



Primary Evaluator

Date: 01/31/2008

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This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 08/06/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46841001 Duah, F. and Harbin, A. (2006) JAU6476 480 SC– Magnitude of the Residue in/on Soybeans: Lab Project Number: RAJAY026. Unpublished study prepared by Bayer CropScience and Pyxant Labs Inc. 489 p.

EXECUTIVE SUMMARY:

Bayer CropScience has submitted field trial data for prothioconazole on soybeans. Twenty-one soybean field trials were conducted in the United States and Canada in Zones 2 (GA; 1 trial), 3 (FL; 1 trial), 4 (AR, LA and MS; 3 trials) and 5 (IA, IL, IN, KS, MN, NE, OH, SD and ON; 15 trials) and 5B (QC; 1 trial) during the 2004-2005 growing seasons.

Each field trial location included a treated plot for the harvest of forage and hay and another plot for the harvest of seed. At both plots, a 4 lb/gal suspension concentrate (equivalent to a flowable concentrate (FIC)) formulation of prothioconazole was applied as three broadcast foliar applications, with 7- to 11-day retreatment intervals, at a target rate of 0.134 lb ai/A/application for a total of 0.391-0.449 lb ai/A. Applications made to the plot for harvest of forage/hay were started at the early to mid-flowering growth stage of the soybean plants, while applications made to the plot for harvest of seed were started when the soybean plants were at the pod development stage. All applications were made using ground equipment and included the use of a non-ionic surfactant. At each site, soybean forage and hay were harvested 5-7 days after the last treatment (DAT), and seeds were harvested at maturity, 19-23 DAT. At two trials, forage and hay samples were also harvested 0, 3, 10 and 14 DAT, and seed samples were also harvested 7, 14, 28 and 35 DAT to examine residue decline.

Samples were analyzed for total prothioconazole-derived residues (prothioconazole and its metabolite prothioconazole-desthio) using LC/MS/MS method (RPA JA/03/01). The method determines prothioconazole as prothioconazole sulfonic acid and prothioconazole-desthio which are reported as prothioconazole equivalents and totaled to yield “total prothioconazole derived residues.” The validated limit of quantitation (LOQ) for total prothioconazole-derived residues



was 0.05 ppm for soybean matrices. Samples were also analyzed for residues of 1,2,4-triazole and triazole conjugates (triazolylalanine and triazolylacetic acid) using an LC/MS/MS method (Morse Meth-160). The validated LOQ was 0.01 ppm for 1,2,4-triazole, and the LOQs were 0.05, 0.03, and 0.02 ppm for forage, hay, and seed, respectively, for the triazole conjugates. The methods are adequate for data collection based on acceptable concurrent method recovery data.

Soybean samples were stored frozen from collection to analysis for up to 18 months prior to analysis of prothioconazole derived residues, an interval supported by available storage stability data. Samples were also analyzed for triazole residues within ~17 months of harvest. Interim storage stability data for triazole residues for up to 6 months are available from the initial prothioconazole petition (PP#4F6830, DPs 303508 and 314517, 8/21/06, S. Funk). Once the ongoing triazole storage stability study is submitted and reviewed by the Agency, these data may be translated to support the storage conditions and durations of samples from the soybean field trials.

The maximum total prothioconazole-derived residues were 4.45 and 18.9 ppm in/on soybean forage and hay, respectively, harvested 5-7 days following treatment at 0.391-0.449 lb ai/A. For mature seed harvested 19-23 days following treatment at 0.393-0.413, the maximum total prothioconazole-derived residues were 0.142 ppm.

Based on the decline trial data, residues in soybean forage and hay generally declined with later harvest intervals. In the two residue decline tests, prothioconazole-derived residues in/on forage declined from averages of 2.8 ppm and 3.7 ppm at 0 DAT to 0.35 ppm and 0.46 ppm at 14 DAT, respectively. Prothioconazole-derived residues in/on hay declined from averages of 16.2 ppm and 18.9 ppm at 0 DAT to 1.40 ppm and 1.81 ppm at 14 DAT. For seeds, prothioconazole-derived residues were too low (<0.05 ppm) to determine decline trends.

The 1,2,4-triazole residues were <0.01-0.01 ppm for both forage and hay samples harvested 5-7 DAT. The triazole conjugate residues were <0.05-0.27 ppm and 0.04-0.40 ppm in the respective forage and hay samples. For composite samples of seed harvested 19-23 DAT, residues of 1,2,4-triazole were <0.01 ppm and residues of triazole conjugates were 0.04-0.08 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the soybean field trial data are classified as scientifically acceptable, pending submission of the final triazole metabolite storage stability results. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Chemistry Summary Document, DP# 331663.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.



A. BACKGROUND INFORMATION

Prothioconazole is a systemic demethylation inhibitor fungicide (Group 3 fungicide) of the triazolinthione chemical class. Currently, prothioconazole is registered for foliar treatment uses on barley, the dried shell and bean subgroup, the oilseed crop group, and wheat grown in the U.S. and Canada, and peanuts and rice in the U.S. only.

The current field trials and processing studies have been submitted in support of a petition for use on soybeans (PP#6F7073). The chemical structure and nomenclature of prothioconazole is presented in Table A.1, and the physicochemical properties of the technical grade of prothioconazole are presented in Table A.2.

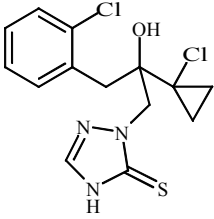
TABLE A.1. Nomenclature of Prothioconazole.	
Compound	
Common name	Prothioconazole
Company experimental names	JAU6476
IUPAC name	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2,4-triazole-3(4H)-thione
CAS name	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
CAS #	178928-70-6
End-use products/EP	Proline® 480 SC (4 lb/gal suspension concentrate)

Table A.2. Physicochemical Properties of Prothioconazole			
Parameter	Value	Reference	
Melting point/range	139.1 to 144.5°C	MRID 46246003	
pH	5.8	MRID 46246003	
Density	1.36 g/mL	MRID 46246003	
Water solubility	<u>mg/L (20°C)</u>	MRID 46246003	
	pH 4		5
	pH 8		300
	pH 9		2000



