



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

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 Oak Ridge, TN

Date: 8/1/05

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 TRB/RD

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

This DER was originally prepared by Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN 37831. The DER has been reviewed by TRB and revised to reflect current OPP policies.

MRID No. 46203206. Hampton, M. M. (January 26, 2004) NOA-407855- Residue levels on wheat (forage, hay, grain and straw) from trials conducted with two variants of a 100EC formulation and a 120EC formulation in Canada during 2003: Syngenta Project Number: CER 0708/03. Unpublished study prepared by Syngenta Crop Protection Canada, Inc., 140 Research Lane, Guelph, Ontario, N1G 4Z3, Canada. 388 pages.

EXECUTIVE SUMMARY: Syngenta Crop Protection has submitted field trial data for cloquintocet-mexyl (CGA-185072) on wheat. Twenty trials were conducted encompassing Canadian Regions 5 (2, Manitoba), 7 (4, Alberta; 3, Saskatchewan), 7A (1, Alberta), and 14 (4, Alberta; 3, Manitoba; 3, Saskatchewan) during the 2003 growing season. The number and locations of the field trials are in accordance with Directive 98-02; Section 9.

Cloquintocet-mexyl is a safener that is applied in the herbicide formulation NOA-407855. At each test location, treatment consisted of a single broadcast spray application of NOA-407855 formulation 100EC Lead Variant (A-12303C). At three sites, two additional test plots were treated with a single broadcast spray application of other NOA-407855 formulations. On one of the additional plots the NOA-407855 formulation was 100EC Alternate Variant (A-12303D), and on the other it was NOA-407855 formulation 120EC Aromatic 200 (A-12413B). All of these formulations contain cloquintocet-mexyl as a safener. All treatments had an application of cloquintocet-mexyl at 0.016 lb a.i./A (0.018 kg a.i./ha). One of the following adjuvant activators was added to the spray mixture for all applications: A12127, A12127S, or MERGE. The single application was applied up to the crop growth stage BBCH 23. Excluding the last two treatments in the two decline trials, pre-harvest intervals (PHIs) for forage, hay, grain and straw were 4-25, 22-50, 58-98 and 58-98 days, respectively.

Residues of metabolite CGA-153433 were quantified using Analytical Method REM 199.02. The method converts all of the cloquintocet-mexyl to this acid metabolite. Quantification of residues was based on LC/MS/MS (liquid chromatography coupled to tandem mass spectrometry). Satisfactory method performance in detecting CGA-153433 was demonstrated by concurrent recoveries. Freezer storage intervals ranged from 36-149 days after harvest. Residues of the cloquintocet-mexyl have been shown to be stable in all matrices for the duration of storage that occurred during the conduct of this study. The results from these trials show that maximum CGA-153433 residues were 0.114 ppm in forage, < 0.02 ppm (the LOQ) in hay and straw, and



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<0.01 ppm (the LOQ) in grain. Residue decline data show that residues of CGA-153433 on forage decrease with increasing PHIs. Since there were no quantifiable residues on hay, grain, and straw at any PHIs, the decline studies provided no evidence that cloquintocet-mexyl residues increase with increasing PHIs on those commodities.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS: Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. All data generated and collected during the conduct of this study was in compliance with the Canadian OECD GLP regulations with the following exceptions:

1. Some study site data (e.g., historical pesticide and fertilizer use, historical planting and cultivation/tillage records, etc.) were obtained from non-GLP grower or property owner records.
2. Soil characteristics (sampling and analysis) were documented but not done to full GLP compliance standards.
3. The weather data was obtained from non-GLP Environment Canada Atmospheric Environment Service Weather Stations or from non-GLP on-site records.
4. The application of maintenance chemicals was documented but was not done to full GLP standards.
5. The field data contained a few accidental GLP deviations. These included some entries that were not dated and initialed at the time of entry; error corrections that were made without date, initials and/or error code; and a few late entries in activity logs and plot maintenance forms in the RTNs.

None of the deviations had an adverse effect on the acceptability of the study. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470 and in Canada's Regulatory Decision Document.

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

A. BACKGROUND INFORMATION: Cloquintocet-mexyl is needed as a safener to prevent damage to the wheat due to phytotoxic effects.

TABLE A.1. Test Compound Nomenclature
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Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

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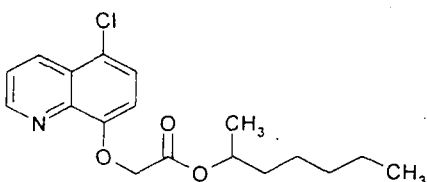
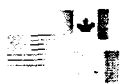
Compound	
Common name	Cloquintocet-mexyl
Company experimental name	CGA 185072
IUPAC name	(5-chloroquinolin-8-yloxy)acetic acid-1-methylhexylester
CAS name	[(5-chloro-8-quinolinyl)oxy]acetic acid-1-methylhexyl ester
CAS #	99607-70-2
End-use product/(EP)	Safener in formulations of Pinoxaden (NOA-407855) as well as in HORIZON® 240EC Herbicide (a synonym for HORIZON® is DISCOVER®).

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	-
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html;
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	



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B. EXPERIMENTAL DESIGN:**B.1. Study Site Information**

TABLE B.1.1 Trial Site Conditions			
Trial Identification (City, Province, Canadian Crop Region) All in 2003. Field test number is also listed.	Soil characteristics	Meteorological data	
	Type 0-10 cm 10-25 cm below 25cm	Overall monthly rainfall range (mm)	Overall range of mean T°C
Elm Creek, Manitoba (5) # T566	Sandy loam Loamy sand Loamy sand	27.7-110.6	12.4-21.2
Elm Creek, Manitoba (5) # T567	Sandy loam Loamy sand Loamy sand	27.7-110.6	12.4-21.2
Delisle, Saskatchewan (7) # T568	Silt clay loam Silt clay loam Silt clay loam	22.8-64.8	12.0-20.7
Vanscoy, Saskatchewan (7) # T569	Silt loam Silt loam Silt loam	22.8-64.8	12.0-20.7
Vanscoy, Saskatchewan (7) # T570	Silt loam Silt loam Silt loam	22.8-64.8	12.0-20.7
Wrentham, Alberta (7) # T571	Loam Loam Clay loam	0-50.8	11.3-20.0
Taber, Alberta (7) # T572	Loam Loam Loam	0-50.8	11.3-20.0
Wrentham, Alberta (7) # T573	Loam Loam Clay loam	0-50.8	11.3-20.0
Taber, Alberta (7) # T574	Loam Loam Loam	0-50.8	11.3-20.0
Taber, Alberta (7A) # T575	Loam Clay loam Clay loam	0-50.8	11.3-20.0
Rosthern, Saskatchewan (14) # T576	Clay loam Clay loam Clay loam	13.4-58.8	12.2-21.6
Lacombe, Alberta (14) # T577	Loam Clay loam Clay loam	10.6-45.2	8.5-16.8



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Trial Identification (City, Province, Canadian Crop Region) All in 2003. Field test number is also listed.	Soil characteristics	Meteorological data	
	Type 0-10 cm 10-25 cm below 25cm	Overall monthly rainfall range (mm)	Overall range of mean T°C
Penhold, Alberta (14) # T578	Loam Clay loam Clay loam	13.2-89.7	8.4-17.2
Penhold, Alberta (14) # T579	Clay loam Clay loam Clay loam	13.2-89.7	8.4-17.2
Lacombe, Alberta (14) # T580	Loam Clay loam Clay loam	10.6-45.2	8.5-16.8
Rosthern, Saskatchewan (14) # T581	Clay loam Clay loam Clay loam	13.4-58.8	12.2-21.6
Hepburn, Saskatchewan (14) # T582	Clay loam Clay loam Clay loam	13.4-58.8	12.2-21.6
Minto, Manitoba (14) # T583	Clay loam Clay loam Clay loam	8.9-64.8	11.5-21.4
Minto, Manitoba (14) # T584	Clay loam Clay loam Clay loam	8.9-64.8	11.5-21.4
Boissevain, Manitoba (14) # T585	Clay loam Clay loam Clay loam	8.9-64.8	11.5-21.4

The actual rainfall and temperature for the residue study period are close to historical values. In five trials (3 at Wrentham, Alberta, and 2 at Taber, Alberta), which all used the same reporting station at Taber, the weather was unusually dry in May, July, and August, while approaching normal in June. Irrigation was not used to supplement rainfall in any field trial.

TABLE B.1.2. Study Use Pattern.							
Location (City, Province, Canadian Crop Region) All in 2003. Field test number is also listed.	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing CGS = crop growth stage	Vol GPA ² (L/ha)	App. Rate ⁵ lb a.i./A (kg a.i./ha)	RTI ³ days	Total Rate ⁴ lb a.i./A (kg a.i./ha)	
Elm Creek, Manitoba (5) # T566	N1	1. Broadcast spray no later than CGS BBCH 23	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Elm Creek, Manitoba (5) # T567	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Delisle, Saskatchewan (7) # T568	N1	1. Broadcast spray no later than CGS BBCH 23.	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127M



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TABLE B.1.2. Study Use Pattern.

Location (City, Province, Canadian Crop Region) All in 2003. Field test number is also listed.	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing CGS = crop growth stage	Vol GPA ² (L/ha)	App. Rate ⁵ lb a.i./A (Kg a.i./ha)	RTI ³ days	Total Rate ⁴ lb a.i./A (Kg a.i./ha)	
	N2	1. Broadcast spray no later than CGS BBCH 23.					
	N3	1. Broadcast spray no later than CGS BBCH 23.					
Vanscoy, Saskatchewan (7) # T569	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127M
Vanscoy, Saskatchewan (7) # T570	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Wrentham, Alberta (7) # T571	N1	1. Broadcast spray no later than CGS BBCH 23.	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Taber, Alberta (7) # T572	N1	1. Broadcast spray no later than CGS BBCH 23.	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Wrentham, Alberta (7) # T573	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Taber, Alberta (7) # T574	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Taber, Alberta (7A) # T575	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Rosthern, Saskatchewan (14) # T576	N1	1. Broadcast spray no later than CGS BBCH 23.	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Lacombe, Alberta (14) # T577	N1	1. Broadcast spray no later than CGS BBCH 23.	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Penhold, Alberta (14) # T578	N1	1. Broadcast spray no later than CGS BBCH 23.	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Penhold, Alberta (14) # T579	N1	1. Broadcast spray no later than CGS BBCH 23.	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Lacombe, Alberta (14) # T580	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Rosthern, Saskatchewan (14) # T581	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Hepburn, Saskatchewan (14) # T582	N1	1. Broadcast spray no later than CGS BBCH 23.	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Minto, Manitoba (14) # T583	N1	1. Broadcast spray no later than CGS BBCH 23.	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127S
	N2	1. Broadcast spray no later than CGS BBCH 23.					
	N3	1. Broadcast spray no later than CGS BBCH 23.					



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TABLE B.1.2. Study Use Pattern.							
Location (City, Province, Canadian Crop Region) All in 2003. Field test number is also listed.	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing CGS = crop growth stage	Vol GPA ² (L/ha)	App. Rate ³ lb a.i./A (kg a.i./ha)	RTI ⁴ days	Total Rate ⁴ lb a.i./A (kg a.i./ha)	
Minto, Manitoba (14) # T584	N1	1. Broadcast spray no later than CGS BBCH 23.	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	MERGE
	N2	1. Broadcast spray no later than CGS BBCH 23.					
	N3	1. Broadcast spray no later than CGS BBCH 23.					
Boissevain, Manitoba (14) # T585	N1	1. Broadcast spray no later than CGS BBCH 23.	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	MERGE

¹EP = End-use Product: N1 = NOA-407855 formulation 100EC Lead Variant (A-12303C); N2 = NOA-407855 formulation 100EC Alternate Variant (A-12303D); N3 = NOA-407855 formulation 120EC Aromatic 200 (A-12413B).

²Gallons per acre. L/ha

³Retreatment Interval

⁴This is the rate of application of the safener cloquintocet-mexyl.

TABLE B.1.3. Trial Numbers and Geographical Locations			
NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
1			
1A			
2			1
3			
4			1
5	2	2	5
5A			
5B			
6			1
7	7	7	5
7A	1	1	
8			6
9			
10			
11			1
12			
13			
14	10	10	



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15			
16			
17			
18			
19			
20			
21			
Total	20	20	20

- B.2. Sample Handling and Preparation:** At least two replicates of each RAC were collected from each of the 20 trials. All samples were put into frozen storage (< 10°C) on the day collected and kept frozen. Details were not presented on the preparation done prior to extraction except to state that samples were completely homogenized.
- B.3. Analytical Methodology:** The analytical method used in this study was Analytical Method 199.02 (unspecified author, 2002). The principle of the analytical method is that an acid hydrolysis extraction will convert cloquintocet-mexyl and all conjugates to its acid metabolite, 5-chloro-8-quinolinoxylacetic acid (CGA-153433). Commodity specific cleanup procedures are followed by analysis by LC/MS/MS (liquid chromatography coupled to tandem mass spectrometry) to detect any CGA-153433 produced by the acid hydrolysis extraction, as well as any that was present previously because of metabolism in the wheat. The LOQ is 0.010 ppm for grain and 0.020 ppm for forage, hay and straw. The LOD is half the LOQ for all commodities. Recoveries of cloquintocet-mexyl residues from samples fortified from 0.02 to 0.20 ppm in forage, hay, and straw and from 0.01 to 0.10 ppm in grain ranged from 83.9-170.1%, with a mean and SD of $104.5 \pm 17.9\%$, as calculated by the reviewer. Although four values exceeded 120%, only one was higher than 125.1%.
- C. RESULTS AND DISCUSSION:** CGA-153433 levels in samples of wheat RACs collected in the 20 field trials are shown in Tables C.3 and C.4. With few exceptions, there was a corresponding control sample for each pair of experimental samples, and the control residue levels of CGA-153433 were always below the LOQ. Forage was the only wheat RAC with quantifiable levels of CGA-153433, with the highest residue level at 0.114 ppm found in a sample with a 6-day PHI. The largest HFT was 0.099 ppm.

Details on storage are shown in Table C.2. No information on storage stability was presented. Wheat forage, which was the commodity held in frozen storage the longest, was stored a maximum of five months. Storage stability was previously known to be an issue regarding study of cloquintocet-mexyl, based on analysis in studies in which this safener was applied to wheat in combination with a different herbicide (PP#7E4920, DP Barcode: D257181, MRID: 46203204, N. Dodd, 4/7/00). It was found that, when stored at -18°C, cloquintocet-mexyl declined 17% in wheat grain stored for 728 days and 31% in wheat straw stored for 731 days. It was concluded that because degradation was shown for



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cloquintocet-mexyl in wheat grain and straw, storage stability data will be required for any future uses on all crops/substrates for which tolerances are requested. It is known from that earlier storage stability studies demonstrated the stability of the acid metabolite CGA-153433 in wheat hay under freezer storage for a minimum of 18 months and in wheat germ for five months. CGA-153433 was also found to be stable in wheat straw for up to 380 days (PP#7E04920, DP Barcode: D257181, MRID 46203203, N. Dodd, 4/7/2000). Syngenta has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage (MRID 46012916, W. Cutchin, in process). Syngenta has also submitted the results of a storage stability study with metabolite CGA-153433 in wheat germ. The results indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage (MRID 46012917, W. Cutchin, in process). There is adequate data on storage stability to support the period of storage in the present study.

The procedural recoveries only tested samples that were fortified with CGA-153433. Results, which are presented in Table C.1, indicate that the concurrent recoveries were almost all within the OPPTS 860.1340 guideline acceptable range of 70-120%. Recoveries overall ranged from 60.5-127.4%, with a mean and SD of $97.4 \pm 15.0\%$ ($n = 36$). One value was less than 70% and one exceeded 120%. These results show that the analytical method effectively measured cloquintocet-mexyl metabolite CGA-153433 residues in wheat RACs. The petitioner presented adequate calibration curves and chromatograms to indicate that the method is free from interferences.

Table 2 of MRID 46203206 almost certainly contains an error of a 0.022 ppm that was transcribed as 0.22 ppm. If this were not an error, 0.22 ppm would have been the maximum value for forage instead of 0.114 ppm. Table C.3 corrects that error, as noted in footnote 3. The decline studies suggest that residues decrease over time in forage. The difference shown in Table C.4 between the CGA-153433 levels in forage at PHI intervals of 4-8 days and 10-31 days is consistent with the conclusion that residues decrease rapidly with time. Since there were no quantifiable residues on hay, grain and straw at any PHIs, the decline studies merely provided no reason to think that cloquintocet-mexyl residues increase with increasing PHIs on those commodities. The three bridging trials that compared different formulations were #T568, #T583 and #T584. Table C.3 shows that the CGA-153433 levels were similar for all formulations.

When trials were in the same region, they were planted in different soil types or with different varieties of wheat or both, or else they were separated by at least 10 km. It seems unlikely that the farming practices used or the reported environmental conditions adversely affected the study. The volume of spray applied per given area was markedly lower in trials #571, #577, and #582. Trial #577 had a long PHI for forage of 15 days. Since the HAFT occurred in trial #582, it is possible that the low volume application increased the residue level



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slightly. The number of trials and their geographic representation was adequate.

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-mexyl from Wheat Forage, Grain Hay and Straw.				
Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
CGA-153433 (acid metabolite of cloquintocet-mexyl)				
Forage	0.2	2	105.3-118.0	111.7 $\pm$ 9.0
Forage	0.1	3	101.3-105.6	103.8 $\pm$ 2.2
Forage	0.02	5	81.3-111.8	97.4 $\pm$ 11.5
Grain	0.05	4	85.7-118.9	102.8 $\pm$ 14.5
Grain	0.01	4	81.8-107.9	93.4 $\pm$ 11.8
Hay	0.2	3	86.1-127.4	103.2 $\pm$ 21.6
Hay	0.1	2	77.6-93.9	85.8 $\pm$ 11.5
Hay	0.02	5	60.5-125.5	94.3 $\pm$ 27.1
Straw	0.2	3	85.1-98.0 ¹	92.2 $\pm$ 6.5
Straw	0.1	1	88.8	88.8
Straw	0.02	4	74.0-109.9	95.6 $\pm$ 16.3

¹Maximum value was assumed to be incorrectly shown as 90.0 in Table 10 of MRID 46203206; by using the value of 98.0 shown in Table 51 of that same MRID, the statistics of the study author and reviewer are in agreement.

TABLE C.2. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days)	Interval of Demonstrated Storage Stability (days)
Forage	<10	89-149	750
Hay	<10	58-129	750
Grain	<10	53-88	165
Straw	<10	36-77	750

TABLE C.3. Residue Data from Crop Field Trials with Cloquintocet-mexyl (measured as CGA-153433).							
Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP¹	Total Rate¹, lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
Elm Creek, Manitoba # T566	5	Wheat AC Barrie	Forage	N1	0.016 (0.018)	25	<LOD, <LOD
Elm Creek, Manitoba # T567	5	Wheat Majestic	Forage	N1	0.016 (0.018)	25	<LOD, <LOD
Delisle, Saskatchewan # T568	7	Wheat Eatonia	Forage	N1	0.016 (0.018)	7	(0.019) ² , 0.024
				N2	0.016 (0.018)	7	0.023, 0.028



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ² , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
				N3	0.016 (0.018)	7	0.026, 0.038
Vanscoy, Saskatchewan # T569	7	Wheat Prodigy	Forage	N1	0.016 (0.018)	7	0.045, 0.045
Vanscoy, Saskatchewan # T570	7	Wheat Eatonia	Forage	N1	0.016 (0.018)	8	0.028
						15	<LOD, <LOD
						22	<LOD
						29	<LOD
Wrentham, Alberta # T571	7	Wheat McKenzie	Forage	N1	0.016 (0.018)	5	0.063, 0.066
Taber, Alberta # T572	7	Wheat Prodigy	Forage	N1	0.016 (0.018)	6	0.038, 0.033
Wrentham, Alberta # T573	7	Wheat Prodigy	Forage	N1	0.016 (0.018)	5	0.062, 0.086
Taber, Alberta # T574	7	Wheat McKenzie	Forage	N1	0.016 (0.018)	6	0.026, 0.030
Taber, Alberta # T575	7	Wheat McKenzie	Forage	N1	0.016 (0.018)	7	0.021, 0.027
Rosthern, Saskatchewan # T576	14	Wheat AC Barrie	Forage	N1	0.016 (0.018)	7	0.051, 0.062
Lacombe, Alberta # T577	14	Wheat AC Crystal	Forage	N1	0.016 (0.018)	15	<LOD, <LOD
Penhold, Alberta # T578	14	Wheat Intrepid	Forage	N1	0.016 (0.018)	7	<LOD, (0.012) ²
Penhold, Alberta # T579	14	Wheat AC Crystal	Forage	N1	0.016 (0.018)	7	<LOD, (0.014) ²
Lacombe, Alberta # T580	14	Wheat AC Intrepid	Forage	N1	0.016 (0.018)	10	<LOD
						17	<LOD, <LOD
						24	<LOD
						31	<LOD
Rosthern, Saskatchewan # T581	14	Wheat AC Eatonia	Forage	N1	0.016 (0.018)	7	0.029, 0.045
Hepburn, Saskatchewan # T582	14	Wheat AC Barrie	Forage	N1	0.016 (0.018)	6	0.114, 0.084
Minto, Manitoba # T583	14	Wheat Super B	Forage	N1	0.016 (0.018)	5	0.091, 0.075
				N2	0.016 (0.018)	5	0.094, 0.063
				N3	0.016 (0.018)	5	0.052, 0.073



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ⁴ , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
Minto, Manitoba # T584	14	Wheat Avonlea	Forage	N1	0.016 (0.018)	7	0.030, 0.022
				N2	0.016 (0.018)	7	0.022 ³ , 0.031
				N3	0.016 (0.018)	7	(0.013) ² , 0.022
Boissevain, Manitoba # T585	14	Wheat AC Barrie	Forage	N1	0.016 (0.018)	4	0.024, 0.026
Elm Creek, Manitoba # T566	5	Wheat AC Barrie	Hay	N1	0.016 (0.018)	39	<LOD, <LOD
Elm Creek, Manitoba # T567	5	Wheat Majestic	Hay	N1	0.016 (0.018)	39	<LOD, <LOD
Delisle, Saskatchewan # T568	7	Wheat Eatonia	Hay	N1	0.016 (0.018)	35	<LOD, <LOD
				N2	0.016 (0.018)	35	<LOD, <LOD
				N3	0.016 (0.018)	35	<LOD, <LOD
Vanscoy, Saskatchewan # T569	7	Wheat Prodigy	Hay	N1	0.016 (0.018)	28	<LOD, <LOD
Vanscoy, Saskatchewan # T570	7	Wheat Eatonia	Hay	N1	0.016 (0.018)	22	<LOD
						29	<LOD
						36	<LOD, <LOD
						43	<LOD
						50	<LOD
Wrentham, Alberta # T571	7	Wheat McKenzie	Hay	N1	0.016 (0.018)	38	<LOD, <LOD
Taber, Alberta # T572	7	Wheat Prodigy	Hay	N1	0.016 (0.018)	28	<LOD, <LOD
Wrentham, Alberta # T573	7	Wheat Prodigy	Hay	N1	0.016 (0.018)	38	<LOD, <LOD
Taber, Alberta # T574	7	Wheat McKenzie	Hay	N1	0.016 (0.018)	33	<LOD, <LOD
Taber, Alberta # T575	0.2916667	Wheat McKenzie	Hay	N1	0.016 (0.018)	36	<LOD, <LOD
Rosthern, Saskatchewan # T576	14	Wheat AC Barrie	Hay	N1	0.016 (0.018)	35	<LOD, <LOD
Lacombe, Alberta # T577	14	Wheat AC Crystal	Hay	N1	0.016 (0.018)	29	<LOD, <LOD



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ⁴ , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
Penhold, Alberta # T578	14	Wheat Intrepid	Hay	N1	0.016 (0.018)	46	<LOD, <LOD
Penhold, Alberta # T579	14	Wheat AC Crystal	Hay	N1	0.016 (0.018)	50	<LOD, <LOD
Lacombe, Alberta # T580	14	Wheat AC Intrepid	Hay	N1	0.016 (0.018)	36	<LOD
						43	<LOD
						50	<LOD, <LOD
						57	<LOD
						64	<LOD
Rosthern, Saskatchewan # T581	14	Wheat AC Eatonia	Hay	N1	0.016 (0.018)	35	<LOD, <LOD
Hepburn, Saskatchewan # T582	14	Wheat AC Barrie	Hay	N1	0.016 (0.018)	34	<LOD, (0.01) ²
Minto, Manitoba # T583	14	Wheat Super B	Hay	N1	0.016 (0.018)	30	<LOD, <LOD
				N2	0.016 (0.018)	30	<LOD, <LOD
				N3	0.016 (0.018)	30	<LOD, <LOD
Minto, Manitoba # T584	14	Wheat Avonlea	Hay	N1	0.016 (0.018)	37	<LOD, <LOD
				N2	0.016 (0.018)	37	<LOD, <LOD
				N3	0.016 (0.018)	37	<LOD, <LOD
Boissevain, Manitoba # T585	14	Wheat AC Barrie	Hay	N1	0.016 (0.018)	28	<LOD, <LOD
Elm Creek, Manitoba # T566	5	Wheat AC Barrie	Grain	N1	0.016 (0.018)	62	<LOD, <LOD
Elm Creek, Manitoba # T567	5	Wheat Majestic	Grain	N1	0.016 (0.018)	62	<LOD, <LOD
Delisle, Saskatchewan # T568	7	Wheat Eatonia	Grain	N1	0.016 (0.018)	60	<LOD, <LOD
				N2	0.016 (0.018)	60	<LOD, <LOD
				N3	0.016 (0.018)	60	<LOD, <LOD
Vanscoy, Saskatchewan # T569	7	Wheat Prodigy	Grain	N1	0.016 (0.018)	62	<LOD, <LOD
						96	<LOD, <LOD
Vanscoy, Saskatchewan # T570	7	Wheat Eatonia	Grain	N1	0.016 (0.018)	59	<LOD



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ⁴ , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
						66	<LOD, <LOD
						74	<LOD
						80	<LOD
Wrentham, Alberta # T571	7	Wheat McKenzie	Grain	N1	0.016 (0.018)	69	<LOD, <LOD
Taber, Alberta # T572	7	Wheat Prodigy	Grain	N1	0.016 (0.018)	75	<LOD, <LOD
Wrentham, Alberta # T573	7	Wheat Prodigy	Grain	N1	0.016 (0.018)	71	<LOD, <LOD
Taber, Alberta # T574	7	Wheat McKenzie	Grain	N1	0.016 (0.018)	76	<LOD, <LOD
Taber, Alberta # T575	0.2916667	Wheat McKenzie	Grain	N1	0.016 (0.018)	85	<LOD, <LOD
Rosthern, Saskatchewan # T576	14	Wheat AC Barrie	Grain	N1	0.016 (0.018)	79	<LOD, <LOD
Lacombe, Alberta # T577	14	Wheat AC Crystal	Grain	N1	0.016 (0.018)	98	<LOD, <LOD
Penhold, Alberta # T578	14	Wheat Intrepid	Grain	N1	0.016 (0.018)	90	<LOD, <LOD
Penhold, Alberta # T579	14	Wheat AC Crystal	Grain	N1	0.016 (0.018)	90	<LOD, <LOD
Lacombe, Alberta # T580	14	Wheat AC Intrepid	Grain	N1	0.016 (0.018)	81	<LOD
						88	<LOD, (0.005) ²
						94	<LOD
						101	<LOD
Rosthern, Saskatchewan # T581	14	Wheat AC Eatonia	Grain	N1	0.016 (0.018)	79	<LOD, <LOD
Hepburn, Saskatchewan # T582	14	Wheat AC Barrie	Grain	N1	0.016 (0.018)	58	<LOD, <LOD
Minto, Manitoba # T583	14	Wheat Super B	Grain	N1	0.016 (0.018)	58	<LOD, <LOD
				N2	0.016 (0.018)	58	<LOD, <LOD
				N3	0.016 (0.018)	58	<LOD, <LOD
Minto, Manitoba # T584	14	Wheat Avonlea	Grain	N1	0.016 (0.018)	66	<LOD, <LOD
				N2	0.016 (0.018)	66	<LOD, <LOD
				N3	0.016 (0.018)	66	<LOD, <LOD



