Image 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: February 28,2002

SUBJECT: ***S*-Metolachlor.** OPPTS 860.1520: Processed Food/Feed Study on/in Soybeans; PC code 108800; Rereg. Case 0001; DP Barcode D280215; MRID No. 44516802.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist Alan Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

S-Metolachlor PC Code: 108800 EPA Barcode: D280215	Processed Food/Feeds GL: OPPTS 860.1520	MRID: 44516802 Case No.: 0001 Submission: S608602

EPA Reviewer: Sherrie J. Kinard, **Date** 28/FEB/02

STUDY TYPE: Processed Food/Feed Study -Soybeans; OPPTS 860.1520

TEST MATERIAL: *S*-Metolachlor

FORMULATION AND TYPE: Dual II Magnum, 7.6 lb/gal EC

SYNONYMS: CGA-77102

CITATIONS: 44516802 Oakes, T. (1998) CGA-77102--Magnitude of the Residues In or On Soybeans: Lab Project Number: ABR-98009: 31-96: 150006. Unpublished study prepared by Novartis Crop Protection, Inc. 460 p.

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

In a series of soybean processing studies (MRID 44516802), *S*-metolachlor (7.6 lb/gal EC) was applied to soybeans as a single foliar application to separate plots at 1.33, 3.99, and 6.7 lb ai/A (1x, 3x, or 5x the maximum proposed post-emergence application rate) at two test sites (IA and IL). Soybeans were harvested 91 days post-treatment, and were processed into hulls, meal, and refined oil using simulated commercial procedures. Combined residues were <LOQ (<0.08 ppm) in/on seeds harvested from the four tests conducted at 1x or 3x and from one of the 5x tests. In the other 5x test, residues of CGA-37913 and CGA-49751 were 0.03 ppm and <0.05 ppm, respectively, for combined residues of <0.08 ppm.

Based on the residue data from the 5x soybean seeds and processed fractions, *S*-metolachlor residues did not concentrate in soybean oil. However, residues concentrated slightly (1.2x) in hulls and meal. Considering the highest average field trial (HAFT) residues of *S*-metolachlor in/on soybean seeds of 0.115 ppm and the average processing factors, the maximum expected residues would be 0.14 ppm in hulls and meal and 0.12 ppm in oil processed from soybeans treated at the maximum application rate. As the maximum expected residue levels in these processed commodities are below the established 0.2 ppm tolerance for soybean seeds, separate tolerances for residues in soybean processed commodities are not necessary for *S*-metolachlor.

These processed food/feed studies are classified acceptable and do satisfy the guideline requirement for a soybean processing study (Residue Chemistry Guidelines OPPTS 860.1520).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

MATERIALS:

1. **Test Compound:**

Active ingredient (ai): *S*-Metolachlor
Formulation or spiking substance: 7.6 lb/gal EC

Physicochemical Properties:

Water and Organic Solvent Solubility (OPPTS 830.7840 and 830.7860)	488 mg/L at 25 C very soluble in benzene, hexane, methanol, octanol, and dichloromethane
n-Octanol/water partition coefficient (Kow) (OPPTS 830.7550)	log Kow = 2.93 at 25 C
pKa (OPPTS 830.7370)	Not available
Vapor Pressure (OPPTS 830.7950)	4.2 mPa at 25 C

2. **Test Commodity:**

Crop: Soybean
Type/Variety: Ciba seeds 3311(IL test site) and Pioneer 9287 (IA test site)
Crop parts used in processing study: Dried seeds, Hulls, Refined Oil, and Meal
Developmental stages (i.e., immature/mature, fresh/dry, etc.):
Application: broadcast foliar application prior to full bloom
Harvest: mature soybeans (91 days post-treatment)

METHODS:

1. **Experimental Design:**

Method of application: Single foliar broadcast at two test sites at 1x, 3x, and 5x
Rate of application (comparison to the maximum application rate):
Application rate(s): 1.33, 3.99 or 6.7 lb ai/A (1x, 3x, or 5x) at both test sites
Number of applications: 1 per treatment/site
Number of test/control samples: At each test site, a single bulk sample was collected for each treatment and one control sample (weight unspecified)

Number of sample replicates: two subsamples were collected for dried seed and one sample of each processed commodity was collected from each test.

2. Test Procedures:

Manner in which test compound was introduced into RAC (i.e., spiking, application; field incurred):

At both test sites (IL and IA), metolachlor (7.6 lb/gal EC) was applied once as a broadcast foliar application to soybeans prior to full bloom to three separate plots at 1.33, 3.99, and 6.7 lb ai/A (1x, 3x, and 5x the maximum proposed rate), using 17-20 gallons of spray mixture/A. Mature soybeans were harvested 91 days post-treatment.

Description of processing procedure and mass balance (include scheme if applicable):

A bulk sample of soybeans from each treatment at both test sites were processed into hulls, refined oil, and meal according to simulated commercial procedures at the Food Protein R&D Center (FPRDC) in Byran, TX. All processed fractions were then placed in frozen (≤ -10 C) storage until analysis. Material balance flow charts were provided.

Analytical method:

Samples of soybean seeds, hulls, meal, and refined oil were analyzed for the combined residues of S-metolachlor using Analytical Method AG-612, a gas chromatographic/ nitrogen-phosphorus detection (GC/NPD) method that is similar to Method I in PAM, Vol. II. This method determines residues of *S*-metolachlor and its metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents. Analyses were conducted by Novartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples of each commodity are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ)

for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on soybean seeds, hull, meal and refined oil.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated seeds, hulls, meal, and oil from each test site were fortified separately with CGA-37913 at 0.02 ppm and with CGA-49751 at 0.05 ppm. These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. The average method recovery from soybean seeds and processed commodities was 106 ± 16% for CGA-37913 and 106 ± 7% for CGA-49751. Adequate chromatograms and sample calculations were provided.

Storage stability:
At each test site, soybean seeds from each treatment were harvested 91 days post-treatment and shipped frozen to the processing facility (FPRDC), where they were stored frozen until processing. Processing was initiated within one month of harvest, and samples were frozen after processing and shipped frozen to the analytical laboratory by overnight courier. The total frozen (≤ -10 C) storage intervals were 223-232 days for seeds (~7 months) and 295-319 days for hulls, meal, and oil (~10 months).

No new storage stability data were submitted with this processing study. However, adequate storage stability data are available (DP Barcodes D222430 and D224237, S. Hummel, 2/25/97) indicating that CGA-37913 and CGA-49751are stable at ≤-10 C for at least 2 years in soybean hulls and meal and corn oil. These data are adequate to support this soybean processing study.

II. RESULTS

TABLE 1. Summary of Procedural Recoveries for Soybean Seeds, Hulls, Meal, and Refined Oil, Spiked with CGA-37913 or CGA-49751

Matrix	Spiking Level (ppm)	% Recovery	Mean
CGA-37913			
Soybean, seed (RAC)	0.02	108, 69	89
Soybean, hulls	0.02	118, 100	109
Soybean, meal	0.02	112, 119	116
Soybean, refined oil	0.02	110, 115	113
CGA-49751			
Soybean, seed (RAC)	0.05	101, 91	96
Soybean, hulls	0.05	112, 109	111

Soybean, meal	0.05	114, 105	110
Soybean, refined oil	0.05	104, 109	107

Comments:
The recovery data for soybean seeds and processed commodities indicate that the GC/NPD method AG-612 is adequate for determining residues of CGA-37913 and CGA-49751for each commodity. Recoveries ranged from 69-118%. The LOQ for CGA-37913 and CGA-49751 is 0.03 and 0.05 ppm, respectively, in/on each commodity.

TABLE 2. Residue Levels of *S*-Metolachlor in Soybean Seeds, Hulls, Meal, and Refined Oil[a]

Matrix	Rate (lbs ai/A)	PHI (days)	Residues[a] (mg/kg)			Processing factor[b]
			CGA-31913	CGA-47951	Combined	
Iowa Tests						
Soybean, seed (RAC)	1.33 (1x)[c]	91	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08	NA
	3.99 (3x)		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08	
	6.7 (5x)		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08	
Soybean, hulls	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		0.03	<0.05	<0.08	1x
Soybean, meal	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		0.04	<0.05	<0.09	1.1x
Soybean, refined oil	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		<0.03	<0.05	<0.08	1x
Illinois Tests						
Soybean, seed (RAC)	1.33 (1x)	91	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08	NA
	3.99 (3x)		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08	
	6.7 (5x)		0.03, 0.03	<0.05, <0.05	<0.08, <0.08	
Soybean, hulls	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		0.05	<0.05	<0.10	1.3x
Soybean, meal	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		0.05	<0.05	<0.10	1.3x
Soybean, refined oil	1.33	91	<0.03	<0.05	<0.08	1x
	3.99		<0.03	<0.05	<0.08	1x
	6.7		<0.03	<0.05	<0.08	1x

[a] The LOQ is 0.03 and 0.05 ppm. for CGA-37913 and CGA-47951, respectively.
[b] The processing factor was calculated using the combined residues.
[c] The maximum proposed postemergence rate for S-metolachlor is 1.33 lb ai/A.

TABLE 3. Processing Factors, Maximum Residues and Proposed Tolerances for Metolachlor in Soybeans Processed Commodities

RAC	Processed Commodity	Processing Factor [a]	HAFT [b] (ppm)	Theoretical Max. Residue (ppm)	Established or recommended Tolerance (ppm) [c]
Soybean	Hulls	1.2x	0.115	0.14	None
	Meal	1.2x		0.14	None
	Refined Oil	1x		0.12	None

[a] Average of concentration factors from the 5x tests and the IA and IL test sites.

[b] The HAFT residue value was taken from the post-emergence field trial data for *S*-metolachlor in which maximum residues were <0.13 and <0.10 ppm in/on two samples of soybean seeds from the NE test (MRID 44516802).

[c] Residues in soybean hulls, meal, and oil are covered by the established 0.2 ppm tolerance for soybean seeds.

Comments:

The combined residues of CGA-37913 and CGA-49751, expressed as *S*-metolachlor, were <LOQ (<0.08 ppm) in/on duplicate samples of soybean seeds harvested 91 days following a single foliar application of *S*-metolachlor (7.6 lb/gal EC) at 1.33 or 3.99 lb ai/A (1x and 3x the maximum post-emergence rate) at both test site and following a single foliar application at 6.7 lb ai/A (5x) at the IA test site. However, at the IL test site, residues of CGA-37913 and CGA-49751 were 0.03 and <0.05 ppm, respectively, (combined residues <0.08 ppm) in/on seeds from the 5x application.

Combined residues were <0.08 ppm (<LOQ) in all fractions processed from seeds from the 1x and 3x treated plots from each test site. For the processed samples from the 5x-treated IA test, combined residues were *<0.08 ppm in hulls and oil but were <0.09 ppm in meal, indicating a slight concentration* (1.1x). For the processed samples from the 5x-treated IL test, combined residues were <0.08 ppm in oil, but showed a slight concentration (1.3x) in both hulls (<0.10 ppm) and meal (<0.10 ppm). Based on the residues in processed fractions and seeds treated at 5x from both test sites, the average concentration factor for hull and meal would be 1.2x. Residues do not appear to concentrate in soybean oil.

Considering the HAFT residues of *S*-metolachlor in/on soybean seeds of 0.115 ppm and the processing factors, the maximum expected residues would be 0.14 ppm in hulls and meal and 0.12 ppm in oil processed from soybeans treated at the maximum application rate. As the maximum expected residue levels in soybean processed commodities are below the established 0.2 ppm tolerance for soybean seeds, separate tolerances for residues in soybean processed commodities are not necessary for *S*-metolachlor.

III. FINAL SUMMARY

Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. The current tolerance for soybean commodities are 0.2

ppm in/on soybean seeds and 8.0 ppm each in/on soybean forage and hay. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. *S*-Metolachlor residues of concern in plants and animal commodities are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96) and include *S*-metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751.

The submitted soybean processing studies are adequate. At the two test sites, combined residues were <LOQ in/on soybean seeds harvested 91 days following a single foliar application of *S*-metolachlor (7.6 lb/gal EC) at 1x and 3x the maximum post-emergence rate; residues were also <LOQ in/on seeds from plants treated at 5x at the IA test site. However, at the IL test site, residues of CGA-37913 and CGA-49751 were 0.03 and <0.05 ppm, respectively, (combined residues <0.08 ppm) in/on seeds from the 5x application.

Considering the processed fractions derived from the 5x-treated seeds, *S*-metolachlor residues did not concentrate in soybean oil. However, residues concentrated slightly in meal (1.1x) from the IA test site and in hulls (1.3x) and meal (1.3x) from the IL test site. Considering the HAFT residues of *S*-metolachlor in/on soybean seeds of 0.115 ppm and the average processing factors, the maximum expected residues would be 0.14 ppm in hulls and meal and 0.12 ppm in oil processed from soybeans treated at the maximum application rate. As the maximum expected residue levels in these processed commodities are below the established 0.2 ppm tolerance for soybean seeds, separate tolerances for residues in soybean processed commodities are not necessary for *S*-metolachlor.

Samples of soybean seeds and processed commodities were stored frozen for 7-10 months prior to analysis. These storage intervals are supported by previously submitted storage stability data.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on the outcome of these processed food/feed studies.

V. REFERENCES

DP Barcode:	D226780
Subject:	Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From:	L. Kutney
To:	R. Giffin
Dated:	11/12/96
MRID(s):	43928901-43928903 and 43928939-43928942

DP Barcodes:	D222430 and D224237
Subject:	Metolachlor (108801) Reregisration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions
From:	S. Hummel
To:	M. Metzger
Dated:	2/25/97
MRID(s):	43881701-43881703 and 43944601

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: *S*-**Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Soybean; PC code 108800; Rereg. Case 0001; DP Barcode D280215; MRID No. 44516802.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist AE Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

S-Metolachlor PC Codes: 108800 EPA Barcode: D280215	Crop Field Trials GL: OPPTS 860.1500	MRID: 44516802 Case No.: 0001 Submission: S608602

EPA Reviewer: Sherrie J. Kinard, Date 28/Feb/02

STUDY TYPE: Crop Field Trials - Soybeans; OPPTS 860.1500

TEST MATERIAL: *S*-Metolachlor

FORMULATIONS AND TYPES: Dual II Magnum (7.6 lb/gal EC)

SYNONYMS: CGA-77102

CITATION: 44516802 Oakes, T. (1998) CGA-77102--Magnitude of the Residues In or On Soybeans: Lab Project Number: ABR-98009: 31-96: 150006. Unpublished study prepared by Novartis Crop Protection, Inc. 460 p.

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

The results from 20 crop field trials (MRID 44516802) conducted on soybeans during 1996 and 1997 have shown that the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent *S*-metolachlor, were <0.13 ppm in/on soybean seeds harvested at maturity, 86-104 days following a post-emergence application of *S*-metolachlor (7.6 lb/gal EC) at 1.33 lb ai/A (1x proposed rate). No data were submitted on residues in/on soybean forage or hay. In four related tests conducted at exaggerated rates, the combined *S*-metolachlor residues were <0.08 ppm in/on soybean seeds harvested 91 days following a post-emergence application at 3.99 or 6.7 lb ai/A (3x or 5x).

The field trial data on soybeans are adequate to support the use of a single post-emergence application of *S*-metolachlor to soybeans prior to full bloom at 1.33 lb ai/A, provided that labels are amended to (i) prohibit the grazing or harvest of soybean forage and hay following the post-emergence use, (ii) prohibit the use of a preplant or pre-emergence application in conjunction with the post-emergence application, and (iii) specify a 90-day PHI for mature seeds. Provided that these label amendments are made, the available data indicate that residues in/on soybeans resulting from a post-emergence application of *S*-metolachlor at 1.33 lb ai/A will not exceed the established 0.2 ppm tolerance for metolachlor residues in/on soybeans. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on soybeans.

The crop field trials for the post-emergence use of *S*-metolachlor on soybeans are classified acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used a gas chromatographic/nitrogen-phosphorus detection (GC/NPD) method (Analytical Method AG-612) to determine residues of *S*-metolachlor in/on soybean seed. Method AG-612 is similar to Method I in PAM, Vol. II, and determines residues *S*-metolachlor and its metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents.

A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples were analyzed by Novartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on soybean seeds.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated seeds from the current field trials were fortified separately with CGA-37913 at 0.02-2.0 ppm and with CGA-49751 at 0.05-2.0 ppm These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. The average method recovery from soybeans seeds was 104 ± 14% for CGA-37913 and 101 ± 12% for CGA-49751. Adequate chromatograms and sample calculations were provided.

The GC/NPD Method AG-612 is adequate for collecting data on residues of *S*-metolachlor in/on soybean seeds.

1. Test Compound

Chemical name: *S*-Metolachlor
IUPAC: 2-chloro-6′ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: (*S*) 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): S-metolachlor
Developmental (Company) name: CGA-77102

2. Trial Numbers and Locations

S-Metolachlor trials

Crop (commodity)	US Growing Regions				Total Trials
	2	4	5	8	
Soybeans (dried seed)					
Submitted	3	2	14	1	20
Requested	2	3	15	none	20

Comments: Geographic representation and the number of crop field trials conducted are adequate to support the proposed use of a single post-emergence application of *S*-metolachlor on soybeans. A total of 20 field trials were conducted using *S*-metolachlor at 1x the proposed post-emergence use rate. Residue decline studies were conducted at two of the test sites, and two other test sites also included a post-emergence application at 3x or 5x rates.

3. Labeled Use Patterns

Current Pre-emergence uses of *S*-Metolachlor on Soybeans [a]

Crop	Application					Comments/Restrictions
	Method/ Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI (days)	
Soybean	Broadcast preplant (surface or incorporated) or preemergence application in the spring, or a broadcast application in the fall to crop stubble after harvest. Application can be made using ground or aerial equipment.	1.3-2.5 [b]	1-2	2.4-2.6	None [c]	The preplant surface application in spring is restricted to the following states: CO, CT, DE, IA, IL, IN, KS, KY, MA, MD, ME, MI, MN, MO, MT, ND, NE, NH, NY, OH, PA, RI, SD, TN, VA, VT, WI, WV, and WY. This type of application may be may as a split (⅔ + ⅓) application on medium or fine soils. The fall application should not be applied to frozen ground and is restricted to IA, MN, ND, SD, WI and portions of NE and IL.

[a] These use directions are summarized from labels of the seven products containing S-metolachlor that are currently registered to Syngenta.

[b] The maximum single application rate is dependent of the soil type, organic matter content, and tillage system. The maximum single application rates are generally as follows: 1.3 lb ai/A for course soils, 1.6 lb ai/A for medium soils, 1.9 lb ai/A for fine soils, and 2.4-2.5 lb ai/A for soils with organic matter contents of 3-20%.

[c] With the exception of one label, PHIs are not specified for soybean forage, hay and seeds. However, the 6.3 lb/gal EC formulation (EPA Reg No. 100-958) specifies a 40-day PHI/PGI for grazing or feeding of treated soybean plants to livestock.

Proposed Post-emergence use of *S*-Metolachlor on Soybeans [a]

Crop	Application					Comments/Restrictions
	Method/Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI (days)	
Soybean	Broadcast post-emergence application to soybeans prior to full bloom	1.33	Not specified [b]	Not specified [b]	90 (dried seed)	No PHI/PGI was proposed for forage and hay, nor was the use of forage and hay prohibited. Applications may include the use of a non-ionic surfactant at 0.5% v/v.

[a] These use directions are based on the current crop field trials (MRID 44516802).

[b] The registrant did not specify a maximum seasonal use rate or number of applications. The registrant also did not indicate whether or not this post-emergence use could be used in combination with the existing preplant and preemergence uses.

Comments: There are currently a total of seven products containing *S*-metolachlor that are registered to Syngenta for use on soybeans: four 7.6 lb/gal EC formulations (EPA Reg. Nos. 100-816, 100-818, 100-964, 100-965, a 6.3 lb/gal EC (EPA Reg. No. 100-958), a 7.6 lb/gal RTU (EPA Reg. No. 100-829), and a 16% G formulation (EPA Reg No. 100-910). Use directions for these products are summarized generally in the above table. None of these products list a post-emergence use of *S*-metolachlor on soybeans, as is used in the current submission.

