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This data-evaluation record (DER) was originally prepared under contract by Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 27-AUG-2009). The DER has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47687903. Hampton, R.E. (2009) Mesotrione – Comparison of the Magnitude of the Residues in or Sweet Corn after Application with the SC or WG Formulation. Unpublished study prepared by Syngenta Crop Protection, Inc. 134 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted crop trial data for mesotrione and its metabolite, 4-(methylsulfonyl)-2-nitrobenzoinc acid (MNBA), on sweet corn matrices using two different formulations. The objective of the study was to determine whether residues in/on sweet corn were similar between the two formulations using side-by-side plots. Three outdoor crop trials were conducted in the North American Free Trade Agreement (NAFTA) Growing Zones 2 (1 trial in NC), 7 (1 trial in ND), and 10 (1 trial in CA) during the 2008 growing season. Each trial site included one control plot and two treated plots. The treated plots each received two broadcast applications of either a 4 lb/gal soluble-concentrate (SC) formulation of mesotrione or a 50% (w/w) wettable-granule (WG) formulation of mesotrione, after crop emergence. Applications were made at a nominal rate of 0.094 lb ai/A, for a total seasonal rate of 0.188 lb ai/A. The re-treatment interval (RTI) was 11-15 days. All applications were made using a tractor or backpack sprayer in 15–26 gal/A; an adjuvant (non-ionic surfactant) was added to the spray mixtures at a nominal rate of 0.25% v/v. Samples of sweet corn forage, ear, and stover were harvested from treated and untreated plots at pre-harvest intervals (PHIs) ranging from 28 to 69 days.

Samples were analyzed for residues of mesotrione and MNBA using Syngenta Method RAM 366/01, a high-performance liquid chromatography method with tandem mass-spectrometry detection (HPLC/MS/MS), with minor modifications. Based on the lowest level of method validation (LLMV), the limit of quantitation (LOQ) was 0.01 ppm for each analyte. The method was adequate for data collection based on acceptable concurrent method recoveries.

Samples were stored frozen at <-10ºC for 49 to 70 days (1.6 to 2.3 months) prior to extraction. All sample extracts were analyzed within 2 days of extraction. Storage stability data submitted with a previous petition for field corn uses demonstrate that mesotrione and MNBA are stable in

corn matrices stored frozen for up to 42 months (Memo, S. Levy, 06-JUN-2001; DP#: 245477). The available corn storage stability data support the storage conditions and intervals of samples from the sweet corn field trials.

Following two broadcast applications of the 4 SC formulation, maximum residues of mesotrione were 0.169 ppm and 0.0942 ppm in sweet corn forage and stover, respectively. Maximum residues of MNBA were 0.0131 ppm and 0.0132 ppm in sweet corn forage and stover, respectively. Residues of mesotrione and MNBA were below the LOQ in/on all ear samples. Following two broadcast applications of the 50 WG formulation, maximum residues of mesotrione were 0.073 ppm in sweet corn forage and 0.094 ppm in sweet corn stover; residues of mesotrione were below the LOQ in sweet corn ears. Residues of MNBA were <LOQ in all sweet corn matrices. Residue levels were similar between the two formulation types.

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# 364044).

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

Mesotrione is a triketone herbicide which inhibits the enzyme *p*-hydroxyphenyl-pyruvate dioxygenase (HPPD), disrupting carotenoid biosynthesis. This process leads to the destruction of chlorophyll, resulting in a bleaching effect in susceptible plants. Mesotrione is intended for preemergence and postemergence use for the selective control of annual broadleaf weeds. The chemical structure and nomenclature of mesotrione and its metabolite MNBA, and the physicochemical properties of the technical grade of mesotrione are presented in Tables A.1 and A.2.

TABLE A.1. Test Compound Nomenclature.