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ² , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
Boissevain, Manitoba # T585	14	Wheat AC Barrie	Grain	N1	0.016 (0.018)	61	<LOD. <LOD
Elm Creek, Manitoba # T566	5	Wheat AC Barrie	Straw	N1	0.016 (0.018)	62	<LOD. <LOD
Elm Creek, Manitoba # T567	5	Wheat Majestic	Straw	N1	0.016 (0.018)	62	<LOD. <LOD
Delisle, Saskatchewan # T568	7	Wheat Eatonia	Straw	N1	0.016 (0.018)	60	<LOD. <LOD
				N2	0.016 (0.018)	60	<LOD. <LOD
				N3	0.016 (0.018)	60	<LOD. <LOD
Vanscoy, Saskatchewan # T569	7	Wheat Prodigy	Straw	N1	0.016 (0.018)	62	<LOD. <LOD
						69	<LOD. <LOD
Vanscoy, Saskatchewan # T570	7	Wheat Eatonia	Straw	N1	0.016 (0.018)	59	<LOD
						66	<LOD. <LOD
						74	<LOD
						80	<LOD
Wrentham, Alberta # T571	7	Wheat McKenzie	Straw	N1	0.016 (0.018)	69	<LOD. <LOD
Taber, Alberta # T572	7	Wheat Prodigy	Straw	N1	0.016 (0.018)	75	<LOD. <LOD
Wrentham, Alberta # T573	7	Wheat Prodigy	Straw	N1	0.016 (0.018)	71	<LOD. <LOD
Taber, Alberta # T574	7	Wheat McKenzie	Straw	N1	0.016 (0.018)	76	<LOD. <LOD
Taber, Alberta # T575	0.2916667	Wheat McKenzie	Straw	N1	0.016 (0.018)	85	<LOD. <LOD
Rosthern, Saskatchewan # T576	14	Wheat AC Barrie	Straw	N1	0.016 (0.018)	79	<LOD. <LOD
Lacombe, Alberta # T577	14	Wheat AC Crystal	Straw	N1	0.016 (0.018)	98	<LOD. <LOD
Penhold, Alberta # T578	14	Wheat Intrepid	Straw	N1	0.016 (0.018)	90	<LOD. <LOD
Penhold, Alberta # T579	14	Wheat AC Crystal	Straw	N1	0.016 (0.018)	90	<LOD. <LOD
Lacombe, Alberta # T580	14	Wheat AC Intrepid	Straw	N1	0.016 (0.018)	81	<LOD
						88	<LOD. <LOD
						94	<LOD
						101	<LOD



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

Trial ID (City, Province/ID#). All in 2003.	Region (Canadian)	Crop/Variety	Commodity or Matrix	EP ¹	Total Rate ¹ , lb a.i./A (kg a.i./ha)	PHI (days)	Residues of CGA-153433 (ppm)
Rosthern, Saskatchewan # T581	14	Wheat AC Eatonia	Straw	N1	0.016 (0.018)	79	<LOD, <LOD
Hepburn, Saskatchewan # T582	14	Wheat AC Barrie	Straw	N1	0.016 (0.018)	58	<LOD, <LOD
Minto, Manitoba # T583	14	Wheat Super B	Straw	N1	0.016 (0.018)	58	<LOD, <LOD
				N2	0.016 (0.018)	58	<LOD, <LOD
				N3	0.016 (0.018)	58	<LOD, <LOD
Minto, Manitoba # T584	14	Wheat Avonlea	Straw	N1	0.016 (0.018)	66	<LOD, <LOD
				N2	0.016 (0.018)	66	<LOD, <LOD
				N3	0.016 (0.018)	66	<LOD, <LOD
Boissevain, Manitoba # T585	14	Wheat AC Barrie	Straw	N1	0.016 (0.018)	61	<LOD, <LOD

¹EP = End-use Product: N1 = NOA-407855 formulation 100EC Lead Variant (A-12303C); N2 = NOA-407855 formulation 100EC Alternate Variant (A-12303D); N3 = NOA-407855 formulation 120EC Aromatic 200 (A-12413B).

²A result shown in parentheses is below the LOQ but at or above the detect level.

³Summary Table 2 in the MRID indicates that this value is 0.22 ppm; however, that table is based on Table 48 in the MRID, in which the number is reported to be 0.022 ppm. The latter number is assumed to be correct and is consistent with statements made in the MRID (p. 17) and this review about the maximum value found and the HAFT.

⁴This is the rate of application of the safener cloquintocet-mexyl.

**TABLE C.4. Summary of Residue Data from Crop Field Trials with Cloquintocet-mexyl
(measured as CGA-153433).**

Commodity	Total Applic. Rate ¹ , lb a.i./A (kg a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT ³	Median (STMdR)	Mean (STMR)	Std. Dev.
CGA-153433									
Forage	0.016 (0.018)	38449	43	<0.01	0.114	0.099	0.03	0.04	0.028
Forage	0.016 (0.018)	38655	15	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Hay	0.016 (0.018)	22-64	60	<0.01	<0.01	<0.01	<0.01	<0.01	NA
Grain	0.016 (0.018)	58-101	60	<0.005	<0.005	<0.005	<0.005	<0.005	NA
Straw	0.016 (0.018)	58-101	60	<0.01	<0.01	<0.01	<0.01	<0.01	NA



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

* HAFT = Highest Average Field Trial.

¹This is the rate of application of the safener cloquintocet-mexyl.

D. CONCLUSION: The field trial residue data are classified as scientifically acceptable. The submitted study did not present adequate storage stability data; however, adequate data on storage stability exist to support the period of storage in the present study. The crop field trials were indicate that the level of residues in RACs is low and that, with increasing time after treatment, the level of residues decreases in forage—the only commodity in which any quantifiable residues were detected.

E. REFERENCES: Determination of NOA 407854, SYN 505164, SYN 502836, SYN 505887 (Metabolites of NOA 407855) and CGA 153433 (metabolites of CGA 185072) in Cereals By LC/LC-MS/MS. Residue Method 199.02, 20 June 2002. – a footnote on p. 300 of MRID 46203206 further identifies this as report CH-4002, Basel/Switzerland.

MRID 46012916, W. Cutchin, in process

MRID 46012917, W. Cutchin, in process

F. DOCUMENT TRACKING:

RDI: W. Cutchin 7/13/05

Petition Number(s): 7E04920

DP Barcode(s): D308470

PC Code: 700099

Template Version September 2003



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Barley

Primary Evaluator Oak Ridge National Laboratory,
 Oak Ridge, TN

Date: 8/1/05

Peer Reviewer

W. Cutchin, Chemist
 TRB/RD

This DER was originally prepared by Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN 37831. The DER has been reviewed by TRB and revised to reflect current OPP policies.

STUDY REPORT:

MRID No. 46203205. Hampton, M.M. (January 26, 2004) NOA-407855 - Residue levels on barley (hay, grain and straw) from trials conducted with two variants of a 100 EC formulation and a 120 EC formulation in Canada during 2003. Laboratory study ID CER 0707/03. Unpublished study prepared by Syngenta Crop Protection, Inc., 140 Research Lane, Guelph, Ontario, N1G 4Z3, Canada. 315 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for the safener cloquintocet-mexyl (CGA-185072) on barley. Residues of the safener metabolite CGA-153433 were measured on barley as part of a field trial for the new emulsifiable concentrate herbicide NOA-407855. One of three herbicide formulations was used on each plot (two variants of a 100 EC formulation and a 120 EC formulation). Three different adjuvants were also tested with each formulation. A total of 16 field trials were conducted in Canada in zones 5, 5B, 7 (2), or 14 (12). The number and locations of field trials are in accordance with Directive 98-02; Section 9.

Barley was grown under normal agricultural conditions on test plots at each field trial location. The herbicide formulation was diluted with water for a targeted treatment rate of 17.5 g cloquintocet-mexyl /ha (0.015 lb/A) were applied. All treatments were made prior to emergence of the 4th tiller/3-6 leaf stage of barley, by one-time broadcast spray using 25-200 L/ha (2.7-21.4 gal/A). At normal commercial maturity, hay samples were cut approximately 26-48 days after treatment and straw and grain were harvested at 54-89 days after treatment. Hay was dried to 4.6-23.3% moisture content. In the decline study, hay samples were cut 7 and 14 days before and after normal harvest maturity and straw and grain samples were harvested 7 days prior and 7 and 14 days after normal harvest. Residues were not determined in processed grain fractions.

Analytical Method 199.02 was used to detect CGA-153433, the acidic metabolite of the safener additive cloquintocet-mexyl. During the acid refluxing of the sample, cloquintocet-mexyl, is oxidized to CGA-153433. The limit of quantitation (LOQ), as presented in the method, is 0.01



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

ppm for each analyte for grain, and 0.02 ppm for hay and straw. The limit of detection (LOD) was established to be $\frac{1}{2}$ LOQ. The quantitation of residues was based on LC-MS/MS peak area comparison with calibration standard solutions. Recovery samples were prepared at the LOQ, at 5X LOQ, and at 10X LOQ for each sample set. Average recoveries ranged from 83.6-106% (n=7-9) for CGA-153433.

Freezer storage time ranged from 38 to 139 days for all samples. Residues of the cloquintocet-mexyl have been shown to be stable in all matrices for the duration of storage that occurred during the conduct of this study. Minimal concentrations of the safener metabolite, CGA-153433, were found in hay. Only two hay samples (0.02 ppm) had residue levels equal to the LOQ and seven hay samples had levels above the LOD but below the LOQ. No safener residues were found in straw or grain. Decline of CGA-153433 could not be determined because all measured residues in the decline study were <LOQ.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. All data generated and collected during the conduct of this study was in compliance with the Canadian OECD GLP regulations with the following exceptions:

1. Some study site data (e.g., historical pesticide and fertilizer use, historical planting and cultivation/tillage records, etc.) were obtained from non-GLP grower or property owner records.
2. Soil characteristics (sampling and analysis) were documented but not done to full GLP compliance standards.
3. The weather data was obtained from non-GLP Environment Canada Atmospheric Environment Service Weather Stations or from non-GLP on-site records.
4. The application of maintenance chemicals was documented but was not done to full GLP standards.
5. The field data contained a few accidental GLP deviations. These included some entries that were not dated and initialed at the time of entry; error corrections that were made without date, initials and/or error code; and a few late entries in activity logs and plot maintenance forms in the RTNs.

None of the deviations had an adverse effect on the acceptability of the study. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D316489 and in Canada's Regulatory Decision Document.



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is needed as a safener to prevent damage to the wheat due to phytotoxic effects.

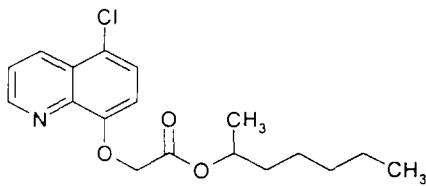
TABLE A.1. Test Compound Nomenclature	
Compound	
Common name	cloquintocet mexyl
Company experimental name	CGA-185072
IUPAC name	5-chloro-8-quinolinoxyacetic acid 1-methylhexyl ester
CAS name	[(5-chloro-8-quinolinyl)oxy]acetic acid-1-methylhexyl ester
CAS #	99607-70-2
End-use product/(EP)	Safener in HORIZON® 240EC Herbicide (a synonym is DISCOVER)

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	69°C	Agrochemicals 1994
pH	not available	
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL_cloquintocet-mexyl.html
Water solubility (20 °C)	0.8 mg/L	Agrochemicals 1994
Solvent solubility (mg/L at ___ °C)	not available	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	not available	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12

B. EXPERIMENTAL DESIGN



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

B.1. Study Site Information

TABLE B.1. Trial Site Conditions			
Trial Identification (City, Province/Year)	Soil characteristics	Meteorological data	
	Types	Overall monthly rainfall range (mm)	Monthly mean temperature (°C) range
St. Pie-de-Bagot, PQ/2003	loamy fine, sand, sand	83.9-136.2	13.6-21.0
Elm Creek, MB/2003	sandy loam, loamy sand, loamy sand	27.7-110.6	12.4-21.2
Wrentham, AB/2003	loam, loam, clay loam	0-50.8	11.3-20.0
Vanscoy, SK/2003	silt loam, silt loam, silt loam	22.8-64.8	12.0-20.7
Lacombe, AB/2003	loam, clay loam, clay loam	10.6-45.2	8.5-16.8
Lacombe, AB/2003	loam, clay loam, clay loam	10.6-45.2	8.5-16.8
Penhold, AB/2003	clay loam, clay loam, clay loam	13.1-103.2	8.4-16.8
Rosthern, SK/2003	clay loam, clay loam, clay loam	13.4-58.8	12.2-21.6
Rosthern, SK/2003	clay loam, clay loam, clay loam	13.4-58.8	12.2-21.6
Hepburn, SK/2003	clay loam, clay loam, clay loam	13.4-58.8	12.2-21.6
Minto, MB/2003	clay loam, clay loam, clay loam	8.9-64.8	11.5-21.4
Boissevain, MB/2003	clay loam, clay loam, loam	8.9-64.8	11.5-21.4
Boissevain, MB/2003	clay loam, clay loam, loam	8.9-64.8	11.5-21.4
Minto, MB/2003	clay loam, clay loam, clay loam	8.9-64.8	11.5-21.4
Penhold, AB/2003	clay loam, clay loam, clay loam	13.1-103.2	8.4-16.8
Kipp, AB/2003	loam, loam, loam	5.1-40.7	10.2-19.6

Data from Tables 13 and 31-39, pp. 70-71 and 98-101, respectively. MRID 46203205.

The actual temperature recordings are within $\pm 4.3^{\circ}\text{C}$ of the average historical values for the residue study period. The actual rainfall was generally below average at all sites and ranged from +38.2 to -79.1 mm of the historical rainfall average. Irrigation was used once at Vanscoy, SK and twice at Kipp, AB.



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE B.2. Study Use Pattern.

Location (City, Province/Year)	EP ¹	Application					Tank Mix Adjuvant (0.7 L/ha)
		Method/Timing	Vol gpa. (L/ha)	App. Rate. lb ai/A (Kg ai/ha)	RTI ² days	Total. lb ai/A (Kg ai/ha) ³	
St. Pie-de-Bagot. PQ/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Elm Creek. MB/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Wrentham. AB/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127M
	NOA-407855 100EC (A-12303D). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127M
	NOA-407855 120EC (A-12413B). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127M
Vanscoy. SK/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Lacombe. AB/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127S
	NOA-407855 100EC (A-12303D). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127S
	NOA-407855 120EC (A-12413B). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	A12127S



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE B.2. Study Use Pattern.

Location (City, Province/Year)	EP ¹	Application					Tank Mix Adjuvant (0.7 L/ha)
		Method/Timing	Vol gpa. (L/ha)	App. Rate. lb ai/A (Kg ai/ha)	RTI ² days	Total. lb ai/A (Kg ai/ha) ³	
Lacombe, AB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage, Feekes 2 (for hay)	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Penhold, AB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Rosthern, SK/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Rosthern, SK/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Hepburn, SK/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Minto, MB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Boissevain, MB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	2.7-3.7 (25-35)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Boissevain, MB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	MERGE
Minto, MB/2003	NOA-407855 100EC (A-12303C), containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	MERGE



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE B.2. Study Use Pattern.

Location (City, Province/Year)	EP ¹	Application					Tank Mix Adjuvant (0.7 L/ha)
		Method/Timing	Vol gpa. (L/ha)	App. Rate, lb ai/A (Kg ai/ha)	RTI ² days	Total, lb ai/A (Kg ai/ha) ³	
	NOA-407855 100EC (A-12303d). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	MERGE
	NOA-407855 120EC (A-12413B). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	10.7-21.4 (100-200)	0.016 (0.018)	None	0.016 (0.018)	MERGE
Penhold, AB/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	8.0-13.4 (75-125)	0.016 (0.018)	None	0.016 (0.018)	A12127S
Kipp, AB/2003	NOA-407855 100EC (A-12303C). containing safener cloquintocet-mexyl	1. Post foliar broadcast spray: prior to emergence of 4 th tiller/3-6 leaf stage	5.3-10.7 (50-100)	0.016 (0.018)	None	0.016 (0.018)	A12127M

Data from Table 2, pp. 47-50, MRID 46203205.

¹ EP = End-use Product² RTI= retreatment interval³ 17.5 g ai/ha of the safener cloquintocet-mexyl were applied.**TABLE B.1.3. Trial Numbers and Geographical Locations**

NAFTA Growing Region	Barley		
	Submitted	Requested	
		Canada	US
1			1
1A			
2			1
3			
4			
5	1	1	2
5A			
5B	1	1	
6			
7	2	2	3



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7A			
8			
9			1
10			1
11			1
12			
13			
14	12	12	
15			
16			
17			
18			
19			
20			
21			
Total	16	16	9

B.2. Sample Handling and Preparation

Hay, straw, and grain were harvested as barley raw agriculture commodities (RAC). Samples of each RAC were taken from twelve separate areas of the plot. At normal commercial maturity, hay samples were cut approximately 26-48 days after treatment and straw and grain were harvested at 54-89 days after treatment. Hay was dried to 4.6-23.3% moisture content. In the decline study, hay samples were cut 7 and 14 days before and after normal harvest maturity and straw and grain samples were harvested 7 days prior and 7 and 14 days after normal harvest.

All RAC samples were frozen (-10°C) immediately after sampling and shipped frozen to University of Guelph Laboratory Services Division, Trace Organics and Pesticides Section. Each field sample was divided and one-half was stored for future analysis (some of these samples for hay and straw were analyzed approximately three months later to confirm the findings of the original analysis). The remaining one-half was completely homogenized in a Hobart grinder or coffee grinder.

B.3. Analytical Methodology

Analytical Method 199.02 was used for determination of residues of CGA-153433, the acidic metabolite of the safener additive cloquintocet-mexyl. A subsample of the homogenized RAC was weighed (10 g for grain and 5 g for hay and straw) into a 500 mL round bottom flask. The sample was refluxed with 1N HCl for one or two hours. After reflux, the extract was allowed to



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

reach room temperature. A portion of extract was centrifuged at 2500 rpm for 20 minutes. The supernatant was filtered and an aliquot was diluted with 3% ammonium hydroxide. This extract was further diluted with water for analysis by LC-MS/MS. During the acid refluxing of the sample, cloquintocet-mexyl is oxidized to CGA-153433. The LOQ, as presented in the method, is 0.01 ppm for grain, and 0.02 ppm for hay and straw. The LOD was established to be $\frac{1}{2}$ LOQ. Fortification standard solutions were prepared by mixing cloquintocet-mexyl and CGA-153433 stock solutions and diluting with 1N HCl to the desired concentrations. Calibration standard solutions were prepared by mixing a CGA-153433 stock solution and diluting it with a 1N HCl: 3% ammonia solution (2:1) to the desired concentrations. The quantitation of residues was based on LC-MS/MS peak area comparison with these calibration standard solutions. The petitioner presented adequate calibration curves and chromatograms to indicate that the method is free from interferences.

C. RESULTS AND DISCUSSION

Freezer storage time ranged from 38 to 139 days for all samples. The report noted that storage stability of the herbicide NOA-407854 and its metabolites had been previously demonstrated for 15 months in wheat forage, straw, and grain. These data were not included with the current study report. The storage stability of the parent safener cloquintocet-mexyl and its metabolite, CGA-153433 were not mentioned. However, in another study, storage stability of the safener metabolite was discussed for wheat hay and wheat germ and stability was shown in wheat straw and grain for up to 380 days (PP#7E4920, DP Barcode: D257181, MRID 46203204, N. Dodd, 4/7/00). Syngenta has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage (MRID 46012916, W. Cutchin, in process). Syngenta has also submitted the results of a storage stability study with metabolite CGA-153433 in wheat germ. The results indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage (MRID 46012917, W. Cutchin, in process). The data for storage stability on wheat commodities can be used to support barley residue field trial data. There is adequate data on storage stability to support the period of storage in the present study.

Results of the method recovery validation are given in Table C.1. The LOQ was 0.01 ppm for grain and was 0.02 ppm for hay and straw. Recovery samples were prepared at the LOQ, at 5X LOQ, and at 10X LOQ for each sample set. The average recoveries ranged from 83.6-106% (n=7-9) for CGA-153433. These results indicate the analytical method is capable of accurately determining residues of CGA-153433 in barley RAC.

Residue levels of the safener metabolite CGA-153433 in barley RAC samples collected at the twelve field trial sites are shown in Tables C.3 and C.4. Minimal concentrations of the safener metabolite, CGA-153433, were found in hay. Only two hay samples (0.02 ppm) had residue



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

levels equal to the LOQ and seven hay samples had levels above the LOD but below the LOQ. No safener residues were found in straw or grain. Residues of CGA-153433 measured in the decline study are given in Table C.4. No residues were detected above the LOQ at any time in any RAC.

TABLE C.1. Concurrent recoveries of CGA-153433 from fortified barley RAC

Commodity/Fortification level ^a	CGA-153433 (% recovery)
Hay	
0.02 ppm	100 ± 21.0 (n=3)
0.10 ppm	79.6 ± 13.0 (n=2)
0.20 ppm	93.8 ± 1.2 (n=2)
Average	92.4 ± 16.2 (n=7)
Straw	
0.02 ppm	79.0 ± 16.1 (n=5)
0.10 ppm	93 ± 2.8 (n=2)
0.20 ppm	92.5 ± 1.8 (n=2)
Average	83.6 ± 13.5 (n=9)
Grain	
0.01 ppm	103 ± 16.0 (n=3)
0.10 ppm	106 ± 12.3 (n=2)
0.20 ppm	111 ± 5.9 (n=2)
Average	106 ± 11.4 (n=7)

Data taken from Table 8, p. 57, MRID 46203205.

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days)	Interval of Demonstrated Storage Stability (days)
Hay	<10	55-139	750
Grain	<10	49-84	165
Straw	<10	38-74	750

TABLE C.3. Residue Data from Crop Field Trials with Cloquintocet-mexyl.

Trial ID (City, Province/Year)	Region	Crop/ Variety	Commodity or Matrix	Total Rate, (g ai/ha) ¹	PHI (days)	Residues of CGA-153433 ² (mg/kg)
St. Pie-de-Bagot, PQ/2003	5B	Barley/Grant	Hay	17.5	29	(0.017); (0.017) ³
			Straw		57	<LOD; <LOD
			Grain		57	<LOD; <LOD
Elm Creek, MB/2003	5	Barley/Conlon	Hay	17.5	33	<LOD; <LOD
			Straw		63	<LOD; <LOD
			Grain		63	<LOD; <LOD



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

Wrentham. AB/2003	7	Barley/Stein	Hay Straw Grain	17.5	48 78 78	<LOD: <LOD <LOD: <LOD <LOD: <LOD
		Barley/Stein	Hay Straw Grain	17.5	48 78 78	<LOD: <LOD <LOD: <LOD <LOD: <LOD
		Barley/Stein	Hay Straw Grain	17.5	48 78 78	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Vanscoy. SK/2003	7	Barley/CDC Dolly	Hay Straw Grain	17.5	28 62. 69 62. 69	0.02: (0.017) <LOD: <LOD: <LOD: <LOD <LOD: <LOD: <LOD: <LOD
Lacombe. AB/2003	14	Barley/Metcalf	Hay Straw Grain	17.5	46 84 84	<LOD: <LOD <LOD: <LOD <LOD: <LOD
		Barley/Metcalf	Hay Straw Grain	17.5	46 84 84	(0.011): <LOD <LOD: <LOD <LOD: <LOD
		Barley/Metcalf	Hay Straw Grain	17.5	46 84 84	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Lacombe. AB/2003	14	Barley/Bold	Hay Straw Grain	17.5	27. 46 84 84	<LOD: <LOD: <LOD: <LOD <LOD: <LOD <LOD: <LOD
Penhold. AB/2003	14	Barley/Metcalf	Hay Straw Grain	17.5	46 89 89	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Rosthern. SK/2003	14	Barley/Kendall	Hay Straw Grain	17.5	35 66 66	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Hepburn. SK/2003	14	Barley/CDC Dolly	Hay Straw Grain	17.5	34 58 58	(0.011): 0.02 <LOD: <LOD <LOD: <LOD
Boissevain. MB/2003	14	Barley/Metcalf	Hay Straw Grain	17.5	33 60 60	(0.011): <LOD <LOD: <LOD <LOD: <LOD
Boisservain. MB/2003	14	Barley/Robust	Hay Straw Grain	17.5	28 60 60	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Minto. MB/2003	14	Barley/Lacey	Hay Straw Grain	17.5	34 57 57	<LOD: <LOD <LOD: <LOD <LOD: <LOD
		Barley/Lacey	Hay Straw Grain	17.5	34 57 57	<LOD: <LOD <LOD: <LOD <LOD: <LOD
		Barley/Lacey	Hay Straw Grain	17.5	34 57 57	<LOD: <LOD <LOD: <LOD <LOD: <LOD
Penhold. AB/2003	14	Barley/Bold	Hay Straw Grain	17.5	46 89 89	<LOD: <LOD <LOD: <LOD <LOD: <LOD



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

Kipp, AB/2003	14	Barley/Stein	Hay	17.5	26	<LOD: <LOD
			Straw		46	<LOD: (0.017): <LOD
			Grain		74	<LOD: <LOD
					74	<LOD: <LOD

Data taken from Table 2, pp. 47-50, MRID 46203205.

¹ Safener refers to active ingredient.² Safener metabolite.³ Numbers in parentheses represent values between the LOD and LOQ: LOQ= 0.01 for grain and 0.02 for hay and straw: LOD = 1/2 LOQ**TABLE C.4. Summary of Residue Data from Crop Field Trials with Cloquintocet-mexyl, as safener in herbicide NOA-407855.**

Commodity	Total Applic. Rate. (lb ai/ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT [*]	Median (STMdR)	Mean (STMR)	Std. Dev.
CGA-153433 (metabolite of safener cloquintocet-mexyl)									
Barley hay	17.5	26-48	45	<LOD	0.02	0.02	0.0185	0.016	0.003
Barley straw	17.5	54-89	42	<LOD	<LOD	n/a	n/a	n/a	n/a
Barley grain	17.5	54-89	42	<LOD	<LOD	n/a	n/a	n/a	n/a

^{*} HAFT = Highest Average Field Trial.**TABLE C.5. Decline of residues of Cloquintocet-mexyl in barley RAC¹**

Test location: City, Province/year	RAC	PHI (days)	Residues (ppm)
Rosthern, Saskatchewan /2003	Hay	22	<LOD
		29	<LOD
		35	<LOD: <LOD
		5	<LOD
		42	<LOD
	Straw	73	<LOD
		80	<LOD
		59	<LOD: <LOD
		66	<LOD
		73	<LOD
	Grain	49	<LOD
		59	<LOD: <LOD
		66	<LOD



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

Test location: City, Province/year	RAC	PHI (days)	Residues (ppm)
Minto, Manitoba /2003	Hay	15	(0.017) ²
		22	<LOD
		28	<LOD; <LOD
		36	<LOD
		43	<LOD
	Straw	46	<LOD
		54	<LOD; <LOD
		60	<LOD
		70	<LOD
	Grain	46	<LOD
		54	<LOD; <LOD
		60	<LOD
		70	<LOD

Data taken from Table 2, pp. 48 and 49, MRID 46203205.

¹Field trial with NOA-407855 applied at 70 g ai/ha as the 100 EC (A-12303C) formulation.²Numbers in parentheses represent values between the LOD and LOQ.

LOQ = Limit of quantitation = 0.01 ppm for grain and 0.02 ppm for hay and straw.

LOD = Limit of detection = ½ LOQ.