Parameter	Value	Reference	
Solvent solubility	<u>g/L at RT</u>	MRID 46246003	
	Acetone		>250
	Acetonitrile		69
	Dichloromethane		88
	Dimethylsulfoxide		126
	Ethyl acetate		>250
	n-Heptane		<0.1
	1-Octanol		58
	Polyethylene glycol		>250
	2-Propanol		87
Xylene	8		
Vapor pressure	<<4 x 10 ⁻⁷ Pa at 20 or 25°C (calculated from determinations at 70°C)	MRID 46246003	
Dissociation constant, pK _a	6.9 (calculated from K _{OW})	MRID 46246003	
Octanol/water partition coefficient, Log(K _{OW}) at 20°C	unbuffered water	4.05	MRID 46246003
	pH 4	4.16	
	pH 7	3.82	
	pH 9	2.00	
UV/visible absorption spectrum	Peak maximum at 257 nm	MRID 46246003	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Twenty-one soybean field trials were conducted in the United States and Canada in Zones 2 (GA; 1 trial), 3 (FL; 1 trial), 4 (AR, LA and MS; 3 trials) and 5 (IA, IL, IN, KS, MN, NE, OH, SD and ON; 15 trials) and 5B (QC; 1 trial) during the 2004-2005 growing seasons. At six study sites, a second trial was conducted in 2005, because the PHI for forage/hay (5 sites) or seed (1 site) could not be met with the first trial.

Each test site included a control plot and two treated plots, one for the harvest of forage and hay and the other for the harvest of mature seed. Treated plots received three broadcast foliar applications of a 4 lb/gal FIC formulation at a target rate of 0.134 lb ai/A/application, for a total of 0.402 lb ai/A. All applications were made using ground equipment and included the use of a non-ionic surfactant. The initial application was made at early to mid-flowering for the forage and hay plots, and at first visible pods to ripe pods at final length stage for the seed plots. Retreatment intervals were 7 to 11 days for all subsequent applications (except for the 2005 Stilwell, KS field trial which had a 17-day RTI for the second application). The study use pattern is detailed in Table B.1.2, and crop varieties are identified in Table C.3.

Soybeans were grown and maintained at each test site using typical agricultural practices for the respective geographical regions (Table B.1.1). Detailed temperature data were reported for all sites, and the study authors noted that temperature and precipitation during the field trials were comparable to historical averages for the trial sites except for the Molino, FL and Sabin, MN field trials which had twice the historical amounts of rainfall during the study period. Rainfall



was supplemented with irrigation at 2 of the 21 sites. Detailed information was also provided on maintenance chemicals and other pesticides used at each site.

Trial Identification (City, State; Year)	Soil characteristics			
	Type	%OM	pH	CEC ¹
Molino, FL; 2004	Sandy loam	2.2	6.3	8.4
Tifton, GA; 2004	Sand	0.79	5.8	3.6
Leland, MS; 2004	Loam	0.6	6.41	7.6
Washington, LA; 2004	Clay	1.2	5.7	22.6
Proctor, AR; 2004	Clay	3.7	5.9	13.1
Proctor, AR; 2005	Sandy clay	2.2	5.8	16.5
Seymour, IL; 2004	Silt loam	3.4	6.8	19.2
Stilwell, KS; 2004	Silt loam	2.6	5.6	15.9
Stilwell, KS; 2005	Silt loam	1.8	6.2	10.6
Springfield, NE; 2004	Silt loam	2.9	6.2	14.1
Sabin, MN; 2004	Silt	3.5	7.9	25
Sabin, MN; 2005	Silt loam	3.5	7.9	25
Rockwood, Ontario; 2004	Loam	2.3	7.8	12.5
Britton, SD; 2004	Loam	3.8	7.6	28.4
Dumfries, MN; 2004	Loam	2.9	6.3	21.0
New Holland, OH; 2004	Loam	2.2	6.9	12.2
New Holland, OH; 2005	Loam	2.2	6.8	12.2
Bagley, IA; 2004	Loam	4	6.5	15.6
York, NE; 2004	Silt loam	3.3	6.5	18.5
Sheridan, IN; 2004	Silt loam	3.0	6.0	12
Sheridan, IN; 2005	Silt loam	1.9	6.7	13
Richland, IA; 2004	Silty clay loam	3.9	6.8	24.6
Geneva, MN; 2004	Sandy clay loam	5.4	6.2	19.2
Hudson, KS; 2004	Fine sandy loam	2.1	6.5	9.2
Carlyle, IL; 2004	Silt loam	1.9	6.6	12
Carlyle, IL; 2005	Silt loam	2.2	6.7	9.9
St. Paul d'Abbotsford, Quebec; 2004	Loamy sand	5.9	5.0	19.61

¹ Unit of measurement was not provided.



TABLE B.1.2. Study Use Pattern.							
Location: City, State or Province; Year (Trial ID#)	Application Information						
	EP ¹	Method; Timing ²	Volume ³ (GPA)	Single Rate (lb ai/A) [kg ai/ha]	RTI ⁴ (days)	Total Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants
Molino, FL; 2004 (14)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications; from early flowering to 10% pods at final length	15-19	0.135-0.167 [0.149-0.154]	9, 10	0.449 [0.504]	NIS ⁵
		Plot 2: 3 broadcast foliar applications from pods at final length to 80% pods ripe	15-16	0.129-0.135 [0.145-0.151]	7, 10	0.394 [0.442]	NIS
Tifton, GA; 2004 (15)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from early flowering to flowering decline	15-16	0.134 [0.150]	8, 9	0.401 [0.450]	NIS
		Plot 2: 3 broadcast foliar applications from 50% pods at final length to first pod ripe	15	0.134 [0.150]	10, 10	0.401 [0.450]	NIS
Leland, MS; 2004 (16)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from 50% flowers open to end of flowering	16	0.130-0.136 [0.146-0.153]	11, 9	0.398 [0.446]	NIS
		Plot 2: 3 broadcast foliar applications from 70% pods at final size to pods at final length	16	0.133-0.140 [0.150-0.157]	10, 10	0.407 [0.457]	NIS
Washington, LA; 2004 (17)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications at early flowering	16-17	0.132-0.135 [0.149-0.151]	8, 10	0.401 [0.450]	NIS
		Plot 2: 3 broadcast foliar applications from 70% pods at final size to 10% pods ripe	18-21	0.133-0.140 [0.150-0.157]	10, 10	0.408 [0.457]	NIS
Proctor, AR; 2004 (18)	4 lb/gal FIC	3 broadcast foliar applications from visible shoots to 50% flowers open (seed plot)	15	0.133-0.134 [0.149-0.150]	10, 10	0.401 [0.449]	NIS
Proctor, AR; 2005 (18A)	4 lb/gal FIC	3 broadcast foliar applications from 3 rd node trifoliolate leaf unfolded to 50% flowers open (forage/hay plot)	15	0.132-0.135 [0.148-0.151]	10, 10	0.401 [0.450]	NIS
Seymour, IL; 2004 (19)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from 20% flowers open to flowering decline	13	0.131-0.136 [0.147-0.152]	8, 10	0.398 [0.446]	NIS
		Plot 2: 3 broadcast foliar applications from 10% pods ripe to all pods ripe	14	0.134-0.137 [0.151-0.154]	9, 8	0.407 [0.457]	NIS
Stilwell, KS; 2004 (20)	4 lb/gal FIC	3 broadcast foliar applications from all pods at final length to 70% pods ripe (seed plot)	15-16	0.133-0.136 [0.149-0.153]	9, 9	0.404 [0.454]	NIS
Stilwell, KS; 2005 (20A)	4 lb/gal FIC	3 broadcast foliar applications from end of flowering to 50% pods at final length (forage/hay plot)	14-15	0.131-0.135 [0.147-0.151]	17, 8	0.399 [0.448]	NIS
Springfield, NE; 2004 (21)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications at early flowering	14	0.133-0.135 [0.150-0.152]	8, 8	0.403 [0.452]	NIS
		Plot 2: 3 broadcast foliar applications from 70% pods at final length to first pod ripe	14-15	0.134 [0.150]	8, 8	0.401 [0.450]	NIS



