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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

Date: 9/14/10

Subject: Azoxystrobin. Petition for the Addition of an Ultra-low Volume Application to Corn. Summary of Analytical Chemistry and Residue Data.

PC Code: 128810
Decision Nos.: 429012
Petition No.: 100-1178
Risk Assessment Type: Single Chemical/Aggregate
TXR No.: NA
MRID No.: 48064701

DP Barcodes: 376966
Registration No.: 100-1178
Regulatory Action: Amended Section 3
Case No.: NA
CAS No.: 131860-33-8
40 CFR: 180.507

Ver.Apr.08

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Risk Integration Minor Use and Emergency Response Branch (RIMUERB)
Registration Division (RD; 7505P)

Through: L. Cheng, Senior Chemist
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Health Effects Division (HED; 7509P)

To: S. Hill/S. Joyner PM 20
RD (7505P)

Executive Summary

This document addresses the adequacy of available residue chemistry data and the submission from Syngenta Crop Protection, Inc. for the purpose of amending the product label for Quilt® (EPA Reg. No.100-1178) containing 7.0% ai (0.62 lb ai/gal) azoxystrobin to include ultra-low volume (ULV) applications to corn.

Azoxystrobin is a broad-spectrum fungicide and belongs to a new class of pesticidal compounds called β-methoxyacrylates, which are derived from the naturally occurring strobilurins. Its biochemical mode of action is inhibition of electron transport. The fungicide is currently registered for use on a variety of field, vegetable, fruit, and nut crops as well as on ornamental plants and turfs. End-use products of azoxystrobin are typically formulated as water dispersible granular (WDG), flowable concentrate (FlC), and soluble emulsion (SE) formulations. These products may be applied as in-furrow at planting or postemergence foliar applications using

Dfcvd 9/28/2010

ground or aerial equipment at maximum seasonal rates of 0.40-2.0 lb ai/A. Azoxystrobin is also registered for seed treatment of many food/feed crops as well as for postharvest uses of banana/plantains and citrus fruits.

Azoxystrobin tolerances have been established in 40 CFR §180.507. Tolerances for plant commodities are listed in 40 CFR §180.507(a)(1) and are expressed in terms of residues of the fungicide, azoxystrobin and the Z-isomer of azoxystrobin. The established tolerances for plant commodities range from 0.01 ppm in/on pecans to 260 ppm in/on herb subgroup 19A, dried leaves. Tolerances for animal commodities are listed in 40 CFR §180.507(a)(2) and are expressed in terms of residues of the azoxystrobin. The established tolerances for livestock commodities range from 0.006 (milk) to 0.07 (meat byproducts) ppm; no tolerances are currently established for poultry commodities.

The nature of the residue in plants, rotational crops, and animals is adequately understood. Acceptable metabolism studies have been conducted on primary crops of grapes, peanuts, and wheat as well as on representative rotational crops. Acceptable metabolism studies on goats and laying hens are also available. The residues of concern in/on plants and rotational crops, for the tolerance expression and risk assessment purposes, are azoxystrobin and its Z-isomer. The residue of concern in livestock is parent azoxystrobin only.

There are adequate residue analytical methods for tolerance enforcement. For analysis of plant commodities for residues of azoxystrobin and its Z-isomer, a gas chromatography with nitrogen phosphorus detector (GC/NPD) method (RAM 243/04) has undergone a Petition Method Validation (PMV) by the Analytical Chemistry Branch (ACB/BEAD). For analysis of animal commodities for residues of azoxystrobin, a GC/NPD method (RAM 255/01) has been validated by an independent laboratory for the analysis of milk, liver and eggs, and by the ACB/BEAD for the analysis of milk and liver.

Crop samples in the current submission were analyzed for residues of azoxystrobin and Z-isomer (R230310) using Syngenta Method RAM 305/03. Final analysis was by high performance liquid chromatography with triple-quadrupole mass-spectrometric detection (LC-MS/MS). Recoveries from the method validation and concurrent recovery studies ranged from 70-99%. The limit of quantitation (LOQ) for both azoxystrobin and its Z-isomer was 0.01 ppm in all matrices. The method was shown to be adequate for data collection.

The requirements for multiresidue methods testing data for azoxystrobin are fulfilled. The available data indicate that azoxystrobin could not be recovered through application of the multiresidue protocols.

Previously submitted storage stability data indicate that residues of azoxystrobin and the Z-isomer are reasonably stable for at least two years under frozen storage in/on numerous commodities. These data are adequate for the purpose of supporting the submitted residue field trials.

Adequate cattle and poultry feeding studies are available to support the livestock dietary burdens resulting from the proposed uses. Dietary burdens were calculated reflecting the most recent guidance concerning revisions of feedstuff percentages and reasonably balanced livestock diets

were constructed. Since the present action will not increase the existing tolerances or establish new tolerances on corn feed items, no increase in animal commodity tolerances are required.

Azoxystrobin was applied to corn forage using one application of 0.129 lb ai/A, and to corn stover and grain using two applications for a total of 0.258 lb ai/A. At each trial site treatment regimens included a non-treated control (UTC), a back-pack sprayer application at > 10 gallons per acre (GPA), an aerial ULV application at 0.5 GPA, and hand controlled-droplet applicator (CDA) application at 0.5 GPA. Forage was harvested at a 26-day PHI, and stover and grain were harvested at a 30-day PHI. The results from these trials show that maximum combined residues are 2.04 ppm, 0.133 ppm, and 0.050 ppm on forage treated at 0.129 lb ai/A with a 26-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. Maximum combined residues are 0.3759 ppm, 1.0876 ppm, and 0.1610 ppm on stover treated at 0.258 lb ai/A with a 30-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. No residues above the LOQ were found in any corn grain sample. The data from the side-by-side residue field trials indicate that the use of ULV applications will not increase the azoxystrobin residue levels on corn commodities. In addition, there are no significant differences between conventional ground, aerial ULV, or CDA applications. No increase in the established corn RAC commodity tolerances is required for the proposed use.

The previously submitted field corn processing data were determined to be adequate. The data indicated that the only corn processed commodity in which the residues of azoxystrobin and its Z isomer concentrated was refined oil, at 5.6 and 5.9x, respectively. Based on the highest average field trial (HAFT; <0.02 ppm) value and an average concentration factor of 5.8x, the maximum expected combined residue in refined corn oil would not exceed the existing grain tolerance of 0.3 ppm. No increase in the established corn processed commodity tolerances is required for the proposed use.

There are adequate field rotational crop data to support the following rotational crop restrictions on the product labels: "Do not plant the following crops for a period of 12 months (unless an azoxystrobin product is registered for use on that crop): buckwheat, millet, oats, and rye. A plantback interval of 36 days is required for leafy vegetables (except *Brassica*) group; *Brassica*, leafy greens subgroup; vegetables, root subgroup; vegetable (tuberous and corm subgroup); and vegetables, leaves of root and tuber group. Crops with registered azoxystrobin uses may be planted immediately after the last treatment."

Since no new tolerances need to established or existing tolerances changed as a result of the findings of this document, international harmonization is not of concern.

Regulatory Recommendations and Residue Chemistry Deficiencies

ARIA recommends for the change in use pattern to include an ULV application.

Since there is no need for changes in any of the existing tolerances and no establishment of new tolerances, or an increase in the product application rate, an updated human health risk assessment is not required.

Background

The chemical structure and nomenclature of azoxystrobin and its Z-isomer, and the physicochemical properties of the technical grade of azoxystrobin are presented in Tables 1 and 2, respectively.