D. CONCLUSION

The field trial residue data are classified as scientifically acceptable. The submitted study did not present adequate storage stability data; however, adequate data on storage stability exist to support the period of storage in the present study. The crop field trials were indicate that the level of residues in RACs is low. Only minimal residues of CGA-153433 were found on hay and none were found on straw or grain. Decline of CGA-153433 could not be determined because all measured residues in the decline study were <LOQ.

E. REFERENCES

Agrochemicals Handbook, The. 1994. Third ed. The Royal Society of Chemistry, Cambridge, England.

MRID 46012916, W. Cutchin, in process

MRID 46012917, W. Cutchin, in process

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/14/05

Petition Number(s): 4E6831

DP Barcode(s): D318489

PC Code: 700099



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Barley

Template Version September 2003



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIA 8.5
Processed Food and Feed - Barley

Primary Evaluator Oak Ridge National Laboratory,
Oak Ridge, TN

Date: 8/1/05

Peer Reviewer W. Cutchin, Chemist
TRB/RD

This DER was originally prepared by Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN 37831. The DER has been reviewed by TRB and revised to reflect current OPP policies.

MRID No. No. 46203204. Lin, K. (January 12, 2004) NOA-407855 - Magnitude of residues on barley. Laboratory study number 825-02. Unpublished study prepared by Dietary Safety Department, Syngenta Crop Protection, Inc., Greensboro, NC 27419. 235 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for the safener cloquintocet-mexyl (CGA-185072) on barley. Residues of the safener metabolite CGA-153433 were measured on barley processed fractions as part of a field trial for the new emulsifiable concentrate herbicide NOA-407855. Samples from a trial conducted in Jerome, ID were used to generate processed grain fractions, including flour, bran, and pearled barley, for determination of potential residue levels.

The herbicide formulation was diluted with water for a targeted treatment rate of 0.016 lb cloquintocet-mexyl/A (0.018 Kg/ha) (1X) for grain. A treatment rate of 5X was also applied. All treatments were made by one-time post-foliar broadcast spray using 14-18 gallons/acre. Grain was harvested at 60 days after treatment.

Syngenta Analytical Method 117-01 was used for determination of residues of CGA-153433 in barley processed grain fractions with the limit of quantitation (LOQ) at 0.01 ppm. The limit of detection (LOD) was 0.005 ppm. The quantitation of residues was based on HPLC/MS/MS peak area comparison with calibration standard solutions. Concurrent recovery samples were prepared at the LOQ level up to 1 ppm for each processed fraction. Recoveries ranged from 84-105% with an average of 92% (n=8) for CGA-153433. Storage stability data for CGA-153433 on barley RAC were not included although limited data on wheat were available.

Residues of CGA-153433 were below the LOQ in all processed grain fractions even at the 5X herbicide application rate. A comparison of the residues in the RAC with those in each processed fraction showed no concentration of residues in processed fractions. The theoretical concentration factors for barley bran and pearled barley are 7.7 and 1.2, respectively.



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 Processed Food and Feed - Barley

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the processed food and feed study is are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is needed as a safener to prevent damage to crops due to phytotoxic effects.

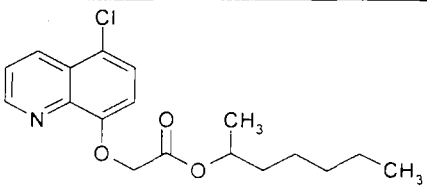
TABLE A.1. Test Compound Nomenclature	
Compound	
Common name	cloquintocet mexyl
Company experimental name	CGA-185072
IUPAC name	5-chloro-8-quinolinoxyacetic acid 1-methylhexyl ester
CAS name	[(5-chloro-8-quinolinyl)oxy]acetic acid-1-methylhexyl ester
CAS #	99607-70-2
End-use product/(EP)	Safener in HORIZON® 240EC Herbicide (a synonym is DISCOVER)

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	69°C	Agrochemicals 1994
pH	not available	
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html;
Water solubility (20°C)	0.8 mg/L	Agrochemicals 1994
Solvent solubility (mg/L at ___°C)	not available	



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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure: highest is from experimental database for EPIWIN v3.12: converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	not available	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

Grain was harvested from a field trial conducted in Jerome, ID during the 2002 growing season. The site contained sandy loam soil, had a monthly rainfall of 0.01-0.86 inches, and a temperature range of 49.9-78.0°C. Irrigation was used to supplement as needed during the trial.

The herbicide formulation NOA-407855, which contains the safener cloquintocet-mexyl, was applied to barley grown under normal agricultural conditions on test lots at the field trial location (Table B.1). Control plots were separated at a sufficient distance to exclude any contamination from the treated plots. The herbicide formulation was diluted with water for a targeted treatment rate of 0.016 lb cloquintocet-mexyl/A (0.018 Kg/ha) were applied. A treatment rate of 5X was also applied for the evaluation of grain commodities. All treatments were made by one-time post foliar broadcast spray using 14-18 gallons/acre.

TABLE B.1. Study Use Pattern.							
Location (City, State/Year)	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing	Vol gpa ² (L/ha)	App. Rate. lb ai/A (Kg ai/ha)	RTI ³ days	Total. lb ai/A (Kg ai/ha) ⁴	
Jerome, ID/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray; crop growth stage 21 (for hay).	17.90 (167.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray; crop growth stage 57 (for straw, grain)	14.85 (138.9)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate



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TABLE B.1. Study Use Pattern.

Location (City, State/Year)	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing	Vol gpa ² (L/ha)	App. Rate. lb ai/A (Kg ai/ha)	RTI ³ days	Total. lb ai/A (Kg ai/ha) ⁴	
		1. Post foliar broadcast spray: crop growth stage 57 (for straw, grain)	15.06 (140.9)	0.080 (0.090)	None	0.080 (0.090)	2% crop oil concentrate

Data from Appendix 1, pp 203-233. MRID 46203204.

¹ EP = End-use Product

² Gallons per acre

³ RTI= retreatment interval

⁴ Approximately 7.25 g a.i./A of the safener cloquintocet-mexyl were applied at the 1X rate.

B.2. Sample Handling and Processing Procedures

Hay, straw, and grain were harvested as barley raw agriculture commodities (RAC). Hay samples were cut approximately 30 days after treatment and straw and grain were harvested at 60 days after treatment. All RAC samples were frozen immediately (temperature not stated) after sampling and grain samples for processing were directly shipped to Food Protein R&D Center, Bryan, TX. Hay and straw samples were cut into 2-inch pieces with a hand shear, and ground in a Hobart foodcutter with dry ice. Grain samples were ground with a table-top mill after removing chaff or other debris. After preparation, the samples were placed in polyethylene bags and stored frozen.

Barley grain was sent fresh to Texas A&M Univ., Food Protein Research and Development Center, Bryan, TX and processed into fractions of pearled barley, flour, and bran using simulated commercial practices (personal contact, Syngenta Representative). After processing, samples were frozen immediately (temperature not stated) after sampling and shipped frozen to Syngenta Greensboro, NC.

B.3. Analytical Methodology

Syngenta Analytical Method 117-01 was used for determination of residues of CGA-153433, the acidic metabolite of the safener additive cloquintocet-mexyl. The principle of the analytical method is that an acid hydrolysis extraction will convert cloquintocet-mexyl and all conjugates to its acid metabolite, 5-chloro-8-quinolinoxylacetic acid (CGA-153433). The sample refluxed with 1N HCl/ACN for two hours. An aliquot of sample final fraction was injected into an HPLC equipped with RP18 to ODS-3 column switching and MS/MS for analysis. Raw data were input into worksheets for calculation of residues. The LOD was 0.005 ppm. The LOQ, as presented in the method, was 0.01 ppm for grain and processed grain fractions, and 0.02 ppm for hay and straw. Fortification standard solutions were prepared by mixing a CGA-153433 stock solution



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and diluting with methanol to the desired concentration. Calibration standard solutions were prepared by mixing the CGA-153433 stock solution and diluting it with 0.2% formic acid to the desired concentrations. The quantitation of residues was based on HPLC/MS/MS peak area comparison with these calibration standard solutions. Adequate sample chromatograms and calibration curves were provided.

C. RESULTS AND DISCUSSION

Freezer storage time ranged from 4.3 to 14.9 months for all samples with the exception of straw from the field trial in ID which was stored for approximately 16 months. CGA-153433 was found to be stable in wheat hay under freezer storage for a minimum of 18 months and in wheat germ for five months. CGA-153433 was also found to be stable in wheat straw and grain for up to 380 days (PP#7E4920, DP Barcode: D257181, MRID 46203204, N. Dodd, 4/7/00). Syngenta has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage (MRID 46012916, W. Cutchin, in process). Syngenta has also submitted the results of a storage stability study with metabolite CGA-153433 in wheat germ. The results indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage (MRID 46012917, W. Cutchin, in process). The data for storage stability on wheat commodities can be used to support barley residue field trial data. There is adequate data on storage stability to support the period of storage in the present study.

Results of the method recovery validation are given in Table C.1. The analytical method limit of quantitation (LOQ) was 0.01 ppm for grain and processed grain fractions. Recovery samples were prepared at the LOQ level up to 1.00 ppm for each sample set; at least one recovery sample was analyzed concurrently for validation of the method performance. Recoveries ranged from 84-105% with an average of 92% (n=8) for CGA-153433. These results indicate the analytical method was capable of accurately determining CGA-153433 residues in barley processed fractions. The petitioner presented adequate calibration curves and chromatograms to indicate that the method is free from interferences.

TABLE C.1: Concurrent recoveries of CGA-153433 from fortified barley RAC and processed fractions	
Commodity/Fortification level	CGA-153433 (% recovery)
Grain prior to process	
0.01	89
1.00	100
Pearled barley	
0.01	87
1.00	105

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TABLE C.1: Concurrent recoveries of CGA-153433 from fortified barley RAC and processed fractions

Commodity/Fortification level	CGA-153433 (% recovery)
Flour	
0.01	86
1.00	102
Bran	
0.01	84
1.00	86
Average of grain fractions	92 ± 8.5

Data taken from Table 3, p. 34. MRID 46203204.

Residues of CGA-153433 were below the LOQ in all processed grain fractions even at the 5X herbicide application rate (Table C.3). A comparison of the residues in the RAC with those in each processed fraction showed no concentration of residues in processed fractions. The theoretical concentration factors for barley bran and pearled barley are 7.7 and 1.2, respectively.

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration Until Extraction (months)	Interval of Demonstrated Storage Stability (months)
Grain (RAC)	not stated	4.3-14.4	25
Processed commodities and AGF	not stated	4.3-14.9	25

TABLE C.3. Residues in barley processed fractions from a field trial in Jerome, ID with Cloquintocet-mexyl, as safener in herbicide NOA-407855

Commodity	Application rate lb ai/A (Kg ai/ha) ¹	PHI (days)	Residues of CGA-153433 ² (ppm)
Grain	1X: 0.016 (0.018) 5X: 0.080 (0.090)	60	<LOQ <LOQ
Pearled barley	1X: 0.016 (0.018) 5X: 0.080 (0.090)	60	<LOQ <LOQ
Flour	1X: 0.016 (0.018) 5X: 0.080 (0.090)	60	<LOQ <LOQ
Bran	1X: 0.016 (0.018) 5X: 0.080 (0.090)	60	<LOQ <LOQ

Data from Table 6, p. 43. MRID 46203204.

LOQ = Limit of quantitation = 0.01 ppm for grain and processed grain fractions and 0.02 ppm for hay and straw; all control samples were <LOQ.

¹ Amount of safener.

² Safener metabolite.



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Processed Food and Feed - Barley

D. CONCLUSION

The processed food and feed study is classified as scientifically acceptable. The submitted study did not present adequate storage stability data; however, adequate data on storage stability exist to support the period of storage in the present study. The processing method for the production of pearled barley, flour, and bran from grain simulated commercial practices. Based on the data given, no residues of CGA-153433 were found in barley processed grain fractions. Although theoretical concentration factors have been developed for barley bran and pearled barley, the results of the current study indicate no potential for concentration of the safener metabolite.

E. REFERENCES

Agrochemicals Handbook, The. 1994. Third ed. The Royal Society of Chemistry, Cambridge, England.

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/14/05
Petition Number(s): 7E04920
DP Barcode(s): D308470
PC Code: 700099

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Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Barley

Primary Evaluator Oak Ridge National Laboratory,
Oak Ridge, TN

Date: 8/1/05

Peer Reviewer W. Cutchin, Chemist
TRB/RD

This DER was originally prepared by Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN 37831. The DER has been reviewed by TRB and revised to reflect current OPP policies.

MRID No. 46203204. Lin. K. (January 12, 2004) NOA-407855 - Magnitude of residues on barley. Laboratory study number 825-02. Unpublished study prepared by Dietary Safety Department. Syngenta Crop Protection, Inc., Greensboro, NC 27419. 235 pages.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted field trial data for the safener cloquintocet-mexyl (CGA-185072) on barley. Residues of the safener metabolite CGA-153433 were measured on barley as part of a field trial for the new emulsifiable concentrate herbicide. A total of 12 field trials was conducted in Regions 2 (VA), 5 (ND, MN, WI), 7 (SD, ND, MT [2]), 9 (CO), 10 (CA), and 11 (WA, ID) during the 2002 growing season. Barley was grown under normal agricultural conditions at each field trial location. The number and locations of field trials are in accordance with OPPTS Guideline 860.1500.

The herbicide formulation was diluted with water for a targeted treatment rate of 0.016 lb cloquintocet-mexyl/A (0.018 Kg/ha) (1X) for hay, straw, and grain. Treatment rates of 3X and 5X were also applied for straw and grain. All treatments were made by one-time post-foliar broadcast spray using 2-20 gallons/acre. Hay samples were cut approximately 30 days after treatment and straw and grain were harvested at 60 days after treatment. Additional samples from the ID trial were used to generate processed grain fractions.

Syngenta Analytical Method 117-01 was used for determination of residues of CGA-153433 in barley samples. During the acid refluxing of the sample, cloquintocet-mexyl is oxidized to CGA. The limit of detection (LOD) was 0.005 ppm. The limit of quantitation (LOQ) was 0.01 ppm for grain and processed grain fractions, and 0.02 ppm for hay and straw. The quantitation of residues was based on HPLC/MS/MS peak area comparison with calibration standard solutions. Concurrent recovery samples were prepared at the LOQ level up to 5 ppm for each RAC sample. Recoveries ranged from 81-113% (n=107) for CGA-153433. Storage stability data for CGA-153433 on barley RAC were not included although limited data on wheat were available.

Minimal concentrations of the safener metabolite CGA-153433 were found in only one hay



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Crop Field Trial - Barley

sample (0.048 ppm) and in three straw samples (0.021-0.050 ppm); all remaining samples contained <LOQ. Following 3x and 5x application rates, CGA-153433 was found at concentrations of 0.087-0.12 ppm only in straw samples from one trial at the 5X rate.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable.

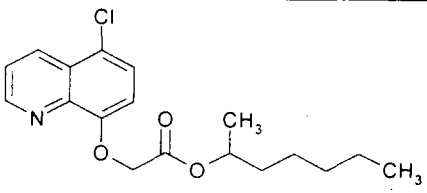
The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470..

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is needed as a safener to prevent damage to crops due to phytotoxic effects.

TABLE A.1. Test Compound Nomenclature	
Compound	
Common name	cloquintocet mexyl
Company experimental name	CGA-185072
IUPAC name	5-chloro-8-quinolinoxyacetic acid 1-methylhexyl ester
CAS name	[(5-chloro-8-quinolinyl)oxy]acetic acid-1-methylhexyl ester
CAS #	99607-70-2
End-use product/(EP)	Safener in HORIZON® 240EC Herbicide (a synonym is DISCOVER)



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	69°C	Agrochemicals 1994
pH	not available	
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html:
Water solubility (20°C)	0.8 mg/L	Agrochemicals 1994
Solvent solubility (mg/L at ___ °C)	not available	
Vapour pressure at 20-25°C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure: highest is from experimental database for EPIWIN v3.12: converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	not available	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1 Trial Site Conditions			
Trial Identification (City, State/Year)	Soil characteristics	Meteorological data	
	Type	Overall monthly rainfall range (in)	Overall temperature (°F) range
Windsor, VA/2002	sandy loam	insufficient data	insufficient data
Gardner, ND/2002	clay loam	3.73-5.65	51.2-73.1
Geneva, MN/2002	sandy loam	2.12-7.67	44.7-75.4
Richmond Township, WI/2002	loam	0.59 ² -5.07	49.0-78.5
Lake Andes, SD/2002	clay loam	0.00-2.03	49.3-81.5
Eldridge, ND/2002	sandy loam	0.77-4.03	50.4-72.8
Dagmar, MT/2002	sandy loam	2.04-3.17	64.1-71.9
Dagmar, MT/2002	sandy loam	2.04-3.17	64.1-71.9
Wellington, CO/2002	sandy clay loam	0.07-2.00	56.4-76.2
Tule Lake, CA/2002	loam	0.03-0.10	61.8-68.6
Ephrata, WA/2002	sand	0.00-0.53	50.0-75.0
Jerome, ID/2002	sandy loam	0.01-0.86	49.9-78.0

Data from Appendix 1, pp. 202-233. MRID 46203204.

²Incomplete time series: 1-9 days are missing.



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Crop Field Trial - Barley

The actual temperature recordings are within $\pm 6.4^{\circ}\text{F}$ of the average historical values for the residue study period. The actual rainfall average was within ± 3.52 inches of the historical rainfall average. Irrigation was used to supplement as needed at Tule Lake, CA, Ephrata, WA, Jerome, ID, and Wellington, CO.

TABLE B.2. Study Use Pattern.

Location (City, State/Year)	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing	Vol gpa ² (L/ha)	App. Rate, lb ai/A (Kg ai/ha)	RTI ³ days	Total, lb ai/A (Kg ai/ha) ⁴	
Windsor, VA/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	15.12 (141.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 35 (for straw, grain)	15.38 (143.9)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Gardner, ND/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage tiller (for hay)	19.05 (178.2)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 23 (for straw, grain)	12.18 (113.9)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 23 (for straw, grain)	12.14 (113.6)	0.048 (0.054)	None	0.048 (0.054)	2% crop oil concentrate
Geneva, MN/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage, Feekes 2 (for hay)	2.08 (19.5)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage, heads showing (for straw, grain)	2.17 (20.3)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Richmond Township, WI/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage, Feekes 2 (for hay)	18.93 (177.1)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage, Feekes 5 (for straw, grain)	17.56 (164.3)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Lake Andes, SD/2002	NOA-407855 120EC, containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	14.54 (136.0)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 32 (for straw, grain)	16.92 (158.3)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE B.2. Study Use Pattern.

Location (City, State/Year)	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing	Vol gpa ² (L/ha)	App. Rate. lb ai/A (Kg ai/ha)	RTI ³ days	Total. lb ai/A (Kg ai/ha) ⁴	
Eldridge, ND/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	16.29 (152.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 41 (for straw, grain)	18.87 (176.5)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Dagmar, MT/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	14.97 (140.0)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 33 (for straw, grain)	15.12 (141.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Dagmar, MT/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	14.89 (139.3)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 33 (for straw, grain)	15.00 (140.3)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Wellington CO/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage first tiller (for hay)	14.86 (139.0)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage flag leaf visible (for straw, grain)	14.90 (139.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Tule Lake, CA/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage post foliar (for hay)	19.16 (179.2)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage post foliar (for straw, grain)	19.23 (179.9)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Ephrata, WA/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	17.68 (165.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 51 (for straw, grain)	17.51 (163.8)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
Jerome, ID/2002	NOA-407855 120EC. containing safener Cloquintocet-mexyl	1. Post foliar broadcast spray: crop growth stage 21 (for hay)	17.90 (167.4)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 57 (for straw, grain)	14.85 (138.9)	0.016 (0.018)	None	0.016 (0.018)	2% crop oil concentrate
		1. Post foliar broadcast spray: crop growth stage 57 (for straw, grain)	15.06 (140.9)	0.080 (0.090)	None	0.080 (0.090)	2% crop oil concentrate



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

Data from Appendix 1, pp 203-233. MRID 46203204.

¹EP = End-use Product² Gallons per acre³ RTI = retreatment interval⁴ Approximately 7.25 g a.i./A of the safener cloquintocet-mexyl were applied at the 1X rate.

The herbicide formulation NOA-407855, which contains the safener cloquintocet-mexyl, was applied to barley grown under normal agricultural conditions on test lots at each field trial location (Table B.2). Control plots were separated at a sufficient distance to exclude any contamination from the treated plots. The herbicide formulation was diluted with water for a targeted treatment rate 0.016 lb cloquintocet-mexyl/A (0.018 Kg/ha) (1X) for hay, straw, and grain. Treatment rates of 3X and 5X were also applied for the evaluation of straw and grain commodities. All treatments were made by one-time post foliar broadcast spray using 2-20 gallons/acre.

The number and locations of the field trials are in accordance with OPPTS Guideline 860.1500 (Table B.3).

TABLE B.1.3. Trial Numbers and Geographical Locations			
NAFTA Growing Region	Barley		
	Submitted	Requested	
		Canada	US
1			1 ^a
1A			
2		1	1 ^a
3			
4			
5	3	1	3
5A			
5B		1	
6			
7	4	2	4
7A			
8			
9	1		1
10	1		1
11	2		2
12			
13			
14		12	



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

15			
16			
17			
18			
19			
20			
21			
Total	12	16	12

^a Either region is acceptable.

B.2. Sample Handling and Preparation

Hay, straw, and grain were harvested as barley raw agriculture commodities (RAC). Two samples of each RAC were taken from each trial. Hay samples were cut approximately 30 days after treatment and straw and grain were harvested at 60 days after treatment. In the decline study, hay samples were cut at 10, 20, 30, and 40 days after treatment and straw and grain samples were harvested at a PHI of 46, 53, 60, and 67 days. All RAC samples were frozen immediately (temperature not stated) after sampling and shipped frozen to Syngenta Greensboro, NC. Grain samples for processing were directly shipped to Texas A&M Univ., Food Protein R&D Center, Bryan, TX.

Hay and straw samples were cut into 2-inch pieces with a hand shear, and ground in a Hobart foodcutter with dry ice. Grain samples were ground with a table-top mill after removing chaff or other debris. After preparation, the samples were placed in polyethylene bags and stored frozen.

B.3. Analytical Methodology

Syngenta Analytical Method 117-01 was used for determination of residues of CGA-153433, the acidic metabolite of the safener additive cloquintocet-mexyl. The principle of the analytical method is that an acid hydrolysis extraction will convert cloquintocet-mexyl and all conjugates to its acid metabolite, 5-chloro-8-quinolinoxylacetic acid (CGA-153433). The sample was refluxed with 1N HCl/ACN for two hours. An aliquot of sample final fraction was injected into an HPLC equipped with RP18 to ODS-3 column switching and MS/MS for analysis. The LOD was 0.005 ppm. The LOQ, as presented in the method, was 0.01 ppm for grain and processed grain fractions, and 0.02 ppm for hay and straw. Fortification standard solutions were prepared by mixing a CGA-153433 stock solution and diluting with methanol to the desired concentration. Calibration standard solutions were prepared by mixing the CGA-153433 stock solution and diluting it with 0.2% formic acid to the desired concentrations. The quantitation of residues was based on HPLC/MS/MS peak area comparison with these calibration standard solutions. Adequate sample chromatograms and calibration curves were provided.



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

C. RESULTS AND DISCUSSION

Freezer storage time ranged from 4.3 to 14.9 months for all samples with the exception of straw from the field trial in ID which was stored for approximately 16 months. CGA-153433 was found to be stable in wheat hay under freezer storage for a minimum of 18 months and in wheat germ for five months. CGA-153433 was also found to be stable in wheat straw and grain for up to 380 days (PP#7E4920, DP Barcode: D257181, MRID 46203204, N. Dodd, 4/7/00). Syngenta has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage (MRID 46012916, W. Cutchin, in process). Syngenta has also submitted the results of a storage stability study with metabolite CGA-153433 in wheat germ. The results indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage (MRID 46012917, W. Cutchin, in process). The data for storage stability on wheat commodities can be used to support barley residue field trial data. There is adequate data on storage stability to support the period of storage in the present study.

Results of the method recovery validation are given in Table C.1. The analytical method LOQ was 0.01 ppm for grain and processed grain fractions and was 0.02 ppm for hay and straw. Recovery samples were prepared at the LOQ level up to 5 ppm for each sample set; at least one recovery sample was analyzed concurrently for validation of the method performance. Recoveries ranged from 81-113% (n=107) for CGA-153433. These results indicate the analytical method was capable of accurately determining CGA-153433 residues in barley RAC. The petitioner presented adequate calibration curves and chromatograms to indicate that the method is free from interferences.

TABLE C.1. Concurrent Recoveries of CGA-153433 from Fortified Barley RAC	
Commodity/Fortification level ^a	CGA-153433 (% recovery)
Hay	0.02 ppm
	95 ± 7.8 (n=17)
	0.50 ppm
	105 ± 7.2 (n=15)
	1.00 ppm
	101
Average	4.00 ppm
	97
Average	5.00 ppm
	102
Average	
100 ± 8.5 (n=35)	



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

TABLE C.1. Concurrent Recoveries of CGA-153433 from Fortified Barley RAC

Commodity/Fortification level ^a	CGA-153433 (% recovery)
Straw	0.02 ppm
	92 ± 3.9 (n=18)
	0.50 ppm
	99 ± 6.3 (n=17)
	5.00 ppm
	100
Average	95 ± 6.1 (36)
Grain	0.01 ppm
	94 ± 4.4 (n=18)
	0.50 ppm
	104 ± 3.9 (n=17)
	2.50 ppm
	105
Average	99 ± 6.6 (33)

Data taken from Table 3, pp. 29-34, MRID 46203204.

^aThe mean recoveries and standard deviations for each fortification level were calculated by the reviewer; average and S.D. for each RAC and the overall average and S.D. were presented in the study.

Residue levels of the safener metabolite CGA-153433 in barley RAC samples collected at the twelve field trial sites are shown in Tables C.2 and C.3. Minimal concentrations of CGA-153433 were found in only one hay sample (0.048 ppm) and in three straw samples (0.021-0.050 ppm). Residue levels following 3x and 5x application rates are also given in Table C.2. Only straw and grain RAC samples were tested at the exaggerated treatment rates. CGA-153433 was found at concentrations of 0.087-0.12 ppm only in straw samples from one trial at the 5X rate.

TABLE C.2. Residue Data from Crop Field Trials with Cloquintocet-mexyl.

Trial ID (City, State/Year)	Region	Crop/ Variety	Commodity or Matrix	Total Rate, lb a.i./A (Kg ai/ha)	PHI (days)	Residues of CGA- 153433 ¹ (ppm)
Windsor, VA/2002	2	Barley/Nomini	Hay	0.016	30	<LOQ: <LOQ
			Straw	(0.018)	60	<LOQ: <LOQ
			Grain		60	<LOQ: <LOQ
Gardner, ND/2002	5	Barley/Robust	Hay	0.016	30	<LOQ: <LOQ
			Straw	(0.018)	60	<LOQ: <LOQ
			Grain		60	<LOQ: <LOQ
Geneva, MN/2002	5	Barley/Royal	Hay	0.016	30	<LOQ: <LOQ
			Straw	(0.018)	60	<LOQ: <LOQ
			Grain		60	<LOQ: <LOQ
Richmond Township, WI/2002	5	Barley/Robust	Hay	0.016	30	<LOQ: <LOQ
			Straw	(0.018)	60	0.026; 0.026
			Grain		60	<LOQ: <LOQ
Lake Andes, SD/2002	7	Barley/Robust	Hay	0.016	30	<LOQ: <LOQ
			Straw	(0.018)	60	0.022; 0.050
			Grain		60	<LOQ: <LOQ



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Crop Field Trial - Barley

Eldridge. ND/2002	7	Barley/Robust	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ 0.021: <LOQ <LOQ: <LOQ
Dagmar. MT/2002	7	Barley/Robust	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ <LOQ: <LOQ <LOQ: <LOQ
Dagmar. MT/2002	7	Barley/Conlin	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ <LOQ: <LOQ <LOQ: <LOQ
Wellington. CO/2002	9	Barley/Moravian	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ <LOQ: <LOQ <LOQ: <LOQ
Tule Lake. CA/2002	10	Barley/Barley	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: 0.048 <LOQ: <LOQ <LOQ: <LOQ
Ephrata. WA/2002	11	Barley/Baroness	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ <LOQ: <LOQ <LOQ: <LOQ
Jerome. ID/2002	11	Barley/Baroness	Hay Straw Grain	0.016 (0.018)	30 60 60	<LOQ: <LOQ <LOQ: <LOQ <LOQ: <LOQ
Gardner. ND/2002	5	Barley/Robust	Straw Grain	0.048 (0.054)	60 60	<LOQ: <LOQ <LOQ: <LOQ
Jerome. ID/2002	11	Barley/Baroness	Straw Grain	0.080 (0.090)	60 60	0.12: 0.087 <LOQ: <LOQ

Data taken from Table 4, pp. 35-41. MRID 46203204.

