage Conditions

Strawberry Matrix	Storage Temp. (°C)	Actual Storage Duration (days) ¹	Limit of Demonstrated Storage Stability (months) ²
Fruit	< -10	12-34	12

¹ Extracts were stored frozen for 0-1 days prior to analysis.

² Storage stability data are available indicating that boscalid is stable in frozen plant commodities for at least 12 months (D278385, M. Nelson, 8/15/03).

Residue levels from samples treated with the dilute vs. concentrated sprays were similar; therefore, residues from the two different spray volume treatments are combined in the following discussion. For the 1.85 lb ai/A/season application, boscalid residues in/on 12 samples of strawberries from the 0-day PHI were 0.86-2.36 ppm (Table C.3.1), with average residues of 1.54 ppm. For the 3.7 lb ai/A/season application, residues in/on 12 samples of strawberries from the 0-day PHI were 2.02-4.12 ppm, with average residues of 3.01 ppm.

The cultural practices used to maintain plants, the weather conditions, and the maintenance chemicals and fertilizer used in the study were typical for the growing region (CA) and did not have a notable impact on the residue data. In addition, the application volume has minimal or no impact on residue levels.

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TABLE C.3.1 Residue Data from Strawberry Field Trials with WDG Formulation Containing 25.2%¹ Boscalid

Trial ID (City, State, Year)	EPA Region	Strawberry Variety	Matrix	Spray Volume (gal/A)	Total Rate (lb ai/A)	PHI (days) ²	Boscalid Residues (ppm) ³
Monterey, CA, 2004	10	Diamante	Berry	~30	1.89	0	1.46, 1.88
				~150	1.86	0	1.98, 1.90
				~30	3.72	0	2.79, 3.85
				~150	3.70	0	3.88, 4.12
Ventura Co, CA, 2004	10	Camarosa	Berry	~30	1.84	0	0.86, 1.20
				~150	1.88	0	0.96, 1.17
				~30	3.70	0	2.43, 2.14
				~150	3.68	0	2.32, 2.02
Tulare, CA, 2005	10	Chandler	Berry	~30	1.85	0	1.24, 1.73
				~150	1.85	0	1.72, 2.36
				~30	3.69	0	2.74, 2.44
				~150	3.72	0	3.66, 3.72

¹ The EP contains 25.2% boscalid and 12.8% pyraclostrobin.
² The current PHI for strawberries is 0 days.
³ The LOQ is 0.05 ppm in/on strawberry fruit; the LOD is 0.005 ppm.

TABLE C.4. Summary of Residue Data for Strawberries from a Crop Field Trial using a WDG Formulation Containing 25.2% Boscalid.

Commodity	Formulation ¹	Total Rate (lb a.i./A)	PHI (days) ²	Residue	Residue Levels (ppm) ³						
					n	Min.	Max.	HAFT ⁴	Median (STMdR ⁵)	Mean (STMR ⁵)	Std. Dev.
Fruit	25.2% WDG	1.84-1.89	0	Parent	12	0.86	2.36	2.04	1.59	1.54	0.46
		3.68-3.72	0	Parent	12	2.02	4.12	4.00	2.77	3.01	0.78

¹ The EP contains 25.2% boscalid and 12.8% pyraclostrobin.
² The current PHI for strawberries is 0 days.
³ For boscalid, the LOQ is 0.05 ppm and the LOD is 0.005 ppm.
⁴ HAFT = Highest Average Field Trial.
⁵ STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The strawberry field trials are adequate. The current field trials reflect the use in CA (Region 10) of up to five foliar applications of a WDG formulation containing 25.2% boscalid at maximum seasonal rates of ~1.85 lb ai/A. Data are also available supporting a higher application rate (twice the lower rate), for which the maximum seasonal rate is ~3.7 lb ai/A for boscalid.

At the lower rate, maximum boscalid residues were 2.36 ppm at a 0-day PHI. At the higher rate, maximum boscalid residues were 4.12 ppm at a 0-day PHI.



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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: 4F6850
DP Barcode: 319565
PC Code: 128008