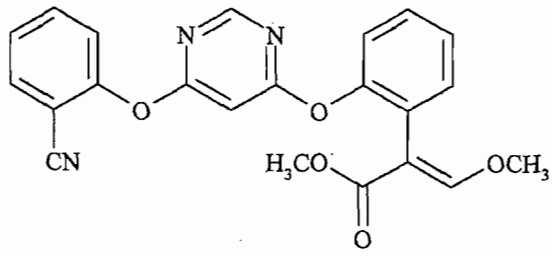
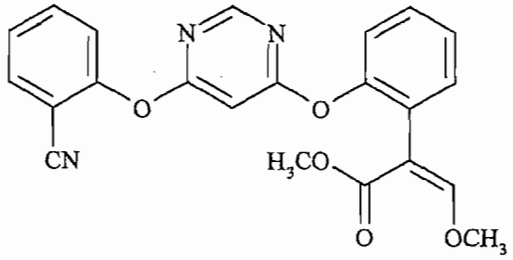
Table 1. Azoxystrobin Nomenclature.	
Compound	
Common name	Azoxystrobin
Company experimental name	ICIA5504 (Zeneca), R215504 (Syngenta)
IUPAC name	Methyl (E)-2-{2-[6-(2-cyanophenoxy)pyramidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS name	Methyl-(E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-(methoxymethylene)-benzeneacetate
CAS registry number	131860-33-8
End-use products (EP)	Quilt® Fungicide (EPA Reg. No. 100-1178)
Regulated metabolite	
Common name	Azoxystrobin, Z-isomer
Chemical name	Methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyramidin-4-yloxy]phenyl}-3-methoxyacrylate

Table 2. Physicochemical Properties of Technical Grade Azoxystrobin.		
Parameter	Value	Reference
Melting point/range	114-116°C	DP#s 218318 and 218448, 3/19/96, J. Garbus
pH	6.4	
Density	1.25 g/cm^3	
Water solubility	(20°C) pH 5.2 6.7 mg/L pH 7.0 6.7 mg/L pH 9.2 5.9 mg/L	

Table 2. Physicochemical Properties of Technical Grade Azoxystrobin.		
Parameter	Value	Reference
Solvent solubility	(mg/mL at 20°C) Hexane 0.057 Octanol 1.4 Methanol 20 Toluene 55 Acetone 86 Ethyl Acetate 130 Acetonitrile 340 Dichloromethane 400	
Vapor pressure	(20°C) $1.1x10^{-13}$ kPa ($8.2x10^{-13}$ mmHg)	
Dissociation constant, pK_a	Not dissociable	
Octanol/water partition coefficient, Log(K_{OW})	log P_{OW} = 2.5	
UV/visible absorption spectrum	Not available	

860.1200 Directions for Use

Table 3. Summary of Directions for Use of Azoxystrobin.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Corn, Field + Pop (includes seed production)						
Foliar Ground, aerial or chemigation	Quilt® Fungicide 0.62 lb/gal SE [100-1178]	0.034-0.068	2	0.271	30 (forage, grain & stover)	Do not apply more than 56 fl. oz./A/season of Quilt. Apply no more than 2 applications of Quilt or any other Group 11 fungicide per year. Do not apply more than 2.0 lbs ai azoxystrobin containing products/ A/season. Do out use less than 0.5 GPA for ULV applications.
Corn, Sweet (includes seed production)						
Foliar Ground, aerial or chemigation	Quilt® Fungicide 0.62 lb/gal SE [100-1178]	0.034-0.068	2	0.271	14 (forage & ears)	Do not apply more than 56 fl. oz./A/season of Quilt. Apply no more than 2 applications of Quilt or any other Group 11 fungicide per year. Do not apply more than 2.0 lbs ai azoxystrobin containing products/ A/season. Do out use less than 0.5 GPA for ULV applications.

Conclusions: The label directions are adequate to allow evaluation of the residue data relative to the proposed use.

860.1300 Nature of the Residue - Plants

PP#5F4541, DP#s 218318 and 218448, J. Garbus, 3/19/96
PP#6F4762, DP#s 230634, 230635, 230636 and 230637, L. Kutney, 4/25/97
HED Metabolism Assessment Review Committee Decision Memo, DP# 251683, W. Wassell, 2/30/98

Adequate metabolism studies on grapes, peanuts, and wheat were submitted in conjunction with earlier azoxystrobin petitions, PP#s 5F4541 and 6F4762. Azoxystrobin undergoes photochemical isomerization to produce the Z-isomer and is extensively metabolized in plants. The parent compound undergoes cleavage of the ether linkages between the phenylacrylate and pyrimidinyl rings and the cyanophenyl and pyrimidinyl rings, with subsequent oxidation, hydrolysis, and/or reduction of the primary metabolites to form numerous secondary metabolites. Azoxystrobin is systemic. HED has determined that the residues of concern in/on plants for the tolerance expression and risk assessment purposes are azoxystrobin and its Z-isomer.

860.1300 Nature of the Residue - Livestock

PP#5F4541, DP#s 218318 and 218448, J. Garbus, 3/19/96
PP#6F4762, DP#s 230634, 230635, 230636 and 230637, L. Kutney, 4/25/97
HED Metabolism Assessment Review Committee Decision Memo, DP# 251683, W. Wassell, 2/30/98

The nature of the residue in animals is adequately understood based on acceptable metabolism studies conducted on goats and laying hens. HED has determined that the residue of concern in livestock is parent azoxystrobin only.

860.1340 Residue Analytical Methods

Enforcement methods

PP#s 5F4541 & 6F4762, DP# 235342, C. Stafford, 5/30/97
PP# 7F4864, DP#s 249657 and 249668, D. Dotson, 1/25/99

Plants: For analysis of plant commodities for residues of azoxystrobin and its Z-isomer, a GC/NPD method (RAM 243/04) has undergone method validation by ACB/BEAD. BEAD comments have been incorporated, and the revised method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in PAM, Volume II. The method LOQ is 0.01 ppm for each analyte in various crop matrices.

Livestock: For analysis of animal commodities for residues of azoxystrobin *per se*, a GC/NPD method (RAM 255/01) has been validated by an independent laboratory for the analysis of milk, liver and eggs, and by the EPA analytical laboratory for the analysis of milk and liver. The EPA laboratory written report (with an EPA addendum to accompany the method) and the method will be submitted to FDA for inclusion in PAM, Volume II. In the interim, copies are available from PIRIB/IRSD (7502P) and ACB/BEAD (7503P). The method LOQ is 0.0025 ppm and 0.01 ppm for each analyte in milk and tissues, respectively.

Data-collection method

DER Reference: 48064701.der.doc

Crop samples were analyzed for residues of azoxystrobin and R230310 using Syngenta Method RAM 305/03 (Nov. 11, 2004), entitled "Residue Analytical Method for the Determination of Residues of Azoxystrobin (1C15504) and R230310 in Crop Samples. Final Determination by

LC-MS/MS" and modifications made to the method dated September 23, 2009. The reported modifications included: 1) documenting the preparation of standard solutions used, 2) identifying the LC-MS/MS detectors and conditions employed, and 3) providing the calculations used for residue determination. Samples were extracted with acetonitrile:water (90:10 v/v; 100 mL minus the water content of the samples). After centrifugation, an aliquot was purified using a C18 SPE procedure. Samples of corn forage, stover, and grain were fortified of 0.01 ppm, at minimum, and up to 25 ppm of both residues of interest during method validation and concurrent recovery studies. The LC-MS/MS method uses a single ion transition, m/z 404.2→372.4, to quantitate azoxystrobin and R230310 residues in/on plant commodities. Recoveries ranged from 70-99%. The chromatograms of control samples of various crop matrices are free from interferences. The LOQ for both analytes was 0.01 ppm in all matrices.

Conclusions: There are adequate residue analytical methods for tolerance enforcement. For analysis of plant commodities for residues of azoxystrobin and its Z-isomer, a GC/NPD method (RAM 243/04) has undergone adequate method validation. For analysis of animal commodities for residues of azoxystrobin *per se*, a GC/NPD method (RAM 255/01) has been validated by an independent laboratory for the analysis of milk, liver and eggs, and by the EPA analytical laboratory for the analysis of milk and liver. For analysis of samples from the crop field trials associated with the current petitions, the LC-MS/MS data gathering method is adequate.