The current soybean field trials were submitted to support a single post-emergence application of *S*-metolachlor to soybeans. The available residue data would support a single post-emergence application of *S*-metolachlor (EC) to soybeans prior to full bloom at 1.33 lb ai/A, with a PHI of 90 days for dried seed. As no residue data were provided for soybean forage and hay from this use, any label directions including a post-emergence application should prohibit the harvesting or grazing of soybean forage and hay by livestock. In addition, the directions should prohibit the combined use of preplant/preemergence application with a post-emergence application.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
Soybean seed	CGA-37913	0.02-2.0	102, 116, 112, 80, 110, 114, 110, 108, 112, 112, 104, 98, 118, 111, 110, 116, 122, 96, 103, 111, 125, 107, 69, 88, 96, 95, 99, 73	69-125	104 ± 14
	CGA-49751	0.05-2.0	96, 83, 122, 93, 105, 89, 94, 101, 115, 123, 98, 93, 110, 94, 102, 105, 113, 117, 95, 91, 110, 100, 103, 105, 100, 101, 83, 73	73-123	101 ± 12

Comments: With the exception of a few marginal recoveries for each analyte (69%, 122%, 123%, 125%), recoveries were within the acceptable 70-120% range. Based on the concurrent method recoveries, the *GC/NPD Method AG-612* is adequate for collecting data on *S*-metolachlor residues in/on soybean seeds.

5. Storage Stability Conditions

Commodities	Analytes	Storage Temperature (°C)	Storage Duration (months)
Soybean seeds	CGA-37913 and CGA49751	≤-15	5-10.5

Comments: Samples of dried seed were collected at maturity (69-104 days post-treatment), frozen, and shipped frozen by freezer truck or by overnight courier to Novartis Crop Protection, Greensboro, NC, where samples were stored at ≤-15 C until extraction for analysis. With the exception of seed samples from the 1997 NC test, which were stored for only 26 days prior to analysis, the total sample storage intervals for soybean seeds were 152-319 days (5-10.5 months).

No new storage stability data were submitted with this study; however, adequate storage stability data are available indicating that CGA-37913 and CGA-49751 are stable during storage at ≤-10 C for up to 2 years in/on peanut nutmeats, potatoes, corn grain, and corn forage (DP Barcode No. D166637, B. Cropp-Kohlligian, 4/16/92). These data are adequate to support the soybean field trials.

6. Application and RAC Information

***S*-Metolachlor**-Dual II Magum (7.64 lb/gal EC)-Soybean

LOCATION (county /state/year)	EPA Region	Soybean Variety	APPLICATION[a]					HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion[c]	Number and wt. of samples
Washington/ MS/ 1996	2	Asgrow A4715	R2	1	1.33	broadcast	16	Mature	dried seed	Duplicate samples were collected from each treatment at each test site and at each sampling interval in the residue decline trials, but information on sample weights were not provided.
Champaign/ IL/ 1996	5	Ciba seeds 3311	R1	1	1.33	broadcast	20	Mature	dried seed	
					3.99		20	Mature	dried seed	
					6.7		20	Mature	dried seed	
Crittenden/ AR/ 1996	4	Hutcheson	Bloom	1	1.33	broadcast	11	Mature	dried seed	
Mitchell/ GA/ 1996	2	S-83-30	first bloom	1	1.33	broadcast	20	Mature	dried seed	
St. Landry/ LA/ 1996	4	RT Asgrow 5601	V5	1	1.33	broadcast	11	Mature	dried seed	
Story/ IA/ 1996	5	Pioneer 9287	V3	1	1.33	broadcast	17	Mature	dried seed	
					3.99	broadcast	17	Mature	dried seed	
					6.7	broadcast	17	Mature	dried seed	
Story/ IA/ 1996	5	Asgrow 2704 STS	V3	1	1.33	broadcast	20	Mature	dried seed	
Shelby/ MO/ 1996	5	Pioneer 9362	V4.5	1	1.33	broadcast	20	Mature	dried seed	
Jackson/ MO/ 1996	5	GX404	V7; 5-7 trifoliate	1	1.33	broadcast	20	Mature	dried seed	
Finney/ KS/ 1996	8	Pioneer Hydrid 9442	3 trifoliate	1	1.33	broadcast	20	Mature	dried seed	
Clinton/ IL/ 1996	5	Round Up ready 4401	6 trifoliate	1	1.33	broadcast	11	Mature[d]	dried seed	
Yankton/ SD/ 1996	5	Golden Harvest 1263	V6	1	1.33	broadcast	18	Mature	dried seed	
York/ NE/ 1996	5	Hack	vegetative	1	1.33	broadcast	20	Mature	dried seed	
Dakota/ MN/ 1996	5	Ciba Seeds 3196	V6; 6-7 trifoliate	1	1.33	broadcast	20	Mature[d]	dried seed	
Steele/ MN/ 1996	5	Parker	V7; 7-8 trifoliate	1	1.33	broadcast	20	Mature	dried seed	

Application and RAC Information *(continued)*

***S*-Metolachlor**-Dual II Magum (7.64 lb/gal EC)-Soybean

LOCATION (county /state/year)	EPA Region	Soybean Variety	APPLICATION[a]					HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion[c]	Number and wt. of samples
Hamilton/ IN/ 1996	5	Pioneer 9342	V5	1	1.33	broadcast	12	Mature	dried seed	Duplicate samples[d] were collected from each treatment at each test site and at each sampling interval in the residue decline trials, but information on sample weights were not provided.
Hamilton/ IN/ 1996	5	Pioneer 9342	V4	1	1.33	broadcast	12	Mature	dried seed	
Fayette/ OH/ 1996	5	GL2930	V5	1	1.33	broadcast	15	Mature	dried seed	
Ingham/ MI/ 1996	5	Dekalb CX228	V4; R1	1	1.33	broadcast	23	Mature	dried seed	
Sampson/ NC/ 1997	2	AG 5601	very early bloom	1	1.33	broadcast	10	Mature	dried seed	

[a] Dual II Magnum is a MAI that also includes the herbicide safener Benoxacor at 0.38 lb/gal. Each application also included a non-ionic surfactant, X-77 or INDUCE at 0.5% v/v.
[b] Based on the available data, the presumed maximum single post-emergence application rate is 1.33 lb ai/A.
[c] Duplicate samples of forage were also collected on the day of application (0-day PHI) from each test except the MI test; however, the forage samples were not analyzed.
[d] Residue decline studies were conducted in IL and MN.

Comments: Provided that any proposed label directions prohibit the feeding of soybean forage and hay to livestock following a post-emergence application and prohibit the use of preplant or preemergence applications of *S*-metolachlor in conjunction with a post-emergence application, the available field trials would adequately support a single post-emergence application to soybeans of *S*-metolachlor (EC) at 1.33 lb ai/A.

7. Site Specific Information

LOCATION (county/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Washington/ MS/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	Not reported (NR)	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Champaign/ IL/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Crittenden/ AR/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Mitchell/ GA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
St. Landry/ LA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Story/ IA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Story/ IA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Shelby/ MO/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Jackson/ MO/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Finney/ KS/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Clinton/ IL/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Yankton/ SD/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
York/ NE/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.

Site Specific Information *(continued)*

LOCATION (county/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Dakota/ MN/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Steele/ MN/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Hamilton/ IN/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Hamilton/ IN/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Fayette/ OH/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Ingham/ MI/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Sampson/ NC/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1. Residue Data Summary from Soybean Crop Field Trials: *S*-Metolachlor - Soybean seeds

Location (county/ state/ year)	Soybean Variety	Formulation	Application			PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Washington/ MS/ 1996	Asgrow A4715	7.64 lb/gal EC	1.33	1	100	92	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Champaign/ IL/ 1996	Ciba seeds 3311	7.64 lb/gal EC	1.33	1	100	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			3.99	1	300	91	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
			6.7	1	500	91	0.03, 0.03	<0.05, <0.05	<0.08, <0.08
Crittenden/ AR/ 1996	Hutcheson	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Mitchell/ GA/ 1996	S-83-30	7.64 lb/gal EC	1.33	1	100	92	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
St. Landry/ LA/ 1996	RT Asgrow 5601	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Story/ IA/ 1996	Pioneer 9287	7.64 lb/gal EC	1.33	1	100	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			3.99	1	300	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			6.7	1	500	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Story/ IA/ 1996	Asgrow 2704 STS	7.64 lb/gal EC	1.33	1		91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Shelby/ MO/ 1996	Pioneer 9362	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Jackson/ MO/ 1996	GX404	7.64 lb/gal EC	1.33	1	100	93	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Finney/ KS/ 1996	Pioneer Hydrid 9442	7.64 lb/gal EC	1.33	1	100	104	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Clinton/ IL/ 1996	Round Up ready 4401	7.64 lb/gal EC	1.33	1	100	69	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						76	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						83	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						90	<0.03, <0.03	<0.05, <0.05	**<0.080, <0.08**
						97	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
Yankton/ SD/ 1996	Golden Harvest 1263	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
York/ NE/ 1996	Hack	7.64 lb/gal EC	1.33	1	100	91	0.08, 0.05	<0.05, <0.05	**<0.13, <0.10**

TABLE 1. Residue Data Summary from Soybean Crop Field Trials: *S*-Metolachlor - Soybean seeds *(continued)*

Location (county/ state/ year)	Soybean Variety	Formulation	Application			PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Dakota/ MN/ 1996	Ciba Seeds 3196	7.64 lb/gal EC	1.33	1	100	70	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						77	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						84	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
						93	<0.03, <0.03	<0.05, <0.05	**<0.080, <0.08**
						100	<0.03, <0.03	<0.05, <0.05	<0.080, <0.08
Steele/ MN/ 1996	Parker	7.64 lb/gal EC	1.33	1	100	92	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Hamilton/ IN/ 1996	Pioneer 9342	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Hamilton/ IN/ 1996	Pioneer 9342	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Fayette/ OH/ 1996	GL2930	7.64 lb/gal EC	1.33	1	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Ingham/ MI/ 1996	Dekalb CX228	7.64 lb/gal EC	1.33	1	100	93	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Sampson/ NC/ 1997	AG 5601	7.64 lb/gal EC	1.33	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

[a]
[b] The proposed maximum post-emergence application rate is 1.33 lb ai/A.
[c] PHI=post-harvest Interval; the proposed PHI is 90 days for soybean seeds.
[d] Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents, and are not corrected for procedural recoveries.
[e] Combined residues in/on soybean seeds resulting from the proposed maximum post-emergence use rate are **bolded.**

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. The current tolerance for soybeans commodities are 0.2 ppm in/on soybean seeds and 8.0 ppm each in/on soybean forage and hay. Permanent tolerances for residues in/on animal commodities range from 0.02 ppm in milk, egg, fat, and meat and meat-byproducts (except liver and kidney) to 0.2 ppm in kidney. Temporary tolerances have also been established on grass forage and hay, spinach, tomatoes, and tomato puree and paste [40 CFR §180.368(b)], and tolerances with regional registrations have also been established for residue in/on dry bulb onions and non-bell peppers [40 CFR §180.368(c)]. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. *S*-Metolachlor residues of concern in plants and animal commodities are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96) and include *S*-metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Grasses Grown for Seed; PC code 108801; Rereg. Case 0001; DP Barcode D280214; MRID No. 44470101.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist A Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

Metolachlor
PC Code: 108801
EPA Barcode: D280214

Crop Field Trials
GL: OPPTS 860.1500
PP#6E04638

MRID: 44470101
Case No.: 0001
Submission: S608601

EPA Reviewer: Sherrie J. Kinard **, Date** 27/Feb/02

STUDY TYPE: Crop Field Trials - Grasses Grown for Seed Production; OPPTS 860.1500

TEST MATERIAL: Metolachlor

FORMULATIONS AND TYPES: Dual® 8E (8 lb/gal EC)

SYNONYMS: CGA-24705

CITATION: 44470101 Oakes, T. (1997) Metolachlor--Magnitude of the Residues in or on Grasses Grown for Seed Following Application of Dual 8E: Lab Project Number: ABR-97010: 441-95. Unpublished study prepared by Novartis Crop Protection, Inc. 243 p. {OPPTS 860.1500}

SPONSOR: Interregional Research Project No. 4 (IR-4)

EXECUTIVE SUMMARY:

In the current five crop field trials (MRID 44470101) conducted in 1995 on grasses grown for seed production in the Pacific Northwest, the combined metolachlor residues were 0.32-11.2 ppm in/on 10 forage samples harvested at the proposed preharvest intervals (PHI; 60 or 150 days), following a single preemergence application of metolachlor (8 lb/gal EC) in the fall at 2.0 lb ai/A (1x the proposed rate). Combined residues were <0.08-0.16 ppm in/on all 10 samples of straw harvested at maturity (240-271 days post-treatment) from all five field trails. As this use is for grasses grown for seed, the straw data can be translated to support a tolerance on grass hay.

In six previously submitted field trials (MRID 42885701; PP#6E04638, DP Barcode D221778, G. Kramer, 2/9/96), combined metolachlor residues were 0.58-1.4 ppm in/on forage samples harvested at the proposed 60-day PHI and <0.08-0.11 ppm in/on straw samples and <0.08-0.04 ppm in/on seed screening samples harvested at maturity (240-306 days post-treatment).

The available data adequately support the proposed use of metolachlor on grasses grown for seed in the Pacific Northwest. These data would support establishing permanent tolerances with a regional registration for metolachlor residues in/on grass forage at 12.0 ppm and in/on grass hay at 0.20 ppm. Separate tolerances for grass straw and seed screening are not required. The petitioner should submit a revised Section F proposing the appropriate tolerances. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on grass commodities.

The crop field trials for metolachlor on grasses grown for seed are classified acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used a gas chromatographic/nitrogen-phosphorus detection (GC/NPD) method (Analytical Method AG-612) to determine residues of metolachlor in/on grass forage and straw samples. Method AG-612 is similar to Method I in PAM, Vol. II, and determines residues metolachlor or *S*-metolachlor and their metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents.

A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples were analyzed by Novartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The reported method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, each expressed in parent equivalents, are 0.03 and 0.05 ppm, respectively, in/on grass forage and straw.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of forage were fortified separately with CGA-37913 and CGA-49751 each at 0.1-20.0 ppm, and samples of straw were fortified separately with CGA-37913 at 0.02-0.5 ppm and CGA-49751 at 0.05-0.5 ppm. These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. The average method recoveries from forage were 83.3 ± 11.0% for CGA-37913 and 78.2 ± 6.4% for CGA-49751, and the average recoveries from straw were 94.3 ± 12.9% for CGA-37913 and 75.0 ± 10.5% for CGA-49751. Adequate chromatograms and sample calculations were provided.

The GC/NPD Method AG-612 is adequate for collecting data on residues of metolachlor in/on grass forage and straw.

1. Test Compounds

Chemical name: Metolachlor
IUPAC: 2-chloro-6′ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): metolachlor
Developmental (Company) name: CGA-24705

2. Trial Numbers and Locations

Metolachlor trials at 1x

Crop (commodity)	US Growing Regions		Total Trials
	11	12	
Grasses (forage and straw)			
Submitted	3	2	5
Requested	3	2	5

Comments: Geographic representation and the number of crop field trials conducted are adequate. In a previous review of data for this petition (PP#6E04638, DP Barcode D221778, G. Kramer, 2/9/96), the Agency requested that the petitioner conduct an additional five field trails on grasses grown for seed: two trials in Region 11 and three trials in Region 12. Including the previously submitted field trials, a total of 11 field trials have now been conducted on grasses (ryegrass, fescue, bromegrass, and bluegrass) grown for seed in the Northwest at 1x the proposed use rate.

3. Proposed Use Pattern

Metolachlor 8 lb/gal EC [a]

Crop	Application					Comments/ Restrictions
	Method/ Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI [b] (days)	
Grasses (grown for seed)	Preemergence broadcast application to fields in the fall	2.0	1	2.0	60 or 150	This use is restricted to the Pacific Northwest (Regions 11 and 12). The PHI for grass forage is 60 days in areas West of the Cascades and 150 days in areas East of the Cascades. Hay may be cut any time between seed harvest and the next application of metolachlor.

[a] Proposed use directions were reviewed in conjunction with PP#6E04638 (DP Barcode D221778, G. Kramer, 2/9/96)
[b] PHI = post-harvest interval, the number of days between the last application and harvest.

Comments: The proposed label directions for grasses grown for seed in the Pacific Northwest were reviewed in conjunction with an earlier review of this petition (PP#6E04638, DP Barcode D221778, G. Kramer, 2/9/96) and deemed adequate.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
Grass forage	CGA-37913	0.1-20.0	**67**, 80, 90, 95, 74, 72, 91, 102, 76, 78, 99, 82, 77	67-102	83.3 ± 11.0
	CGA-49751	0.1-20.0	74, 74, 79, 75, **69**, **69**, 90, 89, 81, 77, 80, 78, 81	69-90	78.2 ± 6.4
Grass straw	CGA-37913	0.02-0.5	106, 89, 102, 107, 88, 74	74-107	94.3 ± 12.9
	CGA-49751	0.05-0.5	71, 91, 84, **65**, **65**, 74	65-91	75.0 ± 10.5

Comments: With the exception of several marginally low recoveries (65-69%) of both analytes from forage and CGA-49751 from straw, recoveries were in the acceptable 70-120% range. Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on metolachlor residues in/on grass forage and straw.

5. Storage Stability Conditions

Commodities	Analytes	Storage Temperature (°C)	Storage Duration (months)
grass forage	CGA-37913 and CGA49751	≤-15 C	5.5-12.1
grass straw	CGA-37913 and CGA49751	≤-15 C	3-4

Comments: Samples of grass forage were harvested at 0-150 days post-treatment and straw samples were harvested at maturity (226-271 days post-treatment). Samples of forage were immediately frozen after collection, whereas straw samples were allowed to field dry for 6-17 days prior to collection. After collection, samples were shipped frozen by freezer truck or by overnight courier to Novartis Crop Protection, Greensboro, NC, where samples were stored at ≤-15 C until extraction for analysis. The total sample storage intervals were 166-369 days for forage and 90-127 days for straw.

No new storage stability data were submitted with this study. However, adequate storage stability data are available (DP Barcodes D222430 and D224237, S. Hummel, 2/25/97) indicating that CGA-37913 and CGA-49751 are stable at ≤-10 C for at least 2 years in corn forage. These data are adequate to support the grass field trials.

6. Application and RAC Information

Metolachlor-Dual 8E (8 lb/gal EC)-Grasses

LOCATION (county/ state/year)	EPA Region	Grass type/ variety	APPLICATION					HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Single Rate (lb ai/A) [a]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion [b]	Number and wt. of samples
Marion/ OR/ 1995 [c]	12	Tall fescue/ Exalibor	preemergence in fall	1	2	broadcast	20	immature and mature	forage, straw, seed screenings	Duplicate samples of each RAC were collected from each test and at sampling interval. Sample weight was not specified
Yamhill/ OR/ 1995	12	Bromegrass/ Mountain	preemergence in fall	1	2	broadcast	10	immature and mature	forage, straw, seed screenings	
Crook/ OR/ 1995	11	Bluegrass/ Bristol	preemergence in fall	1	2	broadcast	20	immature and mature	forage, straw, seed screenings	
Whitman/ WA/ 1995	11	Bromegrass/ Manchar	preemergence in fall	1	2	broadcast	10	immature and mature	forage, straw, seed screenings	
Latah/ ID/ 1995	11	Bluegrass/ Cynthia Grassland West	preemergence in fall	1	2	broadcast	10	immature and mature	forage, straw, seed screenings	

[a] The maximum proposed application rate is 2.0 lb ai/A.

[b] Although samples of seed screenings were collected from each field trial, these samples were not analyzed.

[c] Residue decline in forage over time was examined in this field trial.

Comments: The field trails adequately reflect the proposed use on grasses grown for seed in the Pacific Northwest. However, the petitioner did not analyze the collected samples of grass seed screenings for metolachlor residues.