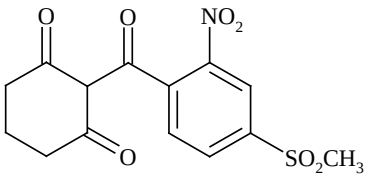
Chemical structure	
Common name	Mesotrione
Company experimental name	ZA1296
IUPAC name	2-(4-mesyl-2- nitrobenzoyl)cyclohexane-1,3-dione
CAS name	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione

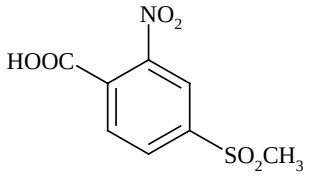
TABLE A.1. Test Compound Nomenclature.	
CAS registry number	104206-82-8
End-use product (EP)	4 lb/gal SC (Callisto® Herbicide; EPA Reg. No. 100-1131)
Compound	
Common name	MNBA
Chemical name	4-(methylsulfonyl)-2-nitrobenzoic acid

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound Mesotrione.		
Parameter	Value	Reference
Melting range	148.7-152.5°C	RD Memo, H. Podall, 24-FEB-2000; DP# 263245.
pH	3.4 (1% dispersion in water; 25°C)	
Density	1.46 g/mL, 20°C	
Water solubility	20°C 160 ppm, unbuffered water 0.22 g/100 mL, pH 4.8 1.5 g/100mL, pH 6.9 2.2 g/100 mL, pH 9	
Solvent solubility	20°C 0.37 g/100 mL, methanol 1.7 g/100 mL, ethyl acetate 0.27 g/100 mL, toluene 10.4 g/100 mL, acetonitrile <0.03 g/100 mL, heptane 8.1 g/100 mL, acetone	
Vapor pressure	4.3×10^{-8} torr, 20°C	
Dissociation constant, pK_a	3.12, 20°C	
Octanol/water partition coefficient, $Log(K_{OW})$	20°C log P_{OW} = 0.11 in unbuffered water log P_{OW} = 0.90 in pH 5 buffer log P_{OW} <-1 at pH 7 and 9 buffered water	
UV/visible absorption spectrum	Absorption maximum in methanol at 256 mu, with a molar extinction coefficient of 2.24 x 104 M cm.	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Refer to Table B.1.1 for trial site conditions, Table B.1.2 for study use patterns, and Table B.1.3 for geographic locations of submitted and requested trials.

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State, EPA Region; Year (Trial No.)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Seven Springs, NC, Region 2; 2008 (E10NC081871)	Loamy sand	0.7	6.4	6.5
Northwood, ND, Region 7; 2008 (C13ND081872)	Loam	5.3	6.6	23.2
Fresno, CA, Region 10; 2008 (W30CA081873)	Sandy loam	0.8	7.4	6.9

[1] OM = organic matter, CEC = cation-exchange capacity.

Cultivation and trial maintenance methods were conducted in accordance with local agricultural practices; maintenance chemicals used at each trial site during the study were reported. Average monthly minimum and maximum temperatures, and total monthly precipitation amounts were reported for each trial during planting only. According to the Study Report, temperature and precipitation were within historical values and no unusual weather occurred during the study. However, temperature and precipitation recordings were not provided for the time period following planting through harvesting. Irrigation was used to supplement rainfall as needed.

TABLE B.1.2. Study Use Pattern.

Trial Identification: City, State; Year (Trial No.)	EP[1]	Application					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)[2]	Rate (lb ai/A)	RTI[3] (days)	Total Rate (lb ai/A)	
Seven Springs, NC; 2008 (E10NC081871)	Callisto™ 4SC	1. Postemergence Broadcast; BBCH 36	15.1	0.0954	--	0.190	0.25% v/v NIS[4]
		2. Postemergence Broadcast; V7-V8, BBCH 37	15.0	0.0943	11		0.25% v/v NIS
	Mesotrione 50 WG	1. Postemergence Broadcast; BBCH 36	15.1	0.0957	--	0.189	0.25% v/v NIS
		2. Postemergence Broadcast; V7-V8, BBCH 37	14.8	0.0932	11		0.25% v/v NIS
Northwood, ND; 2008 (C13ND081872)	Callisto™ 4SC	1. Postemergence Broadcast; BBCH 16	20.3	0.0956	--	0.189	0.25% v/v NIS
		2. Postemergence Broadcast; BBCH 55	19.9	0.0937	15		0.25% v/v NIS
	Mesotrione 50 WG	1. Postemergence Broadcast; BBCH 16	20.4	0.0952	--	0.190	0.25% v/v NIS
		2. Postemergence Broadcast; BBCH 55	20.1	0.0946	15		0.25% v/v NIS
Fresno, CA; 2008 (W30CA081873)	Callisto™ 4SC	1. Postemergence Broadcast; BBCH 15	24.5	0.0923	--	0.188	0.25% v/v NIS
		2. Postemergence Broadcast; BBCH 17	25.5	0.0959	14		0.25% v/v NIS
	Mesotrione 50 WG	1. Postemergence Broadcast; BBCH 15	25.0	0.0939	--	0.188	0.25% v/v NIS
		2. Postemergence Broadcast; BBCH 17	25.0	0.0938	14		0.25% v/v NIS

[1] EP = end-use product. Callisto™ 4SC contains 4 lb ai/gal. Mesotrione 50 WG contains 0.5 lb ai/lb.
[2] GPA = gallons per acre.
[3] RTI = retreatment interval.
[4] NIS = non-ionic surfactant.