860.1360 Multiresidue Methods

PP#5F4541, DP#s 218318 and 218448, J. Garbus, 3/19/96

Data have previously been submitted pertaining to the multiresidue methods testing of azoxystrobin in conjunction with the grape petition (PP#5F4541). The data indicate that azoxystrobin could not be recovered through application of the multiresidue protocols. These data have been forwarded to FDA for inclusion in PAM I.

860.1380 Storage Stability

PP# 7F4864, DP#s 248887 and 249671, D. Dotson, 10/14/98
PP# 7F4864, DP#s 249657 and 249668, D. Dotson, 1/25/99
PP# 9F6058, DP#s 283588 and 287062, ID#s 100-1098 & 100-1093, N. Dodd, 2/6/03

From sampling to extraction, samples of forage, stover and grain were stored frozen for a maximum of 3.0, 2.7 and 2.3 months, respectively, in this study. Adequate storage stability data are available indicating that azoxystrobin and its Z-isomer are reasonably stable under frozen conditions in/on fortified samples of diverse crops. In previous studies, residues were determined to be stable in/on apples, bananas, carrot, cucumbers, grapes, leaf lettuce, oil seed rape, peaches, winter wheat straw, wheat forage, and wine for 2 years. Over the two-year period, residues of both azoxystrobin and its Z-isomer decreased by up to 20% in winter wheat grain and by up to 27% (azoxystrobin only) in tomato, peanut, and pecan, but all recoveries were >70%; residues in these crops were stable (without decrease) for up to 6-8 months.

Previous studies conducted on processed commodities demonstrated that fortified residues of azoxystrobin and its Z-isomer were generally stable under frozen conditions in peanut oil and

meal, tomato juice and paste, and wheat bran for up to one year and in soybean meal, corn grits, and orange oil, juice and pulp for at least 2 years.

Conclusions: There are adequate storage stability data from previous submissions to validate sample storage conditions and durations in the current petition. Residues of azoxystrobin and its Z-isomer were found to be relatively stable over a wide range of commodities under frozen storage conditions for 1-2 years.

860.1400 Water, Fish, and Irrigated Crops

This guideline requirement is not relevant to the current petitions as there are no aquatic uses being proposed for azoxystrobin.

860.1460 Food Handling

This guideline requirement is not relevant to the current petitions as there are no food-handling uses being proposed for azoxystrobin.

860.1480 Meat, Milk, Poultry, and Eggs

PP#9F06058, D260134, M. Nelson, 9/06/2000

Tolerances for residues of azoxystrobin *per se* are currently established [40 CFR §180.507(a)(2)] for the fat (0.03 ppm), meat (0.01 ppm), and meat byproducts (0.07 ppm) of cattle, goat, horse, and sheep. A tolerance of 0.01 ppm each has been established for hog fat, meat, and meat byproducts. A milk tolerance of 0.006 ppm is also established. No tolerances for eggs and poultry meat and meat byproducts have been established.

Magnitude of the residue data for use of azoxystrobin on corn (field, pop and sweet) were previously submitted in support of the establishment of permanent tolerances for the residues of azoxystrobin on the subject crops (PP#9F06058, D260134, M. Nelson, 9/06/2000). As part of that memorandum, the effect of the residues on the reasonably balanced livestock dietary burden was calculated and used to establish the current animal commodity tolerances.

Conclusions: Since the present action will not increase the existing tolerances or establish new tolerances on corn feed items, no increase in animal commodity tolerances are required.

860.1500 Crop Field Trials

DER Reference: 48064701.der.doc

Syngenta has submitted side-by side field trial data for azoxystrobin on field corn to demonstrate that residues resulting from ULV application (<2 GPA) were comparable to or less than residues resulting from typical spray volumes of >10 GPA. Three side-by-side trials were conducted in the United States encompassing EPA growing Zone 3 (GA) during the 2009 growing season.

At each test location, four treatment regimens were conducted. The main treatment plots were

divided into sub-plots to facilitate the harvest. Quilt® Xcel (EPA Reg. No.100-1324) was applied to forage using one application of 0.129 lb ai/A, and to stover and grain using two applications for a total of 0.258 lb ai/A. At each trial site, the four treatment regimens included a non-treated control (UTC), a back-pack sprayer application at > 10 gallons per acre (GPA), an aerial ultra low volume (ULV) application at <2 GPA, and CDA application at <2 GPA. An adjuvant was added to the spray mixture for all applications. Forage was harvested at a 26-day PHI, and stover and grain were harvested at a 30-day PHI.

Crop samples were analyzed for residues of azoxystrobin and R230310 using Syngenta Method RAM 305/03, entitled "Residue Analytical Method for the Determination of Residues of Azoxystrobin (1C15504) and R230310 in Crop Samples. Final Determination by LC-MS/MS" and modifications made to the method dated September 23, 2009. Final analysis was by liquid chromatography with triple-quadrupole mass-spectrometric detection (LC-MS/MS). The limit of quantitation (LOQ) for the analytes, azoxystrobin and the R230310 metabolite, was 0.01 ppm in all matrices. The method was shown to be adequate for data collection by method validation and concurrent recoveries. Previously submitted stability studies in all five of the suggested representative crop groups indicate that the residues of concern will be stable for the duration of the residue studies submitted here.

The results from these trials show that maximum combined residues are 2.0433 ppm, 0.1327 ppm, and 0.0495 ppm on forage treated at 0.129 lb ai/A with a 26-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. Maximum combined residues are 0.3759 ppm, 1.0876 ppm, and 0.1610 ppm on stover treated at 0.258 lb ai/A with a 30-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. No residues above the LOQ were found in any corn grain sample.

Table 3. Summary of Residue Data from Crop Field Trials with Azoxystrobin and R230310.

Commodity	Total Applic. Rate (lb ai/A)	Application Method	PHI (days)	Analyte	Residue Levels (ppm)						
					n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
Forage	0.1289-0.1321	Ground	26	Azoxystrobin	3	0.0213	2.030	0.7310	0.0734	0.3060	0.6480
				R230310	3	<LOQ	0.0284	0.0188	<LOQ	0.0114	0.0089
				Combined	3	0.0313	2.0433	0.7432	0.0801	0.3099	0.6523
	0.1310	Aerial/ ULV	26	Azoxystrobin	3	0.0233	0.1210	0.0995	0.0496	0.0581	0.0372
				R230310	3	<LOQ	0.0117	<LOQ	<LOQ	<LOQ	0.0022
				Combined	3	0.0333	0.1327	0.1397	0.0596	0.0683	0.0376
	0.1240-0.1303	CDA ULV	26	Azoxystrobin	3	<LOQ	0.0395	0.0265	0.0250	0.0255	0.0071
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<LOQ	0.0495	0.0365	0.0295	0.0272	0.0147
Stover	0.2632-0.2643	Ground	30	Azoxystrobin	3	0.0944	0.3440	0.2880	0.126	0.170	0.0924
				R230310	3	0.0191	0.0319	0.0278	0.0245	0.0237	0.0042
				Combined	3	0.1151	0.3759	0.3161	0.1505	0.1942	0.0960
	0.2582	Aerial/ ULV	30	Azoxystrobin	3	0.0647	1.000	0.6260	0.2140	0.2880	0.3150
				R230310	3	<LOQ	0.0876	0.0502	0.0232	0.0260	0.0254
				Combined	3	0.0752	1.0876	0.6785	0.2392	0.3162	0.3387
	0.2583-0.2593	CDA ULV	30	Azoxystrobin	3	0.0161	0.1430	0.1380	0.1205	0.0919	0.0564
				R230310	3	<LOQ	0.0190	0.0170	0.0124	0.0134	0.0055
				Combined	3	0.0261	0.1610	0.1550	0.1359	0.1053	0.0593
Grain	0.2632-0.2643	Ground	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA

Table 3. Summary of Residue Data from Crop Field Trials with Azoxystrobin and R230310.