7. Site Specific Information

LOCATION (county/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Marion/ OR/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	not reported (NR)	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Yamhill/ OR/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Crook/ OR/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Whitman/ WA/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Latah/ ID/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1. Residue Data Summary from Grass Crop Field Trials: Metolachlor - Grass forage and straw [a]

Location (county/ state/ year)	Grass type/variety	Formulation	Application			PHI (days) [c]	Residues (mg/kg) [d]		
			Rate (lb ai/A)	# of Appl.	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Grass Forage									
Marion/ OR/ 1995	Tall fescue/ Exalibor	8 lb/gal EC	2.0	1	100	0	126, 126	4.2, 3.4	130, 129
						20	NS, 3.3	NS, 9.4	NS, 12.7
						40	2.9, 2.6	4.6, 6.8	7.5, 9.4
						60	0.84, 0.82	1.4, 1.8	**2.2, 2.6**
						80	0.40, 0.50	0.52, 0.51	0.92, 1.01
Yamhill/ OR/ 1995	Bromegrass/ Mountain	8 lb/gal EC	2.0	1	100	0	116, 132	1.1, 1.4	117, 133
						60	9.8, 11	0.22, 0.21	**10.0, 11.2**
Crook/ OR/ 1995	Bluegrass/ Bristol	8 lb/gal EC	2.0	1	100	0	151, 152	7.9, 6.1	159, 158
						150	0.51, 0.55	1.5, 1.5	**2.0, 2.1**
Whitman/ WA/ 1995	Bromegrass/ Manchar	8 lb/gal EC	2.0	1	100	0	123, 215	0.56, 0.77	124, 216
						150	0.11, 0.36	0.21, 0.39	**0.32, 0.75**
Latah/ ID / 1995	Bluegrass/ Cynthia Grassland West	8 lb/gal EC	2.0	1	100	0	96, 154	1.0, 0.7	97, 155
						149	0.20, 0.51	1.5, 1.5	**1.7, 2.0**

TABLE 1. Residue Data Summary from Grass Crop Field Trials: Metolachlor - Grass forage and straw *(continued)*

Location (county/ state/ year)	Grass type/variety	Formulation	Application			PHI (days) [c]	Residues (mg/kg) [d]		
			Rate (lb ai/A)	# of Appl.	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Grass Straw									
Marion/ OR/ 1995	Tall fescue/ Exalibor	8 lb/gal EC	2.0	1	100	240	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Yamhill/ OR/ 1995	Bromegrass/ Mountain	8 lb/gal EC	2.0	1	100	226	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Crook/ OR/ 1995	Bluegrass/ Bristol	8 lb/gal EC	2.0	1	100	243	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Whitman/ WA/ 1995	Bromegrass/ Manchar	8 lb/gal EC	2.0	1	100	271	0.08, 0.03	<0.05, <0.05	**<0.13, <0.08**
Latah/ ID / 1995	Bluegrass/ Cynthia Grassland West	8 lb/gal EC	2.0	1	100	251	0.04, <0.03 (0.06, 0.05)	0.10, 0.08 (0.10, 0.08)	**0.14, <0.11 (0.16, 0.13)**

[a] Although samples of grass seed screening were collected from each field trial at maturity (240-271 days post-treatment), these samples were not analyzed for residues.

[b] The proposed maximum rate is a single application of metolachlor at 2.0 lb ai/A.

[c] PHI=post-harvest Interval; the proposed PHI is 60 days for forage grown West of the Cascades and 150 days for forage grown East of the Cascades.

[d] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.

[e] Combined residues in/on forage and straw resulting from the maximum labeled use rate at the proposed PHI are **bolded**.

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. Temporary tolerances have also been established for residues in/on grass forage and hay at 10.0 and 0.2 ppm, respectively [40 CFR §180.368(b)]; these tolerances are set to expire on 12/31/01. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. The residues of concern for *S*-metolachlor in plants and animals are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96).

In the five current grass field trails, the combined residues of CGA-37913 and CGA-49751, each expressed as parent, were 97-216 ppm in/on 10 samples of forage collected immediately following (0-day) a single preemergence application of metolachlor (8 lb/gal EC) in the fall at 2.0 lb ai/A. At the proposed PHIs, the combined residues were 2.2-11.2 ppm in/on four samples of forage harvested 60 days post-treatment from the two tests conducted West of the Cascades and 0.32-2.1 ppm in/on six forage samples harvested 150 days post-treatment from the three tests conducted East of Cascades. In the residue decline study, residues in/on forage decreased steadily from 129-130 ppm at Day 0 to 0.92-1.01 ppm at Day 80.

Combined residues were <0.08-0.16 ppm in/on all 10 samples of straw harvested at maturity (240-271 days post-treatment) from all five field trails. Although seed screening samples were collected at each field trial, these samples were not analyzed for metolachlor residues.

Apparent combined residues were <0.08 ppm (<LOQ) in/on nine of the 13 control samples of forage; the remaining four control samples of forage had apparent combined residues of 0.23-0.50 ppm. Apparent combined residues were <0.08 ppm (<LOQ) in/on all five control samples of straw.

The maximum frozen storage interval from harvest to extraction was 12 months for forage and 4 months for straw; these storage intervals are supported by the available storage stability data.

In addition to the current five field trials, the petitioner previously submitted six grass field trials (MRID 42885701), three each in Regions 11 and 12 (PP#6E04638, DP Barcode D221778, G. Kramer, 2/9/96). In the three earlier tests conducted in Region 12 (West of Cascades), combined metolachlor residues were 0.58-1.4 ppm in/on forage samples harvested at the proposed 60-day PHI. In the three tests conducted in Region 11 (East of Cascades), the combined metolachlor residues were 3.5-8.4 ppm in/on forage harvested 75 days post-treatment in two tests and 0.04 ppm in/on forage harvested 206 days post-treatment in the other tests; however, no forage samples were collected at the proposed 150-day PHI. In all six earlier tests, combined metolachlor residues were <0.08-0.11 ppm in/on straw samples and <0.08-0.04 ppm in/on seed screening samples harvested at maturity (240-306 days post-treatment).

III. CONCLUSIONS

The current grass field trial data are adequate. In the five current tests conducted in Regions 11 and 12, combined metolachlor residues were 0.32-11.2 ppm in/on ten forage samples harvested at the proposed PHIs (60 or 150 days), following a single preemergence application of metolachlor (8 lb/gal EC) in the fall at 2.0 lb ai/A (1x the proposed rate). Combined residues were <0.08-0.16 ppm in/on all 10 samples of straw harvested at maturity (240-271 days post-treatment) from all five field trails. As this use is for grasses grown for seed, the straw data can be translated to support a tolerance on grass hay.

The GC/NPD Method AG-612 is adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent, in/on grass forage and straw. The combined LOQ is 0.08 ppm in/on forage and straw. Although apparent combined residues were detected at 0.23-0.50 ppm in four control samples of forage, these levels are well below the recommended tolerance for forage (12.0 ppm) and no other interferences were observed in the other 13 control forage samples or the 10 control straw samples.

In the six previously submitted field trials (PP#6E04638, DP Barcode D221778, G. Kramer, 2/9/96), combined metolachlor residues were 0.58-1.4 ppm in/on forage samples harvested at the proposed 60-day PHI and <0.08-0.11 ppm in/on straw samples and <0.08-0.04 ppm in/on seed screening samples harvested at maturity (240-306 days post-treatment).

The available data adequately support the proposed use of metolachlor on grasses grown for seed in the Pacific Northwest. These data would support establishing permanent tolerances with a regional registration for metolachlor residues in/on grass forage at 12.0 ppm and in/on grass hay at 0.20 ppm. Tolerances for residues in/on grass straw and seed screening are not required as the Agency considers these commodities to be insignificant livestock feed items (Draft policy on Grasses grown for seed, 9/30/2000).

There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on grass commodities.

IV. STUDY DEFICIENCIES

There are no remaining deficiencies that would have an impact on assessing tolerances for metolachlor residues in/on grass forage and hay from grasses grown for seed.

V. REFERENCES

DP Barcode:	D221778
Subject:	PP#6E04638. Metolachlor in or on Grasses Grown for Seed. Evaluation of Residue Data and Analytical Methods.
From:	G. Kramer
To:	H. Jamerson/K Whitby
Dated:	2/9/96
MRID(s):	42885701

DP Barcode:	D226780
Subject:	Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From:	L. Kutney
To:	R. Giffin
Dated:	11/12/96
MRID(s):	43928901-43928903 and 43928939-43928942

DP Barcodes:	D222430 and D224237
Subject	Metolachlor (108801) Reregistration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions.
From:	S. Hummel
To:	M. Metzger
Dated:	2/25/97
MRID(s):	43881701-43881703 and 43944601

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Cotton Gin-byproducts; PC code 108801; Rereg. Case 0001; DP Barcode D280217; MRID No. 44667401.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

Metolachlor PC Codes: 108801 EPA Barcode: D280217	Crop Field Trials GL: OPPTS 860.1500	MRID: 44667401 Case No.: 0001 Submission: S608604

EPA Reviewer: Sherrie J. Kincaid, Date 27/Feb/02

STUDY TYPE: Crop Field Trials - Cotton (gin byproducts); OPPTS 860.1500

TEST MATERIAL: Metalochlor

FORMULATIONS AND TYPES: Dual 8E (8 lb/gal) and Dual Magnum (7.6 lb/gal EC)

SYNONYMS: CGA-24705 and CGA-77102

CITATION: 44667401 Oakes, T. (1998) Metolachlor and CGA-77102--Magnitude of the Residues in or on Cotton: Lab Project Number: 19-97: ABR-98080. Unpublished study prepared by Novartis Crop Protection, Inc. 477 p. {OPPTS 860.1480}

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

The results from six crop field trials (MRID 44667401) conducted on cotton during 1997 have shown that the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent metolachlor, were <0.08 ppm (<LOQ) in/on undelinted cotton seeds and 3.2 ppm in/on cotton gin byproducts derived from raw cotton harvested 102-160 days following combined pre-emergence and post-emergence broadcast applications of metolachlor (8 lb/gal EC) totaling 4.0 lb ai/A (1x). Based on these data, a tolerance 4.0 ppm should be established for metolachlor residues in/on cotton gin byproducts.

In three additional side-by-side tests conducted in conjunction with the above tests, the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent *S*-metolachlor, were <0.08 ppm (<LOQ) in/on undelinted cotton seeds and 1.2 ppm in/on cotton gin byproducts derived from raw cotton harvested 102-160 days following combined pre-emergence and post-emergence broadcast applications of *S*-metolachlor (7.6 lb/gal EC) totaling 2.67 lb ai/A (1x). Tolerances for metolachlor will cover residues resulting from the use of *S*-metolachlor.

As there are no Mexican, Canadian or Codex MRLs established for metolachlor residues in/on cotton gin byproducts, there are no compatibility issues to be reconciled.

The crop field trials for metolachlor on cotton gin byproducts are classified acceptable and satisfy the guideline requirement for crop field trials and will support S-metolachlor use (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used a gas chromatographic/nitrogen-phosphorus detection (GC/NPD) method (Analytical Method AG-612) to determine residues of metolachlor or *S*-metolachlor in/on undelinted cottonseed and gin byproducts. Method AG-612 is similar to Method I in PAM, Vol. II, and determines residues of metolachlor or S-metolachlor and their metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents. A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples were analyzed by Novartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 mintues, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on cottonseed and gin trash.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated undelinted cottonseeds and gin trash from the current field trials were fortified separately with CGA-37913 at 0.02-2.0 ppm and with CGA-49751 at 0.05-2.0 ppm, and were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. Average method recoveries were 90-95% for CGA-37913 and 81% for CGA-49751. Adequate chromatograms and sample calculations were provided.

The GC/NPD Method AG-612 is adequate for collecting data on residues of metolachlor and *S*-metolachlor in/on cotton seed and cotton gin byproducts.

1. ***Test Compound***

Chemical name: Metolachlor
IUPAC: 2-chloro-6′ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): metolachlor
Developmental (Company) name: CGA-24705

Chemical name: *S*-Metolachlor
IUPAC: 2-chloro-6′ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: (*S*) 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): S-metolachlor
Developmental (Company) name: CGA-77102

2. Trial Numbers and Locations

Metolachlor trials at 1x

Crop (commodity)	US Growing Regions						Total Trials
	2	4	6	8	10		
Cotton (gin byproducts)							
Submitted	1	1	2	1	1		6
Requested	not specified						6

***S*-Metolachlor trials at 1x**

Crop (commodity)	US Growing Regions						Total Trials
		4	6		10		
Cotton (gin byproducts)							
Submitted		1	1		1		3
Requested	not specified						6

Comments: Geographic representation and the number of field trials conducted for cotton gin byproducts are adequate. Of the six metolachlor field trials conducted at 1x, three tests used a mechanical picker for harvesting and three tests used a mechanical stripper for harvesting. Of the three *S*-metolachlor field trials conducted at 1x, two used a mechanical picker and one used a mechanical stripper for harvesting.

3. Labeled Use Patterns

Metolachlor 8 lb/gal EC (Dual 8E Herbicide; EPA Reg No. 100-597)

Crop	Application					Comments/Restrictions [c]
	Method/ Timing	Max. Rate[a] (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI[b] (days)	
Cotton	Broadcast, preplant incorporated (PPI) or pre-emergence (PRE); Post-emergence broadcast or directed when plants are 3-12 inches in height	2	2	4	none	The maximum seasonal rate is 3.0 lb ai/A for coarse soils and 4.0 lb ai/A for medium and fine soils. Do not use in Gaines County, TX. Do apply to sand or loamy sand soils, or to a Taloka silt loam. Do not graze or feed forage or fodder from cotton to livestock.

[a] The maximum single application rate is 1.5 lb ai/A for sandy loam soils and 2.0 lb ai/A for medium and fine textured soils.

[b] PHI = post-harvest interval, the number of days between the last application and harvest.

[c] A minimum retreatment interval is not specified on the label.

***S*-Metolachlor 7.6 lb/gal EC** (Dual Magnum Herbicide; EPA Reg. No. 100-816)

Crop	Application					Comments/Restrictions [c]
	Method/ Timing	Max. Rate[a] (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI[b] (days)	
Cotton	Broadcast, preplant incorporated (PPI) or pre-emergence (PRE); Post-emergence broadcast or directed when plants are 3-12 inches in height	1.3	2	2.5	none	The maximum seasonal rate is 1.9 lb ai/A for coarse soils and 2.5 lb ai/A for medium and fine soils. Do not use in Gaines County, TX. *Do apply to sand or loamy sand soils,* or to a Taloka silt loam. Do not graze or feed forage or fodder from cotton to livestock.

[a] The maximum single application rate is 1.0 lb ai/A for sandy loam soils and 1.3 lb ai/A for medium and fine textured soils.

[b] PHI = post-harvest interval, the number of days between the last application and harvest.

[c] A minimum re-treatment interval is not specified on the label.

Comments: The labeled use directions are adequate.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
Gin trash	CGA-37913	0.02-2.0	**129**, **68**, 76, 134, 76, 86	68-134	95 ± 29
	CGA-49751	0.05-2.0	85, 75, 103, 70, 79, 77	70-103	81 ± 12
Undelinted seed	CGA-37913	0.02-1.0	112, **69**, 95, 82, 92, 91, 89	69-112	90 ± 13
	CGA-49751	0.05-1.0	76, 85, 72, 93, **69**, 87, 82	69-93	81 ± 9

Comments: With the exception of several high recoveries of CGA-37913 from gin trash (129 and 134%) and some marginally low recoveries of both analytes from cotton seed and gin trash (68-69%), recoveries were within the acceptable 70-120% range. Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on metolachlor/*S*-metolachlor residues in/on cottonseed and gin trash.

5. Storage Stability Conditions

Commodity	Active ingredient	Storage Temperature (°C)	Storage Duration (months)
Undelinted cottonseed	CGA-37913/CGA49751	-15	6.5-10.3
Cotton gin byproducts	CGA-37913/CGA49751	-15	6.7-8.9

Comments: Harvested samples of raw seed cotton were shipped frozen by freezer truck or at ambient temperatures by overnight courier to the processing facility, Protein Research and Development Center, Texas A&M University, Bryan, TX, for ginning. Raw cotton was ginned using simulated commercial procedures into lint, undelinted seed, and gin trash. After processing, samples were frozen and shipped by freezer truck to the analytical facility, where samples were stored at ≤-15 C. Total sample storage intervals were 6.7-8.9 months for gin trash and 6.5-10.3 months for undelinted seeds.

No new storage stability data were submitted with this study; however, adequate storage stability data are available (DP Barcodes D222430 and D224237, S. Hummel, 2/25/97) indicating that CGA-37913 and CGA-49751 are stable at ≤-10 C for at least 2 years in corn (grain and forage), soybeans (hulls and meal) and for at least 37 months in cottonseed. These data are adequate to support the residue data submitted for the cotton gin byproduct field trials.

6. Application and RAC Information

Metolachlor-Dual 8E (8 lb/gal EC)-Cotton

LOCATION (county /state/year)	EPA Region	Cotton Variety	APPLICATION[a]						HARVEST PROCEDURES			
			Growth Stage at first appl.	# of appl.	Interval (days)	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Method/ equipment	Number and wt. of samples
Fresno/ CA/ 1997	10	Acala Maxxa	Pre-emergence	2	64	2	broadcast	15	Mature	Cotton	Mechanical picker	Duplicate 100 lb samples of seed cotton
			Post-emergence	1	NA	2	broadcast					
Washington/ MS/ 1997	4	SG-125	Pre-emergence	2	44	2	broadcast	15	Mature	Cotton	Mechanical picker	Duplicate 60-100 lbs samples of seed cotton
			Post-emergence	1	NA	2	broadcast					
Burleson/ TX/ 1997	6	Paymaster 1244RR	Pre-emergence	2	73	2	broadcast	18	Mature	Cotton	Mechanical stripper	Duplicate 100 lb samples of seed cotton
Tom Green/ TX/ 1997	8	336	Pre-emergence	2	31	2	broadcast	13	Mature	Cotton	Mechanical stripper	Duplicate 100 lb samples of seed cotton
Washita/ OK/ 1997	6	Paymaster 200	Pre-emergence	2	41	2	broadcast	11-18	Mature	Cotton	Mechanical stripper	Duplicate 100 lb samples of seed cotton
			Pre-emergence	2	41	1	broadcast					
Macon/ AL/ 1997	2	PM 1220	Pre-emergence	2	37	2	broadcast	25-26	Mature	Cotton	Mechanical picker	Duplicate 100 lb samples of seed cotton
			Post-emergence	1	NA	2	broadcast					

[a] No tank mixes or adjuvants were used.

[b] The maximum single application rate is 1.5 lb ai/A for sandy loam soils and 2.0 lb ai/A on medium and fine textured soils.

S-**Metolachlor**-Dual Magnum (7.6 lb/gal EC)-Cotton

LOCATION (county/state/ year)	EPA Region	Cotton Variety	APPLICATION[a]						HARVEST PROCEDURES			
			Growth Stage at first appl.	# of appl.	Interval (days)	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Method/ equipment	Number and wt. of samples
Fresno/ CA/ 1997	10	Acala Maxxa	Pre-emergence	2	64	1.33	broadcast	15	Mature	Cotton	Mechanical picker	Duplicate 100 lb samples of seed cotton
Washington/ MS/ 1997	4	SG-125	Pre-emergence	2	44	1.33	broadcast	15	Mature	Cotton	Mechanical picker	Duplicate 100 lb samples of seed cotton
Burleson/ TX/ 1997	6	Paymaster 1244RR	Pre-emergence	2	73	1.33	broadcast	18	Mature	Cotton	Mechanical stripper	Duplicate 100 lb samples of seed cotton

[a] No tank mixes or adjuvants were used.
[b] The maximum single application rate is 1.0 lb ai/A for sandy loam soils and 1.3 lb ai/A on medium and fine textured soils.

Comments: The field trials adequately represented the current label directions.