LOQ = Limit of quantitation = 0.01 ppm for grain and processed fractions and 0.02 ppm for hay and straw: all control samples were <LOQ.

¹ Safener metabolite.

TABLE C.2. Summary of Storage Conditions			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days)	Interval of Demonstrated Storage Stability (days)
Forage	<10	89-149	750
Hay	<10	58-129	750
Grain	<10	53-88	165
Straw	<10	36-77	750

TABLE C.3. Summary of Residue Data from Crop Field Trials with Cloquintocet-mexyl, as safener in herbicide NOA-407855.

Commodity	Total Applic. Rate. (lb a.i./A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median (STMdR)	Mean (STMR)	Std. Dev.
CGA-153433 (metabolite of safener Cloquintocet-mexyl)									
Barley hay	0.016	30	24	<LOQ	0.048	0.029	n/a	n/a	n/a
Barley straw	0.016	60	24	<LOQ	0.050	0.036	0.0355	0.031	0.013



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Barley

Barley grain	0.016	60	24	<LOQ	<LOQ	n/a	n/a	n/a	n/a
Barley straw	0.048	60	2	<LOQ	<LOQ	n/a	n/a	n/a	n/a
Barley grain	0.048	60	2	<LOQ	<LOQ	n/a	n/a	n/a	n/a
Barley straw	0.080	60	2	<LOQ	<LOQ	n/a	n/a	n/a	n/a
Barley grain	0.080	60	2	0.087	0.120	0.104	0.104	0.104	0.023

* HAFT = Highest Average Field Trial.

n/a = not applicable.

D. CONCLUSION

The field trial residue data are classified as scientifically acceptable. The submitted study did not present adequate storage stability data; however, adequate data on storage stability exist to support the period of storage in the present study. Based on the data given, only minimal residues of CGA-153433 were found on hay and straw, and none (<LOQ) were found on grain.

E. REFERENCES

Agrochemicals Handbook, The. 1994. Third ed. The Royal Society of Chemistry, Cambridge, England.

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/14/05

Petition Number(s): 7E04920

DP Barcode(s): D308470

PC Code: 700099

Template Version September 2003



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIA 8.5
Processed Food and Feed - Wheat

Primary Evaluator Oak Ridge National Laboratory,
Oak Ridge, TN

Date: 8/1/05

Peer Reviewer W. Cutchin, Chemist
TRB/RD

This DER was originally prepared by Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN 37831. The DER has been reviewed by TRB and revised to reflect current OPP policies.

MRID No. 46203203. Lin. K. (January 16, 2004) NOA-407855 – Magnitude of Residues on Wheat: Syngenta Project Number: 824-02. Unpublished study prepared by Dietary Safety Department, Syngenta Crop Protection, Inc., Greensboro, NC 27419. 284 pages.

EXECUTIVE SUMMARY: Cloquintocet-mexyl (CGA-185072), as part of the NOA-407855 formulation 100EC was applied to wheat in a single post foliar broadcast spray at 0.016 lb a.i./A (0.018 kg a.i./ha) for the 1X treatment and at 0.080 lb a.i./A (0.090 kg a.i./ha) for 5X treatment. Wheat was harvested 62 days after treatment. The wheat grain samples were processed into bran, flour, middlings, shorts and germ.

Residues of metabolite CGA-153433 were quantified using Syngenta Analytical Method 117-01. The method converts all of the cloquintocet-mexyl to this acid metabolite. Quantification of residues was based on HPLC/MS/MS peak area comparisons. Satisfactory method performance in detecting CGA-153433 was demonstrated by concurrent recoveries. Freezer storage intervals ranged from 5.5-5.7 months after harvest for the processed commodities and for aspirated grain fractions (AGF). Previous studies (MRIDs 44399208 and 44399210) have shown that residues of the CGA-185072 and CGA-153433 are stable in/on wheat grain for the duration of frozen storage in the present study (up to 5.7 months). CGA-153433 residues following both the 1X and 5X application rates were below the limit of quantitation (LOQ), 0.01 ppm, in wheat grain and all processed commodities except aspirated grain fractions (AGF). In AGF, CGA-153433 residues were 0.012 and 0.071 ppm, respectively. The maximum theoretical concentration factor for AGF is 8X, and empirical concentration factors averaged 4.2X.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS: Under the conditions and parameters used in the study, the processed food and feed residue data are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document. DP Barcode D308470.



Cloquintocet-mexyl/700099/Syngenta Crop Protection/100
 DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIIA 8.5
 Processed Food and Feed - Wheat

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

A. BACKGROUND INFORMATION: Cloquintocet-mexyl is used as a safener in the formulation of NOA-407855 to prevent damage to the wheat due to phytotoxic effects.

TABLE A.1. Test Compound Nomenclature

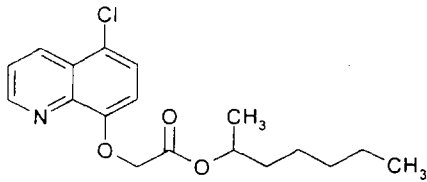
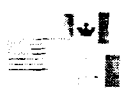
Compound	
Common name	Cloquintocet-mexyl
Company experimental name	CGA 185072
IUPAC name	(5-chloroquinolin-8-yloxy)acetic acid-1-methylhexylester
CAS name	[(5-chloro-8-quinolinyl)oxy]acetic acid-1-methylhexyl ester
CAS #	99607-70-2
End-use product/(EP)	Safener in formulations of Pinoxaden (NOA-407855) as well as in HORIZON® 240EC Herbicide (a synonym for HORIZON® is DISCOVER®).

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point range	ca. 65-69.4 °C	ca. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	-
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	

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 Processed Food and Feed - Wheat

- B. EXPERIMENTAL DESIGN:** Grain was harvested from a field trial conducted in Colony, OK, during the 2003 growing season. The site contained loamy sand soil. It had a monthly rainfall of 0-1.75 inches and an overall temperature range of 2.5-21.6 °C. Irrigation was used to supplement as needed during the trial.

Cloquintocet-mexyl, as part of the NOA-407855 formulation 100EC was applied to wheat in a single post foliar broadcast spray at 0.016 lb a.i./A (0.018 kg a.i./ha) for the 1X treatment and at 0.080 lb a.i./A (0.090 kg a.i./ha) for 5X treatment. Wheat was harvested 62 days after treatment. Control plots were separated from experimental plots at a sufficient distance to exclude contamination. The wheat grain samples were processed into bran, flour, middlings, shorts and germ.

B.1. Application and Crop Information:

TABLE B.1.2. Study Use Pattern.							
Location (City, State, EPA region, Year), Field test number	EP ¹	Application					Tank Mix Adjuvants
		Method/Timing	Vol. GPA ²	Rate ³ , lb a.i./A (kg a.i./ha)	RTI, ³ days	Total Rate ⁴ , lb a.i./A (kg a.i./ha)	
Colony, OK (8) 2003 SCHR01302	N1	1. Post foliar broadcast spray/CGS BBCH 47 for grain (including that for processed commodities) and straw	12.27 114.8	0.016 (0.018)	None	0.016 (0.018)	Merge
	N1	1. Post foliar broadcast spray/CGS BBCH 47 for grain (including that for processed commodities) and straw	12.35 115.5	0.080 (0.090)	None	0.080 (0.090)	Merge

¹EP = End-use Product: N1 = NOA-407855 formulation 100EC.

² Gallons per acre, L/ha

³ Retreatment Interval

⁴ This is the rate of application of the safener cloquintocet-mexyl.

- B.2. Sample Handling and Processing Procedures:** Processed grain fractions (flour, bran, shorts, middlings and germ) as well as AGF were produced from samples from a residue field trial conducted in Colony, OK, for determination of potential concentration in the processed grain fractions or in AGF. Wheat grain samples were put into frozen storage (temperature unspecified) immediately after sampling, and they were shipped directly to the Food Protein R&D Center, TAMU-Riverside Campus, Highway 47, Building 8525, Bryan, TX 77807. Samples were stored frozen (temperature unspecified) immediately upon receipt. Samples were processed by TAMU using simulated commercial processes (personal communication, Syngenta Representative). The period of freezer storage between harvest and extraction ranged from 5.5-5.7 months. Grain samples were ground using a

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tabletop mill after removal of chaff and other debris. After preparation, samples were placed into polyethylene bags and frozen (temperature unspecified).

B.3. Analytical Methodology: Syngenta Analytical Method 117-01 was used for the analysis. The principle of the analytical method is that an acid hydrolysis extraction will convert CGA-185072 and all conjugates to its acid metabolite, 5-chloro-8-quinolinoxylacetic acid (CGA-153433). Commodity specific cleanup procedures are followed by High Performance Liquid Chromatography (HPLC) determination with triple-stage quadrupole mass spectrometry (LC/MS/MS) to detect any CGA-153433 produced by the acid hydrolysis extraction, as well as any that was present previously because of metabolism in the wheat. The limit of detection (LOD) is 0.00125 ng. The LOQ is 0.01 ppm for grain, AGF and all processed commodities. Adequate sample chromatograms and calibration curves were provided.

C. RESULTS AND DISCUSSION: Details on sample storage are shown in Table C.2. All the wheat processed commodities and AGF were held in frozen storage for 5.5-5.7 months and sufficient storage stability data for CGA-185072 and CGA-153433 were provided for wheat grain in previous studies (MRIDs 44399208 and 44399210). Storage stability data are not needed for bran, flour, middlings, and shorts since these matrices are similar to grain and can be covered by the storage stability data on grain (D246730, N. Dodd, 4/7/00). The temperatures of frozen storage was not clearly stated in the document, however, there were indications it was to be $< -10^{\circ}\text{C}$ (e.g. MRID 46203206, page 246 footnote). Syngenta has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. The submitted storage stability data indicate that residues of metabolite CGA-153433 are stable in/on wheat forage and hay for up to ~25 months of frozen storage (MRID 46012916, W. Cutchin, in process). Syngenta has also submitted the results of a storage stability study with metabolite CGA-153433 in wheat germ. The results indicate that residues of the metabolite CGA-153433 are stable in wheat germ for up to 165 days (5.4 months) of frozen storage (MRID 46012917, W. Cutchin, in process). There is adequate data on storage stability to support the period of storage in the present study.

The procedural recoveries only tested samples that were fortified with CGA-153433. Results, which are presented in Table C.1, indicate that the concurrent recoveries were almost all within the OPPTS 860.1340 guideline acceptable range of 70-120%. For the processed commodities themselves, the range was 79-105%. These results show that the analytical method effectively measures CGA-153433 residue in wheat processed commodities. The petitioner presented adequate calibration curves and chromatograms to indicate that the method is free from interferences.



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CGA-153433 levels in wheat grain, AGF, and processed commodities are shown in Tables C.3. There was a corresponding control sample for each experimental sample, and the control residue levels of CGA-153433 were always below the LOQ. CGA-153433 residues were below the LOQ for wheat grain and all processed commodities for both the 1X and 5X application rates, and in AGF they were 0.012 and 0.071 ppm, respectively. The maximum theoretical concentration factor for AGF is 8X, and empirical concentration factors averaged 4.2X.

TABLE C.1. Summary of Concurrent Recoveries of CGA-153433 (Acid Metabolite of Cloquintocet-mexyl) from Grain, Aspirated Grain Fractions (AGF) and Processed Commodities of Wheat.

Matrix	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
CGA-153433				
Grain	2	1	97	97
Grain	0.5	25	91-117	104.8 $\pm$ 7.7
Grain	0.01	28	70-123	95.2 $\pm$ 12.4
AGF	0.01	1	100	100
Bran	0.5	1	90	90
Bran	0.01	1	93	93
Flour	0.5	1	91	91
Flour	0.01	1	85	85
Germ	3	1	85	85
Germ	0.01	1	79	79
Middlings	0.5	1	102	102
Middlings	0.01	1	87	87
Shorts	0.5	1	105	105
Shorts	0.01	1	81	81

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration Until Extraction (months)	Interval of Demonstrated Storage Stability (months)
Grain (RAC)	not stated	4.1-16.3	25
Processed commodities and AGF	not stated	5.5-5.7	25

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TABLE C.3. Residue Data from Wheat Processing Study with Cloquintocet-mexyl.						
Trial ID (City, State/Year) and field test number	EPA Crop Region	Crop/ Variety	Commodity or Matrix	Total Rate ¹ , lb a.i./A (kg a.i./ha)	Nominal PHI (days) [actual PHI ² if it differs]	Residues of CGA-153433 (ppm)
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Grain	0.016 (0.018)	60 [62]	<LOQ; <LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Grain	0.080 (0.090)	60	<LOQ; <LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Grain prior to process	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Grain prior to process	0.080 (0.090)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Aspirated Grain Fractions (AGF)	0.016 (0.018)	60 [62]	0.012
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Aspirated Grain Fractions (AGF)	0.080 (0.090)	60 [62]	0.071
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Bran	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Bran	0.080 (0.090)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Flour	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Flour	0.080 (0.090)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Middlings	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Middlings	0.080 (0.090)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Shorts	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Shorts	0.080 (0.090)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Germ	0.016 (0.018)	60 [62]	<LOQ
Colony, OK / 2003 SCHR01302	8	Wheat Coker 9663	Germ	0.080 (0.090)	60 [62]	<LOQ

¹This is the rate of application of the safener Cloquintocet-mexyl.

²PHIs were calculated based on the dates reported in Table 2, pp. 27-32, of MRID 46203203.

D. CONCLUSION: The processed food and feed residue data are classified as scientifically acceptable. The finding of no quantifiable residues in wheat grain and processed commodities, except AGF, at the 5X application rate indicates that no concentration of CGA-185072 or CGA-153433 occurs during processing. The maximum theoretical



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concentration factor for AGF is 8X, and empirical concentration factors averaged 4.2X.

E. REFERENCES:

Hamilton, L. Syngenta Final Report 128-99, "Residue Stability of CGA-184927 and CGA-185072 and Their Metabolites, CGA-193469 and CGA-153433, Fortified Into Wheat Forage and Hay Under Freezer Conditions", MRID 46012916.

Hamilton, L. Syngenta Final Report 224-01, "Residue Stability of CGA-193469 and CGA-153433, Fortified Into Wheat Germ Under Freezer Conditions", MRID 46012917.

Lin, K. Syngenta Analytical Method 117-01, "Analytical Method for Determination of NOA-07855, NOA-407854, SYN-505164, SYN-502836 and CGA-153433 in Crops by LC/MS/MS Including Validation Data" – no other publication details were provided.

MRID 44399208 Mair, Dr. P. (1995) Report on Special Study 119/93: Residue Stability Study for CGA-184927 and CGA-185072 in Wheat (Grain) Under Freezer Storage Conditions, Laboratory Project Number 119/93, Nexus Study Number 747-95, unpublished study sponsored by Novartis Crop Protection, Inc., 20 pp.

MRID 44399210 Mair, Dr. P. (1993) Two-Year Residue Stability Study of Metabolites CGA-193469 and CGA-153433 (Grain) under Freezer Conditions [Wheat], Laboratory Project Number 300/91 (Final Report), Nexus Study Number 521-92, unpublished study submitted by Novartis Crop Protection, Inc., 7 pp.

F. DOCUMENT TRACKING:

RDI: W. Cutchin. 7/15/05
Petition Number(s): 7E04920
DP Barcode(s): D308470
PC Code: 700099

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 Crop Field Trial - Wheat

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Peer Reviewer W. Cutchin, Chemist
 TRB/RD:

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004. The DER has been reviewed by TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012918 Hamilton, L. (2001) CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Wheat: Lab Study Number: Syngenta Number 446-00. Unpublished study prepared by Syngenta Crop Protection Inc. 195 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection Corporation, Inc. has submitted field trial data on wheat forage, hay, straw, and grain. The petitioner conducted a total of four wheat field trials (three spring wheat and one winter wheat) during the 2000 growing season in Region 11 (ID and WA). The number and location of field trials are not in accordance with OPPTS Guideline 860.1500 and Directive 98-02; Section 9. The petitioner intended the submitted field trials to represent the wheat-growing areas of the Pacific Northwest area of the U.S.

At each field trial site, separate plots were treated with a single postemergence foliar application of an emulsifiable concentrate (EC) formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl. Each trial had three plots, a control and two treated plots. The treated plots had a single postemergence foliar application of the 0.5 lb safener/gal EC formulation made to wheat early in the season at Feekes Growth Stage 2 at 0.016 lb safener/A (7.1 g safener/A). One treated plot was sampled for forage and hay, the other for mature straw and grain. Applications at all plots were made using ground equipment in 10-18 gal/A of water with an adjuvant added to the spray mixture.

Samples of wheat forage were collected at a 0- and a 29- to 30-day PHI, samples of wheat hay were collected at a 29- to 30-day PHI from treatment plot 2, and samples of wheat straw and grain were collected at maturity (56- to 60-day PHI) from treatment plot 3.

The maximum residues of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage, hay, grain, and straw from the submitted wheat field trials are reported below.

Commodity	PHI (days)	Maximum Residue Levels (ppm)		
		Cloquintocet-mexyl	CGA-153433	Total Residues
Spring wheat				



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Commodity	PHI (days)	Maximum Residue Levels (ppm)		
		Cloquintocet-mexyl	CGA-153433	Total Residues
Wheat forage	0	0.57	0.32	0.76
	29-30	<0.05	<0.05	<0.10
Wheat hay	29-30	<0.05	<0.05	<0.10
Wheat straw	56-60	<0.05	<0.05	<0.10
Wheat grain	56-60	<0.02	<0.05	<0.07
Winter wheat				
Wheat straw	61	<0.05	<0.05	<0.10
Wheat grain	61	<0.02	<0.05	<0.07

No residue decline studies were conducted with these field trials. Residue decline studies on wheat have been submitted with a separate set of field trials (46012904CFT.der.wpd, W. Cutchin, in process).

Samples of wheat RACs were analyzed for residues of cloquintocet-mexyl using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated limits of quantitation (LOQs) were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use mass spectroscopy (MS) detection of CGA-153433 (instead of UV detection). The validated LOQ was 0.05 ppm for wheat forage, hay, straw, and grain. These methods are adequate for data collection based on acceptable method recoveries.

The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 89 days (2.9 months) for wheat forage, 67 days (2.2 months) for wheat hay, 62 days (2.0 months) for wheat straw, and 63 days (2.1 months) for wheat grain. The maximum storage intervals of crop samples from harvest to analysis for metabolite CGA-153433 were 98 days (3.2 months) for wheat forage, 73 days (2.4 months) for wheat hay, 68 days (2.2 months) for wheat straw, and 67 days (2.2 months) for wheat grain.

In support of the crop field trial study, the petitioner cited storage stability data (46012916SS.der.wpd, W. Cutchin, in process) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage. Storage stability data submitted previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat straw and grain stored at -18 °C for up to ~6 months, and residues of CGA-153433 are stable in wheat straw stored at -18 °C for 380 days (12.5 months). Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for 727 days (23.9 months). The available



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storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. We note that the crop field trial data only reflect four field trials in Region 11. Crop field trial data for spring and winter wheat from additional regions have been submitted separately (refer to the DERs for MRIDs 46012904 and 46015905; 46012904.de3.wpd and 46015905.de2.wpd). The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener needed in the formulation to prevent damage to wheat due to phytotoxic effects. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00). The petitioner has now submitted data to satisfy the conditions of full registration.

TABLE A.1. Test Compound Nomenclature.	
Chemical structure	<chem>CCCCC(C)OC(=O)COc1ccc(Cl)cc2ncn12</chem>
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS registry number	99607-70-2
End-use product (EP)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)



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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca.. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	—
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html;
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.						
Trial Identification (County, State: Year)	Soil characteristics				Meteorological data	
	Type	%OM	pH	CEC	Overall monthly rainfall range (inches)	Overall average temperature range (°C)
Spring wheat						
Fremont, ID: 2000 (0W-HR-305-00)	Loam	Not applicable			No weather data for the study period (between application and harvest) were provided.	
Lincoln, WA: 2000 (0W-HR-306-00)	Loam	Not applicable				
Lincoln, WA: 2000 (0W-HR-307-00)	Loam	Not applicable				
Winter wheat						
Whitman, WA: 2000 (0W-HR-302-00)	Silt loam	Not applicable			No weather data for the study period (between application and harvest) were provided.	

No weather data for the study period (between application and harvest) were provided, although information for months preceding application was provided. The petitioner stated that “no information was available.”



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TABLE B.1.2. Study Use Pattern.

Location (County, State; Year)	EP ¹	Application						Tank Mix Adjuvants
		Plot ²	Method: Timing	Vol. (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ⁴ (days)	Total Rate (lb safener/A) [g safener/A]	
Spring wheat field trials								
Fremont, ID: 2000 (0W-HR-305-00)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	17	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Full flower	18	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Lincoln, WA: 2000 (0W-HR-306-00)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 3	15	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: End of anthesis	15	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Lincoln, WA: 2000 (0W-HR-307-00)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 3	15	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: 8-9 leaf	15	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Winter wheat field trials								
Whitman, WA: 2000 (0W-HR-302-00)	0.5 lb/gal EC	3	1: Postemergence foliar spray: Stem elongation	10	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v

¹ EP = End-use Product² Treatment Plot 2 received a single postemergence application made early in the season at the Feekes Growth Stage 2.

Treatment Plot 3 received a single postemergence application made late in the season approximately 60 days prior to harvest of mature wheat.

³ GPA = Gallons per acre⁴ RTI = Retreatment Interval**TABLE B.1.3. Trial Numbers and Geographical Locations.**

NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
1			
1A			
2			1
3			
4			1
5			5
5A			
5B			
6			1
7			5



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TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
7A			
8			6
9			
10			
11	3 (spring wheat) 1 (winter wheat)		1
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	3 (spring wheat) 1 (winter wheat)		20

B.2. Sample Handling and Preparation

Samples of wheat forage were collected at a 0- and a 29- to 30-day PHI, samples of wheat hay were collected at a 29- to 30-day PHI from treatment plot 2, and samples of wheat straw and grain were collected at maturity (56- to 60-day PHI) from treatment plot 3. For each plot and sampling interval, a single untreated and duplicate treated samples were collected. Specific harvesting procedures were not described.

After collection, RAC samples were frozen and shipped via freezer truck or overnight courier on dry ice to Syngenta Crop Protection, Inc. (Greensboro, NC) for analysis. At Syngenta, samples were stored frozen (~-20 °C) until analysis.

B.3. Analytical Methodology

Samples of wheat RACs were analyzed by Syngenta for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The limit of detection (LOD), as determined by the smallest standard injection, was 0.40 ng. and the LOQs, as demonstrated by the smallest acceptable recovery level, were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain.



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In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The LOD, as determined by the smallest standard injection, was 0.125 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.05 ppm for wheat forage, hay, straw, and grain. Methods REM 138.01 and REM 138.10 were submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04920: DP Barcode D257181, N. Dodd, 4/7/00).

Method REM 138.01: Briefly, homogenized samples were extracted with acetonitrile and filtered. The extract was cleaned up by partitioning with hexane (2x); the hexane phases were discarded. The acetonitrile phase was cleaned up by solid phase extraction (SPE) on a C-18 cartridge, using acetone to elute residues; this step was omitted for grain samples. Water and saturated sodium chloride solution were added to the extract (only saturated sodium chloride solution was added to grain samples), which was then partitioned three times with hexane:diethyl ether (9:1; v:v). The combined organic phases were subjected to a second SPE on a silica cartridge, using hexane:acetone (8:2, v:v) to elute residues of cloquintocet-mexyl. The eluate was evaporated to dryness, residues were redissolved in hexane:ethanol (9:1, v:v), and the sample was analyzed by HPLC/UV using column switching. We note that the method was modified slightly to increase the LOQ for wheat forage, hay, and straw to 0.05 ppm.

Method REM 138.10: Briefly, homogenized crop samples were extracted with an acetone:citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane:diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol:buffer (50:50, v:v). The methanol:buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water and CGA-153433 was determined by HPLC/MS. We note that in addition to the modification to use MS detection, the method was modified to increase the LOQ for grain to 0.05 ppm.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. Samples of wheat forage, hay, grain, and straw were analyzed for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQs were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The validated LOQ was 0.05 ppm for wheat forage, hay, straw, and grain. These methods are adequate for data collection based on acceptable method recoveries. Apparent residues of cloquintocet-mexyl and



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CGA-153433 were each below the LOQ in/on six samples of untreated forage, three samples of untreated hay, four samples of untreated straw, and four samples of untreated grain.

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 89 days (2.9 months) for wheat forage, 67 days (2.2 months) for wheat hay, 62 days (2.0 months) for wheat straw, and 63 days (2.1 months) for wheat grain. The maximum storage intervals of crop samples from harvest to analysis for metabolite CGA-153433 were 98 days (3.2 months) for wheat forage, 73 days (2.4 months) for wheat hay, 68 days (2.2 months) for wheat straw, and 67 days (2.2 months) for wheat grain.

In support of the crop field trial study, the petitioner cited storage stability data (refer to the DER for MRID 46012916; 46012916.de2.wpd) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage. Storage stability data submitted previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat straw and grain stored at -18 °C for up to ~6 months, and residues of CGA-153433 are stable in wheat straw stored at -18 °C for 380 days (12.5 months). Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for 727 days (23.9 months). The available storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.

Residue data from the wheat field trials are reported in Table C.3. A summary of residue data for wheat forage, hay, straw, and grain following treatment with the 0.5 lb/gal EC formulation is presented in Table C.4. Following treatment of spring wheat with a single broadcast foliar application of the 0.5 lb safener/gal EC formulation made at Feekes Growth Stage 2 at 0.016 lb safener/A (7.1 g safener/A), residues of cloquintocet-mexyl were 0.15-0.57 ppm in/on forage harvested on the day of application and were below the LOQ (<0.05 ppm) in/on forage and hay harvested 29-30 days following treatment. Residues of CGA-153433 were 0.05-0.32 ppm in/on forage harvested on the day of application and were below the LOQ (<0.05 ppm) in/on forage and hay harvested 29-30 days following treatment. Combined residues of cloquintocet-mexyl and CGA-153433 were 0.20-0.76 ppm in/on forage harvested on the day of treatment and <0.10 ppm in/on forage and hay harvested 29-30 days posttreatment.

Residues of cloquintocet-mexyl were below the LOQ (<0.05 ppm) in/on spring wheat straw and below the LOQ (<0.02 ppm) in/on spring wheat grain harvested 56-60 days following a single broadcast foliar application of the 0.5 lb safener/gal EC formulation, made approximately 60 days prior to harvest, at 0.016 lb safener/A (7.1 g safener/A); residues of CGA-153433 were below the LOQ (<0.05 ppm) in/on these samples.