B.1.3. Trial Numbers and Geographical Locations

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Sweet Corn		
	Submitted	Requested*	
		Canada	U.S.
2	1		
7	1		
10	1		
Total	3		

*According to Section (e)(2)(x) of OPPT 860.1500, for registration of additional formulation types, side-by-side studies can be conducted, which involve applications of the registered formulation (the type used to obtain the tolerance) and the new type of formulation to side-by-side plots using the same rates and PHIs. The exact number of side-by-side studies required is decided on a case-by-case basis.

B.2. Sample Handling and Preparation

Duplicate samples were collected from the treated plots and single samples were collected from the control plots. Each forage sample was collected from at least 12 plants (with the ear removed) located in 12 separate areas of the plot. For each ear sample, at least 12 ears (i.e., kernel plus cob with the husks removed) were harvested from 12 separate areas of the treated plot. For each stover sample, the mature dried stalks (i.e., approximately 82-85% dry matter) of at least 12 plants were harvested from 12 separate areas of the plot.

Samples were frozen within 8 hours of harvest and stored frozen (<-10ºC) at the field trial sites until shipment to Syngenta Crop Protection, Inc. Samples were stored frozen (<-10ºC) at Syngenta until preparation. Sample preparation involved compositing and grinding the samples in a Hobert food cutter, using dry ice as needed to keep frozen. The prepared samples were shipped frozen to the analytical laboratory, Morse Laboratories, for extraction and analysis. At the analytical laboratory, samples were stored frozen (<-10ºC) until extraction.

B.3. Analytical Methodology

Samples were analyzed for residues of mesotrione and MNBA using Syngenta Method RAM 366/01 “Residue Analytical Method for the Determinations of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoinc Acid (MNBA) in Crop Samples,” with minor modifications. This method was previously reviewed and forwarded to the U.S. Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Manual (PAM) Volume II as a confirmatory enforcement method for plant commodities (Memo, W. Cutchin, 12-JAN-2005; DP# 283827). Briefly, residues of mesotrione and MNBA were extracted with acetonitrile:water (50:50 v/v) after addition of sodium chloride. Aliquots of the extracts were diluted with ultra-pure water followed by solid-phase extraction (SPE). Residues were eluted from the SPE cartridge using methanol and evaporated to dryness. Residues were then dissolved in ultra-pure water:methanol (90:10 v/v) with ultra-sonication. Samples were analyzed using HPLC/MS/MS. Based on the LLMV, the LOQ was 0.01 ppm for both analytes; the method LOD was not reported.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2. Samples were stored frozen at <-10ºC at the field sites and analytical laboratory, except for brief periods during preparation or sub-sample for analysis. The maximum storage interval from collection to extraction was 69 days (2.2 months) for sweet corn forage samples, 70 days (2.3 months) for ear samples, and 49 days (1.6 months) for corn stover samples. All sample extracts were analyzed within 2 days of extraction. Storage stability data submitted with a previous petition for field corn uses demonstrate that mesotrione and MNBA are stable in corn matrices stored frozen for up to 42 months (Memo, S. Levy, 06-JUN-2001; DP# 245477). The available corn storage stability data will support the storage conditions and intervals of samples from the sweet corn field trials.

Concurrent method recovery data are presented in Table C.1. The method was adequate for data collection based on acceptable concurrent method recovery data in control samples of sweet corn forage, ear, and stover fortified at 0.01 or 0.05 ppm. Recoveries for mesotrione and MNBA were within 70 to 120 % for all sweet corn matrices. Apparent residues of mesotrione and MNBA were each below the LOQ in/on all untreated samples of sweet corn matrices. Adequate sample chromatograms were provided.

Residue data from the sweet corn field trials are reported in Table C.3. A summary of the residue data for sweet corn matrices is presented in Table C.4.