7. Site Specific Information

LOCATION (city/state)/ YEAR	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	Cation Exchange Capacity (CEC)	WEATHER DATA** (T°C, rainfall)
Fresno/ CA/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	Not reported (NR)	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Washington/ MS/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Burleson/ TX/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Tom Green/ TX/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Washita/ OK/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Macon/ AL/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1a. Residue Data Summary from Cotton Crop Field Trials: Metolachlor - Undelinted cottonseed

Location (county, state)/ Year	Crop/ Variety	Formulation	Application					PHI (days) [b]	Harvester equipment	Residues (mg/kg) [c]		
			Rate (lb ai/A)	# of Appl.	Interval Between Appls.	Total Rate (lb ai/A)	% of Max Rate [a]			CGA-37913	CGA-49751	Combined [d]
Fresno/ CA/ 1997	Cotton/ Acala Maxxa	8 lb/gal EC	2	2	64	4	100	160	Mechanical picker	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
		8 lb/gal EC	2	1	NA	2	50	175		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
Washington/ MS/ 1997	Cotton/ SG-125	8 lb/gal EC	2	2	44	4	100	102	Mechanical picker	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
		8 lb/gal EC	2	1	NA	2	50	113		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08

Location (county, state)/ Year	Crop/ Variety	Formulation	Application					PHI (days) [b]	Harvester equipment	Residues (mg/kg) [c]		
			Rate (lb ai/A)	# of Appl.	Interval Between Appls.	Total Rate (lb ai/A)	% of Max Rate [a]			CGA-37913	CGA-49751	Combined [d]
Burleson/ TX/ 1997	Cotton/ Paymaster 1244RR	8 lb/gal EC	2	2	73	4	100	106	Mechanical stripper	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Tom Green/ TX/ 1997	Cotton/ 336	8 lb/gal EC	2	2	31	4	100	132	Mechanical stripper	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Washita/ OK/ 1997	Cotton/ Paymaster 200	8 lb/gal EC	2	2	41	4	100	105	Mechanical stripper	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
		8 lb/gal EC	1	2	41	2	50	105		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
Macon/ AL/ 1997	Cotton/ PM 1220	8 lb/gal EC	2	2	37	4	100	109	Mechanical picker	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			2	1	NA	2	50	130		<0.03, <0.03	<0.05, <0.05	<0.08, <0.08

[a] The labeled maximum seasonal application rate is 4.0 lb ai/A.
[b] PHI=Post-Harvest Interval.
[c] The registrant corrected residue values for samples with concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery.
[d] Combined residues in/on cottonseed resulting from the maximum labeled use rate are **bolded**.

TABLE 1b. Residue Data Summary from Cotton Crop Field Trials: *S*-Metolachlor - Undelinted cottonseed

Location (county, state)/ Year	Crop/ Variety	Formulation	Application					PHI (days) [b]	Harvester equipment	Residues (mg/kg) [c]		
			Rate (lbs ai/A)	# of Appl.	Interval Between Appls.	Total Rate (lbs ai/A)	% of Max Rate [a]			CGA-37913	CGA-49751	Combined [d]
Fresno/ CA/ 1997	Cotton/ Acala Maxxa	7.6 lb/gal EC	1.33	2	64	2.67	100	160	Mechanical picker	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Washington/ MS/ 1997	Cotton/ SG-125	7.6 lb/gal EC	1.33	2	44	2.67	100	102	Mechanical picker	<0.03, NS	<0.05, <0.05	**<0.08, NS**
Burleson/ TX/ 1997	Cotton/ Paymaster 1244RR	7.6 lb/gal EC	1.33	2	73	2.67	100	106	Mechanical stripper	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

[a] The labeled maximum seasonal application rate is 2.5 lb ai/A.
[b] PHI=Post-Harvest Interval
[c] The registrant corrected residue values for samples with concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery.
[d] Combined residues in/on cottonseed resulting from the maximum labeled use rate are **bolded**.

TABLE 2a. Residue Data Summary from Cotton Crop Field Trials: Metolachlor - Cotton gin byproducts

Location (county, state)/ Year	Crop/ Variety	Formulation	Application					PHI (days) [b]	Harvester equipment	Residues (mg/kg) [c]		
			Rate (lbs ai/A)	# of Appl.	Interval Between Appls.	Total Rate (lbs ai/A)	% of Max Rate [a]			CGA-37913	CGA-49751	Combined [d]
Fresno/ CA/ 1997	Cotton/ Acala Maxxa	8 lb/gal EC	2	2	64	4	100	160	Mechanical picker	1.4, 1.7	1.5, 1.5	**2.9, 3.2**
		8 lb/gal EC	2	1	NA	2	50	175		0.29, 0.24	0.28, 0.31	0.57, 0.55
Washington/ MS/ 1997	Cotton/ SG-125	8 lb/gal EC	2	2	44	4	100	102	Mechanical picker	0.40, 0.52	0.38, 0.44	**0.78, 0.96**
		8 lb/gal EC	2	1	NA	2	50	113		0.12, 0.09	0.08, 0.06	0.20, 0.15
Burleson/ TX/ 1997	Cotton/ Paymaster 1244RR	8 lb/gal EC	2	2	73	4	100	106	Mechanical stripper	0.03, 0.07	0.09, 0.15	**0.12, 0.22**
Tom Green/ TX/ 1997	Cotton/ 336	8 lb/gal EC	2	2	31	4	100	132	Mechanical stripper	0.19, 0.28	0.09, 0.08	**0.28, 0.36**
Washita/ OK/ 1997	Cotton/ Paymaster 200	8 lb/gal EC	2	2	41	4	100	105	Mechanical stripper	0.08, 0.11	<0.05, <0.05	**<0.13, <0.16**
		8 lb/gal EC	1	2	41	2	50	105		<0.03, 0.04	<0.05, <0.05	<0.08, <0.09
Macon/ AL/ 1997	Cotton/ PM 1220	8 lb/gal EC	2	2	37	4	100	109	Mechanical picker	0.62, 0.95	0.22, 0.34	**0.84, 1.29**
			2	1	NA	2	50	130		0.19, 0.24	0.05, <0.05	0.24, <0.29

[a] The labeled maximum seasonal application rate is 4.0 lb ai/A.

[b] PHI=Post-Harvest Interval.

[c] The registrant corrected residue values for samples with concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery.

[d] *Combined residues in/on cotton gin byproducts resulting from the maximum labeled use rate are* ***bolded***.

TABLE 2b. Residue Data Summary from Cotton Crop Field Trials: *S*-Metolachlor - Cotton gin byproducts

Location (county, state)/ Year	Crop/ Variety	Formulation	Application					PHI (days) [b]	Harvester equipment	Residues (mg/kg) [c]		
			Rate (lbs ai/A)	# of Appl.	Interval Between Appls.	Total Rate (lbs ai/A)	% of Max Rate [a]			CGA-37913	CGA-49751	Combined [d]
Fresno/ CA/ 1997	Cotton/ Acala Maxxa	7.6 lb/gal EC	1.33	2	64	2.67	100	160	Mechanical picker	0.53, 0.49	0.53, 0.74	**1.06, 1.23**
Washington/ MS/ 1997	Cotton/ SG-125	7.6 lb/gal EC	1.33	2	44	2.67	100	102	Mechanical picker	0.39, NS	0.56, 0.26	**0.95, NS**
Burleson/ TX/ 1997	Cotton/ Paymaster 1244RR	7.6 lb/gal EC	1.33	2	73	2.67	100	106	Mechanical stripper	0.03, 0.04	0.05, 0.07	**0.08, 0.11**

[a] The labeled maximum seasonal application rate is 2.5 lb ai/A.

[b] PHI=Post-Harvest Interval.

[c] The registrant corrected residue values for samples with concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery.

[d] Combined residues in/on cotton gin byproducts resulting from the maximum labeled use rate are **bolded**.

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1 ppm in/on a variety of plant commodities to 30 ppm in/on peanut forage and hay, and include a tolerance of 0.1 ppm for undelinted cotton seed. There is no tolerance for cotton gin byproducts. Permanent tolerances for residues in/on animal commodities range from 0.02 ppm in milk, egg, fat, and meat and meat-byproducts (except liver and kidney) to 0.2 ppm in kidney. Temporary tolerances have also been established on grass forage and hay, spinach, tomatoes, and tomato puree and paste [40 CFR §180.368(b)], and tolerances with regional registrations have also been established for residue in/on dry bulb onions and non-bell peppers [40 CFR §180.368(c)]. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. The residues of concern for *S*-metolachlor in plants and animals are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96).

In a total of 6 tests on cotton, the combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08 ppm (<LOQ) in/on 12 samples of undelinted cotton seed and 0.12-3.2 ppm in/on 12 samples of cotton gin byproducts harvested 102-160 days post-treatment, following a combination of a pre- and post-emergence application of metolachlor (8 lb/gal EC) totaling 4.0 lb ai/A (1x). Three of the tests used mechanical pickers and 3 tests used mechanical strippers for harvesting. For cotton gin byproducts, the field trial mean residue (FTMaR) was 0.94 ppm, and the field trial median residue (FTMdR) was 0.57 ppm. Combined residues were <0.08 ppm (<LOQ) in/on all 6 control samples of undelinted seeds and in/on 5 control samples of gin trash. In one test (MS), combined residues were <0.10 ppm (CGA-37913 at 0.05 ppm; CGA-49751 at <0.05 ppm) in/on the control sample of gin trash.

In three additional tests, conducted side-by-side with three of the above tests, *S*-metolachlor (7.6 lb/gal EC) was applied twice to cotton (pre- and post-emergence) at a maximum rate of 1.33 lb ai/A/application, for a total of 2.6 lb ai/A (1x). The resulting combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08 ppm (<LOQ) in/on 5 samples of undelinted cotton seed and 0.08-1.23 ppm in/on 5 samples of cotton gin byproducts harvested 102-160 days post-treatment. The resulting FTMaR and FTMdR were 0.69 and 0.95 ppm, respectively, for cotton gin byproducts. Mechanical pickers were used in 2 of these tests and a mechanical stripper was used in the third test.

The maximum frozen storage interval from collection to analysis was ~10 months for gin trash samples and 9 months for undelinted cotton seeds. Adequate frozen storage stability data are available to support these crop field trials.

III. CONCLUSIONS

The field trial data on cotton gin byproducts are adequate. In a total of 6 tests, combined metolachlor residues were <0.08 ppm (<LOQ) in/on 12 samples of undelinted seeds and 0.12-3.2 ppm in/on 12 samples of gin byproducts derived from cotton harvested 102-160 day post-treatment, following a combined pre- and post-emergence application of metolachlor (8 lb/gal EC) totaling 4.0 lb ai/A (1x). In 3 related side-by-side tests using *S*-metolachlor, the combined *S*-metalochlor residues were <0.08 ppm (<LOQ) in/on 5 samples of undelinted seeds and 0.08-1.2 ppm in/on 5 samples of gin byproducts derived from cotton harvested 102-160 day post-treatment, following a combined pre- and post-emergence application of *S*-metolachlor (7.6 lb/gal EC) totaling 2.6 lb ai/A (1x).

Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent in/on cotton undelinted seeds and gin byproducts. The combined LOQ is 0.08 ppm in/on by undelinted seeds and gin trash; no interference was observed in representative chromatograms of control samples from the analysis of cotton.

The residue data are acceptable and would support establishing a tolerance of 4.0 ppm for metolachlor residues in/on cotton gin byproducts. The metolachlor tolerance will cover the use of *S*-metolachlor on cotton. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on cotton.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on establishing a tolerance for residues of metolachlor and *S*-metolachlor in/on cotton gin byproducts.

V. REFERENCES

DP Barcode: D226780
Subject: Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From: L. Kutney
To: R. Giffin
Dated: 11/12/96
MRID(s): 43928901-43928903 and 43928939-43928942

DP Barcodes: D222430 and D224237
Subject: Metolachlor (108801) Reregisration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions
From: S. Hummel
To: M. Metzger
Dated: 2/25/97
MRID(s): 43881701-43881703 and 43944601

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor and *S*-Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Peanuts; PC codes 108801 and 108800; Rereg. Case 0001; DP Barcode D280218; MRID No. 44755401.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist Alan Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

EPA Reviewer:_____, **Date** _____

REPRINT THIS PAGE

STUDY TYPE: Crop Field Trials - Peanuts; OPPTS 860.1500

TEST MATERIAL: Metolachlor and *S*-Metolachlor

FORMULATIONS AND TYPES: Dual II (7.8 lb/gal EC) and Dual II Magnum (7.6 lb/gal EC)

SYNONYMS: CGA-24705 and CGA-77102

CITATION: 44755401 Oakes, T. (1998) CGA-77102 and Metolachlor--Magnitude of Residues in or on Peanuts: Lab Project Number: ABR-98055: 30-96: 150009. *Unpublished study* prepared by Novartis Crop Protection. 455 p. {OPPTS 860.1500}

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

The results from 11 crop field trials (MRID 44755401) conducted on peanuts during 1996 and 1997 have shown that the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent metolachlor, were 0.19 ppm in/on peanut nutmeats and 16.5 ppm in/on peanut hay harvested at maturity, 74-94 days following combined preemergence and postemergence layby broadcast applications of metolachlor (7.8 lb/gal EC) totaling 4.0 lb ai/A (1x). No data were submitted on residues in/on peanut forage at the label-specified 30-day PHI.

In six additional side-by-side tests conducted in conjunction with the above tests, the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent *S*-metolachlor, were <0.09 ppm in/on nutmeats and 4.19 ppm in/on hay harvested 86-91 days following combined preemergence and postemergence layby broadcast applications of *S*-metolachlor (7.6 lb/gal EC) totaling 2.67 lb ai/A (1x).

Provided that the metolachlor labels are amended to prohibit the grazing or harvest of peanut forage, the peanut field trial data, reflecting the lower application rate of metolachlor (4.0 lb ai/A/season), are adequate and would support lowering the tolerance on peanut nutmeats to 0.2 ppm and lowering the tolerance for peanut hay to 20.0 ppm. The current tolerance for peanut forage should be revoked. The metolachlor tolerance will also cover the use of *S*-metolachlor on peanuts provided *S*-metolachlor labels are also amended to prohibit the grazing or harvest of peanut forage. As there are no Mexican, Canadian or Codex MRLs established for metolachlor residues in/on peanut nutmeats and hay, there are no compatibility issues to be reconciled.

Provided that use directions on metolachlor and *S*-metolachlor labels are amended to prohibit the grazing or harvesting of peanut forage, the crop field trials for metolachlor and *S*-metolachlor on peanuts are classified acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

metolachlor on peanuts are classified acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used a gas chromatographic/nitrogen-phosphorus detection (GC/NPD) method (Analytical Method AG-612) to determine residues of metolachlor or *S*-metolachlor in/on peanut nutmeats and hay. Method AG-612 is similar to Method I in PAM, Vol. II, and determines residues metolachlor or *S*-metolachlor and their metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents.

A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples were analyzed by Norvartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on both nutmeats and hay.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated nutmeats from the current field trials were fortified separately with CGA-37913 at 0.02 or 0.1 ppm and with CGA-49751 at 0.05 or 0.10 ppm, and samples of untreated hay were fortified separately with CGA-37913 at 0.02-20 ppm and CGA-49751 at 0.05-20 ppm. These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. The average method recovery from nutmeats was 104 ± 12% for CGA-37913 and 98 ± 11% for CGA-49751, and the average method recovery from peanut hay was 77 ± 5% for CGA-37913 and 88 ± 8% for CGA-49751. Adequate chromatograms and sample calculations were provided.

The GC/NPD Method AG-612 is adequate for collecting data on residues of metolachlor and *S*-metolachlor in/on peanut nutmeats and hay.

1. Test Compounds

Chemical name: Metolachlor
IUPAC: 2-chloro-6'ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): metolachlor
Developmental (Company) name: CGA-24705

Chemical name: *S*-Metolachlor
IUPAC: 2-chloro-6'ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide
CAS name: (*S*) 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): S-metolachlor
Developmental (Company) name: CGA-77102

2. Trial Numbers and Locations

Metolachlor trials at 1x

Crop (commodity)	US Growing Regions				Total Trials
	2	3	6	8	
Peanuts (nutmeats and hay)					
Submitted	8 [a]	1	3	none	12
Requested	8	1	2	1	12

[a] One of the GA tests was conducted at 3.0 lb ai/A/seaon (0.75x the maximum label rate).

***S*-Metolachlor trials at 1x**

Crop (commodity)	US Growing Regions				Total Trials
	2	3	6	8	
Peanuts (nutmeats and hay)					
Submitted	4	none	2	none	6
Requested	5	1	2	1	9

Comments: Geographic representation and the number of crop field trials conducted for use of metolachlor or *S*-metolachlor on peanuts are adequate. A total of 11 field trials were conducted using metolachlor at 1x the maximum labeled rate (one test was conducted at 0.75x). At six of these test sites, side-by-side tests were conducted using *S*-metolachlor at 1x the maximum labeled rate. Except at one test site, residues resulting from the use of *S*-metolachlor were lower than from the use of metolachlor.

3. Labeled Use Patterns

Metolachlor 7.8 or 8 lb/gal EC [a]

Crop	Application [a]					Comments/Restrictions [c]
	Method/ Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI [b] (days)	
Peanut	Pre- or post-planting incorporated, or broadcast preemergence application followed by a postemergence broadcast or directed application at lay-by	2.0 (3.0) [c]	2	4	30 (forage) 90 (mature peanuts)	The maximum seasonal rate is 4.0 lb ai/A.

[a] The use directions are the same on the 7.8 lb/gal EC formulation and the two 8 lb/gal EC formulations of metolachlor (EPA Reg. Nos. 100-597,100-673, and 100-711).
[b] PHI = post-harvest interval, the number of days between the last application and harvest.
[c] In the southeast, metolachlor can be applied at up to 3.0 lb ai/A as a preemergence application, but the overall highest seasonal application rate is two applications at 2.0 lb ai/A/application.

S-Metolachlor 7.8 or 8 lb/gal EC [a]

Crop	Application [a]					Comments/Restrictions [c]
	Method/ Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI [b] (days)	
Peanut	Pre- or post-planting incorporated, or broadcast preemergence application followed by a postemergence broadcast or directed application at lay-by	1.33 (1.9) [c]	2	2.7	30 (forage) 90 (mature peanuts)	The maximum seasonal rate is 2.7 lb ai/A.

[a] The use directions are the same on the four 7.6 lb/gal EC formulations of *S*-metolachlor (EPA Reg. Nos. 100-816,100-818, 100-964 and 100-965).
[b] PHI = post-harvest interval, the number of days between the last application and harvest.
[c] In the southeast, *S*-metolachlor can be applied at up to 1.9 lb ai/A as a preemergence application, but the overall highest seasonal application rate is two applications at 1.33 lb ai/A/application.

Comments: With the exception of the PHI for forage, the label use directions are adequate. Residue data were submitted only for mature hay and nutmeats harvested at ~90 days post-treatment. As residue data have not been submitted for peanut forage harvested 30 days post-treatment, the labels should be amended to prohibit the feeding or grazing of livestock on peanut forage.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
Peanut nutmeats	CGA-37913	0.02, 0.1	117, 119, 102, 120, 97, 77, 113, 111, 121, 114, 105, 95, 102, 107, 93, 97, 86, 95, 107	77-121	104 ± 12.1
	CGA-49751	0.05, 0.1	90, 80, 110, 105, 75, 116, 87, 114, 96, 101, 108, 100, 112, 98, 97, 102, 86, 99, 93	75-116	98.4 ± 11.3
Peanut hay	CGA-37913	0.02-20.0	76, 87, 70, 76, 75, 71, 74 , 91, 79, 69, 75, 78, 75, 79, 77, 79, 76, 82, 75	69-91	77.1 ± 5.3
	CGA-49751	0.05-20.0	73, 82, 103, 94, 89, 75, 86, 100, 87, 90, 93, 99, 94, 91, 80, 90, 82, 81, 84	73-103	88.1 ± 8.2

Comments: Recoveries were within the acceptable 70-120% range, with the exception of two marginal recoveries of CGA-37913 from nutmeats (121%) and hay (69%). Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on metolachlor/*S*-metolachlor residues in/on peanut nutmeats and hay.