Residues of cloquintocet-mexyl were below the LOQ in/on winter wheat straw (<0.05 ppm) and grain (<0.02 ppm) harvested 61 days following of a single broadcast foliar application of the 0.5



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lb safener/gal EC formulation, made approximately 60 days prior to harvest, at 0.016 lb safener/A (7.1 g safener/A); residues of CGA-153433 were below the LOQ (<0.05 ppm) in/on these samples.

A total of four wheat field trials (three spring wheat trials and one winter wheat) were conducted during the 2000 growing season. Spring wheat field trials were conducted in Region 11 (ID and WA: 3 trials) and one winter wheat field trial was conducted in Region 11 (WA). The number and location of field trials are not in accordance with OPPTS Guideline 860.1500 and Directive 98-02; Section 9. The petitioner intended the submitted field trials to represent the wheat-growing areas of the Pacific Northwest area of the U.S.

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev
Cloquintocet-mexyl; determined using Modified REM 138.01				
Wheat forage	0.05	5	75. 84. 86. 88. 117	87 ± 16
	0.10	1	89	
	0.20	1	81	
	0.50	1	53	
	1.00	1	99	
	5.00	1	89	
	10.00	1	99	
Wheat hay	0.05	3	79. 86. 89	89 ± 8.8
	0.10	1	87	
	0.50	1	103	
Wheat straw	0.05	3	65. 76. 109	104 ± 29.1
	0.10	1	106	
	0.20	2	94. 127	
	1.00	1	150	
Wheat grain	0.02	4	53. 77. 95. 113	98.0 ± 29.2
	0.10	1	118	
	0.50	1	132	
CGA-153433; determined using Modified REM 138.10				
Wheat forage	0.05	3	64. 73. 77	84 ± 22.4
	0.10	1	67	
	0.20	1	73	
	0.50	1	135	
	1.00	1	98	
	5.00	1	94	
	10.00	1	73	



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TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Wheat hay	0.05	2	62, 70	68 $\pm$ 10.0
	0.10	1	67	
	0.50	1	58	
	1.00	1	84	
Wheat straw	0.05	3	64, 64, 80	67 $\pm$ 9.8
	0.10	1	58	
	0.20	2	59, 63	
	0.50	1	82	
Wheat grain	0.05	2	57, 70	84 $\pm$ 28.0
	0.20	1	71	
	0.50	2	94, 128	

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration ¹	Interval of Demonstrated Storage Stability ²
Cloquintocet-mexyl			
Wheat forage	-20	44-89 days (1.4-2.9 months)	Residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay during up to 18 months of frozen storage.
Wheat hay		46-67 days (1.5-2.2 months)	
Wheat straw		28-62 days (0.9-2.0 months)	Residues of cloquintocet-mexyl are stable in/on wheat straw stored at -18 °C for 6 months.
Wheat grain		30-63 days (1.0-2.1 months)	Residues of cloquintocet-mexyl are stable in/on wheat grain stored at -18 °C for ~6 months.
CGA-153433			
Wheat forage	-20	44-98 days (1.4-3.2 months)	Residues of CGA-153433 are reasonably stable in/on wheat forage and hay during up to ~25 months of frozen storage.
Wheat hay		48-73 days (1.6-2.4 months)	
Wheat straw		30-68 days (1.0-2.2 months)	Residues of CGA-153433 are stable in wheat straw during up to 380 days of frozen storage.
Wheat grain		31-67 days (1.0-2.2 months)	Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for up to 727 days.

¹ From sampling to analysis: wheat samples were analyzed for cloquintocet-mexyl within 0-7 days of extraction and for CGA-153433 within 2-12 days of extraction.

² Refer to the 860.1380 DER (46012916SS.der.wpd, W. Cutchin, in process) and PP#7E04920: DP Barcode D257181, N. Dodd, 4/7/00.



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TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²		
							CGA- 185072	CGA- 153433	Total
Spring Wheat Trials									
Fremont, ID: 2000 (0W-HR-305-00)	11	Spring: Penewawa	2	forage	0.016 [7.1]	0	0.15	0.05	0.20
				forage		29	0.49	0.14	0.63
							<0.05	<0.05	<0.10
			hay	29	<0.05	<0.05	<0.10		
					<0.05	<0.05	<0.10		
			3	straw	0.016 [7.1]	56	<0.05	<0.05	<0.10
				grain		56	<0.05	<0.05	<0.10
							<0.02	<0.05	<0.07
Lincoln, WA: 2000 (0W-HR-306-00)	11	Spring: Krones	2	forage	0.016 [7.1]	0	0.42	0.30	0.72
				forage		30	0.44	0.32	0.76
							<0.05	<0.05	<0.10
			hay	30	<0.05	<0.05	<0.10		
					<0.05	<0.05	<0.10		
			3	straw	0.016 [7.1]	60	<0.05	<0.05	<0.10
				grain		60	<0.05	<0.05	<0.10
							<0.02	<0.05	<0.07
Lincoln, WA: 2000 (0W-HR-307-00)	11	Spring: Krones	2	forage	0.016 [7.1]	0	0.37	0.11	0.48
				forage		30	0.57	0.08	0.65
							<0.05	<0.05	<0.10
			hay	30	<0.05	<0.05	<0.10		
					<0.05	<0.05	<0.10		
			3	straw	0.016 [7.1]	60	<0.05	<0.05	<0.10
				grain		60	<0.05	<0.05	<0.10
							<0.02	<0.05	<0.07
Winter Wheat Trials									
Whitman, WA: 2000 (0W-HR-302-00)	11	Winter: Madsen	3	straw	0.016 [7.1]	61	<0.05	<0.05	<0.10
				grain		61	<0.05	<0.05	<0.10
					61	<0.02	<0.05	<0.07	
						<0.02	<0.05	<0.07	

¹ Treatment Plot 2 received a single postemergence application made early in the season at the Feekes Growth Stage 2.

Treatment Plot 3 received a single postemergence application made late in the season approximately 60 days prior to harvest of mature wheat.

² The petitioner reported residue values corrected for method recovery. The uncorrected residues reported in this table were obtained by the study reviewer from the raw data. Total residue values were calculated by the study reviewer.



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TABLE C.4. Summary of Residue Data from Wheat Crop Field Trials with Cloquintocet-Mexyl.										
Commodity	Total Applic. Rate (lb safener/A) [g safener/A]	PHI (days)	Analyte	Residue Levels (ppm)						
				n	Min.	Max.	HAFT ¹	Median (STMdR ²)	Mean (STMR ³)	Std. Dev.
Spring Wheat										
Wheat, forage	0.016 [7.1]	0	CGA-185072	6	0.15	0.57	0.47	0.43	0.41	0.14
			CGA-153433	6	0.05	0.32	0.31	0.13	0.17	0.12
			Total	6	0.20	0.76	0.74	0.64	0.57	0.21
	0.016 [7.1]	29-30	CGA-185072	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	6	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, hay	0.016 [7.1]	29-30	CGA-185072	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	6	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, straw	0.016 [7.1]	56-60	CGA-185072	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	6	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, grain	0.016 [7.1]	56-60	CGA-185072	6	<0.02	<0.02	<0.02	<0.02	<0.02	0.0
			CGA-153433	6	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	6	<0.07	<0.07	<0.07	<0.07	<0.07	0.0
Winter Wheat										
Wheat, straw	0.016 [7.1]	61	CGA-185072	2	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	2	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	2	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, grain	0.016 [7.1]	61	CGA-185072	2	<0.02	<0.02	<0.02	<0.02	<0.02	0.0
			CGA-153433	2	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	2	<0.07	<0.07	<0.07	<0.07	<0.07	0.0

¹ HAFT = Highest Average Field Trial.

² STMdR = Supervised Trial Median Residue.

³ STMR = Supervised Trial Mean Residue.



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D. CONCLUSION

The submitted field trial data reflect a single postemergence foliar application of an EC formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl made to wheat either early in the season at the Feekes Growth Stage 2 (treatment plot 2) or later in the season approximately 60 days prior to harvest of mature wheat (treatment plot 3). Cloquintocet-mexyl was applied at a rate of 0.016 lb safener/A (7.1 g safener/A). Wheat forage was harvested at a 0- and a 29- to 30-day PHI, wheat hay was harvested at a 29- to 30-day PHI from treatment plot 2, and wheat straw and grain were collected at maturity (56- to 60-day PHI) from treatment plot 3. Acceptable methods were used for quantitation of residues in/on wheat commodities.

E. REFERENCES

DP Barcode: D257181
Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.
From: Nancy Dodd
To: Bipin Gandhi/Robert Forrest
Dated: 4/7/00
MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/29/05.
Petition Number(s): PP#7E04920
DP Barcode(s): D308470
PC Code: 700099

Template Version September 2003



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DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIA 8.1.1
Storage Stability - Wheat Germ

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Approved by W. Cutchin, Chemist
 RD/TRB

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004). The DER has been reviewed by TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012917 Hamilton, L. (2001) Residue Stability of CGA-193469 and CGA-153433. Fortified Into Wheat Germ Under Freezer Storage Conditions: Lab Study Number: Syngenta Number 224-01. Unpublished study prepared by Syngenta Crop Protection Inc. 47 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted the results of a storage stability study with cloquintocet-mexyl metabolite CGA-153433 in wheat germ. Untreated samples of wheat germ were fortified with CGA-153433 at 1.00 ppm. Fortified and unfortified samples of wheat germ were extracted following 0, 33, 95, and 160 days of storage. With the exception of the 0-day sample, extracts were stored for an additional 2-5 days until analysis. The 0-day sample extract was stored for 33 days prior to analysis.

Samples of wheat germ were analyzed for residues of CGA-153433 using a modified version of high pressure liquid chromatography with ultraviolet detector (HPLC/UV) Method REM 138.10, which is current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use mass spectroscopy (MS) detection of CGA-153433 (instead of UV detection). The reported limit of quantitation (LOQ) was 0.05 ppm for wheat germ. The method was adequate for data collection based on acceptable method recoveries.

The results indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the storage stability data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.



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 Storage Stability - Wheat Germ

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported.

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener contained in the formulation Discover™ Herbicide, which contains the herbicide clodinafop-propargyl (CGA-184927). Cloquintocet-mexyl is needed in the formulation to prevent damage to wheat due to phytotoxic effects of CGA-184927. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7F04920; DP Barcode D257181, 4/7/00, N. Dodd). The petitioner has now submitted data to satisfy the conditions of full registration.

TABLE A.1. Test Compound Nomenclature	
Chemical structure	
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS registry number	99607-70-2
End-use products (EPs)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)
Chemical structure of cloquintocet-mexyl acid metabolite	[(5-chloro-8-quinolinyl)oxy]acetic acid



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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca.. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	–
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html;
Water solubility (25 °C)	0.59 mg/L	Tomlin. C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin. C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	

B. EXPERIMENTAL DESIGN

B.1. Sample Handling and Preparation

Samples of untreated wheat grain, from a cloquintocet-mexyl field trial, were shipped frozen to the Texas A&M University, Food Protein Center (Bryan, TX) for processing. Following processing, samples of wheat germ were shipped frozen on dry ice to Syngenta Crop Protection, Inc. (Greensboro, NC). Samples of wheat germ were stored frozen (-20 °C) in polyethylene bottles or bags until preparation for fortification. Subsamples of wheat germ were placed in amber bottles and fortified with CGA-193469 at 1.00 ppm. The petitioner did not specify the solvent used for the standard spiking solution or the stability of this solution. Fortified and unfortified samples were stored in the freezer at approximately -20 °C. Fortified and unfortified samples of wheat germ were extracted following 0, 33, 95, and 160 days of storage. With the exception of the 0-day sample, extracts were stored for an additional 2-5 days until analysis. The 0-day sample extract was stored for 33 days prior to analysis.

B.2. Analytical Methodology

Samples of wheat germ were analyzed by Syngenta for residues of CGA-153433 using a modified version of Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The reported LOQ was 0.05 ppm for wheat germ. Method



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REM 138.10 was submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04924; DP Barcodes D246730 and D253344, 4/7/00, N. Dodd).

Briefly, samples of wheat germ were extracted with an acetone: citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane: diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol: buffer (50:50, v:v). The methanol: buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water, and CGA-153433 was determined by HPLC/MS.

C. RESULTS AND DISCUSSION

The concurrent method validation data included in the study indicate that the HPLC/MS method REM 138.10 is marginally adequate for the determination of residues of CGA-153433 in wheat germ. Although recoveries were low (61-75%), HED concludes that the method is adequate for the purposes of the storage stability study because the standard deviation of the recoveries was low (4.4%). Apparent residues of the metabolite CGA-153433 were reportedly <0.10 ppm in unfortified samples of wheat germ from the 0- and 30-day storage intervals and <0.05 ppm in unfortified samples from the 95- and 160-day intervals.

The results of the storage stability study are presented in Table C.2. The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage. A graph of the stability of CGA-153433 in wheat germ is presented in Figure C.1.

TABLE C.1. Summary of Method Recoveries of CGA-153433 from Wheat Germ.					
Matrix	Spike level (ppm)	Storage Interval (days)	Sample size (n)	Recoveries (%) ¹	Mean
Wheat germ	1.0	0	1	61	61
	1.0	33	2	66.75	71
	1.0	95	2	66.67	67
	1.0	160	2	64.69	66

¹ Results were corrected for control values by the petitioner.



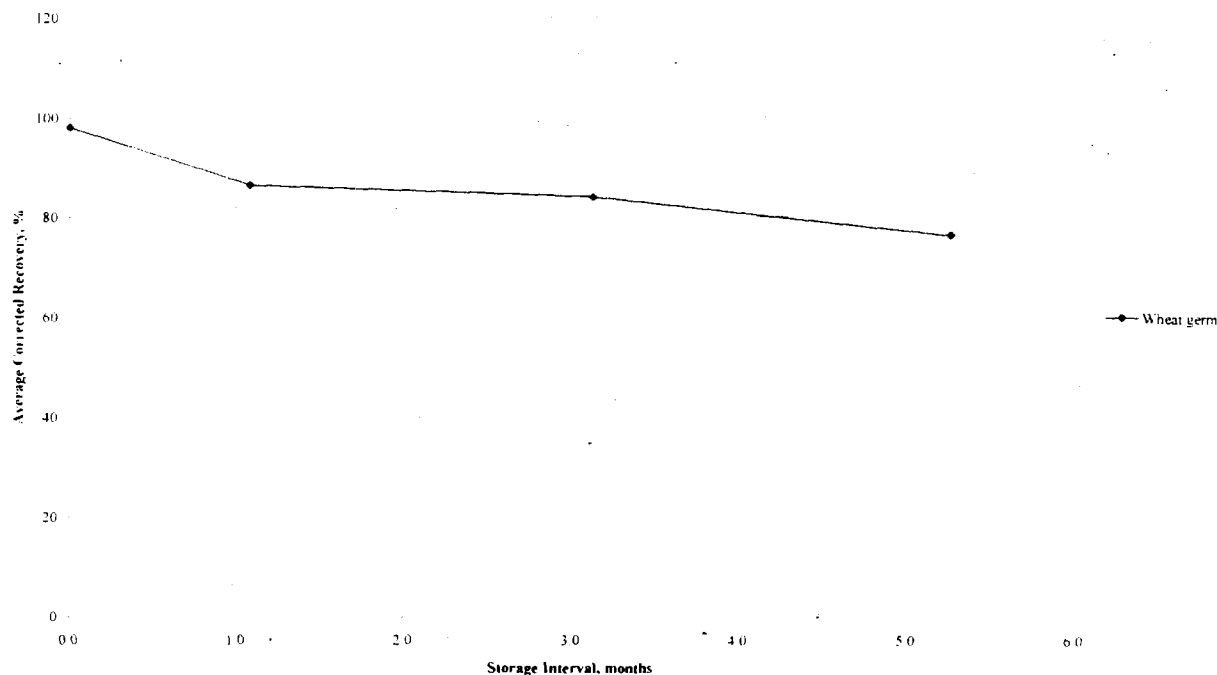
Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Germ

C.2. Stability of CGA-153433 Residues in Wheat Germ Following Storage at -20 °C.				
Commodity	Spike level (ppm)	Storage interval (days) ¹	Recovered residues (ppm)	% Recovery ²
CGA-153433				
Wheat germ	1.0	0 [33]	0.569, 0.635	93, 104
		33 [2]	0.585, 0.632	83, 90
		95 [4]	0.539, 0.580	81, 87
		160 [5]	0.483, 0.529	73, 80

¹ Interval between fortification and extraction; the interval between extraction and analysis is presented in brackets.

² Stored sample recoveries were corrected by the petitioner for control values and procedural recoveries <100%.

FIGURE C.1. Graph of Storage Stability of CGA-153433 in Wheat Germ.



D. CONCLUSION

The submitted storage stability data indicate that residues of the metabolite CGA-153433 are reasonably stable in wheat germ for up to 165 days (5.4 months) of frozen storage.



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability - Wheat Germ

E. REFERENCES

DP Barcode: D257181

Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.

From: Nancy Dodd

To: Bipin Gandhi/Robert Forrest

Dated: 4/7/00

MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/29/05

Petition Number(s): PP#7E04920

DP Barcode(s): D308470

PC Code: 700099

Template Version September 2003



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability - Wheat Forage and Hay

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Approved by

W. Cutchin, Chemist
RD/TRB

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004). The DER has been reviewed by TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012916. Hamilton, L. (2001) Residue Stability of CGA-184927 and CGA-185072 and Their Metabolites, CGA-193469 and CGA-153433, Fortified Into Wheat Forage and Hay Under Freezer Storage Conditions: Lab Study Number: Syngenta Number 128-99. Unpublished study prepared by Syngenta Crop Protection Inc. 120 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted the results of a storage stability study of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage and hay. Untreated samples of wheat forage and hay were fortified with cloquintocet-mexyl and its metabolite CGA-153433 at 1.00 ppm each. Fortified and unfortified samples of wheat forage and hay were extracted following 0, 14, 29, 61, 120, 180, 275, 359, 533, and 769 days of storage for cloquintocet-mexyl, and following 0, 90, 180, 359, 539, and 770 days of storage for metabolite CGA-153433. For cloquintocet-mexyl, extracts were stored for an additional 0-13 days until analysis. For metabolite CGA-153433, extracts were stored for an additional 1-13 days until analysis.

Samples of wheat forage and hay were analyzed for residues of cloquintocet-mexyl using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQ was 0.05 ppm for wheat forage and hay. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use mass spectrometry (MS) detection of CGA-153433 (instead of UV detection). The validated limit of quantitation (LOQ) was 0.05 ppm for wheat forage and hay. These methods are adequate for data collection based on acceptable method recoveries.

The submitted storage stability data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months. When compared to Day-0 recovery



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Forage and Hay

values, residues of cloquintocet-mexyl appear to decline in wheat forage and hay by ~45-50% after ~25 months of frozen storage.

The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the storage stability data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener needed in the formulation to prevent damage to wheat due to phytotoxic effects. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7F04920; DP Barcode D257181, N. Dodd, 4/7/00). The petitioner has now submitted data to satisfy the conditions of full registration.

TABLE A.1. Test Compound Nomenclature	
Chemical structure	
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS registry number	99607-70-2
End-use products (EPs)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Forage and Hay

TABLE A.1. Test Compound Nomenclature

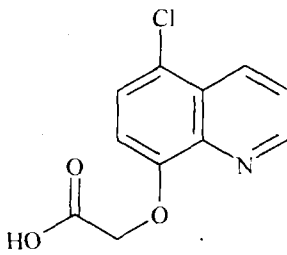
Chemical structure of cloquintocet-mexyl acid metabolite	 [(5-chloro-8-quinolinyl)oxy]acetic acid
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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca.. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	—
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html;
Water solubility (25 °C)	0.59 mg/L	Tomlin. C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure: highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin. C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	

B. EXPERIMENTAL DESIGN

B.1. Sample Handling and Preparation

Samples of untreated wheat forage and hay (from the crop field trials reported in MRID 46012904) were received at Syngenta Crop Protection, Inc. (Greensboro, NC), where they were cut into two-inch pieces, composited in a foodcutter with dry ice, and placed in individual polyethylene bottles or bags. After preparation, subsamples of wheat forage and hay were placed in amber bottles and fortified with cloquintocet-mexyl and its metabolite CGA-153433 at 1.00 ppm each. The petitioner did not specify the solvent used for the standard spiking solution or the stability of this solution. Fortified and unfortified samples were stored in the freezer at approximately -20 °C. Fortified and unfortified samples of wheat forage and hay were extracted



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
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 Storage Stability - Wheat Forage and Hay

following 0, 14, 29, 61, 120, 180, 275, 359, 533, and 769 days of storage for cloquintocet-mexyl. Fortified and unfortified samples of wheat forage and hay were extracted following 0, 90, 180, 359, 539, and 770 days of storage for metabolite CGA-153433. For cloquintocet-mexyl, extracts were stored for an additional 0-13 days until analysis. For metabolite CGA-153433, extracts were stored for an additional 1-13 days until analysis.

B.2. Analytical Methodology

Samples of wheat forage and hay were analyzed by Syngenta for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQ was 0.05 ppm for wheat forage and hay. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The validated LOQ was 0.05 ppm for wheat forage and hay. Methods REM 138.01 and REM 138.10 were submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04924; DP Barcodes D246730 and D253344, N. Dodd, 4/7/00).

Method REM 138.01: Briefly, homogenized samples of wheat forage and hay were extracted with acetonitrile and filtered. The extract was cleaned up by partitioning with hexane (2x); the hexane phases were discarded. The acetonitrile phase was cleaned up by solid phase extraction (SPE) on a C-18 cartridge; residues were eluted with acetone. Water and saturated sodium chloride were added to the eluate, which was then partitioned three times with hexane:diethyl ether (9:1; v:v). The combined organic phases were subjected to a second SPE on a silica cartridge. The silica cartridge was rinsed with hexane:acetone (8:2, v:v), and the eluate was collected for determination of cloquintocet mexyl (CGA-185072). The eluate was evaporated to dryness, residues were redissolved in hexane:ethanol (9:1, v:v), and cloquintocet-mexyl was determined by HPLC/UV using column switching.

Method REM 138.10: Briefly, homogenized samples of wheat forage and hay were extracted with an acetone:citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane:diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol:buffer (50:50, v:v). The methanol:buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water, and CGA-153433 was determined by HPLC/MS.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. Based on these data, HPLC/UV Method REM 138.01 and the HPLC/MS Method REM 138.10 are adequate for the determination of residues of cloquintocet-mexyl and its metabolite CGA-153433, respectively, in/on wheat



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Forage and Hay

forage and hay. Apparent residues of cloquintocet-mexyl and its metabolite CGA-153433 were each nondetectable (<0.05 ppm) in all unfortified samples (one control sample each of wheat forage and hay for each storage interval).

The results of the storage stability study are presented in Table C.2. The submitted storage stability data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to 538 days (~18 months). When compared to Day-0 recovery values, residues of cloquintocet-mexyl appear to decline in wheat forage and hay by ~45-50% after 772 days (~25 months) of frozen storage.

The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to 779 days (~25 months) of frozen storage. Graphs of the stability of cloquintocet-mexyl and CGA-153433 in wheat forage and hay are presented in Figures C.1.1 (cloquintocet-mexyl) and C.1.2 (CGA-153433).

TABLE C.1. Summary of Method Recoveries of Cloquintocet-Mexyl and its metabolite CGA-153433 from Wheat Forage and Hay.					
Matrix	Spike level (ppm)	Storage Interval (months)	Sample size (n)	Recoveries (%) ¹	Mean
Cloquintocet-mexyl					
Wheat forage	1.0	0	2	94. 101	98
	1.0	0.5	2	74. 108	91
	1.0	1.0	2	87. 88	88
	1.0	2.0	2	105. 106	106
	1.0	3.9	2	86. 87	87
	1.0	5.9	2	86. 91	89
	1.0	9.0	2	103. 105	104
	1.0	11.8	2	77. 82	80
	1.0	17.5	2	76. 92	84
	1.0	25.3	2	92. 101	97
Wheat hay	1.0	0	2	93. 97	95
	1.0	0.5	2	90. 100	95
	1.0	1.0	1	75	75
	1.0	2.0	2	108. 110	109
	1.0	3.9	2	91. 93	92
	1.0	5.9	2	74. 76	75
	1.0	9.0	2	103. 109	105
	1.0	11.8	2	84. 98	91
	1.0	17.5	2	81. 82	82
	1.0	25.3	2	105. 112	109



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Forage and Hay

TABLE C.1. Summary of Method Recoveries of Cloquintocet-Mexyl and its metabolite CGA-153433 from Wheat Forage and Hay.

Matrix	Spike level (ppm)	Storage Interval (months)	Sample size (n)	Recoveries (%) ¹	Mean
CGA-153433					
Wheat forage	1.0	0	2	72. 76	74
	1.0	3.0	2	72. 73	73
	1.0	5.9	2	73. 79	76
	1.0	11.8	2	58. 61	60
	1.0	17.7	4	69. 71. 76. 77	73
	1.0	25.3	2	69. 72	71
Wheat hay	1.0	0	2	70. 72	71
	1.0	3.0	2	73. 74	74
	1.0	5.9	2	77. 79	78
	1.0	11.8	2	81. 83	82
	1.0	17.7	2	67. 71	69
	1.0	25.3	2	85. 89	87

¹ Results were corrected for control values by the petitioner.

TABLE C.2. Stability of Cloquintocet-Mexyl and its metabolite CGA-153433 Residues in Wheat Forage and Hay Following Storage at -20 °C.

Commodity	Spike level (ppm)	Storage interval (days) ¹	Recovered residues (ppm)	% Recovery ²
Cloquintocet-mexyl				
Wheat forage	1.0	0 [0]	0.962. 1.01	98. 102
		14 [4]	0.777. 0.900. 0.996. 1.06	85. 99. 100. 106
		29 [1]	0.857. 0.886	98. 101
		61 [0]	1.063. 1.078	106. 108
		120 [5]	0.848. 0.858	98. 99
		180 [1]	0.833. 0.935	94. 106
		275 [13]	0.917. 1.06	92. 106
		359 [1]	0.742. 0.752	94. 95
		533 [5]	0.775. 0.791	92. 94
		769 [3]	0.506. 0.510	53. 53



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIA 8.1.1
 Storage Stability - Wheat Forage and Hay

TABLE C.2. Stability of Cloquintocet-Mexyl and its metabolite CGA-153433 Residues in Wheat Forage and Hay Following Storage at -20 °C.