After two broadcast applications of the 4 lb/gal SC formulation at a nominal rate of 0.094 lb ai/A/application, residues of mesotrione ranged from <LOQ (0.01 ppm) to 0.169 ppm in sweet corn forage, were below the LOQ in sweet corn ears, and ranged from <LOQ to 0.0942 ppm in sweet corn stover. Residues of MNBA ranged from <LOQ to 0.0131 ppm in sweet corn forage, were below the LOQ in sweet corn ears, and ranged from <LOQ to 0.0132 ppm in sweet corn stover. Residues above the LOQ were only detected in samples from the California site.

Following two broadcast applications of the 50 WG formulation at a nominal rate of 0.094 lb ai/A/application, residues of mesotrione ranged from <LOQ (0.01 ppm) to 0.073 ppm in sweet corn forage, were below the LOQ in sweet corn ears, and ranged from <LOQ to 0.094 ppm in sweet corn stover. Residues of MNBA were <LOQ in all sweet corn matrices. Residues above the LOQ were only detected in samples from the California site.

Residue levels were similar between the two formulation types. In general, residues following application of the 50% WG formulation were equal to or less than residues resulting from application of the 4 lb/gal SC formulation.

TABLE C.1. Summary of Concurrent Recoveries of Mesotrione from Sweet Corn Matrices.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries[1] (%)	Mean ± Std. Dev.[2] (%)
Mesotrione				
Sweet corn, forage (without ear)	0.01	2	90,104	97
	0.50	2	88, 92	90
Sweet corn, ear	0.01	1	99	--
	0.50	1	96	--
Sweet corn, stover	0.01	1	105	--
	0.50	1	81	--
MNBA				
Sweet corn, forage (without ear)	0.01	2	112, 113	112
	0.50	1	80	--
Sweet corn, ear	0.01	1	84	--
	0.50	1	92	--
Sweet corn, stover	0.01	1	112	--
	0.50	1	87	--

[1] Recoveries were not corrected for residues in the control since no residues were greater than the LOQ.
[2] Standard deviation only applicable for sample sizes of n≥3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability[2]
Sweet corn, forage (without ear)	<-10ºC	59-69 days (1.9-2.2 months)	Residues of mesotrione are relatively stable in/on fortified corn matrices (forage, stover, and grain) stored frozen for up to 42 months.
Sweet corn, ear		60-70 days (1.9-2.3 months)	
Sweet corn, stover		33-49 days (1.1-1.6 months)	

[1] Duration from harvest to extraction. Samples were prepared between 4 and 36 days after collection and extracted between 28 and 54 days after preparation . All samples were analyzed within 2 days of extraction.
[2] Memo, S. Levy, 06-JUN-2001; DP# 245477.

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

Trial Identification: City, State; Year (Trial No.)	Crop; Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Mesotrione (ppm)	MNBA (ppm)
4 lb/gal SC						
Seven Springs, NC; 2008 (E10NC081871)	Sweet corn; Rogers WH0809	Forage	0.190	32	<LOQ	<LOQ
					<LOQ	<LOQ
		Ear		32	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		53	<LOQ	<LOQ
					<LOQ	<LOQ
Northwood, ND; 2008 (C13ND081872)	Sweet corn; Peaches & Cream	Forage	0.189	28	<LOQ	<LOQ
					<LOQ	<LOQ
		Ear		28	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		66	<LOQ	<LOQ
					<LOQ	<LOQ
Fresno, CA; 2008 (W30CA081873)	Sweet corn; Sweetie 82	Forage	0.188	45	0.0726	<LOQ
					0.169	0.0131
		Ear		45	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		69	0.0942	0.0132
					0.0586	<LOQ
50% WG						
Seven Springs, NC; 2008 (E10NC081871)	Sweet corn; Rogers WH0809	Forage	0.189	32	<LOQ	<LOQ
					<LOQ	<LOQ
		Ear		32	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		53	<LOQ	<LOQ
					<LOQ	<LOQ
Northwood, ND; 2008 (C13ND081872)	Sweet corn; Peaches & Cream	Forage	0.190	28	<LOQ	<LOQ
					<LOQ	<LOQ
		Ear		28	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		66	<LOQ	<LOQ
					<LOQ	<LOQ
Fresno, CA; 2008 (W30CA081873)	Sweet corn; Sweetie 82	Forage	0.188	45	0.0730	<LOQ
					0.0566	<LOQ
		Ear		45	<LOQ	<LOQ
					<LOQ	<LOQ
		Stover		69	0.0942	<LOQ
					0.0720	<LOQ