5. Storage Stability Conditions

Commodities	Analytes	Storage Temperature (°C)	Storage Duration (months)
peanut nutmeats and hay	CGA-37913 and CGA49751	≤-15	1.6-5.5

Comments: Samples of nutmeats and hay were harvested at maturity (65-94 days post-treatment). After digging, whole peanut and hay samples were allowed to field-dry for 2-17 days prior to collection. Samples were then shipped frozen by freezer truck or by overnight courier to Novartis Crop Protection, Greensboro, NC. Whole peanuts were shelled at the analytical facility, and nutmeat and hay samples were stored at ≤-15 C until extraction for analysis. Total sample storage intervals for nutmeats and hay were 48-166 days (1.6-5.5 months) prior to analysis for metolachlor residues.

No new storage stability data were submitted with this study. However, adequate storage stability data are available indicating that CGA-37913 and CGA-49751 are stable during storage at -15 ± 5 C for up to 2 years in/on peanut nutmeats, potatoes, corn grain, and corn forage (DP Barcode No. D166637, B. Cropp-Kohlligian, 4/16/92). These data are adequate to support the peanut field trials.

6. Application and RAC Information

Metolachlor-Dual II (7.8 lb/gal EC)-Peanuts

LOCATION (county /state/year)	EPA Region	Peanut Variety	APPLICATION[a]						HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Interval (days)	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Number and wt. of samples
Mitchell/ GA/ 1996	2	Florunner	at planting	2	43	1.45-1.57	broadcast	20	Mature[c]	nutmeats and hay	Duplicate samples at each tests and sampling interval (in decline studies). Sample weight was not specified.
Tifl/ GA/ 1996	2	Georgia Runner	preplant	2	47	2	broadcast	14-16	Mature	nutmeats and hay	
Mitchell/ GA/ 1996	2	Florunner	preplant	2	43	2	broadcast	20	Mature	nutmeats and hay	
Thomas/ GA/ 1996	2	Georgia Runner	at planting	2	53	2	broadcast	20	Mature	nutmeats and hay	
Macon/ AL/ 1996	2	GK-7 Anderson	preplant	2	45	2	broadcast	21	Mature	nutmeats and hay	
Washita/ OK/ 1996	6	Florunner	preplant	2	47	2	broadcast	15	Mature	nutmeats and hay	
Barnwell/ SC/ 1996	2	Georgia Runner	preplant	2	45	2	broadcast	33-35	Mature	nutmeats and hay	
La Vaca/ TX/ 1996	6	GK-7	preplant	2	55	2	broadcast	20	Mature	nutmeats and hay	
Indian River/ FL/ 1996	3	Florunner	at planting	2	48	2	broadcast	18	Mature	nutmeats and hay	
Isle of Wight/ VA/ 1996	2	NC-VII	preplant	2	49	2	broadcast	20	Mature	nutmeats and hay	
Erath/TX/ 1996	6	Tam Span 90	preplant	2	53	2	broadcast	12	Mature[c]	nutmeats and hay	
Sampson/ NC/ 1997	2	NC-9	preplant	2	61	2	broadcast	10	Mature	nutmeats and hay	

[a] All applications included the herbicide safener Benoxacor.
[b] The maximum single application rate is 3.0 lb ai/A, but the maximum seasonal rate includes two applications at 2.0 lb ai/A.
[c] Residue decline studies were conducted.

***S*-Metolachlor**-Dual II Magnum (7.6 lb/gal EC)-Peanuts

LOCATION (county/state/year)	EPA Region	Peanut Variety	APPLICATION[a]						HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Interval (days)	Single Rate (lb ai/A)[b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Number and wt. of samples
Tift/ GA/ 1996	2	Georgia Runner	preplant	2	47	1.33	broadcast	14-16	Mature	nutmeats and hay	Duplicate samples at each tests. Sample weight was not specified.
Mitchell/ GA/ 1996	2	Florunner	preplant	2	43	1.33	broadcast	20	Mature	nutmeats and hay	
Macon/ AL/ 1996	2	GK-7 Anderson	preplant	2	45	1.33	broadcast	21	Mature	nutmeats and hay	
Washita/ OK/ 1996	6	Florunner	preplant	2	47	1.33	broadcast	15	Mature	nutmeats and hay	
La Vaca/ TX/ 1996	6	GK-7	preplant	2	55	1.33	broadcast	20	Mature	nutmeats and hay	
Sampson/ NC/ 1997	2	NC-9	early bloom	2	61	1.33	broadcast	10	Mature	nutmeats and hay	

[a] All applications included the herbicide safener Benoxacor.
[b] The maximum single application rate is 1.9 lb ai/A, but the maximum seasonal rate includes two applications at 1.33 lb ai/A.

Comments: The field trials adequately represented the current label directions, except that no peanut forage samples were collected. The current labels specify a 30-day PHI for the harvest or grazing of peanut forage.

7. Site Specific Information

LOCATION (county/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Mitchell/ GA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	0.9	6.6	2.49	Air temperature and precipitation within normal range vs. historical weather data.
Tift/ GA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	0.5	6	1.79	Air temperature and precipitation within normal range vs. historical weather data.
Mitchell/ GA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	0.9	7.1	2.84	Air temperature and precipitation within normal range vs. historical weather data.
Thomas/ GA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.1	6.1	3.15	Air temperature and precipitation within normal range vs. historical weather data.
Macon/ AL/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.4	5.4	2.84	Air temperature and precipitation within normal range vs. historical weather data.
Washita/ OK/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	0.8	6.1	3.12	Air temperature and precipitation within normal range vs. historical weather data.
Barnwell/ SC/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	0.9	5.2	1.4	Air temperature and precipitation within normal range vs. historical weather data.
La Vaca/ TX/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	0.7	5.3	4.69	Air temperature and precipitation within normal range vs. historical weather data.
Indian River/ FL/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sand	2	5	3.29	Air temperature and precipitation within normal range vs. historical weather data.
Isle of Wight/ VA/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.4	5.6	2.8	Air temperature and precipitation within normal range vs. historical weather data.
Erath/TX/ 1996	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	0.5	7.9	6.23	Air temperature and precipitation within normal range vs. historical weather data.
Sampson/ NC/ 1997	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	1.5	5.2	3.67	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1a. Residue Data Summary from Peanut Crop Field Trials: Metolachlor - Peanut nutmeats

Location (county/ state/ year)	Peanut Variety	Formulation	Application					PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	RTI [a] (days)	Total Rate (lb ai/A)	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [c]
Mitchell/ GA/ 1996	Florunner	7.8 lb/gal EC	1.45 & 1.57	2	43	3	75	69	<0.03, <0.03	0.05, <0.05	<0.08, <0.08
								77	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
								83	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
								90	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
Tifl/ GA/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	47	4	100	90	<0.03, 0.04	0.05, 0.07	**<0.08, 0.11**
Mitchell/ GA/ 1996	Florunner	7.8 lb/gal EC	2	2	43	4	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Thomas/ GA/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	53	4	100	74	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Macon/ AL/ 1996	GK-7 Anderson	7.8 lb/gal EC	2	2	45	4	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Washita/ OK/ 1996	Florunner	7.8 lb/gal EC	2	2	47	4	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Barnwell/ SC/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	45	4	100	90	<0.03, <0.03	0.06, 0.07	**<0.09, <0.10**
La Vaca/ TX/ 1996	GK-7	7.8 lb/gal EC	2	2	55	4	100	91	0.07, 0.06	0.12, 0.09	**0.19, 0.15**
Indian River/ FL/ 1996	Florunner	7.8 lb/gal EC	2	2	48	4	100	90	0.05, 0.05	0.08, 0.07	**0.13, 0.12**
Isle of Wight/ VA/ 1996	NC-VII	7.8 lb/gal EC	2	2	49	4	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

TABLE 1a. Residue Data Summary from Peanut Crop Field Trials: Metolachlor - Peanut nutmeats *(continued)*

Location (county/ state/ year)	Peanut Variety	Formulation	Application					PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	RTI [a] (days)	Total Rate (lb ai/A)	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Erath/TX/ 1996	Tam Span 90	7.8 lb/gal EC	2	2	53	4	100	65	<0.03, 0.03	<0.05, 0.05	<0.08, 0.08
								74	<0.03, 0.04	0.06, 0.07	<0.09, 0.11
								81	<0.03, <0.03	<0.05, 0.05	<0.08, <0.08
								88	0.03, 0.03	0.06, 0.06	**0.10, 0.10**
								94	<0.03, 0.05	<0.05, 0.07	**<0.08, 0.11**
Sampson/ NC/ 1997	NC-9	7.8 lb/gal EC	2	2	61	4	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

[a] RTI = retreatment interval.
[b] The labeled maximum seasonal application rate is 4.0 lb ai/A.
[c] PHI=post-harvest Interval; the labeled PHI is 90 days for mature peanuts.
[d] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.
[e] Combined residues in/on peanut nutmeats resulting from the maximum labeled use rate are **bolded**.

TABLE 1b. Residue Data Summary from Peanut Crop Field Trials: *S*-Metolachlor - Peanut nutmeats

Location (county/ state/ year)	Peanut Variety	Formulation	Application					PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	RTI [a] (days)	Total Rate (lb ai/A)	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Tifl/ GA/ 1996	Georgia Runner	7.6 lb/gal EC	1.33	2	47	2.67	100	90	<0.03, <0.03	0.05, <0.05	**<0.08, <0.08**
Mitchell/ GA/ 1996	Florunner	7.6 lb/gal EC	1.33	2	43	2.67	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Macon/ AL/ 1996	GK-7 Anderson	7.6 lb/gal EC	1.33	2	45	2.67	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Washita/ OK/ 1996	Florunner	7.6 lb/gal EC	1.33	2	47	2.67	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
La Vaca/ TX/ 1996	GK-7	7.6 lb/gal EC	1.33	2	55	2.67	100	91	<0.03, <0.03	0.06, 0.06	**<0.09, <0.09**
Sampson/ NC/ 1997	NC-9	7.6 lb/gal EC	1.33	2	61	2.67	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

[a] RTI = retreatment interval.

[b] The labeled maximum seasonal application rate is 2.7 lb ai/A.

[c] PHI=post-harvest Interval; the labeled PHI is 90 days for mature peanuts.

[d] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.

[e] Combined residues in/on peanut nutmeats resulting from the maximum labeled use rate are **bolded**.

TABLE 2a. Residue Data Summary from Peanut Crop Field Trials: Metolachlor - Peanut hay

Location (county/ state/ year)	Peanut Variety	Formulation	Application					PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	RTI [a] (days)	Total Rate (lb ai/A)	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [c]
Mitchell/ GA/ 1996	Florunner	7.8 lb/gal EC	1.45 & 1.57	2	43	3	75	69	0.77, 0.77	1.90, 2.30	2.67, 3.07
								77	0.34, 0.39	0.83, 0.62	1.17, 1.01
								83	0.48, 0.47	0.83, 0.75	1.31, 1.15
								90	0.68, 0.62	1.45, 1.08	2.13, 1.70
Tift/ GA/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	47	4	100	90	1.10, 1.91	1.63, 2.49	**2.73, 4.40**
Mitchell/ GA/ 1996	Florunner	7.8 lb/gal EC	2	2	43	4	100	90	0.39, 0.48	0.70, 1.10	**1.09, 1.58**
Thomas/ GA/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	53	4	100	74	0.56, 0.63	1.36, 1.54	**1.92, 2.17**
Macon/ AL/ 1996	GK-7 Anderson	7.8 lb/gal EC	2	2	45	4	100	90	2.00, 1.69	2.86, 1.99	**4.86, 3.68**
Washita/ OK/ 1996	Florunner	7.8 lb/gal EC	2	2	47	4	100	86	1.91, 2.60	5.03, 6.26	**6.94, 8.86**
Barnwell/ SC/ 1996	Georgia Runner	7.8 lb/gal EC	2	2	45	4	100	90	3.10, 3.26	7.25, 6.55	**10.4, 9.81**
La Vaca/ TX/ 1996	GK-7	7.8 lb/gal EC	2	2	55	4	100	91	0.83, 0.76	1.80, 2.16	**2.63, 2.92**
Indian River/ FL/ 1996	Florunner	7.8 lb/gal EC	2	2	48	4	100	90	5.22, 4.40	11.2, 11.2	**16.5, 15.6**
Isle of Wight/ VA/ 1996	NC-VII	7.8 lb/gal EC	2	2	49	4	100	90	0.42, 0.46	0.62, 0.77	**1.04, 1.23**
Erath/TX/ 1996	Tam Span 90	7.8 lb/gal EC	2	2	53	4	100	65	1.42, 2.02	2.76, 4.10	4.18, 6.12
								74	0.66, 1.05	1.49, 1.96	2.15, 3.01
								81	0.85, 0.78	2.77, 1.38	3.62, 2.16
								88	0.64, 0.71	0.89, 1.08	**1.53, 1.79**
								94	0.75, 1.05	1.34, 1.50	**2.09, 2.55**
Sampson/ NC/ 1997	NC-9	7.8 lb/gal EC	2	2	61	4	100	90	0.82, 0.95	1.75, 1.69	**2.57, 2.64**

[a] RTI = retreatment interval.
[b] The labeled maximum seasonal application rate is 4.0 lb ai/A.
[c] PHI=post-harvest Interval; the labeled PHI is 90 days for mature peanuts.
[d] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.
[e] Combined residues in/on peanut hay resulting from the maximum labeled use rate are **bolded**.

TABLE 2b. Residue Data Summary from Peanut Crop Field Trials: *S*-Metolachlor - Peanut hay

Location (county/ state/ year)	Peanut Variety	Formulation	Application					PHI (days) [c]	Residues (mg/kg) [d]		
			Single Rate (lb ai/A)	# of Appl.	RTI [a] (days)	Total Rate (lb ai/A)	% of Max Rate [b]		CGA-37913	CGA-49751	Combined [e]
Tift/ GA/ 1996	Georgia Runner	7.6 lb/gal EC	1.33	2	47	2.67	100	90	0.74, 0.81	1.20, 1.29	**1.94, 2.10**
Mitchell/ GA/ 1996	Florunner	7.6 lb/gal EC	1.33	2	43	2.67	100	90	0.87, 0.85	2.54, 2.38	**3.41, 3.23**
Macon/ AL/ 1996	GK-7 Anderson	7.6 lb/gal EC	1.33	2	45	2.67	100	90	1.08, 1.46	1.19, 1.27	**2.27, 2.73**
Washita/ OK/ 1996	Florunner	7.6 lb/gal EC	1.33	2	47	2.67	100	86	1.22, 0.66	2.97, 1.81	**4.19, 2.47**
La Vaca/ TX/ 1996	GK-7	7.6 lb/gal EC	1.33	2	55	2.67	100	91	0.46, 0.34	1.44, 0.87	**1.90, 1.21**
Sampson/ NC/ 1997	NC-9	7.6 lb/gal EC	1.33	2	61	2.67	100	90	0.36, 0.32	0.79, 0.79	**1.15, 1.11**

[a] RTI = retreatment interval.
[b] The labeled maximum seasonal application rate is 2.7 lb ai/A.
[c] PHI=post-harvest Interval; the labeled PHI is 90 days for mature peanuts.
[d] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.
[e] Combined residues in/on peanut hay harvested at approximately the labeled PHI following the maximum labeled use rate are **bolded.**

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. The current tolerances for peanuts commodities are 0.5 ppm in/on peanuts and 30 ppm in/on peanut forage and hay. Permanent tolerances for residues in/on animal commodities range from 0.02 ppm in milk, egg, fat, and meat and meat-byproducts (except liver and kidney) to 0.2 ppm in kidney. Temporary tolerances have also been established on grass forage and hay, spinach, tomatoes, and tomato puree and paste [40 CFR §180.368(b)], and tolerances with regional registrations have also been established for residue in/on dry bulb onions and non-bell peppers [40 CFR §180.368(c)]. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. The residues of concern for *S*-metolachlor in plants and animals are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96).

In a total of 11 tests on peanuts, the combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08-0.19 ppm in/on 24 samples of peanut nutmeats and 1.04-16.5 ppm in/on 24 samples of peanut hay harvested at maturity (74-94 days post-treatment), following a combination of a pre- and post-emergence application of metolachlor (7.8 lb/gal EC) totaling 4.0 lb ai/A (1x). The field trial mean residues (FTMaR) were 0.10 ppm in/on nutmeats and 4.65 ppm in/on hay, and the field trial median residues (FTMdR) were <0.08 ppm in/on nutmeats and 2.64 ppm in/on hay. Combined residues were <0.08 ppm (<LOQ) in/on all 19 control samples of nutmeats and in/on 13 control samples of hay. In three of the tests, combined residues were 0.11-0.32 ppm in/on control samples of hay; however, residues in these controls did not have an impact on the results as residues were substantially higher in the treated samples from the same sites.

In six additional tests, conducted side-by-side with six of the above tests, *S*-metolachlor (7.6 lb/gal EC) was applied twice to peanuts (pre- and post-emergence) at a maximum rate of 1.33 lb ai/A/application, for a total of 2.67 lb ai/A (1x). The resulting combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08-<0.09 ppm in/on 12 samples of nutmeats and 1.11-4.19 ppm in/on 12 samples of hay harvested at maturity (86-91 days post-treatment). The FTMaR and FTMdR were both <0.08 ppm in/on nutmeats and were 2.31 and 2.02 ppm, respectively, in/on hay.

Two of the metolachlor tests in (GA and TX) were conducted as residue decline studies and examined residues in nutmeats and hay at intervals from 65-94 days post-treatment. For nutmeats, combined residues were generally at or around the LOQ (0.08 ppm) at each sampling interval; therefore, no conclusions could be made about residue decline in nutmeats. However, the residue data for hay indicate that the combined metolachlor residues generally decreased at longer post-treatment intervals.

The maximum frozen storage interval from collection to extraction of analysis was 5.5 months for nutmeats and hay, and is adequately supported by the available storage stability data.

III. CONCLUSIONS

The field trial data on peanuts are adequate provided that the labels are amended to prohibit the grazing or harvest of peanut forage. In a total of 11 tests, combined metolachlor residues were <0.08-0.19 ppm in/on 24 samples of nutmeats and 1.04-16.5 ppm in/on 24 samples of hay harvested 74-94 days post-treatment (90-day PHI), following a combined pre- and post-emergence application of metolachlor (7.8 lb/gal EC) totaling 4.0 lb ai/A (1x). No data depicting residues in/on peanut forage harvested at the labeled 30-day PHI were provided.

In six related side-by-side tests using *S*-metolachlor, the combined *S*-metalochlor residues were <0.08-<0.09 ppm in/on 12 samples of nutmeats and 1.11-4.19 ppm in/on 12 samples of hay harvested 86-91 days post-treatment, following a combined pre- and post-emergence application of *S*-metolachlor (7.6 lb/gal EC) totaling 2.67 lb ai/A (1x).

Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent, in/on peanut nutmeats and hay. The combined LOQ is 0.08 ppm in/on peanut nutmeats and hay; no interference was observed in representative chromatograms of control samples from the analysis of peanuts.

Provided that the metolachlor labels are amended to prohibit the grazing or harvest of peanut forage, the peanut field trial data, reflecting the lower application rate of metolachlor (4.0 lb ai/A/season), are adequate and would support lowering the tolerance on peanut nutmeats to 0.20 ppm and lowering the tolerance for peanut hay to 20.0 ppm. The current tolerance for peanut forage should be revoked. The metolachlor tolerance will also cover the use of *S*-metolachlor on peanuts provided *S*-metolachlor labels are also amended to prohibit the grazing or harvest of peanut forage. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on peanuts.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on reassessing the tolerances for peanut nutmeats and hay.

V. REFERENCES

DP Barcode: D166637
Subject: Soybean Hull Chromatograms and Storage Stability Data Submissions in Response to the Metolachlor Final Registration Standard and Tolerance Reassessment (FRSTR) follow-up (6/14/89).
From: B. Cropp-Kohlligian
To: W. Waldrop
Dated: 4/16/92
MRID(s): 41506501 and 41425502

DP Barcode: D226780
Subject: Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From: L. Kutney
To: R. Giffin
Dated: 11/12/96
MRID(s): 43928901-43928903 and 43928939-43928942

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Tomatoes; PC code 108801; Rereg. Case 0001; DP Barcode D280219; MRID No. 44056101.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist Alan Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

EPA Reviewer: Sherrie J. Kinard, Date 27/Feb/02

STUDY TYPE: Crop Field Trials - Tomatoes; OPPTS 860.1500

TEST MATERIAL: Metolachlor

FORMULATIONS AND TYPES: Dual® 8E (8 lb/gal EC)

SYNONYMS: CGA-24705

CITATION: 44056101 Grunenwald, M. (1996) Metolachlor--Magnitude of the Residues in or on Tomatoes, Including Processed Fractions, Following a Post Application of Dual 8E: Lab Project Number: ABR-94110: 30-92: 130379. Unpublished study prepared by Ciba-Geigy Corp. 332 p.