Commodity	Spike level (ppm)	Storage interval (days) ¹	Recovered residues (ppm)	% Recovery ²
Wheat hay	1.0	0 [2]	1.00, 1.01	105, 106
		14 [1]	0.811, 0.880	86, 93
		29 [0]	0.584, 0.632	78, 84
		61 [1]	0.982, 0.987	98, 99
		120 [5]	0.840, 0.886	92, 97
		180 [2]	0.687, 0.727	92, 97
		275 [13]	0.857, 0.973	86, 97
		359 [4]	0.734, 0.878	81, 97
		533 [5]	0.592, 0.632	73, 78
		769 [3]	0.564, 0.603	56, 60
CGA-153433				
Wheat forage	1.0	0 [1]	0.702, 0.702	95, 95
		90 [9]	0.670, 0.720	92, 99
		180 [2]	0.686, 0.840	89, 110
		359 [13]	0.562, 0.579	94, 97
		539 [1/6]	0.551, 0.583, 0.604, 0.633	75, 79, 83, 85
		770 [9]	0.646, 0.711	91, 101
Wheat hay	1.0	0 [1]	0.732, 0.752	103, 106
		90 [10]	0.660, 0.710	90, 97
		180 [2]	0.628, 0.638	80, 81
		359 [13]	0.765, 0.815	91, 97
		539 [2]	0.531, 0.564	77, 82
		770 [9]	0.721, 0.734	83, 84

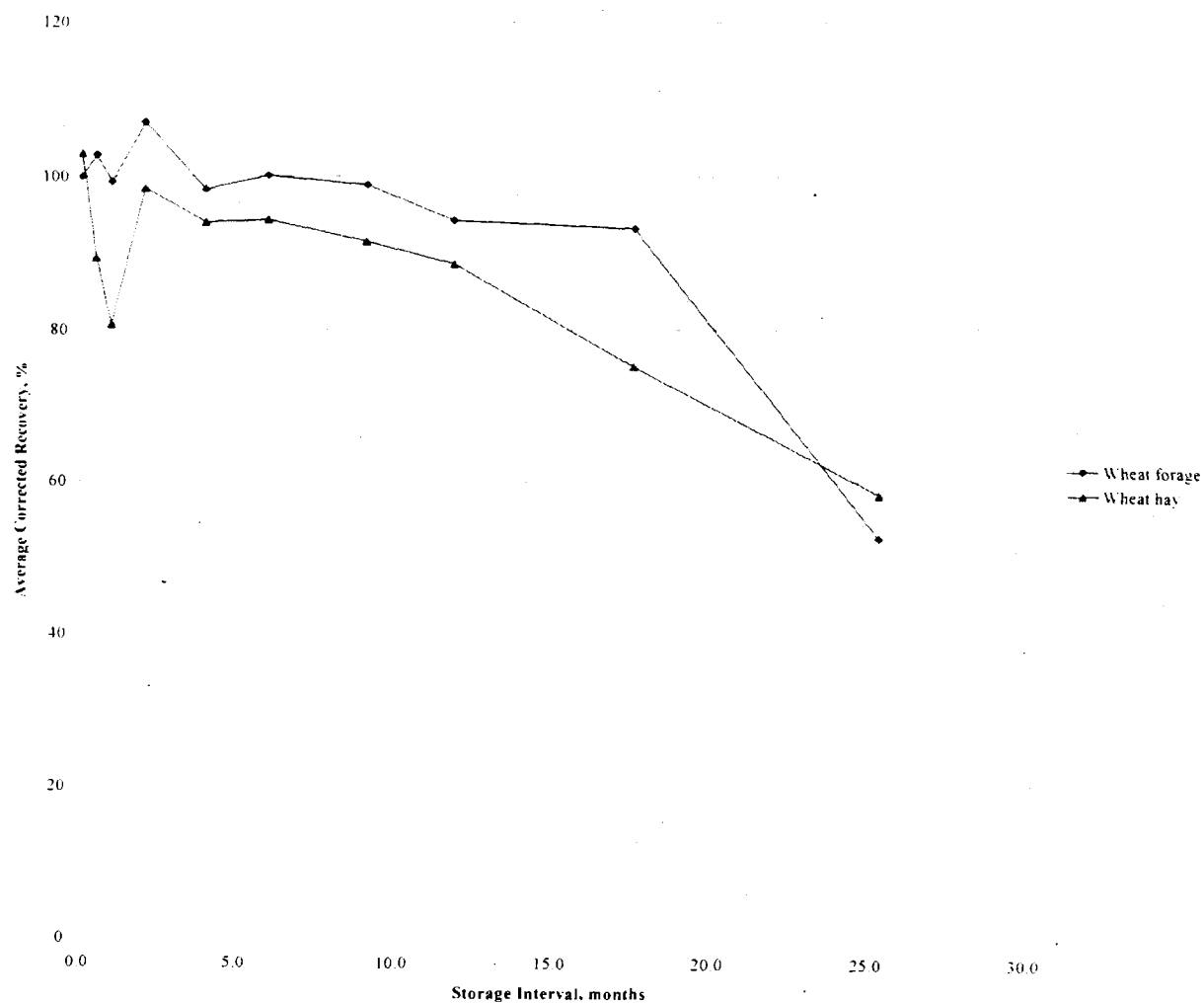
¹ Interval between fortification and extraction: the interval between extraction and analysis is presented in brackets.

² Stored sample recoveries were corrected by the petitioner for control values and procedural recoveries <100%.



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability - Wheat Forage and Hay

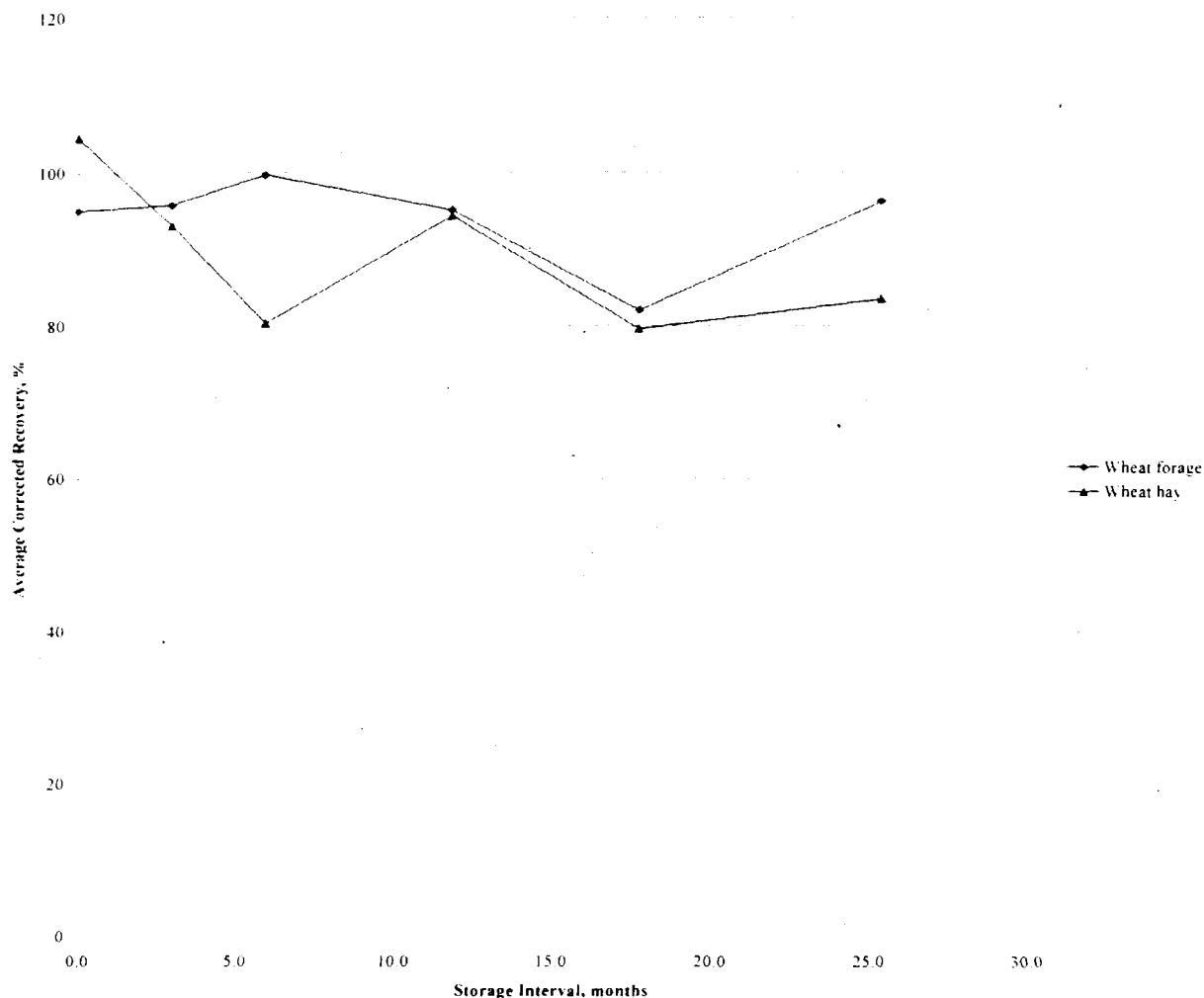
FIGURE C.1.1. Graph of Storage Stability of Cloquintocet-Mexyl in Wheat Forage and Hay.





Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
 Storage Stability - Wheat Forage and Hay

FIGURE C.1.2. Graph of Storage Stability of CGA-153433 in Wheat Forage and Hay.



D. CONCLUSION

The submitted storage stability data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months. When compared to Day-0 recovery values, residues of cloquintocet-mexyl appear to decline in wheat forage and hay by ~45-50% after ~25 months of frozen storage.

The submitted storage stability data indicate that residues of metabolite CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage.



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability - Wheat Forage and Hay

E. REFERENCES

DP Barcode: D257181
Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.
From: Nancy Dodd
To: Bipin Gandhi/Robert Forrest
Dated: 4/7/00
MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/29/05
Petition Number(s): PP#7E04920
DP Barcode(s): D308470
PC Code: 700099

Template Version September 2003



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Wheat

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Approved by W. Cutchin, Chemist
 RD/TRB

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004. The DER has been reviewed by the TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012905 Hamilton, L. (2001) CGA-184927 and CGA-185072 - Magnitude of the Residues In or On Winter Wheat: Lab Study Number: Syngenta Number 1148-00. Unpublished study prepared by Syngenta Crop Protection Inc. 271 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection Corporation, Inc. has submitted field trial data on winter wheat forage and hay. The petitioner conducted a total of eight winter wheat field trials during the 2001 growing season in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 or 8 (KS; 1 trial, on the border between Regions 5 and 8), 6 (OK; 1 trial), and 8 (CO, KS, OK, and TX; 4 trials). The number and location of field trials are not in accordance with OPPTS Guideline 860.1500 and Directive 98-02. The petitioner intended the submitted field trial data to represent residues in winter wheat forage and hay following application in the spring.

At each field trial site, winter wheat was treated with a single postemergence foliar application of an emulsifiable concentrate (EC) formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl. Application was made to winter wheat in the spring, at Feekes Growth Stage 2, at a rate of 0.016 lb safener/A (7.1 g safener/A). Applications were made using ground equipment in 10.6-15.1 gal/A of water with an adjuvant added to the spray mixture. Samples of wheat forage and hay were collected at a 29- to 30-day PHI. In one field trial, additional samples of wheat forage and hay were collected at 0-, 7-, 14-, 21-, 30-, and 37-day PHIs to demonstrate residue decline.

Residues of cloquintocet-mexyl and its metabolite CGA-153433 were each less than the limit of quantitation (LOQ; <0.05 ppm) in/on all samples of winter wheat forage and hay harvested 29-30 days following treatment. Residue decline data show that residues of cloquintocet-mexyl and CGA-153433 decrease in/on wheat forage and hay with increasing sampling intervals, with quantifiable residues only occurring at the 0-day sampling interval.

Samples of wheat forage and hay were analyzed for residues of cloquintocet-mexyl using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) method REM 138.01, the



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Wheat

current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQ was 0.05 ppm. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use mass spectroscopy (MS) detection of CGA-153433 (instead of UV detection). The validated LOQ was 0.05 ppm. These methods are adequate for data collection based on acceptable method recoveries.

The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 104 days (3.4 months) for wheat forage and 117 days (3.8 months) for wheat hay. The maximum storage intervals of crop samples from harvest to analysis for CGA-153433 were 99 days (3.3 months) for wheat forage and 110 days (3.6 months) for wheat hay. In support of the crop field trial study, the petitioner cited storage stability data (46012916SS.der.wpd, W. Cutchin, 7/28/05) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage. The available storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. We note that the crop field trial data only reflect residues in winter wheat forage and hay following application in the spring in Regions 2, 4, 5, 8, 6, and 8. Crop field trial data for spring and winter wheat from additional regions representing residues in/on wheat forage, hay, straw, and grain have been submitted separately. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener. Cloquintocet-mexyl is needed in the formulation to prevent damage to wheat due to phytotoxic effects of CGA-184927. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00). The petitioner has now submitted data to satisfy the conditions of full registration.



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE A.1. Test Compound Nomenclature.

Chemical structure	
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS registry number	99607-70-2
End-use product (EP)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca.. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html ; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	—
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html :
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure: highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	



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 Crop Field Trial - Wheat

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State: Year)	Soil characteristics				Meteorological data	
	Type	%OM	pH	CEC	Overall monthly rainfall range (inches)	Overall average temperature range (°C)
Winter wheat						
Tillar, AR: 2001 (0S-HR-501-00)	Silt loam	Not applicable			No weather data for the study period (between application and harvest) were provided.	
Bunn, NC: 2001 (0S-HR-609-00)	Sandy loam	Not applicable				
Stillwater, OK: 2001 (0S-HR-701-00)	Loam	Not applicable				
Cordell, OK: 2001 (0S-HR-702-00)	Silty clay	Not applicable				
Chillicothe, TX: 2001 (0S-HR-703-00)	Clay loam	Not applicable				
Pratt, KS: 2001 (MW-HR-305-00)	Loam	Not applicable				
Ault, CO: 2001 (MW-HR-306-00)	Sandy clay loam	Not applicable				
Larned, KS: 2001 (MW-HR-307-00)	Loamy sand	Not applicable				

No weather data for the study period (between application and harvest) were provided, although information for months preceding application was provided. The petitioner stated that monthly totals/averages for rainfall and temperature could not be calculated because of insufficient data (ten or more daily values were missing).

TABLE B.1.2. Study Use Pattern.

Location (City, State: Year)	EP ¹						Tank Mix Adjuvants
		Method: Timing	Vol. (GPA ²)	Rate (lb safener/A) [g safener/A]	RTI ³ (days)	Total Rate (lb safener/A) [g safener/A]	
Winter wheat field trials							
Tillar, AR: 2001 (0S-HR-501-00)	0.5 lb/gal EC	1: Postemergence foliar spray: Feekes Growth Stage 2	10.647	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Bunn, NC: 2001 (0S-HR-609-00)	0.5 lb/gal EC	1: Postemergence foliar spray: Feekes Growth Stage 2	14.5	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Stillwater, OK: 2001 (0S-HR-701-00)	0.5 lb/gal EC	1: Postemergence foliar spray: Feekes Growth Stage 3	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
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 Crop Field Trial - Wheat

TABLE B.1.2. Study Use Pattern.

Location (City, State: Year)	EP ¹						Tank Mix Adjuvants
		Method: Timing	Vol. (GPA ²)	Rate (lb safener/A) [g safener/A]	RTI ³ (days)	Total Rate (lb safener/A) [g safener/A]	
Cordell, OK: 2001 (0S-HR-702-00)	0.5 lb/gal EC	1: Postemergence foliar spray; Feekes Growth Stage 2	13.6	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Chillicothe, TX: 2001 (0S-HR-703-00)	0.5 lb/gal EC	1: Postemergence foliar spray; Feekes Growth Stage 2	13.8	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Pratt, KS: 2001 (MW-HR-305-00)	0.5 lb/gal EC	1: Postemergence foliar spray; Feekes Growth Stage 2	15.1	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Ault, CO: 2001 (MW-HR-306-00)	0.5 lb/gal EC	1: Postemergence foliar spray; Feekes Growth Stage 2	14.15	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v
Larned, KS: 2001 (MW-HR-307-00)	0.5 lb/gal EC	1: Postemergence foliar spray; Feekes Growth Stage 2	14.93	0.016 [7.1]	NA	0.016 [7.1]	Score, 1.0% v/v

¹ EP = End-use Product² GPA = Gallons per acre³ RTI = Retreatment Interval**TABLE B.1.3. Trial Numbers and Geographical Locations.**

NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
1			
1A			
2	1		1
3			
4	1		1
5	1 ¹		5
5A			
5B			
6	1		1
7			5
7A			
8	4		6
9			
10			
11			1
12			



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
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 Crop Field Trial - Wheat

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	8		20

¹ This winter wheat field trial was conducted in Pratt County, KS, and may be classified as either Region 5 or 8.

B.2. Sample Handling and Preparation

Samples of wheat forage and wheat hay were collected at a 29- to 30-day PHI. In one field trial, additional samples of wheat forage and hay were collected at 0-, 7-, 14-, 21-, 30-, and 37-day PHIs to demonstrate residue decline. For each sampling interval, a single untreated and duplicate treated samples were collected. Specific harvesting procedures were not described. After collection, RAC samples were frozen and shipped via freezer truck or overnight courier with dry ice to Syngenta Crop Protection, Inc. (Greensboro, NC) for analysis. At Syngenta, samples were stored frozen (~-20 °C) until analysis.

B.3. Analytical Methodology

Samples of wheat forage and hay were analyzed by Syngenta for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The limit of detection (LOD), as determined by the smallest standard injection, was 0.40 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.05 ppm. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The LOD, as determined by the smallest standard injection, was 0.125 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.05 ppm. Methods REM 138.01 and REM 138.10 were submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00).



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 Crop Field Trial - Wheat

Method REM 138.01: Briefly, homogenized samples were extracted with acetonitrile and filtered. The extract was cleaned up by partitioning with hexane (2x); the hexane phases were discarded. The acetonitrile phase was cleaned up by solid phase extraction (SPE) on a C-18 cartridge, using acetone to elute residues. Water and saturated sodium chloride solution were added to the eluate, which was then partitioned three times with hexane:diethyl ether (9:1, v:v). The combined organic phases were subjected to a second SPE on a silica cartridge, using hexane:acetone (8:2, v:v) to elute residues of cloquintocet-mexyl. The eluate was evaporated to dryness, residues were redissolved in hexane:ethanol (9:1, v:v), and the sample was analyzed by HPLC/UV using column switching. We note that the method was modified slightly to increase the LOQ for forage and hay to 0.05 ppm.

Method REM 138.10: Briefly, homogenized samples were extracted with an acetone:citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane:diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol:buffer (50:50, v:v). The methanol:buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water and CGA-153433 was determined by HPLC/MS.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. Samples of wheat forage and hay were analyzed for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQ was 0.05 ppm. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The method was modified to use MS detection of CGA-153433 (instead of UV detection). The validated LOQ was 0.05 ppm. These methods are adequate for data collection based on acceptable method recoveries. Apparent residues of cloquintocet-mexyl and CGA-153433 were each below the LOQ in/on 13 samples each of untreated forage and hay.

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 104 days (3.4 months) for wheat forage and 117 days (3.8 months) for wheat hay. The maximum storage intervals of crop samples from harvest to analysis for CGA-153433 were 99 days (3.3 months) for wheat forage and 110 days (3.6 months) for wheat hay. In support of the crop field trial study, the petitioner cited storage stability data (46012916SS.der.wpd, W. Cutchin, in process) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage. The available storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.



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 Crop Field Trial - Wheat

Residue data from the wheat field trials are reported in Table C.3. A summary of residue data for winter wheat forage and hay following treatment with the 0.5 lb/gal EC formulation is presented in Table C.4. Residues of cloquintocet-mexyl and its metabolite CGA-153433 were each less than the method LOQ (<0.05 ppm) in/on winter wheat forage and hay harvested 29-30 days following a single broadcast foliar application of the 0.5 lb/gal EC formulation made in the spring (Feekes Growth Stage 2) at 0.016 lb safener/A (7.1 g safener/A).

Residue decline data show that residues of cloquintocet-mexyl and CGA-153433 generally decrease in/on wheat forage and hay with increasing sampling intervals, with the maximum residues occurring at the 0-day sampling interval. Residues of cloquintocet-mexyl declined from 0.862-0.941 ppm in/on wheat forage and 0.119-0.165 ppm in/on wheat hay at the 0-day PHI to below the LOQ (<0.05 ppm) at the 7-day PHI, and remained <LOQ through the 37-day PHI. Residues of CGA-153433 declined from 0.140-0.173 ppm in/on wheat forage and 0.652-0.688 ppm in/on wheat hay at the 0-day PHI to below the LOQ (<0.05 ppm) at the 7-day PHI, and remained <LOQ through the 37-day PHI.

A total of eight winter wheat field trials were conducted during the 2001 growing season in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 or 8 (KS; 1 trial, on the border between Regions 5 and 8), 6 (OK; 1 trial), and 8 (CO, KS, OK, and TX; 4 trials). The number and location of field trials are not in accordance with OPPTS Guideline 860.1500 and Directive 98-02. The petitioner intended the submitted field trial data to represent residues in winter wheat forage and hay following application in the spring.

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Cloquintocet-mexyl; determined using Modified REM 138.01				
Wheat forage	0.05	16	71, 74, 77, 80, 80, 81, 85, 87, 88, 90, 95, 102, 116, 118, 118, 125	93 $\pm$ 18
	0.10	4	91, 105, 107, 113	
	0.20	3	69, 84, 93	
	0.50	5	59, 104, 106, 110, 111	
	1.00	3	68, 83, 110	
	5.00	2	62, 120	
	10.00	1	81	
Wheat hay	0.05	6	96, 97, 106, 113, 122, 128	107 $\pm$ 11
	0.10	2	102, 115	
	0.20	3	97, 103, 115	
	0.50	1	112	
	1.00	1	91	



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.
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 Crop Field Trial - Wheat

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
CGA-153433; determined using Modified REM 138.10				
Wheat forage	0.05	10	51, 57, 58, 65, 85, 86, 87, 91, 100, 104	79 $\pm$ 15
	0.10	4	65, 69, 83, 86	
	0.20	2	79, 102	
	0.50	3	75, 81, 82	
	1.00	1	72	
	5.00	1	85	
Wheat hay	0.05	8	63, 69, 70, 75, 77, 83, 92, 94	77 $\pm$ 11
	0.10	2	70, 76	
	0.20	4	59, 67, 69, 73	
	0.50	3	65, 81, 89	
	1.00	3	76, 81, 84	
	5.00	1	98	

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC or Extract)	Storage Temp. (°C)	Analyte	Actual Storage Duration ¹	Interval of Demonstrated Storage Stability ²
Wheat forage	-20	Cloquintocet-mexyl	39-104 days (1.3-3.4 months)	Residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay during up to 18 months of frozen storage.
Wheat hay			44-117 days (1.4-3.8 months)	
Wheat forage		CGA-153433	39-99 days (1.3-3.3 months)	Residues of CGA-153433 are reasonably stable in/on wheat forage and hay during up to ~25 months of frozen storage.
Wheat hay			46-110 days (1.5-3.6 months)	

¹ From sampling to analysis. Wheat samples were analyzed for cloquintocet-mexyl within 0-5 days of extraction and for CGA-153433 within 1-8 days of extraction; certain sample extracts were reanalyzed up to 21 days after sample extraction.

² Refer to the 860.1380 (46012916SS.der.wpd. W. Cutchin, in process).

TABLE C.3. Residue Data from Winter Wheat Field Trials with Cloquintocet-Mexyl.

Trial ID (City, State: Year)	Region	Winter Wheat Variety	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ¹		
						CGA- 185072	CGA- 153433	Total
Tillar, AR: 2001 (0S-HR-501-00)	4	Terrall 8555	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10
						<0.05	<0.05	<0.10
			hay		30	<0.05	<0.05	<0.10
						<0.05	<0.05	<0.10
Bunn, NC: 2001 (0S-HR-609-00)	2	Roane/ Foundation Seed	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10
						<0.05	<0.05	<0.10
			hay		30	<0.05	<0.05	<0.10
						<0.05	<0.05	<0.10



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 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Winter Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (City, State: Year)	Region	Winter Wheat Variety	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ¹			
						CGA- 185072	CGA- 153433	Total	
Stillwater, OK: 2001 (OS-HR-701-00)	6	Jaguar-OK	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
Cordell, OK: 2001 (OS-HR-702-00)	8	Custer/ Grower Saved Seed	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
Chillicothe, TX: 2001 (OS-HR-703-00)	8	Jagger	forage	0.016 [7.1]	29	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		29	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
Pratt, KS: 2001 (MW-HR-305-00)	5/8	2137	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
Ault, CO: 2001 (MW-HR-306-00)	8	Platte, Roggen Co.	forage	0.016 [7.1]	0	0.862	0.140	1.002	
						0.941	0.173	1.114	
					7	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					14	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					21	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					37	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		0	0.119	0.652	0.771	
						0.165	0.688	0.853	
					7	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					14	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					21	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
					37	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
Larned, KS: 2001 (MW-HR-307-00)	8	Jagger	forage	0.016 [7.1]	30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	
			hay		30	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10	



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc.

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

¹ The petitioner reported residue values corrected for method recovery. The uncorrected residues reported in this table were obtained by the study reviewer from the raw data. Total residue values were calculated by the study reviewer.

TABLE C.4. Summary of Residue Data from Winter Wheat Crop Field Trials with Cloquintocet-Mexyl.										
Commodity	Total Applic. Rate (lb safener/A) [g safener/A]	PHI (days)	Analyte	Residue Levels (ppm)						
				n	Min.	Max.	HAFT ¹	Median (STMdR ²)	Mean (STMR ³)	Std. Dev.
Wheat. forage	0.016 [7.1]	29-30	CGA-185072	16	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	16	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
Wheat. hay	0.016 [7.1]	29-30	CGA-185072	16	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	16	<0.05	<0.05	<0.05	<0.05	<0.05	0.0

¹ HAFT = Highest Average Field Trial.

² STMdR = Supervised Trial Median Residue.

³ STMR = Supervised Trial Mean Residue.

D. CONCLUSION

The submitted field trial data reflect a single postemergence foliar application of an EC formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl made to winter wheat in the spring at Feekes Growth Stage 2. Cloquintocet-mexyl was applied at a rate of 0.016 lb safener/A (7.1 g safener/A). Wheat forage and hay were harvested at a 29- to 30-day PHI. Acceptable methods were used for quantitation of residues in/on wheat commodities.

E. REFERENCES

DP Barcode: D257181

Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.

From: Nancy Dodd

To: Bipin Gandhi/Robert Forrest

Dated: 4/7/00

MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/29/05

Petition Number(s): PP#7E04920

DP Barcode(s): D308470

PC Code: 700099

Template Version September 2003



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Wheat

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Approved by W. Cutchin, Chemist
 RD/TRB

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004. The DER has been reviewed by the TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012904 Hamilton, L. (2002) CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Wheat: Lab Study Number: Syngenta Number 127-98. Unpublished study prepared by Syngenta Crop Protection Inc. 1120 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection Corporation, Inc. has submitted the final report for field trial data on wheat forage, hay, straw, and grain. An interim report of these wheat field trial data has been reviewed previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00); that submission included only the results from spring wheat crop field trials and did not include the results of analyses of spring wheat straw samples for CGA-153433.

A total of 20 wheat field trials (6 spring wheat trials and 14 winter wheat) were conducted during the 1998-1999 growing seasons. Spring wheat field trials were conducted in Regions 5 (MN and ND; 2 trials) and 7 (MT, ND, and SD; 4 trials). Winter wheat field trials were conducted in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 (IL, KS, and MO; 3 trials), 6 (OK; 1 trial), 8 (CO, KS, NM, OK, and TX; 6 trials), and 11 (WA; 1 trial). In addition, one trial was conducted in Region 5 (NE) close enough to the border with Region 7 to support geographic representation requirements for Region 7.

At each field trial site, separate plots were treated with a single postemergence foliar application of an emulsifiable concentrate (EC) formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl. Applications at all plots, with the exception of two trials, were made using ground equipment in 5-20 gal/A of water with an adjuvant added to the spray mixture. Each trial had at least three plots, a control and two treated plots. The first treated plot (#1) an application to wheat early in the season at Feekes Growth Stage 2 at 0.016 lb safener/A (7.1 g safener/A) and were sampled for forage and hay. The second treated plot (#2) had an application to wheat approximately 60 days prior to harvest of mature wheat, at 0.016 lb safener/A (7.1 g safener/A) and were sampled for mature straw and grain. At two trials, one spring wheat (ND) and one winter wheat (OK), applications to treated plots (#5) were made to wheat approximately 60 days prior to harvest of mature wheat, at an exaggerated rate of 0.078 lb safener/A (35.5 g safener/A)



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and were sampled for mature straw and grain. At three trials (one spring wheat and two winter wheat), applications were made using a concentrated spray volume (2 gal/A) to simulate aerial application.