TABLE B.1.2. Study Use Pattern.							
Location: City, State or Province; Year (Trial ID#)	Application Information						
	EP ¹	Method; Timing ²	Volume ³ (GPA)	Single Rate (lb ai/A) [kg ai/ha]	RTI ⁴ (days)	Total Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants
Sabin, MN; 2004 (22)	4 lb/gal FIC	3 broadcast foliar applications from 30% flowers open to 30% pods at final length (forage/hay plot)	11-12	0.131-0.135 [0.148-0.152]	9, 10	0.401 [0.450]	NIS
Sabin, MN; 2005 (22A)	4 lb/gal FIC	3 broadcast foliar applications from 10% flowers open to end of flowering (seed plot)	16-17	0.132-0.134 [0.148-0.150]	8, 10	0.399 [0.447]	NIS
Rockwood, Ontario; 2004 (23)	4 lb/gal FIC	<u>Plot 1:</u> 3 broadcast foliar applications from 3 rd node trifoliolate leaf unfolded to 60% flowers open	11	0.134-0.137 [0.151-0.154]	9, 10	0.408 [0.458]	NIS
		<u>Plot 2:</u> 3 broadcast foliar applications from 70% pods at final length to 40% leaves discolored or fallen	9-10	0.133-0.135 [0.150-0.151]	9, 10	0.402 [0.451]	NIS
Britton, SD; 2004 (24)	4 lb/gal FIC	<u>Plot 1:</u> 3 broadcast foliar applications from 3 rd node trifoliolate leaf unfolded to 20% flowers open	10	0.133 [0.149]	8, 9	0.398 [0.447]	NIS
		<u>Plot 2:</u> 3 broadcast foliar applications from 70% pods at final length to 30% pods ripe	10	0.133 [0.149]	10, 8	0.398 [0.447]	NIS
Dumfries, MN; 2004 (25)	4 lb/gal FIC	<u>Plot 1:</u> 3 broadcast foliar applications from shoot visible to 30% flowers open	19	0.134-0.136 [0.150-0.152]	10, 9	0.404 [0.453]	NIS
		<u>Plot 2:</u> 3 broadcast foliar applications from 50% pods at final length to all pods at final length	19	0.134 [0.150]	8, 10	0.402 [0.451]	NIS
New Holland, OH; 2004 (26)	4 lb/gal FIC	3 broadcast foliar applications from pods at final length to 30% leaves discolored or fallen (seed plot)	16	0.134-0.138 [0.151-0.155]	11, 11	0.409 [0.459]	NIS
New Holland, OH; 2005 (26A)	4 lb/gal FIC	3 broadcast foliar applications from 20% flowers open to end of flowering (forage/hay plot)	15-16	0.132-0.137 [0.148-0.154]	9, 9	0.406 [0.455]	NIS
Bagley, IA; 2004 (27)	4 lb/gal FIC	<u>Plot 1:</u> 3 broadcast foliar applications from 20% flowers open to flowering decline	17	0.129-0.139 [0.145-0.156]	8, 8	0.403 [0.452]	NIS
		<u>Plot 2:</u> 3 broadcast foliar applications from 30% pods at final length to all pods at final length	14	0.132-0.135 [0.148-0.151]	8, 9	0.401 [0.450]	NIS
York, NE; 2004 (28)	4 lb/gal FIC	<u>Plot 1:</u> 3 broadcast foliar applications from 5 th node trifoliolate leaf unfolded to 8 th node trifoliolate leaf unfolded	20	0.133-0.137 [0.149-0.154]	9, 10	0.404 [0.453]	NIS
		<u>Plot 2:</u> 3 broadcast foliar applications from 70% pods at final length to first pod ripe	20	0.133-0.134 [0.149-0.150]	10, 9	0.399 [0.448]	NIS
Sheridan, IN; 2004 (29)	4 lb/gal FIC	3 broadcast foliar applications from first flowers open to end of flowering (seed plot)	16-17	0.130-0.132 [0.146-0.148]	9, 10	0.393 [0.441]	NIS