Commodity	Total Applic. Rate (lb ai/A)	Application Method	PHI (days)	Analyte	Residue Levels (ppm)						
					n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA
	0.2582	Aerial/ ULV	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA
	0.2583-0.2593	CDA ULV	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA

* HAFT = Highest Average Field Trial.
LOQ = 0.01

Conclusions: The data from the side-by-side residue field trials indicate that the use of ULV applications will not increase the azoxystrobin residue levels on corn commodities. In addition, there are no significant differences between conventional ground, aerial ULV, or hand CDA applications. No increase in the established corn RAC commodity tolerances is required for the proposed use. ARIA recommends for the change in use pattern to include an ULV application.

860.1520 Processed Food and Feed

PP#9F06058, D260134, M. Nelson, 9/06/2000

The previously submitted field corn processing data were determined to be adequate. No concentration of residues of azoxystrobin and the Z isomer was observed in dry milled fractions, corn grits, meal, flour, and refined oil, and the wet milled fraction, corn starch, processed from field corn grain bearing detectable residues. The data indicate that combined residues of azoxystrobin and its Z isomer concentrated in the wet milled fraction, refined oil, at 5.6 and 5.9x (PP#9F06058, D260134, M. Nelson, 9/06/2000). The HAFT residue of corn grain treated using conventional ground, aerial ULV, or hand CDA applications from the submitted field corn studies was <0.02 ppm for the combined azoxystrobin and Z isomer residues.

Conclusions: The only corn processed commodity that exhibits concentration of the azoxystrobin residues was refined oil. Based on the HAFT (<0.02 ppm) value and an average concentration factor of 5.8x, the maximum expected combined residue in refined corn oil (0.12 ppm) would not exceed the existing tolerance of 0.3 ppm. No increase in the established corn processed commodity tolerances is required for the proposed use.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for azoxystrobin and its Z-isomer metabolite are currently available in the EPA National Pesticide Standards Repository (personal communication with Dallas Wright, ACB, 8/8/07). Standard should be supplied as requested by the repository.

860.1850 Confined Accumulation in Rotational Crops

PP#6F4762, DP#s 230634, 230635, 230636 and 230637, L. Kutney, 4/25/97
PP#9F6058, DP# 260134, M. Nelson, 9/6/00

Adequate confined studies have previously been presented in PP#6F4762 and re-evaluated in PP#9F6058. TRR, expressed as [^{14}C]azoxystrobin equivalents, accumulated at >0.01 ppm in the RACs of lettuce, radishes, and wheat planted in sandy loam soil 30, 200, and 365 DAT of the soil with [^{14}C]azoxystrobin at 1.8 lb ai/A. Residues were highest in RACs from the 30-DAT interval and declined in subsequent plantback intervals.

Azoxystrobin was identified in all RACs at the 30-DAT interval. In 30-DAT samples, the Z-isomer was only identified in wheat forage and straw. Compound 42 was the major metabolite identified in 30-DAT lettuce and wheat forage and straw. In 30-DAT radish roots, azoxystrobin was the major metabolite and in 30-DAT radish tops, metabolites G_2, N_1, and N_2 were the major metabolites. In 30-DAT wheat grain, ^{14}C-starch was found to account for the largest portion of radioactivity. Several conjugated metabolites (compound 42 and the M, N, and O metabolites) of primary crop metabolites were identified, indicating that azoxystrobin is more extensively metabolized in rotational crops than in primary crops. The residues of concern in rotational crops are parent and the Z-isomer.

860.1900 Field Accumulation in Rotational Crops

PP#6F4762, DP#s 230634, 230635, 230636 and 230637, L. Kutney, 4/25/97
PP#9F6058, DP#s 283588 and 287062, N. Dodd, 2/6/03
PP#9F6058, DP# 298114, L. Cheng, 12/20/05

Limited field rotational crop studies, with applications made at 0.8 lb ai/A seasonal rate to the primary crop, were initially submitted in PP#6F4762. Subsequently, additional limited field rotational crop studies, with applications made at 1.6 or 2.0 lb ai/A seasonal rate to the primary crop, were submitted and reviewed in PP#9F6058.

The results of the limited field accumulation study (MRID 45640307) indicate that residues of azoxystrobin and its Z-isomer (R230310) will not occur in mustard greens, turnip roots, turnip tops, and wheat grain planted 36 days after application of azoxystrobin, as an 80% water dispersible granular formulation, to a primary crop at a rate of 1.6 lb ai/A/season. This study also indicated that small amounts of residues of azoxystrobin *per se* may occur in/on wheat matrices other than grain at a plantback interval of approximately 60 days after treatment (i.e., 0.02 ppm in wheat forage at 61 DAT; 0.01 ppm in wheat hay at 45 DAT; 0.04 ppm in wheat straw at 59 DAT). No residues of the Z-isomer (R230310) were found in any matrix at any plantback interval.

In the other limited field accumulation study (MRID 45872401), Azoxystrobin 80 WG (water dispersible granules) and 2.08 SC (flowable concentrate) were applied to the primary crop, leaf lettuce, as six foliar broadcast sprays for a total of 2.0 lb ai/A (~1x the maximum proposed/established seasonal rate for rotated crops). The rotational crops of leaf lettuce, garden beets, and wheat were planted at plantback intervals of 30 and 60 days. For crops planted 30 days posttreatment, residues of parent were 0.03-0.13 ppm in/on wheat forage samples, 0.02-0.12 ppm in/on hay samples, 0.09-0.18 ppm in/on straw samples, and <0.01 ppm in/on grain samples; <0.01-0.01 ppm in/on leaf lettuce; and <0.01 ppm in/on garden beet tops and roots. For crops planted 60 days posttreatment, residues of parent were 0.02-0.21 ppm in/on wheat forage, 0.02-

0.11 ppm in/on hay, 0.03-0.19 ppm in/on straw, and <0.01 ppm in/on grain; <0.01-0.02 ppm in/on leaf lettuce; and <0.01 ppm in/on garden beet tops and roots. Residues of R230310 were all <0.01 ppm except in wheat straw; in wheat straw, residues of R230310 ranged from <0.01 to 0.01 ppm at plant-back intervals of 30 or 60 days.

The supplemental label for the Abound® Flowable Fungicide, submitted in conjunction with PP#6F7106, includes the following restrictions listed under the General Use Precautions: "Do not plant the following crops for a period of 12 months (unless an azoxystrobin product is registered for use on that crop): buckwheat, millet, oats and rye. A plantback interval of 36 days is required for leafy vegetables (except Brassica) group; Brassica, leafy greens subgroup; vegetables, root subgroup; vegetable (tuberous and corm subgroup; and vegetables, leaves of root and tuber group. Azoxystrobin is registered for use on all other rotated crops, and all other crops may be planted immediately after the last treatment." This is a revision of the rotational crop restrictions on the currently registered label dated 2/23/2007, to remove the 12-month PBI restriction for barley, nongrass animal feeds (alfalfa and clover), sorghum, triticale, wheat, and wild rice.

Conclusions: There are adequate field rotational crop data to support the established rotational crop restrictions on the product labels.

860.1550 Proposed Tolerances

The submitted study indicates that there is no need for changes in any of the existing tolerances and no establishment of new tolerances. Since no new tolerances need to established or existing tolerances changed as a result of the findings of this document, international harmonization is not of concern.