The winter wheat field trials were conducted with two types of early season application: application in the fall or application in the spring. Of the 14 winter wheat trials, a total of 8 trials were conducted reflecting application in the fall, in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 (KS; 1 trial), 6 (OK; 1 trial), and 8 (KS, OK, and TX; 4 trials). The remaining 6 trials were conducted reflecting early season application in the spring, in Regions 5 (IL and MO; 2 trials), 7 (NE; 1 trial), 8 (CO and NM; 2 trials), and 11 (WA; 1 trial). The petitioner has stated that they will not be supporting application of clodinafop-propargyl with the safener cloquintocet-mexyl to winter wheat in the fall; application to winter wheat will be restricted to a spring postemergence foliar application. Because the petitioner does not wish to use the results from winter wheat forage and hay fall application trials, geographic representation of residue trials is not adequate for forage and hay.

Samples of wheat forage were collected at a 0- and a 27- to 33-day PHI, samples of wheat hay were collected at a 27- to 47-day PHI from treatment plot #2, and samples of wheat straw and grain were collected at maturity (57- to 63-day PHI) from treatment plot #3. To demonstrate residue decline, additional samples of wheat forage and hay were collected at posttreatment intervals of 0, 7, ~14, ~21, ~30, and 37 days from treatment plot #2, and wheat straw and grain were collected at posttreatment intervals of ~45, ~52, ~60, and ~66 days from treatment plot 3 from one spring wheat trial (ND) and two winter wheat trials (KS and OK). Samples of wheat grain were collected from treatment plot #5 at a single ND spring wheat field trial and a single OK winter wheat trial for generation of samples of aspirated grain fractions and processed wheat commodities; refer to the 860.1520 DER for MRID 46012904 (MRID 46012904PFFwheat.der.wpd, W. Cutchin, in process).

The maximum residues of cloquintocet-mexyl and its metabolite CGA-153433 in/on wheat forage, hay, grain, and straw from the submitted wheat field trials in which wheat was treated at 0.016 lb ai/A are reported below.

Commodity	PHI (days)	Maximum Residue Levels (ppm)		
		Cloquintocet-mexyl	CGA-153433	Total Residues
Spring wheat				
Wheat forage	0	1.68	0.41	2.00
	29-32	<0.05	<0.05	<0.10
Wheat hay	29-47	<0.05	<0.05	<0.10
Wheat straw	57-61	<0.05	<0.05	<0.10
Wheat grain	57-61	<0.02	<0.05	<0.07
Winter wheat - spring application				
Wheat forage	0	1.56	0.45	1.76
	27-33	<0.05	<0.05	<0.10



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Commodity	PHI (days)	Maximum Residue Levels (ppm)		
		Cloquintocet-mexyl	CGA-153433	Total Residues
Wheat hay	27-33	<0.05	<0.05	<0.10
Wheat straw	58-69	<0.05	<0.05	<0.10
Wheat grain	58-69	<0.02	<0.05	<0.07

In the two trials in which wheat was treated at an exaggerated rate, residues of cloquintocet-mexyl were <0.05 ppm in/on straw and <0.02 ppm in/on grain, and residues of CGA-153433 were <0.05 ppm in/on straw and grain harvested 59 or 61 days following treatment at 0.078 lb ai/A.

Residue decline data show that residues of cloquintocet-mexyl and CGA-153433 decrease in/on wheat forage and hay with increasing sampling intervals, with the maximum residues occurring at the 0-day sampling interval. Residues of cloquintocet-mexyl were <0.05 and <0.02 ppm in/on wheat straw and grain, respectively, and residues of CGA-153433 were <0.05 ppm at all sampling intervals (45-67 days posttreatment) in the decline studies.

Samples of wheat forage, hay, grain, and straw were analyzed for residues of cloquintocet-mexyl using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated limits of quantitation (LOQ) were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain. In addition, samples were analyzed for residues of the metabolite CGA-153433 using HPLC/UV Method REM 138.10, the current enforcement method for residues of CGA-153433 in wheat commodities. The validated LOQ was 0.05 ppm for wheat forage, hay, straw, and grain. These methods are adequate for data collection based on acceptable method recoveries. When the results of the spring wheat field trials were submitted previously (PP#7E04920, DP Barcode D257181, MRID 44755303, N. Dodd, 4/7/00), the petitioner reported that straw samples could not be analyzed for residues of CGA-153433 "using current methodology." The current submission includes results for straw samples, which appear to have been analyzed for CGA-153433 after the previous submission. The petitioner did not provide any discussion of this issue (i.e., did not explain whether changes to the method were required to allow analysis of straw samples) and did not provide any raw data for the analyses of spring wheat straw samples for CGA-153433.

The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 187 days (6.1 months) for forage, 134 days (4.4 months) for hay, 148 days (4.9 months) for straw, and 141 days (4.6 months) for grain. The maximum storage intervals of crop samples from harvest to analysis for CGA-153433 were 253 days (8.3 months) for forage, 231 days (7.6 months) for hay, 308 days (10.1 months) for straw, and 222 days (7.3 months) for grain.

In support of the crop field trial study, the petitioner cited storage stability data (refer to the 46012916CFT.der.wpd, W. Cutchin, in process) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on



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wheat forage and hay for up to ~25 months of frozen storage. Storage stability data submitted previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat straw and grain stored at -18 °C for up to ~6 months, and residues of CGA-153433 are stable in wheat straw stored at -18 °C for 380 days (12.5 months). Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for 727 days (23.9 months). The available storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically unacceptable but upgradable with the submission of additional data. To fulfill geographic representation requirements, winter wheat forage and hay data from an additional 8 field trials reflecting spring application, conducted in Regions 2 (1 trial), 4 (1 trial), 5 (1 trial), 6 (1 trial), and 8 (4 trials), are required. We note that additional winter wheat crop field trial data intended to represent residues in winter wheat forage and hay following application in the spring have been submitted separately (46012905CFT.der.wpd, W. Cutchin, in process). In addition, the petitioner must submit the raw data for the analyses of spring wheat straw samples for residues of CGA-153433 and provide a discussion of any changes to HPLC/UV method REM 138.10 that were required to allow analysis of straw samples.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.

COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener contained in the formulation Discover™ Herbicide. Cloquintocet-mexyl is needed in the formulation to prevent damage to wheat due to phytotoxic effects. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00). The petitioner has now submitted data to satisfy the conditions of full registration.



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TABLE A.1. Test Compound Nomenclature.

Chemical structure	
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyloxy)acetate
CAS registry number	99607-70-2
End-use product (EP)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound

Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html ; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	—
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html ;
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure; highest is from experimental database for EPIWIN v3.12; converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	



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B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.						
Trial Identification (County, State: Year)	Soil characteristics				Meteorological data	
	Type	%OM	pH	CEC	Overall monthly rainfall range (inches)	Overall average monthly temperature range (°C)
Spring wheat						
Grand Forks, ND: 1998 (0W-HR-210-98)	Loam	Not applicable			2.66-4.63	14.4 to 20.6
Polk, MN: 1998 (0W-HR-211-98)	Silty clay loam	Not applicable			2.12-6.04	15.4 to 21.2
McHenry, ND: 1998 (0W-HR-212-98)	Sandy clay loam	Not applicable			0.19-2.84	9.1 to 21.5
Sheridan, MT: 1998 (0W-HR-213-98)	Sandy clay loam	Not applicable			0.43-3.82	13.7 to 21.6
Fergus, MT: 1998 (0W-HR-214-98)	Loam	Not applicable			0.91-4.72	11.0 to 20.1
Charles Mix, SD: 1998 (0W-HR-215-98)	Silty clay	Not applicable			2.00-5.97	8.4 to 23.7
Winter wheat						
Drew, AR: 1998-1999 (0S-HR-101-98)	Silt loam	Not applicable			0.79-11.57	7.3 to 26.0
Payne, OK: 1998-1999 (0S-HR-710-98)	Loam	Not applicable			0.64-8.13	3.9 to 24.0
Washita, OK: 1998-1999 (0S-HR-711-98)	Loam	Not applicable			0.08-5.81	3.4 to 24.4
Castro, TX: 1998-1999 (0S-HR-712-98)	Clay loam	Not applicable			0.00-4.29	4.8 to 23.8
Sampson, NC: 1998-1999 (0S-HR-601-98)	Loamy sand	Not applicable			1.54-7.96	8.2 to 26.9
Sedgwick, KS: 1998-1999 (MW-HR-304-98)	Silty clay loam	Not applicable			0.39-7.55	0.4 to 27.9
Pratt, KS: 1998-1999 (MW-HR-305-98)	Loamy sand	Not applicable			0.08-5.25	1.3 to 27.2
Pratt, KS: 1998-1999 (MW-HR-306-98)	Loamy sand	Not applicable			0.08-5.25	1.3 to 27.2
Whitman, WA: 1999 (0W-HR-311-98)	Silt loam	Not applicable			0.03-0.70	8.1 to 22.4
Champaign, IL: 1999 (04-HR-001-98)	Clay loam	Not applicable			1.17-4.51	-6.0 to 25.4
Curry, NM: 1999 (0S-HR-713-98)	Sandy clay loam	Not applicable			0.00-3.24	8.5 to 22.9
Adair, MO: 1999 (MW-HR-201-99)	Not provided	Not applicable			Not provided	Not provided
Hall, NE: 1999 (MW-HR-601-98)	Silt loam	Not applicable			0.79-6.48	4.0 to 26.0



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TABLE B.1.1. Trial Site Conditions.

Trial Identification (County, State: Year)	Soil characteristics				Meteorological data	
	Type	%OM	pH	CEC	Overall monthly rainfall range (inches)	Overall average monthly temperature range (°C)
Weld, CO: 1999 (MW-HR-307-98)	Clay loam	Not applicable			1.03-7.41	7.9 to 24.3

The average monthly temperatures as well as total monthly rainfall were reported for each trial site. In addition, the petitioner included the departures from normal averages when available. Weather conditions appeared to be comparable to the average limits; no unusual conditions were reported.

No field trial raw data were provided for the winter wheat field trial in Adair, MO (MW-HR-201-99).

TABLE B.1.2. Study Use Pattern.

Location (County, State: Year)	EP ¹	Application						Tank Mix Adjuvants
		Plot ²	Method: Timing	Vol. (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ⁴ (days)	Total Rate (lb safener/A) [g safener/A]	
Spring wheat field trials								
Grand Forks, ND: 1998 (OW-HR-210-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2-3	7.0	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Feekes 6-8	7.0	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	4 ^a	1: Postemergence foliar spray: Feekes 6-8	7.0	0.047 [21.5]	NA	0.47 [21.5]	Score. 1.0% v/v
	0.5 lb/gal EC	5	1: Postemergence foliar spray: Feekes 6-8	7.0	0.078 [35.5]	NA	0.078 [35.5]	Score. 1.0% v/v
Polk, MN: 1998 (OW-HR-211-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	10	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Feekes 10.5	10	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
McHenry, ND: 1998 (OW-HR-212-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Feekes 8-9	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Sheridan, MT: 1998 (OW-HR-213-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	2.0	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Feekes 10.5	2.0	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Fergus, MT: 1998 (OW-HR-214-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	11	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: 31 inches height	10	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v



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TABLE B.1.2. Study Use Pattern.

Location (County, State; Year)	EP ¹	Application						Tank Mix Adjuvants
		Plot ²	Method: Timing	Vol. (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ⁴ (days)	Total Rate (lb safener/A) [g safener/A]	
Charles Mix. SD: 1998 (0W-HR-215-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray: Feekes 2	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray: Feekes 6	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Winter wheat field trials								
Drew. AR: 1998- 1999 (0S-HR-101-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	11	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 10	11	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Whitman. WA: 1999 (0W-HR-311-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring: Feekes 2	10	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: stem elongation	10	0.032 ⁵ [14.2]	NA	0.032 [14.2]	Score. 1.0% v/v
Champaign. IL: 1999 (04-HR-001-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring: Feekes 2	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 10-10.3	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Payne. OK: 1998- 1999 (0S-HR-710-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 10.1	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Washita. OK: 1998-1999 (0S-HR-711-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	19	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 10.51	19	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	5	1: Postemergence foliar spray in the spring: Feekes 10.51	19	0.078 [35.5]	NA	0.078 [35.5]	Score. 1.0% v/v
Castro. TX: 1998- 1999 (0S-HR-712-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	2	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 9-10	2	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v



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Crop Field Trial - Wheat

TABLE B.1.2. Study Use Pattern.								
Location (County, State; Year)	EP ¹	Application						Tank Mix Adjuvants
		Plot ²	Method: Timing	Vol. (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ⁴ (days)	Total Rate (lb safener/A) [g safener/A]	
Curry, NM: 1999 (OS-HR-713-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring; Feekes 2	12	0.016 [7.1]	NA	0.016 [7.1]	Score. 0.93% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; Feekes 9	9	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Sampson, NC: 1998-1999 (OS-HR-601-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	5	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Boot	5	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Adair, MO: 1999 * (MW-HR-201-99)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring; growth stage not specified	5	0.016 [7.1]	NA	0.016 [7.1]	Score. 1% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; growth stage not specified	5	0.016 [7.1]	NA	0.016 [7.1]	Score. 1% v/v
Hall, NE: 1999 (MW-HR-601-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring; Feekes 2	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; Feekes 8	20	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Sedgwick, KS: 1998-1999 (MW-HR-304-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	13	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; Feekes 9	13	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Pratt, KS: 1998- 1999 (MW-HR-305-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	13	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; Feekes 9	13	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
Pratt, KS: 1998- 1999 (MW-HR-306-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the fall: Feekes 2	2	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring; Feekes 10	2	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v



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 Crop Field Trial - Wheat

TABLE B.1.2. Study Use Pattern.

Location (County, State: Year)	EP ¹	Application						Tank Mix Adjuvants
		Plot ²	Method: Timing	Vol. (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ⁴ (days)	Total Rate (lb safener/A) [g safener/A]	
Weld, CO: 1999 (MW-HR-307-98)	0.5 lb/gal EC	2	1: Postemergence foliar spray in the spring: Feekes 2	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
	0.5 lb/gal EC	3	1: Postemergence foliar spray in the spring: Feekes 10.5	15	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v

¹ EP = End-use Product

² Treatment Plot 2 received a single postemergence application made early in the season at the Feekes Growth Stage 2.

Treatment Plot 3 received a single postemergence application made late in the season approximately 60 days prior to harvest of mature wheat.

Treatment plot 5 received a single postemergence application made at an exaggerated rate late in the season approximately 60 days prior to harvest of mature wheat. Exaggerated rate application was made to generate samples for processing: refer to the 860.1520 DER for MRID 46012904 (46012904.de4.wpd).

³ GPA = Gallons per acre

⁴ RTI = Retreatment Interval

⁵ The treatment for plot 3 was inadvertently superimposed over Treatment 2 after forage and hay were harvested, yielding a 2x total treatment rate.

⁶ No raw data for this field trial were included in the submission.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
1			
1A			
2	1 (winter wheat)		1
3			
4	1 (winter wheat)		1
5	2 (spring wheat) 4 ¹ (winter wheat)		5
5A			
5B			
6	1 (winter wheat)		1
7	4 (spring wheat)		5
7A			
8	6 ² (winter wheat)		6
9			
10			
11	1 (winter wheat)		1
12			



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 Crop Field Trial - Wheat

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Region	Wheat		
	Submitted	Requested	
		Canada	US
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	6 (spring wheat) 14 (winter wheat)		20

¹ The winter wheat trial conducted in NE was conducted in Region 5 but close to the border with Region 7, and therefore may be used to satisfy geographic representation requirements for Region 7.

² The two winter wheat field trials conducted in Pratt County, KS may be classified as either Region 5 or 8; for the purposes of this submission, the trials were assigned to Region 8.

B.2. Sample Handling and Preparation

Samples of wheat forage were collected at a 0- and a 27- to 33-day PHI, samples of wheat hay were collected at a 27- to 47-day PHI from treatment plot #2, and samples of wheat straw and grain were collected at maturity (57- to 63-day PHI) from treatment plot #3. To demonstrate residue decline, additional samples of wheat forage and hay were collected at 0-, 7-, 13/14-, 20/21-, 29/30/31-, and 37-day PHIs from treatment plot #2, and wheat straw and grain were collected at 45/47-, 51/52/53-, 58/59/63-, and 65/66/67-day PHIs from treatment plot #3 from one spring wheat trial (ND) and two winter wheat trials (KS and OK). For each plot and sampling interval, a single untreated and duplicate treated samples were collected. Specific harvesting procedures were not described.

After collection, RAC samples were frozen and shipped via freezer truck or overnight courier with dry ice to Syngenta Crop Protection, Inc. (Greensboro, NC), where samples were stored frozen (-20 °C) until analysis.

Samples of wheat grain from the control plot #1 and treatment plot #5 were collected from a single ND spring wheat field trial and a single OK winter wheat trial for generation of samples of aspirated grain fractions and processed wheat commodities (46012904PFF.der.wpd, W. Cutchin, in process).

B.3. Analytical Methodology



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Samples of wheat RACs were analyzed by Syngenta for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The limit of detection (LOD), as determined by the smallest standard injection, was 0.40 ng, and the LOQs, as demonstrated by the smallest acceptable recovery level, were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC/UV Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The LOD, as determined by the smallest standard injection, was 0.125 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.05 ppm for wheat forage, hay, straw, and grain. Methods REM 138.01 and REM 138.10 were submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00).

Method REM 138.01: Briefly, homogenized samples were extracted with acetonitrile and filtered. The extract was cleaned up by partitioning with hexane (2x); the hexane phases were discarded. The acetonitrile phase was cleaned up by solid phase extraction (SPE) on a C-18 cartridge, using acetone to elute residues; this step was omitted for grain samples. Water and saturated sodium chloride solution were added to the extract (only saturated sodium chloride solution was added to grain samples), which was then partitioned three times with hexane:diethyl ether (9:1; v:v). The combined organic phases were subjected to a second SPE on a silica cartridge, using hexane:acetone (8:2, v:v) to elute residues of cloquintocet-mexyl. The eluate was evaporated to dryness, residues were redissolved in hexane:ethanol (9:1, v:v), and the sample was analyzed by HPLC/UV using column switching. We note that the method was modified slightly to increase the LOQ for wheat forage, hay, and straw to 0.05 ppm.

Method REM 138.10: Briefly, homogenized crop samples were extracted with an acetone:citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane:diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol:buffer (50:50, v:v). The methanol:buffer solution was evaporated to dryness, redissolved in 0.005 M PIC Reagent A solution, and CGA-153433 was determined by HPLC/UV using column switching. For selected samples the methanol:buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water, and CGA-153433 was determined by HPLC/MS. We note that method was modified to increase the LOQ for grain to 0.05 ppm.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. Samples of wheat forage, hay, grain, and straw were analyzed for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The validated LOQs were 0.05 ppm for wheat forage, hay, and straw, and 0.02 ppm for wheat grain. In addition, samples were analyzed for residues of the metabolite CGA-153433 using HPLC/UV Method REM 138.10, the current enforcement method for



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 Crop Field Trial - Wheat

residues of CGA-153433 in wheat commodities. The validated LOQ was 0.05 ppm for wheat forage, hay, straw, and grain. These methods are adequate for data collection based on acceptable method recoveries. Apparent residues of cloquintocet-mexyl and CGA-153433 were each below the LOQ in/on 52 samples of untreated wheat forage, 35 samples of untreated wheat hay, 29 samples of untreated wheat straw, and 29 samples of untreated wheat hay.

When the results of the spring wheat field trials were submitted previously (PP#7E04920, DP Barcode D257181, MRID 44755303, N. Dodd, 4/7/00), the petitioner reported that straw samples could not be analyzed for residues of CGA-153433 "using current methodology." The current submission includes results for straw samples, which appear to have been analyzed for CGA-153433 after the previous submission. The petitioner did not provide any discussion of this issue (i.e., did not explain whether changes to the method were required to allow analysis of straw samples) and did not provide any raw data for the analyses of spring wheat straw samples for CGA-153433.

Residue data from the wheat field trials are reported in Table C.3. A summary of residue data for wheat forage, hay, straw, and grain following treatment with the 2 lb ai/gal EC formulation is presented in Table C.4. A total of 20 wheat field trials (6 spring wheat and 14 winter wheat trials) were conducted during the 1998-1999 growing seasons. Spring wheat field trials were conducted in Regions 5 (MN and ND; 2 trials) and 7 (MT, ND, and SD; 4 trials). Winter wheat field trials were conducted in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 (IL, KS, and MO; 3 trials), 6 (OK; 1 trial), 8 (CO, KS, NM, OK, and TX; 6 trials), and 11 (WA; 1 trial). In addition, one trial was conducted in Region 5 (NE) close enough to the border with Region 7 to support geographic representation requirements for Region 7.

The winter wheat field trials were conducted with two types of early season application: application in the fall or application in the spring. Of the 14 winter wheat trials, a total of 8 trials were conducted reflecting application in the fall, in Regions 2 (NC; 1 trial), 4 (AR; 1 trial), 5 (KS; 1 trial), 6 (OK; 1 trial), and 8 (KS, OK, and TX; 4 trials). The remaining 6 trials were conducted reflecting early season application in the spring, in Regions 5 (IL and MO; 2 trials), 7 (NE; 1 trial), 8 (CO and NM; 2 trials), and 11 (WA; 1 trial).

The petitioner has stated that they will not be supporting application of clodinafop-propargyl to winter wheat in the fall; application to winter wheat will be restricted to a spring postemergence foliar application. We note that harvest of winter wheat hay 0 or 30 days following application in the fall is not typical agronomic practice; in general, if herbicides are applied to winter wheat in the fall, hay would not typically be harvested until the spring. Residue results for forage and hay samples that were harvested following a fall application to winter wheat will not be discussed below [residue results for forage and hay samples harvested following fall application are included in Tables C.3 and C.4].

Because the petitioner does not wish to use the results from winter wheat forage and hay fall application trials, geographic representation of residue trials is not adequate for forage and hay. To fulfill geographic representation requirements, winter wheat forage and hay data from an



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 Crop Field Trial - Wheat

additional 8 field trials reflecting spring application, conducted in Regions 2 (1 trial), 4 (1 trial), 5 (1 trial), 6 (1 trial), and 8 (4 trials), must be submitted. We note that additional winter wheat crop field trial data have been submitted separately; refer to the DER for MRID 46012905 (46012904.de2.wpd).

Following treatment of spring wheat with a single broadcast foliar application made at Feekes Growth Stage 2 at 0.016 lb safener/A (7.1 g safener/A), residues of cloquintocet-mexyl were 0.16-1.68 ppm in/on forage harvested on the day of application and were <0.05 ppm in/on forage and hay harvested 29-47 days following treatment. Residues of CGA-153433 were 0.14-0.41 ppm in/on forage harvested on the day of treatment and were below the LOQ (<0.05 ppm) in/on forage and hay harvested 29-47 days following treatment. Combined residues of cloquintocet-mexyl and CGA-153433 were 0.34-2.00 ppm in/on forage harvested on the day of treatment and <0.10 ppm in/on forage and hay harvested 29-47 days posttreatment.

Following treatment of winter wheat with a single broadcast foliar application made in the spring at Feekes Growth Stage 2 at 0.016 lb safener/A (7.1 g safener/A), residues of cloquintocet-mexyl were 0.21-1.56 ppm in/on forage harvested on the day of application and were <0.05 ppm in/on forage and hay harvested 29-32 days following treatment. Residues of CGA-153433 were 0.05-0.45 ppm in/on forage harvested on the day of treatment and were <0.05 ppm in/on forage and hay harvested 29-32 days following treatment. Combined residues of cloquintocet-mexyl and CGA-153433 were 0.26-1.76 ppm in/on forage harvested on the day of treatment and <0.10 ppm in/on forage and hay harvested 29-32 days posttreatment.

Residues of cloquintocet-mexyl were <0.05 ppm in/on spring and winter wheat straw and <0.02 ppm in/on spring and winter wheat grain, and residues of CGA-153433 were <0.05 ppm in/on spring and winter wheat straw and grain harvested 57-69 days following a single broadcast foliar application of the 0.5 lb safener/gal EC formulation, made approximately 60 days prior to harvest.

In the two trials in which wheat was treated at an exaggerated rate, residues of cloquintocet-mexyl were <0.05 ppm in/on straw and <0.02 ppm in/on grain, and residues of CGA-153433 were <0.05 ppm in/on straw and grain harvested 59 or 61 days following treatment at 0.078 lb ai/A.

We note that, at one spring wheat trial conducted in MT and two fall application winter wheat trials conducted in KS and TX, applications were made using a concentrated spray volume (2 gal/A) to simulate aerial application. Residues from the MT and KS trials were consistent with those from trials reflecting normal spray volumes; however, results from the TX winter wheat trial represented the maximum residue values and the HFT for winter wheat forage following fall application.

Residue decline data show that cloquintocet-mexyl residues generally decrease in/on wheat forage and hay with increasing sampling intervals, with the maximum residues occurring at the 0-day sampling interval. In three residue decline trials, residues of cloquintocet-mexyl declined



from 0.14-1.04 ppm in/on forage at the 0-day PHI to below the method LOQ (<0.05 ppm) at the 7-day PHI, and remained below the LOQ through the 36- to 38-day PHI. Residues of cloquintocet-mexyl declined from 0.12-1.12 ppm in/on hay at the 0-day PHI to <0.05 -0.10 ppm at the 7-day PHI, and continued to decline to <0.05 ppm at the 36- to 38-day PHI. Residues of cloquintocet-mexyl were <0.05 and <0.02 ppm in/on wheat straw and grain, respectively, at all sampling intervals (45-67 days posttreatment) in the decline studies.

Residues of CGA-153433 were also found to decrease in/on forage and hay with increasing sampling intervals, with the maximum residues occurring at the 0-day sampling interval. In two of the decline trials, residues of CGA-153433 declined from 0.17-0.20 ppm in/on forage and 0.12-0.22 ppm in/on hay at the 0-day PHI to <0.05 ppm at the 7-day PHI, and remained at those levels through the 36- to 38-day PHI. In the third decline trial (KS), residues of CGA-153433 declined in/on wheat forage from 0.23 and 0.26 ppm at the 0-day PHI to <0.05 ppm at the 7-day PHI, increased to 0.08 and 0.10 ppm at the 20-day PHI, and remained at those levels for the remaining intervals; residues in/on wheat hay declined from 0.55 and 0.62 ppm at the 0-day PHI to 0.11 and 0.14 ppm at the 7-day PHI, and remained at those levels for the remaining intervals. Residues of CGA-153433 were <0.05 ppm in/on wheat straw and grain at all sampling intervals (45-67 days posttreatment) in the decline studies.

We note that all results presented by the petitioner were corrected for concurrent method recovery (when recovery was $<100\%$); uncorrected results were only found on the individual residue results sheets in the raw data. The petitioner should note that if corrected residue results are presented, the results should be **clearly** identified as corrected results, with an explanation of how the correction was made, and that uncorrected results should **also** be presented.

Sample storage conditions and intervals are summarized in Table C.2. The maximum storage intervals of crop samples from harvest to analysis for cloquintocet-mexyl were 187 days (6.1 months) for forage, 134 days (4.4 months) for hay, 148 days (4.9 months) for straw, and 141 days (4.6 months) for grain. The maximum storage intervals of crop samples from harvest to analysis for CGA-153433 were 253 days (8.3 months) for forage, 231 days (7.6 months) for hay, 308 days (10.1 months) for straw, and 222 days (7.3 months) for grain.

In support of the crop field trial study, the petitioner cited storage stability data (46012916SS.der.wpd, W. Cutchin, in progress) submitted in conjunction with the current petition; these data indicate that residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay for up to ~18 months, and residues of CGA-153433 are reasonably stable in/on wheat forage and hay for up to ~25 months of frozen storage. Storage stability data submitted previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat straw and grain stored at -18°C for up to ~6 months, and residues of CGA-153433 are stable in wheat straw stored at -18°C for 380 days (12.5 months). Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20°C for 727 days (23.9 months). The available storage stability data support the storage conditions and intervals of samples from the submitted wheat field trials.