Location: City, State or Province; Year (Trial ID#)	Application Information						
	EP ¹	Method; Timing ²	Volume ³ (GPA)	Single Rate (lb ai/A) [kg ai/ha]	RTI ⁴ (days)	Total Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants
Sheridan, IN; 2005 (29A)	4 lb/gal FIC	3 broadcast foliar applications from 20% flowers open to end of flowering (forage/hay plot)	18-21	0.132 [0.148]	10, 10	0.397 [0.445]	NIS
Richland, IA; 2004 (30)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from early flowering to 50% pods at final length	14-18	0.133-0.138 [0.149-0.154]	9, 9	0.403 [0.453]	NIS
		Plot 2: 3 broadcast foliar applications from 50% pods at final length to 30% pods ripe	14-18	0.133-0.135 [0.150-0.152]	8, 10	0.403 [0.452]	NIS
Geneva, MN; 2004 (31)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from shoots visible to 40% flowers open	15-16	0.132-0.135 [0.148-0.152]	8, 9	0.401 [0.450]	NIS
		Plot 2: 3 broadcast foliar applications from 70% pods at final length to first pod ripe	17	0.133-0.136 [0.150-0.152]	9, 8	0.403 [0.453]	NIS
Hudson, KS; 2004 (32)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from 60% flowers open to 70% pods at final length	18-19	0.129-0.140 [0.145-0.157]	9, 10	0.403 [0.453]	NIS
		Plot 2: 3 broadcast foliar applications when 70% pods at final length	18	0.133-0.134 [0.149-0.150]	10, 10	0.400 [0.449]	NIS
Carlyle, IL; 2004 (33)	4 lb/gal FIC	3 broadcast foliar applications from 70% pods at final length to all pods at final length (seed plot)	10	0.134-0.135 [0.150-0.151]	9, 9	0.403 [0.452]	NIS
Carlyle, IL; 2005 (33A)	4 lb/gal FIC	3 broadcast foliar applications from 50% flowers open to 60% flowers open (forage/hay plot)	15-18	0.133-0.135 [0.149-0.152]	8, 10	0.403 [0.452]	NIS
St. Paul d'Abbotsford, Quebec; 2004 (34)	4 lb/gal FIC	Plot 1: 3 broadcast foliar applications from early flowering to end of flowering	12-13	0.129-0.133 [0.145-0.149]	8, 10	0.391 [0.439]	NIS
		Plot 2: 3 broadcast foliar applications from 50% pods at final length to all pods at final length	13-18	0.134-0.141 [0.150-0.159]	9, 8	0.413 [0.464]	NIS

¹ EP = End-use Product

² Two plots were treated at each site; Plot 1 for the harvest of forage and hay, and Plot 2 for the harvest of seed. At several trial sites treatment of the seed plot occurred first (2004), and a second plot for forage and hay was treated in 2005.

³ GPA = Gallons per acre

⁴ RTI = Retreatment Interval

⁵ All applications included the use of a non-ionic surfactant (NIS).

NAFTA Growing Zones	Soybean		
	Submitted	Requested	
		Canada	U.S.
1			
1A			
2	1		2



TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Soybean		
	Submitted	Requested	
		Canada	U.S.
3	1 ¹		
4	3		3
5	15		15
5A			
5B	1		
6			
7			
7A			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	21		20

¹ This trial was conducted in the north-west corner of FL near Region 2.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of soybean forage and hay were collected at 5-7 DAT, and control and duplicate treated samples of seed were collected at maturity, 19-23 DAT. In two of the field trials used to examine residue decline, forage and hay were also harvested at 0, 3, 10, and 14 DAT, and seed was also harvested at 7, 14, 28, and 35 DAT. Samples were frozen within 2.5 hours of collection and remained frozen until shipment by freezer truck to Bayer Research Park (Stilwell, KS), where samples were homogenized and stored at <-15 °C. For analysis, samples were shipped frozen to Pyxant Labs Inc., and stored at <-20 °C until analysis.

For analysis of triazole and its metabolites, the treated seed samples were composited by PHI for each EPA region. The composite seed samples were homogenized and stored frozen (<-20 °C) at Pyxant Labs Inc.



B.3. Analytical Methodology

Samples of soybean forage, hay and seed were analyzed for residues of total prothioconazole-derived residues (prothioconazole and its metabolite prothioconazole-desthio) using LC/MS/MS method (RPA JA/03/01) with minor modifications. Briefly, samples were extracted with a mixture of methanol, 30% hydrogen peroxide, and 5% aqueous sodium bicarbonate at 65 EC for 2 hours. Prothioconazole is converted to a mixture of prothioconazole-desthio and prothioconazole sulfonic acid because of the oxidative extraction procedures; prothioconazole-desthio remains unchanged by the extraction procedures. The cooled extract was fortified with an isotopically labeled internal standard, cleaned up by C18 solid-phase extraction (SPE), and mixed with 1% aqueous acetic acid for analysis by LC/MS/MS. The results for prothioconazole sulfonic acid and prothioconazole-desthio are reported in prothioconazole equivalents and then totaled to yield “total prothioconazole derived residues.” The method was modified to use a different solvent for preparation of the fortification solutions and to use slightly different m/z values for the monitored ions. The validated LOQ for total prothioconazole-derived residues was 0.05 ppm for soybean matrices. The calculated limit of detection (LOD; based on the standard deviation of fortification recoveries at the LOQ and residues in the control sample) was 0.024 ppm for forage and 0.008 ppm for hay and seed.

Samples were also analyzed for residues of 1,2,4-triazole and the triazole conjugates (triazolylalanine and triazolylacetic acid) using an LC/MS/MS method (Morse Meth-160, Pyxant revision #2) with minor modifications. Briefly, crop matrices were extracted with methanol:water (80:20, v:v), and three separate aliquots of the extract were removed for isolation and determination of each of the three analytes. Isotopically labeled internal standard was added to each aliquot. For 1,2,4-triazole, the aliquot was mixed with dansyl chloride to form the dansyl derivative of 1,2,4-triazole, which was partitioned into ethyl acetate and then redissolved in acetonitrile (ACN)/water for LC/MS/MS analysis. For triazolylalanine, the aliquot was cleaned up by SPE, derivatized to the butyl ester using butanolic HCl, and then further derivatized using heptafluorobutyric anhydride (HFBA). The mixture was redissolved in ACN/water for LC/MS/MS analysis. For determination of triazolylacetic acid, the aliquot was cleaned up by SPE, derivatized to the butyl ester using butanolic HCl, and then redissolved in ACN/water for LC/MS/MS analysis. The method was modified to use different calibration standards and mobile phase gradients in the LC system. The validated LOQs were 0.01 ppm for 1,2,4-triazole, and the LOQs were 0.05, 0.03, and 0.02 ppm in forage, hay, and seed, respectively, for the triazole conjugates. The calculated LOD for 1,2,4-triazole was 0.001 ppm for hay and 0.003 ppm for forage and seed, and 0.007, 0.016 and 0.030 ppm for total triazole conjugates from seed, forage and hay, respectively.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2.1. Samples were stored frozen for up to 18 months prior to analysis for total prothioconazole-derived residues and ~17 months for analysis of triazole metabolites. Storage stability data are available indicating that prothioconazole and its desthio metabolite are stable at -15 °C for up to ~13 months in wheat (forage, hay and grain) and canola seed (46477701.der; PP# 4F6830, DP#s 303508 and 314517,



8/21/06, S. Funk); additional data from a marginally acceptable storage stability study indicate stability for up to 35 months in wheat forage and hay, and canola seed. The petitioner states that storage stability data are also available indicating that 1,2,4-triazole residues are stable at -15 °C for up to 24 months in wheat straw and wheat grain, but less stable in wheat forage (48% decomposition) and canola seed (73% decomposition) and that total residues for triazole conjugates are stable at -15 °C for up to 24 months in wheat forage, wheat straw and wheat grain, and relatively stable in canola seed (\leq 36% decomposition); these data are not currently available to the Agency. Once the ongoing triazole storage stability study is completed and reviewed by the Agency, these data may be translated to support the storage conditions and durations of samples from the soybean field trials.