References

DP#s:	318318 and 218448
Subject:	PP No. 5F4541: New Chemical: Azoxystrobin (ICIA5504) in/on Grape RACs. Evaluation of Analytical Methods and Residue Data.
From:	J. Garbus
To:	J. Bazuin/C. Giles-Parker
Dated:	03/19/96
MRIDs:	43678102-07, 43678193-95, 43678200-10 and 43694201-06

DP#s:	230634, 230635, 230636, and 230637
Subject:	PP#6F4762. Azoxystrobin. Permanent Tolerance Petition for Use on Bananas, Peaches, Peanuts, Tomatoes, and Wheat. Evaluation of Analytical Methodology and Residue Data.
From:	L. Kutney
To:	C. Giles-Parker/J. Bazuin
Dated:	04/25/97
MRIDs:	44058715-30, 44058732-36, and 44073203-05

DP#s:	248887 and 249671
Subject:	PP#7F4864. Tolerance Petition for use of Azoxystrobin on Cucurbits. AND PP#8F4995. Tolerance Petition for use of Azoxystrobin on Bananas, Potatoes, and Stone Fruits.
From:	D. Dotson
To:	C. Giles-Parker/J. Bazuin
Dated:	10/14/98
MRIDs:	44319305, 44452303, 44595105, 44595109-11, 44595114, 44595116, 44613501 and 44613503

DP#:	250297
Subject:	PP#8F4995 and PP#7F4864. Azoxystrobin (Abound Fungicide, EPA Reg. No. 10182-415) in or on Canola, Wheat, Peanuts, Tree Nuts, and Rice. Briefing Memorandum for Metabolism Assessment Review Committee.
From:	W. Wassell
To:	G. Kramer, MARC
Dated:	11/06/98
MRIDs:	None

DP#:	251683
Subject:	Azoxystrobin. Conclusions of the Metabolism Assessment Review Committee at Meeting of 11/10/98.
From:	W. Wassell
To:	G. Kramer, MARC
Dated:	12/30/98
MRIDs:	None

DP#s:	249657 and 249668
Subject:	PP# 7F4864. Tolerance Petition for use of Azoxystrobin on Peanut Hay, Pistachios, Rice, Tree Nuts, and Wheat. AND PP# 8F4995. Tolerance Petition for use of Azoxystrobin on Canola.
From:	D. Dotson
To:	C. Giles-Parker/J. Bazuin
Dated:	01/25/99
MRIDs:	44319303, 44319304, 44319306-08, 44452303, 44595104-08, 44595113, 44595115 and 44613502

DP#:	260134
Subject:	PP#9F06058: Azoxystrobin. Evaluation of Residue Chemistry Data to Support Permanent Tolerances for Use of Azoxystrobin on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables (Except Brassica), Leaves of Root and Tuber Vegetables, Peanuts, Root and Tuber Vegetables, Soybeans, and Wild Rice; Higher Tolerances for the Fat and Meat Byproducts of Cattle, Goats, Horses and Sheep; and, apples (Inadvertant Residues).
From:	M.J. Nelson
To:	J. Bazuin/C. Giles-Parker

Dated:	09/06/00
MRIDs:	44915206-32 and 44983101
DP#:	278801
Subject:	Azoxystrobin. Registration on Legume Vegetables, a Tolerance for Imported Hops, and a Nonfood Use on Sunflowers. Summary of Analytical Chemistry and Residue Data.
From:	N. Dodd
To:	J. Bazuin/C. Giles-Parker
Dated:	07/31/02
MRIDs:	45221601-08, 45221610, 45287501 and 45287502
DP#s:	283588 and 287062
Subject:	PP#9F06058 and ID#s 000100-01098 and 000100-01093. Azoxystrobin. Condition-of-Registration Data, Including Bridging Data from the 50 WDG Formulation to the 2.08 FlC Formulation on Spinach, Garden Beet, Green Onion and Celery; Storage Stability Data; and Limited Field Rotational Crop Data.
From:	N. Dodd
To:	J. Bazuin/C. Giles-Parker
Dated:	02/06/03
MRIDs:	45640301, 45640302, 45640304-07, and 45738101
DP#:	298114
Subject:	Azoxystrobin. Heritage Fungicide (EPA Reg. No. 100-1093. Condition-of-Registration Data: Limited Field Rotational Crop Data. Petition Number 9F6058.
From:	L. Cheng
To:	J. Bazuin/C. Giles-Parker
Dated:	12/20/05
MRIDs:	45872401
DP#s:	312949, 312951, 312953 and 317291
Subject:	Azoxystrobin Use on Dill, Chive, Sunflowers, Canola, and Post-Harvest Citrus. Review of Analytical Methods and Residue Data. Petition #s 3E6637, 3E6749, 4E6823 & 5E6916.
From:	W. Cutchin
To:	B. Madden/D. Rosenblatt
Dated:	1/23/06
MRIDs:	460069001, 46046601-04, 46219201, and 46509101
DP#:	328984
Subject:	Azoxystrobin. Uses on Foliage of Legume Vegetables, Group 7; Fruiting Vegetables, Group 8 (Except Tomato); Pea and Bean, Succulent and Dried Shelled (Except Soybeans), Subgroups 6B and 6C; and Nongrass Animal Feeds, Group 18. Summary of Analytical Chemistry and Residue Data. Petition Number 4E6823.
From:	W. Cutchin
To:	S. Jackson/D. Rosenblatt

Dated: 6/19/06
MRIDs: None

DP#: 334571 and 340016
Subject: Azoxystrobin. Petitions for the Establishment of Permanent Tolerances for New/Amended Uses on Non-grass Animal Feeds (Crop Group 18), Sorghum, Wheat, Cotton and Wild Rice. PP#s6F7106 & 7F7198. Summary of Analytical Chemistry and Residue Data.
From: W. Cutchin
To: T. Kish/J. Bazuin
Dated: 3/12/08
MRIDs: None

Template Version September 2005

Azoxystrobin/128810/Syngenta
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 – Field Corn (Side-by-Side Trials: Ground, Aerial-ULV, CDA-ULV)

Primary Evaluator W. Cutchin, Chemist Date: 9/13/10
Alternative Risk Integration and Assessment (ARIA)
Risk Integration, Minor Use, Emergency Response Branch (RIMUERB)/Registration Division (RD)

Approved by Debra Rate, Ph.D., Biologist
(ARIA/RIMUERB/RD

STUDY REPORTS:

MRID No. 48064701 Hampton, R. (2010) Azoxystrobin and Propiconazole (SC) (A15909C) - Magnitude of the Residues in or on Field Corn from Side-by-Side Bridging Field Plots that Compare Ground, ULV Aerial, and ULV Controlled-Droplet Applications: Final Report. Project Number: T004398/08, ML09/1567/SYN. Unpublished study prepared by Syngenta Crop Protection, Inc. 311 p.

EXECUTIVE SUMMARY:

Syngenta has submitted side-by side field trial data for azoxystrobin on field corn to demonstrate that residues resulting from ULV application (<2 GPA) were comparable to or less than residues resulting from typical spray volumes of >10 GPA. Three side-by-side trials were conducted in the United States encompassing EPA growing Zone 3 (GA) during the 2009 growing season.

At each test location, four treatment regimens were conducted. The main treatment plots were divided into sub-plots to facilitate the harvest of forage which received one application of 0.129 lb ai/A, and stover and grain which received two applications for a total of 0.258 lb ai/A. At each trial site, the four treatment regimens included a non-treated control (UTC), a back-pack sprayer application at > 10 gallons per acre (GPA), an aerial ultra low volume (ULV) application at <2 GPA, and a hand-held controlled-droplet applicator (CDA) application at <2 GPA. An adjuvant was or added to the spray mixture for all applications. Forage was harvested at a 26-day PHI, and stover and grain were harvested at a 30-day PHI.

Crop samples were analyzed for residues of azoxystrobin and R2303 10 using Syngenta Method RAM 305/03, entitled "Residue Analytical Method for the Determination of Residues of Azoxystrobin (1C15504) and R230310 in Crop Samples. Final Determination by LC-MS/MS" and modifications made to the method dated September 23, 2009. Final analysis was by liquid chromatography with triple-quadrupole mass-spectrometric detection (LC-MS/MS). The limit of quantitation (LOQ) for the analytes, azoxystrobin and the R230310 metabolite, was 0.01 ppm in all matrices. The method was shown to be adequate for data collection by method validation and concurrent recoveries. Previously submitted stability studies in all five of the suggested representative crop groups indicate that the residues of concern will be stable for the duration of the residue studies submitted here.