LOQ = 0.01 ppm

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

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	Std. Dev.
4 lb/gal SC									
Mesotrione									
Sweet corn, forage	0.188 to 0.190	28 to 45	6	<0.01	0.169	0.121	0.010	0.047	0.065
Sweet corn, ears	0.188 to 0.190	28 to 45	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0
Sweet corn, stover	0.188 to 0.190	53 to 69	6	<0.01	0.0942	0.0764	0.010	0.032	0.036
MNBA									
Sweet corn, forage	0.188 to 0.190	28 to 45	6	<0.01	0.0131	0.0116	0.010	0.011	0.001
Sweet corn, ears	0.188 to 0.190	28 to 45	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0
Sweet corn, stover	0.188 to 0.190	53 to 69	6	<0.01	0.0132	0.0116	0.010	0.011	0.001
50% WG									
Mesotrione									
Sweet corn, forage	0.188 to 0.190	28 to 45	6	<0.01	0.073	0.065	0.010	0.028	0.029
Sweet corn, ears	0.188 to 0.190	28 to 45	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0
Sweet corn, stover	0.188 to 0.190	53 to 69	6	<0.01	0.0942	0.0831	0.010	0.034	0.038
MNBA									
Sweet corn, forage	0.188 to 0.190	28 to 45	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0
Sweet corn, ears	0.188 to 0.190	28 to 45	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0
Sweet corn, stover	0.188 to 0.190	53 to 69	6	<0.01	<0.01	<0.01	<0.01	<0.01	0.0

[1] For calculations of median, mean, and standard deviation, the LOQ was used for any results reported as <LOQ in Table C.3.
[2] HAFT = highest-average field trial.

D. CONCLUSION

The submitted field trial data are adequate and reflect the use of two broadcast applications of mesotrione (4 SC and 50 WG formulations) at a nominal rate of 0.094 lb ai/A/application. Side-by-side treatment plots were established at three trials, with one treatment plot for 4 SC applications and one treatment plot for 50 WG applications. An acceptable method was used for the quantitation of residues of mesotrione and MNBA, and adequate data are available to support sample storage intervals and conditions used in the study.

Following two broadcast applications of the 4 lb/gal SC formulation, maximum residues of mesotrione were 0.169 ppm and 0.0942 ppm in sweet corn forage and stover, respectively. Maximum residues of MNBA were 0.0131 ppm and 0.0132 ppm in sweet corn forage and stover,

respectively. Residues of mesotrione and MNBA were below the LOQ in all ear samples. Following two broadcast applications of the 50% WG formulation, maximum residues of mesotrione were 0.073 ppm in sweet corn forage and 0.094 ppm in sweet corn stover; residues were below the LOQ in sweet corn ears. Residues of MNBA were <LOQ in all sweet corn matrices.

Residues were similar between the two formulation types. It does not appear that the agricultural practices used or weather conditions adversely impacted the results of the study; however, temperature and precipitation recordings were not provided for the time period following planting through harvesting.

E. REFERENCES

DP#: 263245
Subject: Product Chemistry Review of Mesotrione (ZA 1296 Technical (dry)).
From: H. Podall
To: J. Tompkins/J. Stone
Date: 24-FEB-2000

DP#s: 245477 and 260267
Subject: PP#: 8F04954. Mesotrione in/on Field Corn. Evaluation of Residue Data and Analytical Methods. PC Code: 122990.
From: S. Levy
To: J. Stone/ J. Tompkins
Dated: 06-JUN-2001

DP#: 283827
Subject: Mesotrione. Summary of Analytical Chemistry and Residue Data for Sweet Corn, PP#2F06443, and Response to Data Deficiencies of a Previous HED Review (PP#8F04954, DP Barcodes: D245477 and D260267, 6/6/01, S. Levy).
From: W. Cutchin
To: J. Stone/ J. Miller
Dated: 12-JAN-2005

F. DOCUMENT TRACKING

RDI: G.F. Kramer (14-SEP-2009), RAB1 Chemists (16-SEP-2009)
Registration Number: 100-RGUO-Mesotrione 50WG
DP#: 364044
PC Code: 122990

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