Concurrent method recovery data are presented in Table C.1. The LC/MS/MS methods used to determine prothioconazole, prothioconazole-desthio, 1,2,4-triazole, and triazole conjugates (triazolylalanine and triazolylacetic acid) residues in/on soybean commodities are adequate for data collection based on the concurrent method recovery data. Average concurrent recoveries of prothioconazole fortified at 0.05 ppm and 0.15-20 ppm were 75% with a standard deviation of 12% from forage, 92% with a standard deviation of 14% from hay, and 90% with a standard deviation of 10% from seed. For prothioconazole sulfonic acid fortified at 0.05 ppm and 6-10 ppm (forage and hay only) average concurrent recoveries were 80% with a standard deviation of 9% from forage, 99% with a standard deviation of 8% from hay, and 100% with a standard deviation of 4% from seed. For desthio-prothioconazole fortified at 0.05 ppm and 0.15-15 ppm average concurrent recoveries were 90% with a standard deviation of 11% from forage, 99% with a standard deviation of 11% from hay, and 95% with a standard deviation of 6% from seed. The LOQ is 0.05 ppm for prothioconazole-derived residues in all matrices.

Average concurrent recoveries of 1,2,4-triazole fortified at 0.01 ppm were 92% with a standard deviation of 8% from forage, 105% with a standard deviation of 5% from hay, and 89% with a standard deviation of 6% from seed; average concurrent recoveries of triazolylalanine fortified at 0.02-0.05 ppm and 0.1-0.3 ppm were 91% with a standard deviation of 6% from forage, 79% with a standard deviation of 4% from hay, and 81% with a standard deviation of 8% from seed; and average concurrent recoveries of triazolylacetic acid fortified at 0.01 ppm and 0.02-0.20 ppm were 99% with a standard deviation of 4% from forage, 91% with a standard deviation of 12% from hay, and 91% with a standard deviation of 7% from seed. The LOQ for 1,2,4-triazole was 0.01 ppm in all matrices; and the LOQs for triazole conjugates were 0.05, 0.03, and 0.02 ppm for forage, hay, and seed, respectively.

Apparent residues of prothioconazole, its desthio-metabolite, and the triazole metabolites were each below the respective LOQ in/on all samples of untreated soybean forage, hay and seed. Adequate example calculations and sample chromatograms were provided.

Residue data from the soybean field trials are reported in Tables C.3.1. (total prothioconazole-derived residues), C.3.2. (triazole metabolites in forage and hay) and C.3.3 (triazole metabolites in composite seed). A summary of the residue data for soybean matrices is presented in Table C.4. Following foliar applications of the 4 lb/gal FIC at 0.391-0.449 lb ai/A, residues of prothioconazole-derived residues were <0.05-4.45 ppm in/on forage and 1.46-18.9 ppm in/on



hay 5-7 DAT. For mature seed harvested 19-23 days following treatment at 0.393-0.413 lb ai/A, the total prothioconazole-derived residues were <0.05-0.142 ppm.

Based on the residue decline trial data, prothioconazole residues in soybean forage and hay generally declined with later harvest intervals. In the two residue decline tests, prothioconazole-derived residues in/on forage declined from averages of 2.8 ppm and 3.7 ppm at 0 DAT to 0.35 ppm and 0.46 ppm at 14 DAT, respectively. Prothioconazole-derived residues in/on hay declined from averages of 16.2 ppm and 18.9 ppm at 0 DAT to 1.40 ppm and 1.81 ppm at 14 DAT. For seeds, prothioconazole-derived residues were too low (<0.05 ppm) to determine decline trends.

The 1,2,4-triazole residues were <0.01-0.01 ppm for both forage and hay samples harvested 5-7 days after treatment. The triazole conjugate residues were <0.05-0.27 ppm and 0.04-0.40 ppm in the respective forage and hay samples. For composite samples of seed harvested 19-23 DAT, residues of 1,2,4-triazole were <0.01 ppm and residues of triazole conjugates were 0.04-0.08 ppm.

Matrix	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Soybean, forage	Prothioconazole (JAU6476)	0.05	12	68, 71, 68, 77, 77, 75, 113, 68, 63, 85, 66, 70	75 ± 13
		12.5	3	79, 70, 70	73 ± 5
		Total	15	63-113	75 ± 12
	Prothioconazole Sulfonic Acid	0.05	12	75, 72, 76, 73, 72, 78, 73, 75, 81, 73, 94, 99	75 ± 9
		10	3	87, 85, 87	86 ± 1
		Total	15	72-99	80 ± 9
	Desthio-Prothioconazole	0.05	12	106, 88, 94, 99, 85, 105, 93, 82, 81, 70, 91, 110	92 ± 12
		10	3	85, 78, 79	81 ± 4
		Total	15	70-110	90 ± 11
	1,2,4-Triazole	0.01	7	84, 83, 99, 96, 87, 105, 87	92 ± 8
	Triazolylalanine	0.05	7	89, 92, 101, 86, 86, 93, 99	92 ± 6
		0.3	3	87, 84, 91	87 ± 4
		Total	10	84-101	91 ± 6
	Triazolylacetic Acid	0.01	7	100, 99, 105, 101, 103, 101, 92	100 ± 4
		0.2	3	100, 95, 97	97 ± 3
Total		10	92-105	99 ± 4	