The results from these trials show that maximum combined residues are 2.058 ppm, 0.2217 ppm, and 0.0495 ppm on forage treated at 0.129 lb ai/A with a 26-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. Maximum combined residues are 0.3759 ppm, 1.0876 ppm, and 0.1610 ppm on stover treated at 0.258 lb ai/A with a 30-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. No residues above the LOQ were found in any corn grain sample.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP#376966.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The following deviations from regulatory requirements were reported:

1. NOAA weather data were not collected according to the FIFRA-GLP requirements of 4OCFRPart 160.
2. Spray-mix storage-stability data were not generated as required in 40 CFR Part 160.
3. The application of maintenance chemicals and irrigation practices did not conform to GLP requirements.
4. Analysis of soil characteristics did not conform to GLP requirements.
5. Field history from farmers records were not generated nor maintained under GLP.
6. Sample weights taken in the field were determined by non-GLP procedures (i.e., approximation on a non-GLP scale).

None of these deviations had a negative impact on the validity of the study.

A. BACKGROUND INFORMATION

Azoxystrobin is a broad-spectrum fungicide and belongs to a class of pesticidal compounds called β-methoxyacrylates, which are derived from the naturally occurring strobilurins (Group 11 fungicide). The biochemical mode of action is inhibition of electron transport. The fungicide is currently registered for use on a variety of field, vegetable, fruit, and nut crops as well as on ornamental plants and turf.

The chemical structure and nomenclature of azoxystrobin and its Z-isomer, and the physicochemical properties of the technical grade of azoxystrobin are presented in Tables A.1 and A.2, respectively.

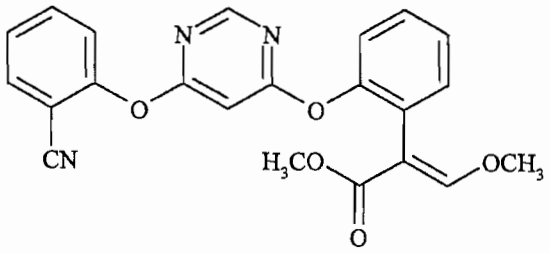
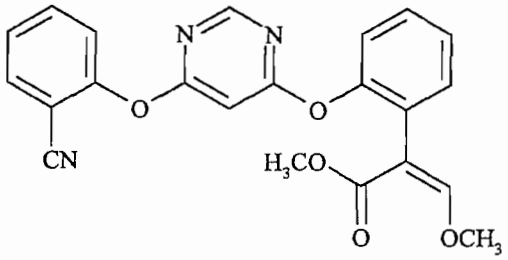
TABLE A.1. Azoxystrobin Nomenclature.	
Compound	
Common name	Azoxystrobin
Company experimental name	ICIA5504 (Zeneca), R215504 (Syngenta)
IUPAC name	methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyramidin-4-yloxy]phenyl}-3-methoxyacrylate
CAS name	methyl-(*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-(methoxymethylene)-benzeneacetate
CAS registry number	131860-33-8
End-use products (EP)	Quilt® Fungicide (EPA Reg. No. 100-1178)
Regulated metabolite Z-isomer	
Common name	Azoxystrobin, Z-isomer
Company name	R230310
Chemical name	methyl (*Z*)-2-{2-[6-(2-cyanophenoxy)pyramidin-4-yloxy]phenyl}-3-methoxyacrylate

TABLE A.2. Physicochemical Properties of Technical Grade Azoxystrobin.			
Parameter	Value		Reference
Melting range	114-116°C		DP#s 218318 and 218448, J. Garbus, 03/19/1996
pH	6.4		
Density	1.25 g/cm^3		
Water solubility (20°C)	pH 5.2 pH 7.0 pH 9.2	6.7 mg/L 6.7 mg/L 5.9 mg/L	
Solvent solubility (20°C)	Hexane Octanol Methanol Toluene Acetone Ethyl Acetate Acetonitrile Dichloromethane	0.057 mg/L 1.4 mg/L 20 mg/L 55 mg/L 86 mg/L 130 mg/L 340 mg/L 400 mg/L	
Vapor pressure (20°C)	1.1×10^{-13} kPa (8.2×10^{-13} mm Hg)		
Dissociation constant, pK_a	Not dissociable		
Octanol/water partition coefficient, $Log(K_{OW})$	$\log P_{OW} = 2.5$		

TABLE A.2. Physicochemical Properties of Technical Grade Azoxystrobin.		
Parameter	Value	Reference
UV/visible absorption spectrum	Not available	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1 Trial Site Conditions.				
Trial Identification (City, State/Year)	Soil characteristics			
	Type	%OM	pH	CEC meq/g
E19-9691 (Montezuma, GA/2009)	Loamy Sand	2.1	5.7	8.5
E19-9692 (Henderson, GA/2009)	Loamy Sand	1.9	5.2	6.6
E19-9693 (Olgethorpe, GA/2009)	Loamy Sand	1.4	6.2	6.0

The actual temperature recordings were within average historical values for the residue study period. The actual rainfall average was within the historical rainfall average. Irrigation was used to supplement each of the trials as needed. No meteorological abnormalities were reported occurring during the conduct of the study, at any of the trial sites.

TABLE B.1.2. Study Use Pattern.

Location (City, State/Year) Trial ID	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing *	Volume[2]	Rate (lb ai/A) (g ai/ha)	RTI[3] (days)	Total Rate (lb ai/A) (g ai/ha)	
E19-9691 (Montezuma, GA/2009)	Quilt Xcel™	1. Untreated Control					
		2. Ground broadcast					
		Forage	19.87	0.1317	---	0.1317	COC 0.5% (v/v)
		Stover/Grain	20.43	0.1580	---		
			20.02	0.1303	6	0.2643	COC 0.5% (v/v)
		3. Aerial-ULV[4]					
		Forage	0.463	0.1310	---	0.1310	COC 10% (v/v)
		Stover/Grain	0.463	0.1310	---		
			0.449	0.1272	6	0.2582	COC 10% (v/v)
		4. CDA[5]-ULV					
		Forage	0.640	0.1303	---	0.1303	COC 10% (v/v)
		Stover/Grain	0.640	0.1303	---		
			0.630	0.1283	6	0.2587	COC 10% (v/v)
E19-9692 (Henderson, GA/2009)	Quilt Xcel™	1. Untreated Control					
		2. Ground broadcast					
		Forage	20.13	0.1321	---	0.1321	COC 0.5% (v/v)
		Stover/Grain	19.91	0.1306	---		
			20.39	0.1327	6	0.2633	COC 0.5% (v/v)
		3. Aerial-ULV					
		Forage	0.463	0.1310	---	0.1310	COC 10% (v/v)
		Stover/Grain	0.463	0.1310	---		
			0.449	0.1272	6	0.2582	COC 10% (v/v)
		4. CDA-ULV					
		Forage	0.480	0.1240	---	0.1240	COC 10% (v/v)
		Stover/Grain	0.490	0.1295	---		

TABLE B.1.2. Study Use Pattern.

Location (City, State/Year) Trial ID	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing *	Volume[2]	Rate (lb ai/A) (g ai/ha)	RTI[3] (days)	Total Rate (lb ai/A) (g ai/ha)	
			0.490	0.1298	6	0.2593	COC 10% (v/v)
E19-9693 (Olgethorpe, GA/2009)	Quilt Xcel™	1. Untreated Control					
		2. Ground broadcast Forage	19.65	0.1289	---	0.1289	COC 0.5% (v/v)
		Stover/Grain	20.10	0.1319	---		
			20.18	0.1314	6	0.2632	COC 0.5% (v/v)
		3. Aerial-ULV[4] Forage	0.463	0.1310	---	0.1310	COC 10% (v/v)
		Stover/Grain	0.463	0.1310	---		
			0.449	0.1272	6	0.2582	COC 10% (v/v)
		4. CDA[5] -ULV Forage	0.500	0.1294	---	0.1294	COC 10% (v/v)
		Stover/Grain	0.500	0.1294	---		
			0.500	0.1289	6	0.2583	COC 10% (v/v)

[1] EP = End-use Product
[2] Gallons per acre, L/ha
[3] Retreatment Interval
[4] ULV = Ultra Low Volume
[5] CDA = Controlled Droplet Applicator
* Applications for forage were made 26 days before harvest. The two applications for stover and grain were made 36 and 30 days PHI, respectively.