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

The results from 13 crop field trials (MRID 44056101) conducted on tomatoes during 1992 have shown that the maximum combined residues of CGA-37913 and CGA-49751, each expressed as parent metolachlor, were below the limit of quantitation (<LOQ; combined <0.08 ppm) in/on 26 samples of tomatoes harvested 83-91 days following a single post-emergence application of metolachlor (EC) at 3.0 lb ai/A (1x proposed rate). Combined residues were also ≤0.08 ppm in/on tomatoes harvested 86 or 89 days following an exaggerated application at 2x (2 tests), 3x (2 tests), or 5x (1 test). In the other 5x test, combined residues were <0.11 ppm in/on tomatoes.

The registrant must provide copies of labels including the proposed use on tomatoes. Provided that label directions for metolachlor (EC) specify a maximum of one post-emergence application of 3.0 lb ai/A and a PHI of 90 days, the tomato field trial data are adequate and would support a permanent tolerance of 0.1 ppm for residues of metolachlor in/on tomatoes. These data would also support use of *S*-metolachlor (EC) on tomatoes at a maximum rate of 1.9 lb ai/A. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on tomatoes.

The crop field trials for metolachlor on tomatoes are deemed acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used a gas chromatographic/nitrogen-phosphorus detection (GC/NPD) method (Analytical Method AG-612) to determine residues of metolachlor in/on tomatoes. Method AG-612 is similar to Method I in PAM, Vol. II, and determines residues metolachlor or *S*-metolachlor and their metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents.

A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples were analyzed by Norvartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on tomato fruit.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated tomatoes from the current field trials were fortified separately with CGA-37913 at 0.02-0.5 ppm and with CGA-49751 at 0.05-0.50 ppm. These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. The average method recovery from tomato fruits was 97.7 ± 13.8% for CGA-37913 and 99.0 ± 10.9% for CGA-49751. Adequate chromatograms and sample calculations were provided.

The GC/NPD Method AG-612 is adequate for collecting data on residues of metolachlor in/on tomatoes.

1. <u>Test Compounds</u>

Chemical name: Metolachlor
IUPAC: 2-chloro-6'ethyl-*N*-(2-methyoxy-1-methylethyl) acet-*o*-toluidide
CAS name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide
CAS #: 51218-45-2
Common name (ANSI, BSI or ISO): metolachlor
Developmental (Company) name: CGA-24705

2. Trial Numbers and Locations

Metolachlor trials at 1x

Crop (commodity)	US Growing Regions						Total Trials
	1	2	3	5	6	10	
Tomatoes (fruit)							
Submitted	2	1	2	3	1	4	13
Requested	1	1	2	1	0	11	16

Comments: Geographic representation and the number of crop field trials conducted for a post-emergence use of metolachlor on tomatoes are adequate. Although only 13 field trials were conducted using metolachlor at 1x the proposed maximum rate, the studies were conducted prior to issuance of the current guidance and the combined metolachlor residues in/on all tomato samples were <LOQ in all 13 1x-field trials.

3. Proposed Use Pattern

Metolachlor 8 lb/gal EC [a]

Crop	Application					Comments/ Restrictions [c]
	Method/ Timing	Max. Rate (lb ai/A)	Max. Number	Total Rate (lb ai/A)	PHI [b] (days)	
Tomato	Post-emergence broadcast application after transplanting or seedling emergence	3.0	1	3.0	90	none

[b] PHI = post-harvest interval, the number of days between the last application and harvest.

Comments: The registrant did not provide a copy of the proposed use directions for metolachlor on tomatoes; a sample of a label (EC) including directions for tomatoes is required. Based upon the field trial data, the registrant is supporting use of a single application of metolachlor (EC) to tomatoes as a post-emergence application to transplants or seedlings at up to 3.0 lb ai/A with a 90-day PHI.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
Tomato fruit	CGA-37913	0.02-0.50	97, 110, 113, 109, 92, 102, 105, 63, 112, 83, 90, 91, 109, 104, 86	63-113	97.7 ± 13.8
	CGA-49751	0.05-0.50	99, 95, 103, 91, 92, 100, 95, 102, 128, 77, 95, 96, 105, 109, 98	77-128	99.0 ± 10.9

Comments: Recoveries were within the acceptable 70-120% range, with the exception of one low recovery (63%) of CGA-37913 and one high recovery (128%) of CGA-49751. Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on metolachlor residues in/on tomatoes.

5. Storage Stability Conditions

Commodities	Analytes	Storage Temperature (°C)	Storage Duration (months)
Tomato fruit	CGA-37913 and CGA49751	≤-15 C	20-26

Comments: Samples of tomato fruits were harvested at maturity (86-109 days post-treatment) and frozen. Samples were shipped frozen by freezer truck or by overnight courier to Novartis Crop Protection, Greensboro, NC, where samples were stored at ≤-15 C until extraction for analysis. The total sample storage interval for tomato fruits was 20-26 months.

No new storage stability data were submitted with this study. However, adequate storage stability data are available indicating that CGA-37913 and CGA-49751 are stable during storage at -20 C for up to 2 years in tomatoes (DP Barcode No. D166637, B. Cropp-Kohlligian, 4/16/92). These data are adequate to support the tomato field trials.

6. Application and RAC Information

Metolachlor-Dual 8E (8 lb/gal EC)-Tomatoes

LOCATION (county /state/year)	EPA Region	Tomato Variety	APPLICATION					HARVEST PROCEDURES		
			Growth Stage at first appl.	# of appl.	Single Rate (lb ai/A) [a]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Number and wt. of samples
Fresno/ CA/ 1992	10	Cal Ace	4-6" seedlings	1	3	broadcast	20	Mature [b]	Fruit	Duplicate samples were collected from each test and at sampling interval (in decline studies). Sample weight was not specified.
Fresno/ CA/ 1992	10	1854-L UC-82	vegetative (51 DAP) [c]	1	3	broadcast	20	Mature	Fruit	
					6					
					9					
					15					
Indian River/ FL/ 1992	3	Sunny	at transplanting	1	3	broadcast	31	Mature	Fruit	
					6					
Indian River/ FL/ 1992	3	Sunny	at transplanting	1	3	broadcast	31	Mature	Fruit	
Cameron/ TX/ 1992	6	Homestead 24	4" transplants	1	3	broadcast	22	Mature	Fruit	
Barnwell/ SC/ 1992	2	Celebrity	5" transplants	1	3	broadcast	30	Mature	Fruit	
Contra Costa/ CA/ 1992	10	Murietta	vegetative (39 DAP)	1	3	broadcast	58	Mature	Fruit	
Fresno/ CA/ 1992	10	Keno	at transplanting	1	3	broadcast	20	Mature	Fruit	
Ottawa/ MI/ 1992	5	Jackpot	at transplanting	1	3	broadcast	23	Mature [b]	Fruit	
Hamilton/ IN/ 1992	5	Burpee Big Boy	4-5 leaf stage	1	3	broadcast	24	Mature	Fruit	
Fayette/ OH/ 1992	5	Ohio 696	vegetative	1	3	broadcast	21	Mature	Fruit	
					6					
					9					
					15					
Hunterdon/ NJ/ 1992	1	Better Boy	early seedling	1	3	broadcast	22	Mature [b]	Fruit	
					6					
Lehigh/ PA/ 1992	1	Better Boy	early seedling	1	3	broadcast	21	Mature	Fruit	

[a] The maximum proposed application rate is 3.0 lb ai/A.
[b] Residue decline studies were conducted at two test sites (MI and NJ).
[c] DAP = days after planting.

Comments: A sample label containing the proposed used directions for tomatoes was not submitted. The registrant must submit labels for the EC formulations containing use directions for tomatoes. The available tomato residue data would support use of a single post-emergence broadcast application of metolachlor (EC) at up to 3.0 lb ai/A, with a 90-day PHI. These residue data could also support a similar use of *S*-metolachlor on tomatoes at up to 1.9 lb ai/A.

7. Site Specific Information

LOCATION (county/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Fresno/ CA/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	not reported (NR)	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Fresno/ CA/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Indian River/ FL/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sand	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Indian River/ FL/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sand	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Cameron/ TX/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Barnwell/ SC/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loamy sand	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Contra Costa/ CA/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Fresno/ CA/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Ottawa/ MI/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Hamilton/ IN/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Fayette/OH/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Hunterdon/ NJ/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.
Lehigh/ PA/ 1992	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Clay loam	NR	NR	NR	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1. Residue Data Summary from Tomato Crop Field Trials: Metolachlor - Tomato

Location (county/ state/ year)	Tomato Variety	Formulation	Application			PHI (days) [b]	Residues (mg/kg) [c]		
			Rate (lb ai/A)	# of Appl.	% of Max Rate [a]		CGA-37913	CGA-49751	Combined [d]
Fresno/ CA/ 1992	Cal Ace	8 lb/gal EC	3	1	100	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Fresno/ CA/ 1992	1854-I, UC-82	8 lb/gal EC	3	1	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			6	1	200	86	<0.03	<0.05	<0.08
			9	1	300	86	<0.03, 0.03	<0.05, <0.05	<0.08, <0.08
			15	1	500	86	0.03, 0.06	<0.05, <0.05	<0.08, <0.11
Indian River/ FL/ 1992	Sunny	8 lb/gal EC	3	1	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			6	1	200	86	<0.03	<0.05	<0.08
Indian River/ CA/ 1992	Sunny	8 lb/gal EC	3	1	100	86	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Cameron/ TX / 1992	Homestead 24	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Barnwell/ SC/ 1992	Celebrity	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Contra Costa/ CA/ 1992	Murietta	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Fresno/ CA/ 1992	Keno	8 lb/gal EC	3	1	100	83	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Ottawa/ MI/ 1992	Jackpot	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
						105	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
Hamilton/ IN/ 1992	Burpee Big Boy	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Fayette/ OH/ 1992	Ohio 696	8 lb/gal EC	3	1	100	89	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			6		200	89	<0.03	<0.05	<0.08
			9		300	89	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
			15		500	89	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
Hunterdon/ NJ/ 1992	Better Boy	8 lb/gal EC	3	1	100	91	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
						109	<0.03	<0.05	<0.08, <0.08
			6		200	91	<0.03, <0.03	<0.05, <0.05	<0.08, <0.08
						109	<0.03	<0.05	<0.08, <0.08
Lehigh/ PA/ 1992	Better Boy	8 lb/gal EC	3	1	100	90	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**

[a] The proposed maximum rate is a single application of metolachlor at 3.0 lb ai/A.

[b] PHI=post-harvest Interval; the proposed PHI is 90 days for mature tomatoes.

[c] The registrant corrected residue values for samples using concurrent method recoveries of <100%; however, residue values in this report are not corrected for method recovery. Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.

[d] Combined residues in/on tomatoes resulting from the maximum labeled use rate at the proposed PHI are **bolded**.

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. Permanent tolerances for residues in/on animal commodities range from 0.02 ppm in milk, egg, fat, and meat and meat-byproducts (except liver and kidney) to 0.2 ppm in kidney. Temporary tolerances have also been established in/on tomatoes at 0.1 ppm and in tomato puree and paste at 0.3 and 0.6 ppm, respectively [40 CFR §180.368(b)]. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. The residues of concern for *S*-metolachlor in plants and animals are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96).

In a total of 13 tests, the combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08 ppm (<LOQ) in/on 26 samples of tomatoes harvested 83-91 days following a single post-emergence application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x the proposed rate). Combined residues were also <LOQ in/on all 13 control samples of tomatoes.

At two of the test sites, metolachlor (8 lb/gal EC) was also applied to separate plots as a post-emergence application at exaggerated rates of 6, 9, and 15 lb ai/A (2x, 3x, and 5x). Residues of CGA-49751 were <0.05 ppm (<LOQ) in/on all ten samples of tomatoes harvested 86 or 89 days following applications at 2x, 3x, and 5x. Residues of CGA-37913 were also ≤LOQ (≤0.03 ppm) in/on the six samples treated at 2x or 3x, and in/on the two samples treated at 5x from one of the sites (OH). At the other test site (CA), residues of CGA-37913 were 0.03 and 0.06 ppm in/on two samples harvested 86 days following an application at 5x. Combined residues were ≤0.08 ppm in/on all exaggerated rate samples, except one 5x-treated sample from the CA test site bearing combined residues of <0.11 ppm.

The maximum frozen storage interval from harvest to extraction was 26 months for tomatoes; this storage interval is supported by the available storage stability data.

III. CONCLUSIONS

The tomato field trial data are adequate; however, the registrant must still provide a copy of a label including the proposed use on tomatoes. In a total of 13 tests, combined metolachlor residues were <0.08 ppm (<LOQ) in/on 26 samples of tomatoes harvested 83-91 days following a single post-emergence application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x proposed rate).

Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent, in/on tomatoes. The combined LOQ is 0.08 ppm in/on tomatoes; no interference was observed in representative chromatograms of control samples from the analysis of tomatoes.

Provided that label directions for metolachlor (EC) specify a maximum of one post-emergence application of 3.0 lb ai/A and a PHI of 90 days, the tomato field trial data are adequate and would support a permanent tolerance of 0.1 ppm for residues of metolachlor in/on tomatoes. These data would also support use of *S*-metolachlor (EC) on tomatoes at a maximum rate of 1.9 lb ai/A. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on tomatoes.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on assessing a tolerance for metolachlor on tomatoes.

V. REFERENCES

DP Barcode:	D226780
Subject:	Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From:	L. Kutney
To:	R. Giffin
Dated:	11/12/96
MRID(s):	43928901-43928903 and 43928939-43928942

III. CONCLUSIONS

The tomato field trial data are adequate; however, the registrant must still provide a copy of a label including the proposed use on tomatoes. In a total of 13 tests, combined metolachlor residues were <0.08 ppm (<LOQ) in/on 26 samples of tomatoes harvested 83-91 days following a single post-emergence application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x proposed rate).

Based on the concurrent method recoveries, the GC/NPD Method AG-612 is adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent, in/on tomatoes. The combined LOQ is 0.08 ppm in/on tomatoes; no interference was observed in representative chromatograms of control samples from the analysis of tomatoes.

Provided that label directions for metolachlor (EC) specify a maximum of one post-emergence application of 3.0 lb ai/A and a PHI of 90 days, the tomato field trial data are adequate and would support a permanent tolerance of 0.1 ppm for residues of metolachlor in/on tomatoes. These data would also support use of *S*-metolachlor (EC) on tomatoes at a maximum rate of 1.9 lb ai/A. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on tomatoes.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on assessing a tolerance for metolachlor on tomatoes.

V. REFERENCES

DP Barcode:	D226780
Subject:	Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From:	L. Kutney
To:	R. Giffin
Dated:	11/12/96
MRID(s):	43928901-43928903 and 43928939-43928942

DP Barcodes:	D222430 and D224237
Subject	Metolachlor (108801) Reregistration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions
From:	S. Hummel
To:	M. Metzger
Dated:	2/25/97
MRID(s):	43881701-43881703 and 43944601

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor.** OPPTS 860.1520: Processed Food/Feed Study inTomatoes; PC code 108801; Rereg. Case 0001; DP Barcode D280219; MRID No. 44056101.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist A. Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

Metolachlor	**Processed Food.Feeds**	**MRID: 44056101**
PC Code: 108801	**GL: OPPTS 860.1520**	**Case No.: 0001**
EPA Barcode: D280219		**Submission: S608605**

EPA Reviewer: Sherrie J. Kinard, **Date** 27/Feb/02

STUDY TYPE: Processed Food/Feed Study -Tomatoes; OPPTS 860.1520

TEST MATERIAL: Metolachlor

FORMULATIONS AND TYPES: Dual® 8E (8 lb/gal EC)

SYNONYMS: CGA-24705

CITATION: 44056101 Grunenwald, M. (1996) Metolachlor--Magnitude of the Residues in or on Tomatoes, Including Processed Fractions, Following a Post Application of Dual 8E: Lab Project Number: ABR-94110: 30-92: 130379. Unpublished study prepared by Ciba-Geigy Corp. 332 p.

SPONSOR: Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.)

EXECUTIVE SUMMARY:

In a series of tomato processing studies (MRID 44056101), selective herbicide metolachlor (8 lb/gal EC) was applied to tomatoes as a single foliar application to separate plots at 3.0, 9.0 and 15.0 lb ai/A (1x, 3x, or 5x the maximum proposed foliar application rate) at two test sites (CA and OH). Tomatoes were harvested ~90 days post-treatment, and were processed into stewed/canned tomatoes, wet and dry pomace, juice, puree, and paste using simulated commercial procedures. Tomato puree and paste are currently the only regulated processed commodities of tomatoes.

The combined residues of metabolites CGA-37913 and CGA-49751, expressed as parent metolachlor, were less than the limit of quantitation (LOQ, <0.08 ppm) in/on tomatoes harvested ~90 days following a single foliar application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x proposed use rate) at both test sites. Residues of CGA-49751 were also <LOQ (<0.05 ppm) in/on tomatoes from the 3x and 5x applications, but residues of CGA-39713 were 0.03-0.04 ppm in/on tomatoes from the 3x application and 0.03-0.06 ppm in/on tomatoes from the 5x application.

Based on data from the 5x studies, residues do not appear to concentrate in stewed tomatoes and juice, and concentrated only slightly in wet pomace (1.2x) and puree (1.4x). Concentrations were more substantial in dry pomace (3.3x) and paste (2.2x).

As residues were <LOQ (<0.08 ppm) in/on all 26 tomato samples from the 1x field trials (13 tests), the maximum expected residues can be extrapolated using the maximum residue values

for each processed fraction from the 5x application. Using this method, the maximum expected residues resulting from a 1x application of metolachlor would be 0.03 ppm in puree and 0.05 ppm in paste. As these levels are below the 0.1 ppm temporary tolerance for tomatoes, the established temporary tolerances, set to expire 6/30/02 [40 CFR §180.368(b)] for metolachlor residues in/on tomato puree (0.3 ppm), and tomato paste (0.6 ppm) are not necessary.

These processed food/feed studies are classified acceptable and do satisfy the guideline requirement for a tomato processing study on metolachlor (Residue Chemistry Guidelines OPPTS 860.1520). These data also support the use of S-metolachlor on tomatoes at 0.63x the maximum metolachlor rate.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

MATERIALS:

1. **Test Compound:**
   Active ingredient (ai): Metolachlor
   Formulation or spiking substance: 8 lb/gal EC

   Physicochemical Properties:

Water and Organic Solvent Solubility (OPPTS 830.7840 and 830.7860)	488 mg/L at 25 C very soluble in benzene, hexane, methanol, octanol, and dichloromethane
n-Octanol/water partition coefficient (Kow) (OPPTS 830.7550)	log Kow = 2.93 at 25 C
pKa (OPPTS 830.7370)	Not available
Vapor Pressure (OPPTS 830.7950)	4.2 mPa at 25 C

2. **Test Commodity:**
   Crop: Tomato
   Type/Variety: 1854-L UC-82 (CA test site) and Ohio 696 (OH test site)
   Crop parts used in processing study: Mature fruit
   Developmental stages (i.e., immature/mature, fresh/dry, etc.):
   Application: broadcast foliar application vegetative seedlings
   Harvest: mature tomato fruits (86 or 89 days post-treatment)

METHODS:

1. **Experimental Design:**

Method of application: Single foliar broadcast at two test sites at 1x, 3x, and 5x

Rate of application (comparison to the maximum application rate):

Application rate(s): 3.0, 9.0 or 15.0 lb ai/A (1x, 3x, or 5x) at both test sites

Number of applications: 1 per treatment/site

Number of test/control samples: At each test site, a single bulk sample was collected for each treatment and one control sample (weight unspecified).