TABLE C.1. Summary of Concurrent Recoveries of Prothioconazole from Soybean Matrices.					
Matrix	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Soybean, hay	Prothioconazole (JAU6476)	0.05	11	89, 82, 75, 84, 83, 82, 90, 83, 88, 86, 83	84 ± 4
		12.5	2	101, 105	103
		20.0	3	125, 119, 97	114 ± 15
		Total	16	75-125	92 ± 14
	Prothioconazole Sulfonic Acid	0.05	11	106, 91, 103, 106, 102, 101, 94, 90, 101, 85, 94	98 ± 7
		6.0	3	102, 98, 100	100 ± 2
		10	2	115, 109	112
		Total	16	85-115	99 ± 8
	Desthio-Prothioconazole	0.05	11	102, 76, 98, 89, 98, 95, 105, 84, 99, 102, 108	96 ± 10
		10	2	117, 113	115
		15.0	3	104, 101, 102	102 ± 2
		Total	16	75-117	99 ± 11
	1,2,4-Triazole	0.01	8	94-110	105 ± 5
	Triazolylalanine	0.03	8	83, 81, 86, 77, 73, 72, 83, 78	79 ± 5
		0.30	3	76, 80, 75	77 ± 3
		Total	11	72-86	79 ± 4
	Triazolylacetic Acid	0.01	8	81, 105, 106, 101, 98, 93, 86, 70	94 ± 12
		0.02	3	81, 90, 76	82 ± 7
		Total	11	70-106	91 ± 12
	Soybean, seed	Prothioconazole (JAU6476)	0.05	11	102, 98, 91, 89, 100, 94, 94, 100, 99, 89, 82
0.15			3	74, 72, 78	75 ± 3
Total			14	72-102	90 ± 10
Prothioconazole Sulfonic Acid		0.05	11	100, 105, 102, 92, 96, 103, 96, 104, 102, 101, 96	100 ± 4
Desthio-Prothioconazole		0.05	11	92, 96, 81, 89, 95, 98, 97, 107, 99, 98, 89	95 ± 7
		0.15	3	95, 98, 95	96 ± 2
		Total	14	81-107	95 ± 6
1,2,4-Triazole		0.01	8	81-99	89 ± 6
Triazolylalanine		0.02	8	81, 83, 80, 89, 89, 87, 91, 70	84 ± 7
		0.1	3	71, 70, 77	73 ± 4
		Total	11	70-91	81 ± 8
Triazolylacetic Acid		0.01	8	96, 87, 86, 94, 99, 96, 101, 88	93 ± 6
		0.2	3	88, 80, 81	83 ± 4
		Total	11	80-101	91 ± 7



Matrix	Analyte	Storage Temp. (°C)	Actual Storage Duration ¹	Limit of Demonstrated Storage Stability
Soybean forage, hay and seed	Prothioconazole	<-15	390-540 days (12.8-17.8 months)	12.7 and 35 months in wheat forage, hay and grain and canola seed ²
	Desthio-prothioconazole			
	1,2,4-Triazole		464-530 days (15.3-17.4 months)	Awaiting final report ³
	Triazolylalanine			
	Triazolylacetic Acid			

¹ Duration from harvest to analysis; extracts were analyzed within 18 days of extraction.

² DP#s 303508 and 314517, 8/21/06, S Funk.

³ The petitioner submits that 24-month data of an ongoing 3-year storage stability study indicate that residues of 1,2,4-triazole are relatively stable ($\leq 30\%$ decomposition) in frozen wheat straw and grain, but less stable in wheat forage and canola seed, and residues of the triazole conjugates are relatively stable in wheat forage, straw and grain and canola seed; however only the 6-month interim data (MRID 46246211) have been submitted to the Agency to date.

Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Total Prothioconazole-Derived Residues (ppm) ¹
Molino, FL; 2004 (JA014-04D)	3	Pioneer 96M20	0.449	Forage	0	2.26, 3.37 ²
					3	1.20, 1.50
					7	0.626, 0.746
					10	0.544, 0.498
					14	0.326, 0.369
				Hay	0	19.2, 13.2
					3	6.75, 6.40
					7	2.70, 2.55
					10	1.56, 1.64
					14	1.27, 1.52
			0.394	Seed	7	ND, ND
					14	ND, (0.015)
					21	(0.023), (0.012)
					28	(0.025), (0.024)
					35	(0.026), (0.021)
Tifton, GA; 2004 (JA015-04H)	2	Pioneer RR	0.401	Forage	7	1.39, 1.09
				Hay	7	5.53, 2.35
			0.401	Seed	21	(0.035), (0.032)
Leland, MS; 2004 (JA016-04H)	4	Pioneer 9492RR	0.398	Forage	7	1.99, 1.61
				Hay	7	5.90, 6.89
			0.407	Seed	20	(0.048), 0.055
Washington, LA; 2004 (JA017-04H)	4	DP 5915RR	0.401	Forage	7	1.75, 1.75
				Hay	7	6.74, 6.04
			0.408	Seed	21	(0.015), (0.013)



TABLE C.3.1 Residue Data from Soybean Field Trials with Prothioconazole.						
Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Total Prothioconazole-Derived Residues (ppm) ¹
Proctor, AR; 2005 (JA018-04HA)	4	AG 4403RR	0.401	Forage	7	4.45, 4.04
				Hay	7	17.6, 18.9
Proctor, AR; 2004 (JA018-04H)		DP 5634RR	0.401	Seed	21	0.060, (0.046)
Seymour, IL; 2004 (JA019-04H)	5	Stine 2788	0.398	Forage	0	3.71 ² , 3.60 ²
					3	2.47 ² , 2.01
					7	1.19, 1.43
					10	1.12, 1.12
					14	0.482, 0.429
				Hay	0	19.6, 18.1
					3	8.94, 10.2
					7	6.18, 5.14
					10	4.12, 5.01
				0.407	Seed	7
			14			(0.029), (0.029)
			21			(0.014), (0.019)
			28			(0.012), ND
			35			ND, (0.016)
Stilwell, KS; 2005 (JA020-04HA)	5	Taylor 427RR	0.399	Forage	7	1.61, 1.57
				Hay	7	7.21, 5.17
Stilwell, KS; 2004 (JA020-04H)		Fontanelle	0.404	Seed	23	(0.043), 0.071
Springfield, NE; 2004 (JA021-04H)	5	NKS28W2	0.403	Forage	5	1.34, 1.51
				Hay	5	4.78, 5.01
			0.401	Seed	19	(0.025), (0.021)
Sabin, MN; 2004 (JA022-04H)	5	Jim	0.401	Forage	7	0.705, 0.736
				Hay	7	4.14, 4.29
Sabin, MN; 2005 (JA022-04HA)		RG 200RR	0.399	Seed	19	(0.017), (0.019)
Rockwood, Ontario; 2004 (JA023-04H)	5	DKB06-52	0.408	Forage	7	0.620, 0.689
				Hay	7	8.72, 6.51
			0.402	Seed	21	(0.032), (0.035)
Britton, SD; 2004 (JA024-04H)	5	Cropland RT 0907	0.398	Forage	7	2.17, 1.70
				Hay	7	7.16, 5.47
			0.398	Seed	19	ND, ND
Dumfries, MN; 2004 (JA025-04H)	5	Cropland RT 1447	0.404	Forage	7	1.82, 1.56
				Hay	7	6.65, 8.23
			0.402	Seed	21	(0.037), (0.039)
New Holland, OH; 2005 (JA026-04HA)	5	SC 9374	0.406	Forage	6	1.03, 1.19
				Hay	6	1.62, 1.46



TABLE C.3.1 Residue Data from Soybean Field Trials with Prothioconazole.

Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Total Prothioconazole-Derived Residues (ppm) ¹
New Holland, OH; 2004 (JA026-04H)		SC 9373	0.409	Seed	20	0.142, 0.103
Bagley, IA; 2004 (JA027-04H)	5	92M70	0.403	Forage	7	1.61, 1.51
				Hay	7	6.93, 5.69
				0.401	Seed	19
York, NE; 2004 (JA028-04H)	5	Dyna Gro DG	0.404	Forage	7	0.967, 0.656
				Hay	7	4.31, 4.32
			0.399	Seed	19	(0.019), (0.024)
Sheridan, IN; 2005 (JA029-04HA)	5	Dairyland 3410 RR	0.397	Forage	7	(0.242), (0.242)
				Hay	6	6.93, 4.26
Sheridan, IN; 2004 (JA029-04H)			0.393	Seed	21	ND, ND
Richland, IA; 2004 (JA030-04H)	5	Pioneer 93M80	0.403	Forage	7	0.485, 0.091
				Hay	7	6.99, 4.28
			0.403	Seed	21	(0.022), (0.033)
Geneva, MN; 2004 (JA031-04H)	5	Pioneer 91M50	0.401	Forage	7	2.31, 2.75
				Hay	7	8.35, 8.11
			0.403	Seed	20	(0.029), (0.030)
Hudson, KS; 2004 (JA032-04H)	5	Pioneer 93B85	0.403	Forage	6	1.19, 1.34
				Hay	6	5.25, 5.26
			0.400	Seed	21	(0.036), (0.044)
Carlyle, IL; 2005 (JA033-04HA)	5	NK 43-B1	0.403	Forage	7	0.091, 0.088
				Hay	7	2.38, 1.91
Carlyle, IL; 2004 (JA033-04H)		BT-383CR	0.403	Seed	21	(0.033), (0.019)
St. Paul d'Abbotsford, Quebec; 2004 (JA034-04H)	5B	NK0880	0.391	Forage	5	1.98, 2.84
				Hay	5	7.37, 5.59
			0.413	Seed	20	(0.019), (0.020)

¹ The total prothioconazole-derived residues included prothioconazole and prothioconazole-desthio residues. The LOQ was 0.05 ppm for prothioconazole-derived residues. The LODs for prothioconazole-derived residues were 0.024 ppm for forage and 0.008 ppm for hay and seed. Values in parentheses are between the LOD and the LOQ. ND= Not detected and below the LOD.

² The average of duplicate analyses is reported.

TABLE C.3.2 Forage and Hay Triazole Residue Data from Soybean Field Trials with Prothioconazole.

Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Residues (ppm) ¹	
						1,2,4-Triazole	Triazole Conjugate
Molino, FL; 2004 (JA014-04D)	3	Pioneer 96M20	0.449	Forage	7	ND	0.11
				Hay	7	ND	0.06
Tifton, GA; 2004 (JA015-04H)	2	Pioneer RR	0.401	Forage	7	ND	0.06
				Hay	7	(0.004)	0.19



TABLE C.3.2 Forage and Hay Triazole Residue Data from Soybean Field Trials with Prothioconazole.							
Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Residues (ppm) ¹	
						1,2,4-Triazole	Triazole Conjugate
Leland, MS; 2004 (JA016-04H)	4	Pioneer 9492RR	0.398	Forage	7	ND	0.09
				Hay	7	(0.002)	0.18
Washington, LA; 2004 (JA017-04H)	4	DP 5915RR	0.401	Forage	7	ND	ND
				Hay	7	ND	0.05
Proctor, AR; 2005 (JA018-04HA)	4	AG 4403RR	0.401	Forage	7	ND	(0.024)
				Hay	7	(0.006)	0.06
Seymour, IL; 2004 (JA019-04H)	5	Stine 2788	0.398	Forage	7	ND	(0.046)
				Hay	0	ND	0.10
Stilwell, KS; 2005 (JA020-04HA)	5	Taylor 427RR	0.399	Forage	7	ND	0.23
				Hay	7	(0.003)	0.05
Springfield, NE; 2004 (JA021-04H)	5	NKS 28W2	0.403	Forage	5	ND	0.06
				Hay	5	(0.002)	0.19
Sabin, MN; 2004 (JA022-04H)	5	Jim	0.401	Forage	7	ND	0.27
				Hay	7	(0.005)	0.08
Rockwood, Ontario; 2004 (JA023-04H)	5	DKB 0652	0.408	Forage	7	ND	0.05
				Hay	7	0.01	0.40
Britton, SD; 2004 (JA024-04H)	5	Cropland RT 0907	0.398	Forage	7	ND	(0.026)
				Hay	7	ND	0.08
Dumfries, MN; 2004 (JA025-04H)	5	Cropland RT 1447	0.404	Forage	7	ND	(0.047)
				Hay	7	ND	0.20
New Holland, OH; 2005 (JA026-04HA)	5	SC 9374	0.406	Forage	6	ND	0.10
				Hay	6	ND	0.28
Bagley, IA; 2004 (JA027-04H)	5	92M70	0.403	Forage	7	ND	0.07
				Hay	7	ND	0.19
York, NE; 2004 (JA028-04H)	5	Dyna Gro DG	0.404	Forage	7	ND	0.06
				Hay	7	ND	0.26
Sheridan, IN; 2005 (JA029-04HA)	5	Dairyland 3410 RR	0.397	Forage	7	ND	(0.045)
				Hay	6	ND	0.07
Richland, IA; 2004 (JA030-04H)	5	Pioneer 93M80	0.403	Forage	7	ND	(0.023)
				Hay	7	ND	0.04
Geneva, MN; 2004 (JA031-04H)	5	Pioneer 91M50	0.401	Forage	7	ND	0.06
				Hay	7	(0.002)	0.19
Hudson, KS; 2004 (JA032-04H)	5	Pioneer 93B85	0.403	Forage	6	ND	0.14
				Hay	6	ND	0.17
Carlyle, IL; 2005 (JA033-04HA)	5	NK 43-B1	0.403	Forage	7	ND	0.07
				Hay	7	ND	0.17



TABLE C.3.2 Forage and Hay Triazole Residue Data from Soybean Field Trials with Prothioconazole.

Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate (lb ai/A)	Commodity or Matrix	PHI (days)	Residues (ppm) ¹	
						1,2,4-Triazole	Triazole Conjugate
St. Paul d'Abbotsford, Quebec; 2004 (JA034-04H)	5B	NK0880	0.391	Forage	5	ND	0.06
				Hay	5	ND	0.17

¹ Residues are expressed in terms of each analyte. The LOQ for 1,2,4-triazole was 0.01 ppm; and the LOQs for triazole conjugates were 0.05 and 0.03 ppm for forage and hay, respectively. The LODs for 1,2,4-triazole were 0.003 ppm for forage and 0.001 ppm for hay; and the LODs for triazole conjugates were 0.016 and 0.030 ppm for forage and hay, respectively. Values in parentheses are between the LOD and the LOQ. ND= Not detected and below the LOD.

TABLE C.3.3 Composite Seed Triazole Residue Data from Soybean Field Trials with Prothioconazole.

Trial: City, State or Province; Year (Trial ID#)	Zone	Variety	Total Rate ¹ (lb ai/A)	Commodity or Matrix	PHI (days)	Residues (ppm) ²	
						1,2,4-Triazole	Triazole Conjugate
Molino, FL; 2004 (JA014-04D)	2/3	Pioneer 96M20	0.401	Seed	21	ND, ND	0.048, 0.057
Tifton, GA; 2004 (JA015-04H)		Pioneer RR					
Leland, MS; 2004 (JA016-04H)	4	Pioneer 9492RR	0.401	Seed	21	ND, ND	0.061, 0.055
Washington, LA; 2004 (JA017-04H)		DP 5915 RR					
Proctor, AR; 2004 (JA018-04H)		DP 5634 RR					
Seymour, IL; 2004 (JA019-04H)	5	Stine 2788	0.401	Seed	21	ND, ND	0.043, 0.043
Stilwell, KS; 2004 (JA020-04H)		Fontanelle					
Springfield, NE; 2004 (JA021-04H)		NKS28W2					
Sabin, MN; 2005 (JA022-04HA)		RG 200 RR					
Rockwood, Ontario; 2004 (JA023-04H)		DKB06-52					
Britton, SD; 2004 (JA024-04H)		Cropland RT 0907					
Dumfries, MN; 2004 (JA025-04H)		Cropland RT 1447					
New Holland, OH; 2004 (JA026-04H)		SC 9373					
Bagley, IA; 2004 (JA027-04H)		92M70					
York, NE; 2004 (JA028-04H)		Dyna Gro DG					
Sheridan, IN; 2004 (JA029-04H)		Dairyland 3410 RR					
Richland, IA; 2004 (JA030-04H)		Pioneer 93M80					
Geneva, MN; 2004 (JA031-04H)		Pioneer 91M50					
Hudson, KS; 2004 (JA032-04H)		Pioneer 93B85					
Carlyle, IL; 2004 (JA033-04H)		BT-383CR					
St. Paul d'Abbotsford, Quebec; 2004 (JA034-04H)	5B	NK0880	0.413	Seed	20	ND, ND	0.075, 0.076

¹ The total rate was based on the nominal rate.

² Residues are expressed in terms of each analyte. The LOQ for 1,2,4-triazole was 0.01 ppm and the LOQ for triazole conjugates was 0.02 ppm for seed. The LOD for 1,2,4-triazole was 0.003 ppm and the LOD for triazole conjugates was 0.007 ppm for seed. ND= Not detected and below the LOD.



TABLE C.4. Summary of Residue Data from Soybean Field Trials with Prothioconazole.									
Matrix	Total Rate (lb ai/A)	PHI (days)	Residues (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median (STMdR)	Mean (STMR)	Std. Dev.
Total Prothioconazole-Derived Residues									
Forage	0.391-0.449	5-7	42	<0.05	4.45	4.25	1.37	1.39	0.95
Hay		5-7	42	1.46	18.9	18.3	5.56	5.97	3.36
Seed	0.393-0.413	19-23	42	<0.05	0.142	0.12	0.05	0.05	0.02
1,2,4-Triazole Residues									
Forage	0.391-0.449	5-7	21	<0.01	0.01	NA	0.01	0.01	0.00
Hay		5-7	21	<0.01	0.01	NA	0.01	0.01	0.00
Seed	0.393-0.413	19-23	8	<0.01	<0.01	<0.01	<0.01	<0.01	0.00
Triazole Conjugate Residues									
Forage	0.391-0.449	5-7	21	<0.05	0.27	NA	0.06	0.08	0.06
Hay		5-7	21	0.04	0.40	NA	0.17	0.15	0.09
Seed	0.393-0.413	19-23	8	0.04	0.08	0.08	0.06	0.06	0.01

¹ The LOQ was used for all residues reported below the LOQ (see Tables C.3.1-C.3.3) in the statistical calculations. The LOQ was 0.05 ppm for prothioconazole-derived residues; the LOQ for 1,2,4-triazole was 0.01 ppm; and the LOQs for triazole conjugate were 0.05, 0.03, and 0.02 ppm for forage, hay, and seed, respectively.

² HAFT = Highest Average Field Trial.

D. CONCLUSION

The soybean field trial data are adequate and reflect the use of three broadcast foliar applications of the 4 lb/gal FIC formulation of prothioconazole to soybeans from early flowering through pod development at 0.391-0.449 lb ai/A/season, with PHIs of 7 days for forage and hay, and 21 days for seed. An acceptable method was used for quantitation of prothioconazole-derived and triazole metabolite residues in/on soybean matrices, and adequate storage stability data support prothioconazole-derived residues from the study; however, additional storage stability data are required for the triazole metabolites in/on soybean forage, hay and seed.

E. REFERENCES

DP#s: 303508 and 314517
 Subject: Prothioconazole. Petition for Establishment of Tolerances for Use on Barley, Oilseed (Except Sunflower and Safflower) Crop Group, Dried Shelled Peas and Bean (Except Soybean) Crop Subgroup, Peanut, Rice, and Wheat. Summary of Analytical Chemistry and Residue Data. PP#4F6830.
 From: S. Funk
 To: L. Coppolino
 Date: 08/21/06
 MRIDs: 46246139, 46246141-50, 46246201-11, 46246213-27, and 4677701-04



Prothioconazole/PC Code 113961/Bayer CropScience/264

DACO 7.4.1/7.4.2/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/Residue Decline - Soybean

F. DOCUMENT TRACKING

RDI: S. Funk (01/31/2008); Leung Cheng

Petition Number: 6F7073

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