TABLE B.1.3. Trial Numbers and Geographical Locations.

EPA Growing Zones	Side-by-Side Field Trials Field Corn	
	Submitted	Requested
		U.S.
1		
1A		
2	3	3
3		
4		
5		
5A		
5B		
6		
7		
7A		
8		
9		
10		
11		
12		
13		
Total	3	3

B.2. Sample Handling and Preparation

All samples of forage, stover and grain were collected by hand. To avoid contamination, a single composite sample was collected first from the UTC plot; three representative, composite samples then were collected in three separate, independent passes through the respective treated plot.

An individual sample was a composite from 12 plants from separate areas of the plot. For the forage sample, the entire aerial portion of the plant was cut within 6 in. of the soil surface upon attaining the 'late dough' stage (BBCH 87). For stover, fully mature stalks (BBCH 89) were cut for the forage sample, but the ear was removed. Due to the size of the plants at harvest, each plant was divided into 3 pieces of similar length, i.e., a top, middle and bottom portion. A sub-sample consisting of four pieces from each of the top, middle and bottom portions was taken to ensure that all 12 plants were represented in the final forage and stover samples. The ears were shelled, and the shelled kernels without the cob comprised the grain sample.

After harvest, each RAC sample was labeled with a unique sample-identification code. Samples were placed in the freezer on the day of collection and maintained in a frozen state until shipment. Samples were shipped frozen via freezer truck (forage) or overnight courier with dry ice (stover and grain) to Syngenta Crop Protection, Inc. (Greensboro, NC).

Crop samples were stored frozen upon receipt at Syngenta, excluding periods during which the samples were prepared. Forage, stover and grain samples were ground with dry ice in a Hobart foodcutter according to the corresponding SOP (dry ice was added as needed to keep samples frozen). After preparation, samples were stored in polyethylene bags or bottles labeled with the Trial ID Code, Syngenta Task Number, Sample Code, and crop identification and were shipped frozen to Morse Laboratories (Sacramento, CA) for analysis.

Freezers at the trial sites, Syngenta, and Morse were maintained at temperatures <-5°C, excluding transient periods when freezers were opened for sample removal, thereby ensuring frozen storage and, consequently, sample quality.

B.3. Analytical Methodology

Crop samples were analyzed for residues of azoxystrobin and R2303 10 using Syngenta Method RAM 305/03 (Nov. 11, 2004), entitled "Residue Analytical Method for the Determination of Residues of Azoxystrobin (1C15504) and R230310 in Crop Samples. Final Determination by LC-MS/MS" and modifications made to the method dated September 23, 2009. The reported modifications included: 1) documenting the preparation of standard solutions used, 2) identifying the LC-MS/MS detectors and conditions employed, and 3) providing the calculations used for residue determination. The modifications were verified prior to the analysis of any treated samples and were presented in Appendix 2 of the submitted study.

To summarize, samples were extracted with acetonitrile:water (90:10 v/v; 100 mL minus the

water content of the samples). After centrifugation, an aliquot was purified using a C18 SPE procedure. Final determination was by LC-MS/MS. Details of the pertinent instrument conditions were presented in Appendix 3 of the study. The LOQ for both analytes in all matrices was 0.01 ppm.

C. RESULTS AND DISCUSSION

From sampling to extraction, samples of forage, stover and grain were stored frozen for a maximum of 3.0, 2.7 and 2.3 months, respectively, in this study. Sample-storage intervals between sampling and extraction are shown in Table C.2 and are summarized below (analysis of extracts was performed within 5 days of extraction).

Previously, residues of azoxystrobin and R230310 were demonstrated to be stable in soybean meal, corn grits, carrot root, leaf lettuce, grain sorghum forage, orange oil, and orange juice under freezer storage conditions for at least 24 months (DP#248887, D. Dotson, 10/14/1998). According to the guidelines set forth in EPA OPPTS 860.1380 (Storage Stability Data), stability can be extended to all types of crops if stability has been proven in at least five diverse crop groups. Based on the previously submitted data, the residues of concern will be stable for the duration of the residue studies submitted here.

Samples of corn forage, stover, and grain were fortified of 0.01 ppm, at minimum, and up to 25 ppm of both residues of interest during method validation and concurrent recovery studies. The mean recoveries of azoxystrobin and R230310 residues from corn forage, stover grain are summarized in the following table. Recoveries ranged from 70-99%. The chromatograms of control samples of various crop matrices are free from interferences. The LOQ for both analytes was 0.01 ppm in all matrices. The method was shown to be adequate for data collection by method validation and concurrent recoveries.

The results from these trials show that the maximum combined residues are 2.058 ppm, 0.2217 ppm, and 0.0495 ppm on forage treated at 0.129 lb ai/A with a 26-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. Maximum combined residues are 0.3759 ppm, 1.0876 ppm, and 0.1610 ppm on stover treated at 0.258 lb ai/A with a 30-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. No residues above the LOQ were found in any corn grain sample.

TABLE C.1. Summary of Concurrent Recoveries of Azoxystrobin and R230310 from Field Corn.

Matrix		Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%)
Method Validation					
Forage	Azoxystrobin	0.01	3	89, 73, 79	80 ± 8.1
		12	3	89, 85, 83	86 ± 3.1
		Overall	6	73-89	83 ± 6.2
	R230310	0.01	3	97, 72, 77	82 ± 13
		12	3	88, 88, 87	88 ± 0.6
		Overall	6	72-97	85 ± 8.9
Stover	Azoxystrobin	0.01	3	90, 86, 103	93 ± 8.9
		25	3	94, 85, 97	92 ± 6.2

		Overall	6	85-103	92 ± 6.9
	R230310	0.01	3	84, 72, 79	78 ± 6
		25	3	96, 84, 97	92 ± 7.2
		Overall	6	72-97	85 ± 9.7
Grain	Azoxystrobin	0.01	3	105, 103, 107	105 ± 2
		0.05	3	105, 106, 107	106 ± 1
		Overall	6	103-107	106 ± 1.5
	R230310	0.01	3	112, 112, 104	109 ± 4.6
		0.05	3	104, 110, 108	107 ± 3.1
		Overall	6	104-112	108 ± 3.7
Concurrent Recoveries					
Forage	Azoxystrobin	0.01	3	93, 77, 90	87 ± 8.5
		12	3	87, 85, 88	87 ± 1.5
		Overall	6	77-93	87 ± 5.5
	R230310	0.01	3	87, 72, 86	82 ± 8.4
		12	3	87, 87, 88	87 ± 0.58
		Overall	6	72-88	84 ± 6.2
Stover	Azoxystrobin	0.01	3	96, 78, 70	81 ± 13
		25	3	96, 99, 88	94 ± 5.7
		Overall	6	70-99	88 ± 12
	R230310	0.01	3	82, 71, 77	77 ± 5.5
		25	3	96, 96, 80	91 ± 9.2
		Overall	6	71-96	84 ± 10
Grain	Azoxystrobin	0.01	3	90, 94, 79	88 ± 7.8
		0.05	3	91, 90, 95	91 ± 1.5
		Overall	6	79-95	90 ± 5.4
	R230310	0.01	3	83, 87, 93	88 ± 6.1
		0.05	3	96, 92, 98	95 ± 3.1
		Overall	6	83-98	92 ± 5.8

TABLE C.2. Summary of Storage Conditions of Azoxystrobin.