Number of sample replicates: At the processing facility, a single sample of unwashed tomatoes was collected for each test, along with a single sample of each processed fraction.

2. **Test Procedures:**

Manner in which test compound was introduced into RAC (i.e., spiking, application):

At both test sites (CA and OH), metolachlor (8 lb/gal EC) was applied once as a broadcast foliar application to tomatoes at either 51 days after planting seeds or 14 days after transplanting. At each site, metolachlor was applied to separate plots at 3.0, 9.0, and 15.0 lb ai/A (1x, 3x, and 5x the maximum proposed rate), using ~20 gallons of spray mixture/A. Mature tomatoes were harvested 86 or 89 days post-treatment.

Description of processing location, procedure, and mass balance (include scheme if applicable):

At each test site a single bulk sample of control tomatoes and tomatoes treated at 1x, 3x, and 5x were harvested at maturity (86 or 89 days post-treatment) and shipped fresh directly to the processing facility. Tomatoes from the CA tests were processed by the National Food Laboratory (NFL), Dublin, CA, and tomatoes from the OH tests were processed by Wm. J. Engler and Associates, Moses Lake, WA. Tomatoes were processed using simulated commercial procedures into washed fruits, stewed tomatoes, juice, paste, puree, and wet and dry pomace. After processing, all fractions were frozen and shipped to Novartis, where samples were stored at -15 C, until analysis.

Analytical method:

Samples of tomatoes and each processed fraction were analyzed for the combined residues of metolachlor using Analytical Method AG-612, a gas chromatographic/ nitrogen-phosphorus detection (GC/NPD) method that is similar to Method I in PAM, Vol. II. This method determines residues of metolachlor and its metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents. Analyses were conducted by Novartis Crop Protection, Human Safety Department, Greensboro, NC, using minor modifications.

Samples of each commodity are initially refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using an alumina column followed by a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. Confirmatory analyses using GC/MSD were also conducted on selected samples. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. Confirmatory analyses using GC/MSD were also conducted on selected samples having appreciable residues of either analyte. The method LOQ for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on tomatoes and each processed fraction.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated tomatoes and each processed fraction from each test site were fortified separately with CGA-37913 and CGA-49751. These fortified samples were analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples using GC/NPD and GC/MSD are detailed below in Tables 1a and 1b. For the GC/NPD analyses, the average method recovery from tomato fruits and processed fractions was 97.0 ± 13.8% for CGA-37913 and 93.6 ± 11.8% for CGA-49751. For the GC/MSD analyses, the average method recovery was 105 ± 33% for CGA-37913 and 109 ± 14.5% for CGA-49751. Adequate chromatograms and sample calculations were provided.

Storage stability:

In each test, a bulk sample of tomato fruits were harvested at maturity (86 or 89 days post-treatment) and shipped fresh to the processing facility. As the processing facility, samples were frozen after collection and shipped by overnight courier to Novartis Crop Protection, Greensboro, NC, where samples were stored at ≤-15 C until extraction for analysis. The total sample storage interval for tomato fruits and processed fractions was 22-24 months.

No new storage stability data were submitted with this study. However, adequate storage stability data are available indicating that CGA-37913 and CGA-49751 are stable during storage at -20 C for up to 2 years in tomatoes (DP Barcode No. D166637, B. Cropp-Kohlligian, 4/16/92). These data are adequate to support the tomato processing study.

II. RESULTS

TABLE 1a. Summary of Procedural Recoveries (GC/NPD) for Tomatoes and Tomato Processed Fractions, spiked with CGA-37913 or CGA-49751.

Matrix	Spiking Level (ppm)	% Recovery	Mean
CGA-37913			
Tomato, unwashed (RAC)	0.20	94, 109	102
Tomato, washed	0.10	117, 107	112
Tomato, stewed	0.10, 0.20	71, 126	99
Tomato, wet pomace	0.10, 0.20	99, 78	89
Tomato, dry pomace	0.50, 8.0	97, 93, 96	95
Tomato, puree	0.20	81, 94	88
Tomato, juice	0.10	104, 85	95
Tomato, paste	0.20, 8.0	104, 94	99
		Overall average ± S.D. =	97.0 ± 13.8
CGA-49751			
Tomato, unwashed (RAC)	0.20	97, 109	103
Tomato, washed	0.10	113, 99	106
Tomato, stewed	0.10, 0.20	75, 105	90
Tomato, wet pomace	0.10, 0.20	106, 86	96
Tomato, dry pomace	0.50, 8.0	88, 89, 73	83
Tomato, puree	0.10, 0.20	101, 88	95
Tomato, juice	0.10	97, 76	87
Tomato, paste	0.20, 8.0	92, 97	95
		Overall average ± S.D. =	93.6 ± 11.8

TABLE 1b. Summary of Procedural Recoveries from Confirmatory Analysis (GC/MSD) of Tomatoes and Tomato Processed Fractions, spiked with CGA-37913 or CGA-49751.

Matrix	Spiking Level (ppm)	% Recovery
CGA-37913		
Tomato, unwashed (RAC)	0.20	93
Tomato, washed	0.10	83
Tomato, stewed	0.20	111
Tomato, wet pomace	0.10	150
Tomato, dry pomace	0.50, 8.0	107, 79, 71
Tomato, puree	0.10	72
Tomato, juice	0.10	88
Tomato, paste	0.20, 8.0	167, 141
	Overall average ± S.D. =	105 ± 33
CGA-49751		
Tomato, puree	0.10	124
Tomato, paste	0.20, 8.0	110, 95
	Overall average ± S.D. =	109 ± 14.5

Comments:
The recovery data for tomatoes and tomato processed commodities indicate that the GC/NPD method AG-612 is adequate for determining residues of CGA-37913 and CGA-49751 in/on each commodity. Average recoveries for both analytes ranged from 88-112%. The LOQ for CGA-37913 and CGA-49751 is 0.03 and 0.05 ppm, respectively, in/on each commodity.

TABLE 2. Residues of Metolachlor in Tomatoes and Processed Tomato Fractions

Matrix	Rate (lbs ai/A)	PHI (days)	Residues [a] (mg/kg)			Processing factors [b]
			CGA-31913	CGA-47951	Combined	
California Tests						
Tomato, unwashed (RAC)	3.0 (1x) [c]	86	<0.03	<0.05	<0.08	NA
	9.0 (3x)		0.03	<0.05	<0.08	
	15.0 (5x)		0.06	<0.05	<0.11	
Tomato, washed	3.0	86	<0.03	<0.05	<0.08	--
	9.0		<0.03	<0.05	<0.08	1x
	15.0		0.05	<0.05	<0.10	0.9x
Tomato, stewed and canned	3.0	86	<0.03	<0.05	<0.08	--
	9.0		<0.03	<0.05	<0.08	1x
	15.0		<0.03	<0.05	<0.08	0.7x
Tomato, wet pomace	3.0	86	<0.03 (0.07)[d]	0.05	<0.08	--
	9.0		0.05 (0.10)	0.05	0.10	1.3x
	15.0		0.09 (0.14)	<0.05	<0.14	1.3x
Tomato, dry pomace	3.0	86	0.06 (0.07)	0.04	0.10	--
	9.0		0.17 (0.21)	0.09	0.26	3.3x
	15.0		0.24 (0.27)	0.11	0.35	3.2x
Tomato, puree	3.0	86	<0.03	<0.05	<0.08	--
	9.0		0.04	0.06	0.10	1.3x
	15.0		0.06	0.08	0.14	1.3x
Tomato, juice	3.0	86	<0.03	<0.05	<0.08	--
	9.0		<0.03	<0.05	<0.08	1.0x
	15.0		<0.03	<0.05	<0.08	0.7x
Tomato, paste	3.0	86	0.03 (0.07)	<0.05 (<0.05)	<0.08	--
	9.0		0.12 (0.20)	0.09 (0.10)	0.21	2.6x
	15.0		0.14 (0.27)	0.13 (0.14)	0.27	2.5x

TABLE 2. Residues of Metolachlor in Tomatoes and Processed Tomato Fractions *(continued)*.

Matrix	Rate (lbs ai/A)	PHI (days)	Residues [a] (mg/kg)			Processing factors [b]
			CGA-31913	CGA-47951	Combined	
Ohio Tests						
Tomato, unwashed (RAC)	3.0 (1x) [c]	89	<0.03 (<0.03)	<0.05	<0.08	NA
	9.0 (3x)		0.04 (0.04)	<0.05	<0.09	
	15.0 (5x)		0.03 (0.04)	<0.05	<0.08	
Tomato, washed	3.0	89	<0.03 (<0.03)	<0.05	<0.08	--
	9.0		<0.03 (0.03)	<0.05	<0.08	0.9x
	15.0		<0.03 (<0.03)	<0.05	<0.08	1x
Tomato, stewed and canned	3.0	89	<0.03 (<0.03)	<0.05	<0.08	--
	9.0		<0.03 (0.04)	<0.05	<0.08	0.9x
	15.0		<0.03 (0.04)	<0.05	<0.08	1x
Tomato, wet pomace	3.0	89	<0.03	<0.05	<0.08	--
	9.0		0.03	<0.05	<0.08	0.9x
	15.0		0.03	<0.05	<0.08	1x
Tomato, dry pomace	3.0	89	0.08 (0.08)	0.06	0.14	--
	9.0		0.17 (0.14)	0.10	0.27	3.0x
	15.0		0.18 (0.16)	0.08	0.26	3.3x
Tomato, puree	3.0	89	0.03 (<0.03)	<0.05	<0.08	--
	9.0		0.06 (0.05)	<0.05	<0.11	1.2x
	15.0		0.05 (0.05)	<0.05	<0.10	1.4x
Tomato, juice	3.0	89	<0.03 (<0.03)	<0.05	<0.08	--
	9.0		<0.03 (<0.03)	<0.05	<0.08	0.9x
	15.0		<0.03 (<0.03)	<0.05	<0.08	1x
Tomato, paste	3.0	89	0.06 (0.06)	<0.05 (0.07)	<0.11	--
	9.0		0.10 (0.11)	0.05 (0.10)	0.15	1.7x
	15.0		0.09 (0.09)	0.06 (0.10)	0.15	1.9x

[a] Residues of CGA-37913 and CGA-49751 are expressed in parent equivalents and are not corrected for concurrent method recoveries. The LOQ is 0.03 and 0.05 ppm for CGA-37913 and CGA-47951, respectively, in each matrix. Apparent residue in/on all control samples were <LOQ.

[b] The processing factor was calculated only for the exaggerated applications that resulted in quantifiable residues in the RAC. Concentration factors were calculated using results from the GC/NPD analyses.

[c] The maximum proposed post-emergence rate for metolachlor on tomatoes is 3.0 lb ai/A.

[d] Residue values in parentheses are from confirmatory analysis using GC/MSD.

TABLE 3. Processing Factors, Maximum Residues and Proposed Tolerances for Metolachlor in Tomato Processed Fractions

RAC	Processed Fractions [a]	Processing Factor [b]	HAFT [c] (ppm)	Theoretical Max. Residue [d] (ppm)	Maximum residues at 5x / Extrapolated to 1x [e] (ppm)	Temporary Tolerances (ppm) [f]
Tomato	Washed fruit	1x	<0.08	<0.08	<0.11/ <0.02	0.1
	stewed/canned	0.9x		<0.08	<0.08/ <0.02	none
	wet pomace	1.2x		0.10	<0.14/ <0.05	none
	dry pomace	3.3x		0.26	0.35/ 0.07	none
	puree	1.4x		0.11	0.14/ 0.03	0.3
	juice	0.9x		<0.08	<0.08/ <0.02	none
	paste	2.2x		0.18	0.27/ 0.05	0.6

[a] The only currently regulated processed fractions from tomatoes are puree and paste.
[b] Average processing factors were calculated using on results from the 5x processing tests.
[c] Highest Average Field Trial residues were <0.08 ppm (<LOQ) in/on all tomato samples from the 1x field trials (MRID 44056101).
[d] Calculated using the average processing factor and the HAFT.
[e] Maximum residues in each commodity from the 5x application, followed by residues extrapolated down to a 1x treatment.
[f] Temporary tolerances for metolachlor have been established for tomato fruit, puree, and paste.

Comments:

The combined residues of CGA-37913 and CGA-49751, expressed as metolachlor, were <LOQ (<0.08 ppm) in/on tomatoes harvested ~90 days following a single foliar application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x proposed use rate) at both test sites. Residues of CGA-49751 were also <LOQ (<0.05 ppm) in/on tomatoes from the 3x and 5x applications. However, residues of CGA-39713 were 0.03-0.04 ppm in/on tomatoes from the 3x application and 0.03-0.06 ppm in/on tomatoes from the 5x application (Table 2).

Combined residues were <0.08 ppm (<LOQ) in stewed tomatoes and juice from the 1x, 3x, and 5x treatments, but residues were detected in wet and dry pomace, puree, and paste (Table 2).

Residues do not appear to concentrate in stewed tomatoes (0.7-1x) and juice (0.7-1x), but concentrated slightly in wet pomace (0.9-1.3x) and puree (1.2-1.4x). Concentrations were more substantial in dry pomace (3.0-3.3x) and paste (1.7-2.6x). Based on the residues in processed fractions and tomatoes treated at 5x from both test sites, the average concentration factors for puree and paste, the only currently regulated tomato processed commodities, would be 1.4x and 2.2x, respectively (Table 3).

Considering the HAFT residues for metolachlor in/on tomatoes following a 1x application were <0.08 ppm (<LOQ) and the processing factors for puree (1.4x) and paste (2.2x), the maximum expected residues would be 0.11 ppm in puree and 0.18 ppm in paste (Table 3). However, as residues were <LOQ in/on all tomato samples from the 1x applications, the maximum expected

residues can also be extrapolated using the maximum residue values for each processed fraction from the 5x application. Using this method (Table 3), the maximum expected residues resulting from a 1x application would be 0.03 ppm in puree and 0.05 ppm in paste. As these levels are below the established 0.1 ppm temporary tolerance for tomatoes, separate tolerances for metolachlor residues in tomato puree and paste are not required.

III. FINAL SUMMARY

Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. Temporary tolerances have been established (set to expire 6/30/02) for metolachlor residues in/on tomatoes, tomato puree (0.3 ppm), and tomato paste (0.6 ppm) [40 CFR §180.368(b)]. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751.

The submitted tomato processing studies are adequate. The combined residues of CGA-37913 and CGA-49751, expressed as metolachlor, were <LOQ (<0.08 ppm) in/on tomatoes harvested ~90 days following a single foliar application of metolachlor (8 lb/gal EC) at 3.0 lb ai/A (1x proposed use rate) at both test sites. Residues of CGA-49751 were also <LOQ (<0.05 ppm) in/on tomatoes from the 3x and 5x applications, but residues of CGA-39713 were 0.03-0.04 ppm in/on tomatoes from the 3x application and 0.03-0.06 ppm in/on tomatoes from the 5x application.

Based on data from the 5x studies, residues do not appear to concentrate in stewed tomatoes and juice, and concentrated only slightly in wet pomace (1.2x) and puree (1.4x). Concentrations were more substantial in dry pomace (3.3x) and paste (2.2x).

As residues were <LOQ (<0.08 ppm) in/on all 26 tomato samples from the 1x field trials, the maximum expected residues can be extrapolated using the maximum residue values for each processed fraction from the 5x application. Using this method, the maximum expected residues resulting from a 1x application would be 0.03 ppm in puree and 0.05 ppm in paste, which are the only currently regulated tomato processed fractions. As these levels are below the established 0.1 ppm temporary tolerance for tomatoes, separate tolerances for metolachlor residues in tomato puree and paste are not required.

These data may also be used to support the use of *S*-metolachlor on tomatoes at a maximum use rate of 1.9 lb ai/A (DP Barcode D226780, L. Kutney, 11/12/96).

Samples of tomato and tomato processed commodities were stored frozen for 22-24 months prior to analysis. These storage intervals are supported by previously submitted storage stability data.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on the outcome of these processed food/feed studies.

V. REFERENCES

DP Barcode: D226780
Subject: Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From: L. Kutney
To: R. Giffin
Dated: 11/12/96
MRID(s): 43928901-43928903 and 43928939-43928942

DP Barcodes: D222430 and D224237
Subject: Metolachlor (108801) Reregisration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions
From: S. Hummel
To: M. Metzger
Dated: 2/25/97
MRID(s): 43881701-43881703 and 43944601

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 28, 2002

SUBJECT: **Metolachlor.** OPPTS 860.1500: Magnitude of the Residue in Spinach; PC code 108801; Rereg. Case 0001; DP Barcode D280216; MRID No. 44615401.

FROM: Sherrie L. Kinard, Chemist Sherrie L. Kinard
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist A. Nielsen 2/28/02
Reregistration Branch II
Health Effects Division (7509C)

TO: Anne Overstreet, Chemical Review Manager
Reregistration Branch III
Special Review and Reregistration Division (7508W)

EPA Reviewer: Sherrie J. Kinard, Date 27/Feb/02

STUDY TYPE: Crop Field Trials - Spinach; OPPTS 860.1500

TEST MATERIAL: Metolachlor

FORMULATIONS AND TYPES: Dual® 8E (8 lb/gal EC)

SYNONYMS: CGA-24705

CITATION: 44615401 Lurvey, E. (1998) Metolachlor: Magnitude of Residues in/on Spinach: Lab Project Number: 01217.94-BER02: 01217.95-CAR29: 01217.94-AR01. Unpublished study prepared by USDA-ARS-NRI-Environmental Chemistry Laboratory. 716 p. {OPPTS 860.1500}

SPONSOR: Interregional Research Project No. 4 (IR-4)

EXECUTIVE SUMMARY:

The results from 11 crop field trials (MRID 44615401) conducted on spinach during 1994 and 1995 have shown that the combined residues of CGA-37913 and CGA-49751, each expressed as parent metolachlor, were <0.08-<0.38 ppm in/on 22 samples of spinach harvested 34-69 days following a single pre-emergence soil application of metolachlor (8 lb/gal EC) at 1.0 lb ai/A (1x proposed rate/crop). Combined residues were also <0.08-0.263 ppm in/on 10 samples of spinach harvested 41-69 days following an pre-emergence application at 2.0 lb ai/A (2x).

The spinach field trials are adequate provided that the proposed label directions for metolachlor (EC) on spinach are amended to specify a maximum seasonal rate of 1.0 lb ai/A and a PHI of 40 days. If the petitioner intends to support the 3.0 lb ai/A seasonal rate, data would be required reflecting pre-emergence applications at 1.0 lb ai/A/crop to three successive spinach crops.

The temporary tolerance for residues in/on spinach is 0.3 ppm; however, the available data indicate that a level of 0.50 ppm would be more appropriate for a permanent tolerance on spinach. In addition, these data would support a similar use of *S*-metolachlor (EC) on spinach at a maximum rate of 0.6 lb ai/A. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on spinach.

The crop field trials for metolachlor on spinach are classified acceptable and satisfy the guideline requirement for crop field trials (Residue Chemistry Guidelines OPPTS 860.1500).

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality were provided.

I. MATERIALS AND METHODS

The registrant used gas chromatographic/nitrogen-phosphorus detection (GC/NPD) methods, Analytical Methods AG-338 (modified) and AG-612, to determine residues of metolachlor in/on spinach. These methods are similar to Method I in PAM, Vol. II, and determine residues metolachlor and its metabolites as CGA-37913 and CGA-49751 following acid hydrolysis. The combined residues of CGA-37913 and CGA-49751 are expressed in parent equivalents.

A brief description and procedural recovery data were submitted in conjunction with the subject residue field trial data. Samples from the 1994 field trials were analyzed at the USDA-ARS-NRI-Environmental Chemistry Laboratory (ECL), Beltsville, MD, using an updated version (6/90) of Method AG-338. Samples from the 1995 field trials were analyzed at the IR-4 Western Region Leader Laboratory (WRLL), Davis, CA, using Method AG-612, which is an updated version of AG-338.