Field Corn	Storage Temperature (°C)	Actual Storage Duration (days / months)	Interval of Demonstrated Storage Stability (months)
Forage	<-5	91/3.0	24
Stover		81/2.7	24
Grain		69/2.3	24

TABLE C.3. Residue Data from Crop Field Trials with Azoxystrobin.

Trial ID (City, State/Year)	EPA Growing Zone	Crop/ Variety	Matrix	Total Rate (lb ai/A)	Applica. Method	PHI (days)	Azoxystrobin	R230310	Combined Residues (ppm)
E19-9691 (Montezuma, GA/2009)	2	Field Corn	Forage	0.1317	Ground	26	0.0734, 0.0613, 0.0213	<0.01, <0.01, <0.01	0.0834, 0.0713, 0.0313
				0.1310	Aerial ULV	26	0.0233, 0.0282, 0.0496	<0.01, <0.01, <0.01	0.0333, 0.0382, 0.0596
				0.1303	CDA-ULV	26	0.0226, 0.0195, 0.0332	<0.01, <0.01, <0.01	0.0326, 0.0295, 0.0432
			Stover	0.2643	Ground	30	0.2670, 0.3440, 0.2540	0.0268, 0.0319, 0.0247	0.2938, 0.3759, 0.2787
				0.2582	Aerial ULV	30	0.2901, 1.0000, 0.5880	0.0308, 0.0876, 0.0322	0.3278, 1.0876, 0.6202
				0.2587	CDA-ULV	30	0.1250, 0.0962, 0.1350	0.0109, 0.0124, 0.0158	0.1359, 0.1086, 0.1508
			Grain	0.2643	Ground	30	ND, ND, ND	ND, ND, ND	ND, ND, ND

TABLE C.3. Residue Data from Crop Field Trials with Azoxystrobin.

Trial ID (City, State/Year)	EPA Growing Zone	Crop/ Variety	Matrix	Total Rate (lb ai/A)	Applica. Method	PHI (days)	Azoxystrobin	R230310	Combined Residues (ppm)
				0.2582	Aerial ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
				0.2587	CDA-ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
E19-9692 (Henderson, GA/2009)	2	Field Corn	Forage	0.1321	Ground	26	0.1720, 0.0701, 0.1650	0.0284, <0.01, 0.0231	0.2004, 0.0801, 0.1419
				0.1310	Aerial ULV	26	0.1190, 0.0585, 0.2100	<0.01, <0.01, 0.0117	0.1290, 0.0685, 0.2217
				0.1240	CDA-ULV	26	0.0246, 0.0154, 0.0395	<0.01, <0.01, <0.01	0.0346, 0.0254, 0.0495
			Stover	0.2633	Ground	30	0.1290, 0.0944, 0.1160	0.0259, 0.0207, 0.0201	0.1549, 0.1151, 0.1361
				0.2582	Aerial ULV	30	0.0652, 0.0647, 0.2140	<0.01, 0.0106, 0.0261	0.0752, 0.0753, 0.2401
				0.2593	CDA-ULV	30	0.0240, 0.0161, 0.0168	<0.01, <0.01, <0.01	0.0340, 0.0261, 0.0268
			Grain	0.2643	Ground	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
				0.2582	Aerial ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
				0.2587	CDA-ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
E19-9693 (Olgethorpe, GA/2009)	2	Field Corn	Forage	0.1289	Ground	26	0.1110, 2.0300, 0.0522	0.0132, 0.0133, <0.01	0.1242, 2.0433, 0.0622
				0.1310	Aerial ULV	26	0.0453, 0.0261, 0.0522	<0.01, <0.01, <0.01	0.0553, 0.0361, 0.0622
				0.1294	CDA-ULV	26	ND, ND, ND	ND, ND, ND	ND, ND, ND
			Stover	0.2632	Ground	30	0.1260, 0.1020, 0.1020	0.0245, 0.0191, 0.0195	0.2765, 0.1211, 0.1215
				0.2582	Aerial ULV	30	0.2160, 0.0741, 0.0832	0.0232, <0.01, 0.0132	0.2392, 0.0841, 0.0964
				0.2583	CDA-ULV	30	0.1430, 0.1420, 0.1290	0.0159, 0.0190, 0.0162	0.1589, 0.1610, 0.1452
			Grain	0.2632	Ground	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
				0.2582	Aerial ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND
				0.2583	CDA-ULV	30	ND, ND, ND	ND, ND, ND	ND, ND, ND

TABLE C.4.1. Summary of Residue Data from Crop Field Trials with Azoxystrobin and R230310.

Commodity	Total Applic. Rate (lb ai/A)	Application Method	PHI (days)	Analyte	Residue Levels (ppm)						
					n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
Forage	0.1289-0.1321	Ground	26	Azoxystrobin	3	0.0213	2.030	0.7310	0.0734	0.3060	0.6480
				R230310	3	<LOQ	0.0284	0.0188	<LOQ	0.0114	0.0089
				Combined	3	0.0313	2.0433	0.7432	0.0801	0.3099	0.6523
	0.1310	Aerial/ ULV	26	Azoxystrobin	3	0.0233	0.1210	0.0995	0.0496	0.0581	0.0372
				R230310	3	<LOQ	0.0117	<LOQ	<LOQ	<LOQ	0.0022
				Combined	3	0.0333	0.2217	0.1397	0.0596	0.0782	0.0610
	0.1240-0.1303	CDA ULV	26	Azoxystrobin	3	<LOQ	0.0395	0.0265	0.0250	0.0255	0.0071
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<LOQ	0.0495	0.0365	0.0295	0.0272	0.0147
Stover	0.2632-0.2643	Ground	30	Azoxystrobin	3	0.0944	0.3440	0.2880	0.126	0.170	0.0924
				R230310	3	0.0191	0.0319	0.0278	0.0245	0.0237	0.00424
				Combined	3	0.1151	0.3759	0.3161	0.1549	0.2082	0.0980
	0.2582	Aerial/ ULV	30	Azoxystrobin	3	0.0647	1.000	0.6260	0.2140	0.2880	0.3150

TABLE C.4.1. Summary of Residue Data from Crop Field Trials with Azoxystrobin and R230310.

Commodity	Total Applic. Rate (lb ai/A)	Application Method	PHI (days)	Analyte	Residue Levels (ppm)						
					n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
				R230310	3	<LOQ	0.0876	0.0502	0.0232	0.0260	0.0254
				Combined	3	0.0725	1.0876	0.6785	0.2392	0.3162	0.3387
	0.2583-0.2593	CDA ULV	30	Azoxystrobin	3	0.0161	0.1430	0.1380	0.1205	0.0919	0.0564
				R230310	3	<LOQ	0.0190	0.0170	0.0124	0.0117	0.00552
				Combined	3	0.0261	0.1610	0.1550	0.1359	0.1053	0.5927
Grain	0.2632-0.2643	Ground	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA
	0.2582	Aerial/ ULV	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA
	0.2583-0.2593	CDA ULV	30	Azoxystrobin	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				R230310	3	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	NA
				Combined	3	<0.02	<0.02	<0.02	<0.02	<0.02	NA

* HAFT = Highest Average Field Trial.
LOQ = 0.01

D. CONCLUSION

The study was conducted consistent with standard agricultural practices as per proposed experimental designs. No anomalous weather events were recorded. Adequate storage stability data exist to support the study. The analytical method was shown to be adequate for data collection by method validation and concurrent recoveries. The results from these trials show that maximum combined residues are 2.058 ppm, 0.2217 ppm, and 0.0495 ppm on forage treated at 0.129 lb ai/A with a 26-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. Maximum combined residues are 0.3759 ppm, 1.0876 ppm, and 0.1610 ppm on stover treated at 0.258 lb ai/A with a 30-day PHI using conventional ground, aerial ULV, or hand CDA application, respectively. No residues above the LOQ were found in any corn grain sample.

E. REFERENCES

DP#248887, D. Dotson, 10/14/1998

F. DOCUMENT TRACKING

RDI: D. Rate (Date).
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