For both methods, samples are first refluxed in 6 N HCl for 16 hours and filtered. For analysis of CGA-37913, an aliquot of the acid extract is made basic. Residues are partitioned into hexane, and cleaned up using a silica Sep Pak. Residues of CGA-37913 are then analyzed by GC/NPD. For analysis of CGA-49751, residues in an aliquot of the acidic hydrolysate are partitioned directly into dichloromethane, washed with a 5% sodium carbonate solution, and cleaned up using a silica Sep Pak. Residue of CGA-49751 are then derivatized with boron trichloride/2-trichloroethanol at 90°C for 30 minutes, partitioned into hexane, and cleaned up on an alumina column. The derivatized residues are then determined by GC/NPD. The method limits of quantitation (LOQ) for CGA-37913 and CGA-49751, expressed in parent equivalent, are 0.03 and 0.05 ppm, respectively, in/on spinach.

Concurrent method recoveries were provided to determine the adequacy of the method for data collection purposes. Samples of untreated spinach the current field trials were fortified separately with CGA-37913 and CGA-49751 and analyzed concurrently with the treated samples. The results of concurrent method analyses of fortified untreated samples are detailed below. For Method AG-338 (modified), the average method recoveries were unacceptable (160 and 210%) for CGA-37913 from samples fortified at 0.05 and 0.1 ppm, but were acceptable (90 and 92%) for CGA-37913 from samples fortified at 0.5 and 1.0 ppm; the average method recoveries for CGA-49751 were 83-113%. For Method AG-612, the average method recoveries were 88-99% for CGA-37913 from spinach samples fortified at 0.03-1.0 ppm and 102-117% for CGA-49752 from spinach samples fortified at 0.05-1.0 ppm. Adequate chromatograms and sample calculations were provided.

The GC/NPD Methods AG-338 (modified) and AG-612 are adequate for collecting data on residues of metolachlor in/on spinach.

1. Test Compounds

Chemical name: Metolachlor

IUPAC: 2-chloro-6'ethyl-*N*-(2-methyoxy-1-methyl ethyl) acet-*o*-toluidide

CAS name: 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide

CAS #: 51218-45-2

Common name (ANSI, BSI or ISO): metolachlor

Developmental (Company) name: CGA-24705

2. Trial Numbers and Locations

Metolachlor trials at 1x

Crop (commodity)	US Growing Regions							Total Trials
	1	2	4	5	6	9	10	
Spinach (leaves)								
Submitted	1	3	1	1	2	0	3	11
Requested	1	2	0	0	2	1	2	8

Comments: The number of crop field trials conducted for a preemergence use of metolachlor on spinach are adequate, and although the distribution of field trial varied from the recommended distribution, geographic representation is also adequate. In addition to the 1x tests, the petitioner also conducted 5 tests at 2x the proposed rate in Region 6 (2 tests) and Region 10 (3 tests).

3. Proposed Use Pattern

Metolachlor 8 lb/gal EC

Crop	Application					Comments/ Restrictions
	Method/ Timing	Max. Single Rate (lb ai/A)	Max. No. per Season	Total Seasonal Rate (lb ai/A)	PHI [a] (days)	
Spinach	Preemergence broadcast application	1.0 [b]	3	3.0	None	A maximum of one application is allowed per crop with up to three applications per season.

[a] PHI = post-harvest interval, the number of days between the last application and harvest.

[b] Maximum recommended rates are based on soil type: coarse soils, 0.5 lb ai/A; medium textured soils, 0.75 lb ai/A; and fine textured soils, 1.0 lb ai/A.

Comments: The proposed use directions are not adequate as none of the field trials examined residues resulting from multiple croppings of spinach, each treated 1.0 lb ai/A/crop, for a

maximum seasonal rate of 3 lb ai/A/season. Based upon the available spinach field trial data, the petitioner should amend the proposed label to specify use of a single pre-emergence broadcast application of metolachlor (EC) at up to 1.0 lb ai/A to one crop of spinach per year, with a 40-day PHI. The available residue data could also be used to support a similar use of *S*-metolachlor on spinach at up to 0.6 lb ai/A.

4. Analytical Method Validation (Concurrent)

Crop matrix	Analyte	Spiking Level (mg/kg)	Recoveries obtained (%)	Range (%)	Mean ± SD (%)
CG/NPD Method AG-338 (modified), 1994 samples					
Spinach	CGA-37913	0.05	200, 160, 280, 200	160-280	210 ± 50
		0.10	160, 160, 160	NA	160
		0.50	66, 106, 86, 116, 88	66-116	92 ± 19
		1.00	101, 79, 79, 99	79-101	90 ± 12
	CGA-49751	0.05	100, 120, 120, 100	100-120	110 ± 12
		0.10	120, 110, 110	110-120	113 ± 6
		0.50	94, 134, 108, 80, 78	78-134	99 ± 23
		1.00	69, 97, 110, 55	55-110	83 ± 25
CG/NPD Method AG-612, 1995 samples					
Spinach	CGA-37913	0.03	107, 127, 92, 65, 65, 73	65-127	88 ± 25
		0.50	99, 120, 86, 87, 105, 115, 118, 84, 81	81-120	99 ± 16
		1.00	84, 103, 91, 107, 109, 98, 99, 63, 84, 86, 78, 88	63-109	91 ± 13
	CGA-49751	0.05	113, 125, 120, 124, 104, 116	104-125	117 ± 8
		0.50	127, 114, 108, 101, 103, 90, 82, 89	82-127	102 ± 15
		1.00	89, 97, 99, 110, 107, 103, 112, 114, 120, 147, 136, 111	89-147	112 ± 16

Comments: In the analysis of the 1994 samples (Method AG-338, modified), recoveries of both analytes were unusually high (100-280%) at the lower fortification levels (0.05 and 0.1 ppm); however, recoveries at the 0.5 and 1.0 ppm fortifications were in the acceptable 70-120% range, except for three marginal recoveries (55, 66, and 69%). In the analysis of the 1995 samples (Method AG-612), recoveries of both analytes were generally acceptable at each fortification level, although recoveries of CGA-49751 tended to be high with average recoveries of 102-117%. Based on the concurrent method recoveries, these GC/NPD Methods are adequate for collecting data on metolachlor residues in/on spinach.

5. Storage Stability

Sample Storage Conditions

Commodities	Analytes	Tests	Storage Temperature (°C)	Storage Duration (months)
Spinach	CGA-37913/ CGA-49751	1994	≤-20	4.5-5.8
		1995	-20 ± 6	6.5-13.2

Stability of CGA-39713 and CGA-49751 in Spinach Stored at -20 C

Commodity	Analyte	Spiked Residue Level (ppm)	Storage interval (days)	Fresh Spike Recovery	Recovery in Stored Sample
Spinach (1994 tests)	CGA-37913	0.1	166	none	160, 150
		0.5			96, 96
		1.0			99, 92
	CGA-49751	0.1	166	none	70, 60
		0.5			80, 94
		1.0			103, 103
Spinach (1995 tests)	CGA-39713	1.0	342	88	112, 102, 101
	CGA-49751	1.0	342	111	87, 94, 78

Comments: Samples of spinach (leaves and stems) from all tests were harvested at maturity (34-69 days post-treatment) and immediately frozen. Samples from 1994 tests were then shipped frozen by freezer truck to ECL, Beltsville, MD, where samples were stored at ≤-20 C until extraction for analysis; the total storage interval for the 1994 tests was 138-178 days (5-6 months). Samples from the 1995 tests were shipped by freezer truck or on dry ice by overnight courier to WRLL, Davis, CA, either directly or via Beltsville, MD. Samples were then stored at WRLL at -20 C until extraction for analysis; the total storage interval for the 1995 tests was 190-401 days (6-13 months).

To support the storage intervals in the spinach tests, the petitioner separately fortified duplicate control samples from the 1994 tests with CGA-37913 and CGA-49751 at 0.1, 0.5 and 1.0 ppm. These samples were later analyzed after 166 days of storage at -20 C. The petitioner also separately fortified triplicate control samples from the 1995 tests with CGA-37913 and CGA-49751 at 1.0 ppm; these samples were then analyzed after 342 days of storage at -20 C. Although zero day analyses were conducted on the stored samples and recoveries from the stored samples were variable, the storage stability indicate that residues of CGA-37913 and CGA49751 are stable in frozen spinach for at least 342 days (11 months). Considering that these analytes have also been shown to be stable in frozen corn forage for up to 2 years (DP Barcodes D222430 and D224237, S. Hummel, 2/25/97), the above data are adequate to support the storage intervals in the current spinach field trials.

6. Application and RAC Information

Metolachlor-Dual or Dual 8E (8 lb/gal EC)-Spinach

LOCATION (city /state/year)	EPA Region	Spinach Variety	APPLICATION					HARVEST PROCEDURES		
			Growth Stage at first appl. [a]	# of appl.	Single Rate (lb ai/A) [b]	Method	Spray Volume (gal/A)	Growth Stage/ Harvest	Harvested Portion	Number and wt. of samples
Alma/ AR/ 1994	4	Fall Green	preemergence	1	1	broadcast soil	20	Mature	leaves and stems	Duplicate samples were collected from each test, but sample weights were not specified
Crossville/ TN/ 1994	2	Asgrow Hybrid Seven R	preemergence	1	1	broadcast soil	33	Mature	leaves and stems	
Riverhead/ NY/ 1994	1	Melody	preemergence	1	1	broadcast soil	30	Mature	leaves and stems	
Salisbury/ MD/ 1995	2	Melody	preemergence	1	1	broadcast soil	24	Mature	leaves and stems	
East Lansing/ MI/ 1995	5	Ambassador	preemergence	1	1	broadcast soil	20	Mature	leaves and stems	
Bridgeton/ NJ/ 1995	2	Kent	preemergence	1	1	broadcast soil	40	Mature	leaves and stems	
Salinas/ CA/ 1995	10	Polka	preemergence	1	1	broadcast soil	47	Mature	leaves and stems	
					2					
Holtville/ CA/ 1995	10	Bloomsdale Long Standing	preemergence	1	1	broadcast soil	42	Mature	leaves and stems	
					2					
Monterey/ CA/ 1995	10	Bossanova	preemergence	1	0.94	broadcast soil	53	Mature	leaves and stems	
					2.18					
Weslaco/ TX/ 1995	6	Fall Green	preemergence	1	1.04	broadcast soil	30	Mature	leaves and stems	
					2.16					
Weslaco/ TX/ 1995	6	Fall Green	preemergence	1	1.02	broadcast soil	30	Mature	leaves and stems	
					2.03					

[a] Preemergence broadcast soil application was made 0-14 days after planting.; none of the applications included a adjuvant.

[b] The maximum proposed application rate is 1.0 lb ai/A/crop; however, the seasonal application rate is 3.0 lb ai/A.

Comments: The current field trials do not reflect the proposed use directions for spinach as none of the tests examined residues resulting from multiple croppings of spinach, each treated 1.0 lb ai/A/crop, for a maximum seasonal rate of 3 lb ai/A/season. The available spinach residue data would support use of a single pre-emergence broadcast application of metolachlor (EC) at up to 1.0 lb ai/A to one crop of spinach per year, with a 40-day PHI. These residue data could also support a similar use of *S*-metolachlor on spinach at up to 0.6 lb ai/A.

7. Site Specific Information

LOCATION (city/state/ year)	FARMING PRACTICES			SOIL CHARACTERISTICS				
	CULTIVATION/ IRRIGATION*	FERTILIZER	MAINTENANCE CHEMICALS/RATE/TIMING	TYPE	% Organic Matter (OM)	pH	CEC (meq/100 g)	WEATHER DATA** (T°C, rainfall)
Alma/ AR/ 1994	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silt loam	0.4	6.3	not reported (NR)	Air temperature and precipitation within normal range vs. historical weather data.
Crossville/ TN/ 1994	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.3	6.3	NR	Air temperature and precipitation within normal range vs. historical weather data.
Riverhead/ NY/ 1994	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	NR	5.8	NR	Air temperature and precipitation within normal range vs. historical weather data.
Salisbury/ MD/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.1	5.8	NR	Air temperature and precipitation within normal range vs. historical weather data.
East Lansing/ MI/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.7	6.2	NR	Air temperature and precipitation within normal range vs. historical weather data.
Bridgeton/ NJ/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.7	6.3	NR	Air temperature and precipitation within normal range vs. historical weather data.
Salinas/ CA/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy loam	1.3	7.3	NR	Air temperature and precipitation within normal range vs. historical weather data.
Holtville/ CA/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	1	7.4	NR	Air temperature and precipitation within normal range vs. historical weather data.
Monterey/ CA/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Silty clay loam	1.8	7.2	NR	Air temperature and precipitation within normal range vs. historical weather data.
Weslaco/ TX/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Fine sandy loam	0.4	7.5	NR	Air temperature and precipitation within normal range vs. historical weather data.
Weslaco/ TX/ 1995	Common cultural practices used to maintain plants	Maintenance chemicals and fertilizer used did not effect residue data		Sandy clay loam	NR	8.3	NR	Air temperature and precipitation within normal range vs. historical weather data.

II. RESULTS

TABLE 1. Residue Data Summary from Spinach Crop Field Trials: Metolachlor - Spinach

Location (city/ state/ year)	Spinach Variety	Formulation	Application			PHI (days) [b]	Residues (mg/kg) [c]		
			Rate (lb ai/A)	# of Appl.	% of Max Rate [a]		CGA-37913	CGA-49751	Combined [d]
Alma/ AR/ 1994	Fall Green	8 lb/gal EC	1	1	100	49	0.04, 0.33	0.10, <0.05	**0.14, <0.38**
Crossville/ TN/ 1994	Asgrow Hybrid Seven R	8 lb/gal EC	1	1	100	45	0.09, 0.09	<0.05, <0.05	**<0.14, <0.14**
Riverhead/ NY/ 1994	Melody	8 lb/gal EC	1	1	100	56	0.04, 0.05	<0.05, <0.05	**<0.09, <0.10**
Salisbury/ MD/ 1995	Melody	8 lb/gal EC	1	1	100	41	0.062, 0.107	0.085, 0.067	**0.147, 0.174**
East Lansing/ MI/ 1995	Ambassador	8 lb/gal EC	1	1	100	39	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
Bridgeton/ NJ/ 1995	Kent	8 lb/gal EC	1	1	100	34	0.099, 0.077	0.068, 0.089	**0.167, 0.166**
Salinas/ CA/ 1995	Polka	8 lb/gal EC	1	1	100	46	<0.03, <0.03	0.061, <0.05	**<0.091, <0.08**
			2	1	200	46	0.044, 0.045	0.102, 0.129	0.146, 0.174
Holtville/ CA/ 1995	Bloomsdale Long Standing	8 lb/gal EC	1	1	100	67	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			2	1	200	67	<0.03, 0.036	<0.05, <0.05	<0.08, <0.086
Monterey/ CA/ 1995	Bossanova	8 lb/gal EC	0.94	1	94	41	<0.03, <0.03	<0.05, <0.05	**<0.08, <0.08**
			2.18	1	218	41	0.032, <0.03	0.065, 0.081	0.097, <0.111
Weslaco/ TX/ 1995	Fall Green	8 lb/gal EC	1.04	1	104	69	0.037, 0.031	<0.05, <0.05	**<0.087, <0.081**
			2.16	1	216	69	0.070, 0.075	<0.05, 0.188	<0.120, 0.263
Weslaco/ TX/ 1995	Fall Green	8 lb/gal EC	1.02	1	102	69	0.037, <0.03	0.062, <0.05	**0.099, <0.08**
			2.03	1	203	69	0.065, 0.059	0.139, 0.132	0.204, 0.191

[a] The proposed maximum rate of metolachlor (EC) is 1.0 lb ai/A/crop, with a total seasonal rate of 3.0 lb ai/A.

[b] PHI=Post-Harvest Interval; a PHI was not proposed.

[c] Residues of both CGA-37913 and CGA-49751 are expressed in parent equivalents.

[d] Combined residues in/on spinach resulting from the maximum proposed use rate (1.0 lb ai/A/crop) are **bolded**.

Comments: Permanent tolerances for residues of metolachlor in/on plant and animal commodities have been established under 40 CFR §180.368(a) and are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor and its metabolites, determined as CGA-37913 and CGA-49751, each expressed as the parent compound. Permanent tolerances for residues in/on plant commodities range from 0.1-30 ppm in/on a variety of plant commodities. A temporary tolerance has also been established for metolachlor residues in/on spinach at 0.3 ppm [40 CFR §180.368(b)], set to expire 6/30/02. Tolerances for metolachlor presently cover residues resulting from the use of *S*-metolachlor.

The nature of the residue in plants and animals is adequately understood. Metolachlor residues of concern in plants and animal commodities include metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751. The residues of concern for *S*-metolachlor in plants and animals are the same as for metolachlor (DP Barcode D226780, L. Kutney, 11/12/96).

In a total of 11 tests, the combined residues of CGA-37913 and CGA-49751, each expressed as parent, were <0.08-<0.38 ppm in/on 22 samples of spinach harvested 34-69 days following a single pre-emergence broadcast soil application of metolachlor (8 lb/gal EC) at ~1.0 lb ai/A (1x the proposed rate). Combined residues were <0.08 ppm (<LOQ) in/on 21 control samples of spinach and <0.082 ppm in/on a single control sample from one test.

At five of the test sites, metolachlor (8 lb/gal EC) was also applied to separate plots as a pre-emergence broadcast soil application at ~2.0 lb ai/A (2x). In these tests, the combined metolachlor residues were <0.08-0.263 ppm in/on 10 samples of spinach harvested 41-69 days post-treatment.

The maximum frozen storage interval from harvest to extraction was 13 months for spinach; this storage interval is supported by the available storage stability data.

III. CONCLUSIONS

Provided that the proposed use directions are amended, the submitted spinach field trial data are adequate. In a total of 11 tests, combined metolachlor residues were <0.08-<0.38 ppm in/on 22 samples of spinach harvested 34-69 days following a single broadcast pre-emergence application of metolachlor (8 lb/gal EC) at 1.0 lb ai/A (1x propose rate/crop).

Based on the concurrent method recoveries, the GC/NPD Methods AG-338 and AG-612 are adequate for collecting data on combined residues of CGA-37913 and CGA-49751, expressed as parent, in/on spinach. The combined LOQ is 0.08 ppm in/on spinach; no interference was observed in representative chromatograms of control samples from the analysis of spinach.

The available spinach field trial data would support a permanent tolerance of 0.50 ppm for residues of metolachlor in/on spinach provided that the label directions for metolachlor (EC) on spinach are amended to specify a maximum seasonal rate of 1.0 lb ai/A and a PHI of 40 days. These data would also support a similar use of *S*-metolachlor (EC) on spinach a maximum rate of 0.6 lb ai/A. If the petitioner intends to support the 3.0 lb ai/A seasonal rate,

data would be required reflecting pre-emergence applications at 1.0 lb ai/A/crop to three successive spinach crops. There are no Mexican, Canadian or Codex MRLs established for combined metolachlor residues in/on spinach.

IV. STUDY DEFICIENCIES

There were no deficiencies that would have an impact on assessing a tolerance for metolachlor on spinach.

V. REFERENCES

DP Barcode:	D226780
Subject:	Replacement of Metolachlor Technical (Racemic Metolachlor) with Alpha-Metolachlor (formerly called Chiral Metolachlor) Technical; Review of Bridging Data.
From:	L. Kutney
To:	R. Giffin
Dated:	11/12/96
MRID(s):	43928901-43928903 and 43928939-43928942

DP Barcodes:	D222430 and D224237
Subject:	Metolachlor (108801) Reregisration Case No. 0001. Craven Replacement Data for Peanuts treated at layby; Safflower, including processed fractions; and Storage stability data on tomato, potato, and soy processed fractions
From:	S. Hummel
To:	M. Metzger
Dated:	2/25/97
MRID(s):	43881701-43881703 and 43944601

13544

042102

Chemical: (S)-2-Chloro-N-(2-ethyl-6-methylphenyl)-

PC Code: 108800
HED File Code 11000 Chemistry Reviews
Memo Date: 02/28/2002
File ID: DPD280215
Accession Number: 412-02-0282

HED Records Reference Center
05/22/2002