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 Crop Field Trial - Wheat

We note that in certain cases, forage, hay, and straw sample extracts were stored for >30 days prior to analysis for residues of CGA-153433. The petitioner did not specifically state how extracts were stored prior to analysis. The petitioner should note for future submissions that HED generally requires supporting storage stability data if extracts are stored >30 days prior to analysis. For the purposes of this submission only, HED will not require supporting storage stability data for extract storage because concurrent method recoveries from fortified samples analyzed at the same time as the stored extracts (fortified sample were presumably stored as long as the extracts) were within the range of recoveries observed for CGA-153433 in wheat forage, hay, and straw.

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Cloquintocet-mexyl; determined using Modified REM 138.01				
Wheat forage	0.05	34	65. 65. 70. 70. 70. 76. 76. 77. 78. 79. 81. 81. 82. 84. 85. 91. 92. 94. 94. 94. 96. 99. 99. 100. 100. 100. 109. 110. 111. 119. 121. 123. 129. 133	95 $\pm$ 18
	0.10	10	62. 76. 100. 104. 105. 107. 125. 127. 129. 130	
	0.20	3	80. 96. 103	
	0.50	7	80. 89. 92. 94. 100. 103. 107	
	1.00	6	83. 86. 92. 102. 113. 118	
	5.00	3	75. 87. 94	
	10.00	3	81. 85. 94	
	20.00	1	87	
Wheat hay	0.05	21	62. 65. 65. 67. 71. 75. 82. 87. 90. 91. 96. 99. 105. 105. 106. 107. 110. 112. 115. 125. 132	95 $\pm$ 20
	0.10	2	80. 80	
	0.20	9	63. 67. 68. 76. 91. 106. 111. 120. 121	
	0.50	5	92. 96. 103. 108. 114	
	1.00	5	76. 108. 112. 114. 119	
	10.00	1	91	
Wheat straw	0.05	18	62. 65. 69. 69. 69. 87. 90. 93. 95. 95. 100. 101. 104. 105. 115. 116. 124. 125	100 $\pm$ 20
	0.10	2	119. 127	
	0.20	4	94. 113. 115. 126	
	0.50	5	63. 87. 87. 105. 111	
	1.00	5	88. 93. 101. 122. 127	
	5.00	4	88. 99. 106. 129	



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TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Wheat grain	0.02	18	74. 83. 85. 89. 90. 91. 94. 98. 99. 102. 107. 112. 116. 116. 123. 124. 125. 133	104 $\pm$ 16
	0.05	1	128	
	0.10	6	91. 95. 103. 104. 115. 130	
	0.20	5	74. 84. 107. 111. 121	
	0.50	3	102. 119. 128	
	1.00	4	89. 91. 99. 110	
CGA-153433: determined using Modified REM 138.10				
Wheat forage	0.05	33	54. 56. 58. 59. 59. 61. 61. 61. 63. 63. 64. 64. 65. 68. 68. 69. 69. 70. 70. 72. 72. 73. 74. 75. 75. 76. 77. 78. 85. 87. 88. 99. 102	71 $\pm$ 11
	0.10	11	57. 57. 60. 65. 66. 66. 68. 70. 71. 73. 85	
	0.20	2	73. 75	
	0.50	8	62. 62. 64. 70. 72. 74. 86. 90	
	1.00	8	58. 62. 65. 73. 77. 78. 80. 86	
	5.00	4	62. 64. 87. 88	
	10.00	2	58. 80	
	20.00	1	108	
Wheat hay	0.05	17	51. 53. 61. 64. 68. 76. 88. 92. 95. 95. 96. 104. 111. 112. 124. 124. 136	80 $\pm$ 23
	0.10	2	60. 74	
	0.20	10	52. 62. 68. 70. 71. 83. 83. 97. 111. 112	
	0.50	5	56. 62. 62. 65. 74	
	1.00	5	54. 58. 67. 70. 70	
	10.00	2	56. 74	
Wheat straw	0.05	17	58. 59. 60. 61. 64. 64. 64. 72. 74. 75. 76. 81. 82. 83. 84. 85. 88	70 $\pm$ 9
	0.10	2	66. 68	
	0.20	4	57. 61. 63. 72	
	0.50	5	60. 62. 62. 67. 79	
	1.00	6	65. 65. 73. 73. 77. 92	
	5.00	4	68. 68. 72. 74	



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 Crop Field Trial - Wheat

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Wheat grain	0.05	19	53. 54. 59. 60. 60. 61. 61. 64. 66. 66. 66. 70. 71. 72. 74. 74. 75. 76. 77	70 $\pm$ 13
	0.10	5	60. 64. 69. 72. 77	
	0.20	5	66. 69. 75. 90. 97	
	0.50	4	68. 68. 70. 79	
	1.00	6	56. 65. 67. 70. 71. 127	

TABLE C.2. Summary of Storage Conditions.			
Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration ¹	Interval of Demonstrated Storage Stability ²
Cloquintocet-mexyl			
Wheat forage	-20	Wheat treated in the fall: 36-259 days (1.2-8.5 months)	Residues of cloquintocet-mexyl are reasonably stable in/on wheat forage and hay during up to 18 months of frozen storage.
		Wheat treated in the spring: 27-187 days (0.9-6.1 months)	
Wheat hay	-20	Wheat treated in the fall: 49-359 days (1.6-11.8 months)	
		Wheat treated in the spring: 38-134 days (1.2-4.4 months)	
Wheat straw	-20	15-148 days (0.5-4.9 months)	Residues of cloquintocet-mexyl are stable in/on wheat straw stored at -18 °C for 6 months.
Wheat grain	-20	20-141 days (0.7-4.6 months)	Residues of cloquintocet-mexyl are stable in/on wheat grain stored at -18 °C for ~6 months.
CGA-153433			
Wheat forage	-20	Wheat treated in the fall: 195-443 days (6.4-14.6 months)	Residues of CGA-153433 are reasonably stable in/on wheat forage and hay during up to ~25 months of frozen storage.
		Wheat treated in the spring: 46-253 days (1.5-8.3 months)	
Wheat hay	-20	Wheat treated in the fall: 49-359 days (1.6-11.8 months)	
		Wheat treated in the spring: 38-231 days (1.2-7.6 months)	
Wheat straw	-20	30-308 days (1.0-10.1 months)	Residues of CGA-153433 are stable in wheat straw during up to 380 days of frozen storage.
Wheat grain	-20	47-222 days (1.5-7.3 months)	Pending receipt of additional information. HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for up to 727 days.

¹ From sampling to analysis: wheat samples were analyzed for cloquintocet-mexyl within 0-23 days of extraction and for CGA-153433 within 0-52 days of extraction.

² Refer to the 860.1380 DER (46012916SS.der.wpd. W. Cutchin, in process) and PP#7E04920: DP Barcode D257181, N. Dodd, 4/7/00.



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.												
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²					
							CGA- 185072	CGA- 153433	Total			
Spring Wheat Trials ³												
Grand Forks, ND: 1998 (0W-HR-210-98)	5	Spring: Russ	2	forage	0.016 [7.1]	0	1.17	0.26	1.43			
				forage		32	1.68	0.32	2.00			
							<0.05	<0.05	<0.10			
			hay	32	<0.05	<0.05	<0.10					
					<0.05	<0.05	<0.10					
			3	straw	0.016 [7.1]	61	<0.05	<0.05	<0.10			
				grain		<0.05	<0.05	<0.10				
						<0.02	<0.05	<0.07				
			5	straw	0.078 [35.5]	61	<0.05	<0.05	<0.10			
				grain		61	<0.02	<0.05	<0.10			
Polk, MN: 1998 (0W-HR-211-98)	5	Spring: Sharp	2	forage	0.016 [7.1]	0	1.15	0.38	1.53			
				forage		29	1.19	0.25	1.44			
							<0.05	<0.05	<0.10			
			hay	29	<0.05	<0.05	<0.10					
					<0.05	<0.05	<0.10					
			3	straw	0.016 [7.1]	58	<0.05	<0.05	<0.10			
				grain		<0.05	<0.05	<0.10				
						<0.02	<0.05	<0.07				
			McHenry, ND: 1998 (0W-HR-212-98) (decline study)	7	Spring: 2375	2	forage	0.016 [7.1]	0	0.14	0.20	0.34
									7	0.16	0.18	0.34
<0.05	<0.05	<0.10										
14	<0.05	<0.05							<0.10			
	<0.05	<0.05							<0.10			
21	<0.05	<0.05							<0.10			
	<0.05	<0.05							<0.10			
30	<0.05	<0.05							<0.10			
	<0.05	<0.05							<0.10			
37	<0.05	<0.05							<0.10			
	<0.05	<0.05	<0.10									
hay	0.016 [7.1]	0	0.17	0.22	0.39							
		7	0.18	0.22	0.40							
			<0.05	<0.05	<0.10							
		14	<0.05	<0.05	<0.10							
			<0.05	<0.05	<0.10							
		21	<0.05	<0.05	<0.10							
			<0.05	<0.05	<0.10							
		<0.05	<0.05	<0.10								



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²		
							CGA- 185072	CGA- 153433	Total
						30	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						37	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
			3	straw	0.016 [7.1]	45	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						52	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						59	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						66	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
				grain	0.016 [7.1]	45	<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07
						52	<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07
						59	<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07
						66	<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07
Sheridan, MT: 1998 (OW-HR-213-98)	7	Spring: Grandin	2	forage	0.016 [7.1]	0	0.58	0.24	0.82
							0.60	0.14	0.74
				forage		30	<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	30	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
				straw		60	<0.05	<0.05	<0.10
			3	grain	0.016 [7.1]	60	<0.05	<0.05	<0.10
							<0.02	<0.05	<0.07
Fergus, MT: 1998 (OW-HR-214-98)	7	Spring: Granden	2	forage	0.016 [7.1]	0	0.68	0.41	1.09
							0.80	0.38	1.18
				forage		30	<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	47	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
				straw		57	<0.05	<0.05	<0.10
			3	grain	0.016 [7.1]	57	<0.05	<0.05	<0.10
							<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.										
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²			
							CGA- 185072	CGA- 153433	Total	
Charles Mix. SD: 1998 (0W-HR-215-98)	7	Spring: Butte 86	2	forage	0.016 [7.1]	0	0.16	0.19'	0.35	
				forage		30	0.16	0.21	0.37	
							<0.05	<0.05	<0.10	
			hay	30	<0.05	<0.05	<0.10			
					<0.05	<0.05	<0.10			
			3	straw	0.016 [7.1]	60	<0.05	<0.05	<0.10	
				grain		<0.05	<0.05	<0.10		
						<0.02	<0.05	<0.07		
						<0.02	<0.05	<0.07		
Winter Wheat Trials; Plot 2 application in the fall										
Drew. AR: 1998- 1999 (0S-HR-101-98)	4	Winter: Jackson	2	forage	0.016 [7.1]	0	1.76	0.14	1.90	
				forage		31	2.21	0.13	2.34	
							<0.05	<0.05	<0.10	
			hay	31	<0.05	<0.05	<0.10			
					<0.05	0.07	<0.12			
			3	straw	0.016 [7.1]	<0.05	0.08	<0.13		
				grain		59	<0.05	<0.05	<0.10	
						<0.05	<0.05	<0.10		
						<0.02	<0.05	<0.07		
Payne. OK: 1998-1999 (0S-HR-710-98) (decline study)	6	Winter: Jagger	2	forage	0.016 [7.1]	0	0.20	0.17	0.37	
						7	0.21	0.17	0.38	
							<0.05	<0.05	<0.10	
						14	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
						20	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
						29	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
						38	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
						hay	0	0.12	0.15	0.27
								0.13	0.12	0.25
							7	<0.05	<0.05	<0.10
								<0.05	<0.05	<0.10
							14	<0.05	<0.05	<0.10
								<0.05	<0.05	<0.10
							20	<0.05	<0.05	<0.10
								<0.05	<0.05	<0.10
29	<0.05	<0.05	<0.10							
	<0.05	<0.05	<0.10							



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100

DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3

Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.												
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²					
							CGA- 185072	CGA- 153433	Total			
			3	straw	0.016 [7.1]	38	<0.05	<0.05	<0.10			
						<0.05	<0.05	<0.10				
						45	<0.05	<0.05	<0.10			
						<0.05	<0.05	<0.10				
						51	<0.05	<0.05	<0.10			
						<0.05	<0.05	<0.10				
				58	<0.05	<0.05	<0.10					
				<0.05	<0.05	<0.10						
				65	<0.05	<0.05	<0.10					
				<0.05	<0.05	<0.10						
				45	<0.02	<0.05	<0.07					
				<0.02	<0.05	<0.07						
			51	<0.02	<0.05	<0.07						
			<0.02	<0.05	<0.07							
			58	<0.02	<0.05	<0.07						
			<0.02	<0.05	<0.07							
			65	<0.02	<0.05	<0.07						
			<0.02	<0.05	<0.07							
Washita, OK: 1998-1999 (0S-HR-711-98)	8	Winter: Coker 9803	2	forage	0.016 [7.1]	0	0.54	0.22	0.76			
						0.59	0.24	0.83				
				hay		33	<0.05	<0.05	<0.10			
						<0.05	<0.05	<0.10				
			3	straw	0.016 [7.1]	59	<0.05	<0.05	<0.10			
				<0.05		<0.05	<0.10					
				grain		59	<0.02	<0.05	<0.07			
				<0.02		<0.05	<0.07					
			5	straw	0.078 [35.5]	59	<0.05	<0.05	<0.10			
				grain		59	<0.02	<0.05	<0.07			
			Castro, TX: 1998-1999 (0S-HR-712-98)	8	Winter: TAM 200	2	forage	0.016 [7.1]	0	1.92	0.12	2.04
									2.61	0.09	2.70	
hay	27	<0.05					<0.05		<0.10			
	<0.05	<0.05					<0.10					
3	straw	0.016 [7.1]				60	<0.05	<0.05	<0.10			
	<0.05					<0.05	<0.10					
	grain					60	<0.02	<0.05	<0.07			
	<0.02					<0.05	<0.07					



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²		
							CGA- 185072	CGA- 153433	Total
Sampson, NC: 1998-1999 (OS-HR-601-98)	2	Winter: Coker 9803	2	forage	0.016 [7.1]	0	0.91	0.51	1.42
							1.10	0.41	1.51
						30	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	30	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						60	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
Sedgwick, KS: 1998-1999 (MW-HR-304-98)	5	Winter: Karl	2	forage	0.016 [7.1]	0	1.24	0.09	1.33
							1.40	0.09	1.49
						29	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	29	<0.05	0.08	<0.13
							<0.05	0.09	<0.14
						63	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
Pratt, KS: 1998- 1999 (MW-HR-305-98) (decline study)	8	Winter: Jagger	2	forage	0.016 [7.1]	0	0.82	0.20	1.02
							1.04	0.23	1.27
						7	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						13	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						20	<0.05	0.08	<0.13
							<0.05	0.10	<0.15
				hay	0.016 [7.1]	31	<0.05	0.06	<0.11
							<0.05	0.07	<0.12
						36	<0.05	0.08	<0.13
							<0.05	0.08	<0.13
						0	1.01	0.55	1.56
							1.12	0.62	1.74
						7	0.08 ⁴	0.11	0.19
							0.10 ⁴	0.14	0.24
						13	0.08	0.09	0.17
							0.10	0.12	0.22
						20	0.06	0.09	0.15
							0.06	0.11	0.17
						31	<0.05	0.10	<0.15
							0.06	0.13	0.19
						36	<0.05	0.10	<0.15



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.										
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²			
							CGA- 185072	CGA- 153433	Total	
			3	straw	0.016 [7.1]	47	<0.05	0.10	<0.15	
							<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
							53	<0.05	<0.05	<0.10
								<0.05	<0.05	<0.10
								<0.05	<0.05	<0.10
						63	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
						67	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
				grain	0.016 [7.1]		47	<0.02	<0.05	<0.07
								<0.02	<0.05	<0.07
							53	<0.02	<0.05	<0.07
						<0.02		<0.05	<0.07	
						63	<0.02	<0.05	<0.07	
							<0.02	<0.05	<0.07	
Pratt, KS: 1998- 1999 (MW-HR-306- 98)	8	Winter: Jagger	2	forage	0.016 [7.1]	0	0.58 ⁴	0.05	0.63	
							1.57 ⁴	0.06	1.63	
						31	<0.05	<0.05 ⁴	<0.10	
							<0.05	0.07 ⁴	<0.12	
						31	<0.05 ⁴	0.06	<0.11	
							0.05 ⁴	0.10	0.15	
			3	straw	0.016 [7.1]	59	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
				grain		59	<0.02	<0.05	<0.07	
							<0.02	<0.05	<0.07	
Winter Wheat Trials; Plot 2 application in the spring										
Whitman, WA: 1999 (OW-HR-311-98)	11	Winter: Rod and Madsen Mix	2	forage	0.016 [7.1]	0	0.21	0.05	0.26	
							0.28	0.05	0.33	
				forage		29	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
				hay		30	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
			3	straw	0.032 [14.2]	69	<0.05	<0.05	<0.10	
							<0.05	<0.05	<0.10	
				grain		69	<0.02	<0.05	<0.07	
							<0.02	<0.05	<0.07	



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²		
							CGA- 185072	CGA- 153433	Total
Champaign, IL: 1999 (04-HR-001-98)	5	Winter: Madison	2	forage	0.016 [7.1]	0	0.83	0.34	1.17
				forage		31	0.96	0.45	1.41
				forage			<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	31	<0.05	<0.05	<0.10
				hay			<0.05	<0.05	<0.10
				straw		61	<0.05	<0.05	<0.10
				straw			<0.05	<0.05	<0.10
				grain		61	<0.02	<0.05	<0.07
Curry, NM: 1999 (0S-HR-713-98)	8	Winter: TAM 105	2	forage	0.016 [7.1]	0	1.44	0.24	1.68
				forage		29	1.56	0.20	1.76
				forage			<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	29	<0.05	<0.05	<0.10
				hay			<0.05	<0.05	<0.10
				straw		63	<0.05	<0.05	<0.10
				straw			<0.05	<0.05	<0.10
				grain		63	<0.02	<0.05	<0.07
Adair, MO: 1999 (MW-HR-201-99)	5	Winter: Coker 9474	2	forage	0.016 [7.1]	0	0.61	0.09	0.70
				forage		30	0.67	0.23	0.90
				forage			<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	30	<0.05	<0.05	<0.10
				hay			<0.05	<0.05	<0.10
				straw		60	<0.05	<0.05	<0.10
				straw			<0.05	<0.05	<0.10
				grain		60	<0.02	<0.05	<0.07
Hall, NE: 1999 (MW-HR-601-98)	5	Winter: Nekota HRW	2	forage	0.016 [7.1]	0	0.26	0.15	0.41
				forage		29	0.37	0.16	0.53
				forage			<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	29	<0.05	<0.05	<0.10
				hay			<0.05	<0.05	<0.10
				straw		59	<0.05	<0.05	<0.10
				straw			<0.05	<0.05	<0.10
				grain		59	<0.02	<0.05	<0.07
				grain			<0.02	<0.05	<0.07



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.3. Residue Data from Wheat Field Trials with Cloquintocet-Mexyl.									
Trial ID (County, State: Year)	Region	Wheat Type: Variety	Plot ¹	Commodity or Matrix	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Residues (ppm) ²		
							CGA- 185072	CGA- 153433	Total
Weld. CO: 1999 (MW-HR-307- 98)	8	Winter: Platte	2	forage	0.016 [7.1]	0	0.96	0.11	1.07
							1.07	0.11	1.18
						32	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
			3	hay	0.016 [7.1]	32	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
						63	<0.05	<0.05	<0.10
							<0.05	<0.05	<0.10
				grain		63	<0.02	<0.05	<0.07
							<0.02	<0.05	<0.07

¹ Treatment Plot 2 received a single postemergence application at Feekes Growth Stage 2. Treatment Plot 3 received a single postemergence application approximately 60 days prior to harvest of mature wheat. Treatment plot 5 received a single postemergence application at an exaggerated rate approximately 60 days prior to harvest of mature wheat.

² The petitioner reported residue values corrected for method recovery. The uncorrected residues reported in this table were obtained by the study reviewer from the raw data. Total residue values were calculated by the study reviewer.

³ The results of the spring wheat field trials, with the exception of CGA-153433 residues in/on straw, were reported previously (MRID 44755303; PP#7E04920; DP Barcode D257181; N. Dodd, 4/7/00).

⁴ Replicate analyses of a single sample: the maximum residue is reported.

TABLE C.4. Summary of Residue Data from Wheat Crop Field Trials with Cloquintocet-Mexyl.										
Commodity	Total Applic. Rate (lb safener/A) [g safener/A]	PHI (days)	Analyte	Residue Levels (ppm)						
				n	Min.	Max.	HAFT ¹	Median (STMdR ²)	Mean (STMR ³)	Std. Dev.
Spring Wheat										
Wheat. forage	0.016 [7.1]	0	CGA-185072	12	0.16	1.68	1.43	0.64	0.71	0.51
			CGA-153433	12	0.14	0.41	0.40	0.25	0.26	0.09
			Total	12	0.34	2.00	1.72	0.96	0.97	0.56
	0.016 [7.1]	29-32	CGA-185072	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat. hay	0.016 [7.1]	29-47	CGA-185072	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat. straw	0.016 [7.1]	57-61	CGA-185072	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat. grain	0.016 [7.1]	57-61	CGA-185072	12	<0.02	<0.02	<0.02	<0.02	<0.02	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.07	<0.07	<0.07	<0.07	<0.07	0.0



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.4. Summary of Residue Data from Wheat Crop Field Trials with Cloquintocet-Mexyl.										
Commodity	Total Applic. Rate (lb safener/A) [g safener/A]	PHI (days)	Analyte	Residue Levels (ppm)						
				n	Min.	Max.	HAFT ¹	Median (STMdR ²)	Mean (STMR ³)	Std. Dev.
Winter Wheat - Fall Application										
Wheat, forage	0.016 [7.1]	0	CGA-185072	16	0.20	2.61	2.27	1.07	1.17	0.70
			CGA-153433	16	0.05	0.51	0.46	0.16	0.18	0.12
			Total	16	0.37	2.70	2.37	1.38	1.35	0.68
	0.016 [7.1]	27-33	CGA-185072	16	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	16	<0.05	0.07	0.06	<0.05	0.05	0.01
			Total	16	<0.10	<0.12	0.11	<0.10	0.10	0.01
Wheat, hay	0.016 [7.1]	27-33	CGA-185072	16	<0.05	0.06	0.06	<0.05	0.05	0.003
			CGA-153433	16	<0.05	0.13	0.12	0.06	0.07	0.02
			Total	16	<0.10	0.19	0.17	0.11	0.12	0.03
Winter Wheat - Spring Application										
Wheat, forage	0.016 [7.1]	0	CGA-185072	12	0.21	1.56	1.50	0.75	0.77	0.45
			CGA-153433	12	0.05	0.45	0.40	0.16	0.18	0.12
			Total	12	0.26	1.76	1.72	0.99	0.95	0.51
	0.016 [7.1]	29-32	CGA-185072	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, hay	0.016 [7.1]	29-32	CGA-185072	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	12	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	12	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, straw	0.016 ⁴ [7.1]	58-69	CGA-185072	28	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			CGA-153433	28	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	28	<0.10	<0.10	<0.10	<0.10	<0.10	0.0
Wheat, grain	0.016 ⁴ [7.1]	58-69	CGA-185072	28	<0.02	<0.02	<0.02	<0.02	<0.02	0.0
			CGA-153433	28	<0.05	<0.05	<0.05	<0.05	<0.05	0.0
			Total	28	<0.07	<0.07	<0.07	<0.07	<0.07	0.0

¹ HAFT = Highest Average Field Trial.

² STMdR = Supervised Trial Median Residue.

³ STMR = Supervised Trial Mean Residue.

⁴ In one trial, wheat plants inadvertently received both an early season and late season application, yielding an application rate of 0.032 lb ai/A (14.2 g ai/A).



Cloquintocet-mexyl/CGA-185072/700099/Syngenta Crop Protection, Inc./100
 DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
 Crop Field Trial - Wheat

TABLE C.4. Summary of Residue Data from Crop Field Trials with Cloquintocet-mexyl (measured as CGA-153433).				
Commodity	PHI (days)	Maximum Residue Levels (ppm)		
		Cloquintocet-mexyl	CGA-153433	Total Residues
Spring wheat				
Wheat forage	0	1.68	0.41	2.00
	29-32	<0.05	<0.05	<0.10
Wheat hay	29-47	<0.05	<0.05	<0.10
Wheat straw	57-61	<0.05	<0.05	<0.10
Wheat grain	57-61	<0.02	<0.05	<0.07
Winter wheat - spring application				
Wheat forage	0	1.56	0.45	1.76
	27-33	<0.05	<0.05	<0.10
Wheat hay	27-33	<0.05	<0.05	<0.10
Wheat straw	58-69	<0.05	<0.05	<0.10
Wheat grain	58-69	<0.02	<0.05	<0.07

D. CONCLUSION

The submitted field trial data reflect a single postemergence foliar application of an EC formulation containing 0.5 lb/gal of the safener cloquintocet-mexyl made to wheat either early in the season at the Feekes Growth Stage 2 (treatment plot 2) or later in the season approximately 60 days prior to harvest of mature wheat (treatment plot 3). Cloquintocet-mexyl was applied at a rate of 0.016 lb safener/A (7.1 g safener/A). Wheat forage was harvested at a 0- and a 27- to 33-day PHI, wheat hay was harvested at a 27- to 47-day PHI from treatment plot 2, and wheat straw and grain were collected at maturity (57- to 63-day PHI) from treatment plot 3. Acceptable methods were used for quantitation of residues in/on wheat commodities.

E. REFERENCES

DP Barcode: D257181
 Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.
 From: Nancy Dodd
 To: Bipin Gandhi/Robert Forrest
 Dated: 4/7/00
 MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303



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DACO 7.4.1/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Wheat

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/28/05

Petition Number(s): PP#7E04920

DP Barcode(s): D308470

PC Code: 700099

Template Version September 2003



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DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIA 8.5
Processed Food and Feed - Wheat

Primary Evaluator Dynamac Corporation
 Germantown, MD

Date: 8/1/05

Approved by W. Cutchin, Chemist 
 RD/TRB

This DER was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 12/15/2004). The DER has been reviewed by TRB and revised to reflect current OPP policies.

STUDY REPORT:

46012904 Hamilton, L. (2002) CGA-184927 and CGA-185072 - Magnitude of the Residues in or on Wheat: Lab Study Number: Syngenta Number 127-98. Unpublished study prepared by Syngenta Crop Protection Inc. 1120 p.

EXECUTIVE SUMMARY:

Syngenta Crop Protection, Inc. has submitted a processing study with wheat. In two trials conducted in ND (spring wheat) and OK (winter wheat), wheat grain (RAC) was harvested 59 or 61 days following a single broadcast foliar application of the 0.5 lb/gal emulsifiable concentrate (EC) formulation at 0.016 lb safener/A (7.1 g safener/A; 1x the field trial application rate) or 0.078 lb safener/A (35.5 g safener/A; 5x the field trial application rate); both application rates were used at both sites. Wheat grain was processed into germ, bran, middlings, shorts, and flour (including low grade and patent) using simulated commercial processing procedures. In addition, a sample of wheat aspirated grain fractions was generated for each trial site. An interim report of these wheat processing data has been reviewed previously (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00); that submission included only the results from the processed commodities of the spring wheat samples.

Residues of cloquintocet-mexyl and its metabolite CGA-153433 were each below the limit of quantitation (LOQ; <0.02 ppm for cloquintocet-mexyl and <0.05 ppm for CGA-153433) in/on wheat grain treated with the 0.5 lb ai/gal EC formulation at 0.016 or 0.078 lb ai/A. Residues of cloquintocet-mexyl were below the LOQ in all samples of spring and winter wheat aspirated grain fractions and processed commodities (germ, bran, middlings, shorts, low grade flour, patent flour, and flour). Residues of CGA-153433 were also below the LOQ (<0.05 ppm) in all samples of spring and winter wheat aspirated grain fractions and processed commodities.

Samples of wheat grain, processed commodities, and aspirated grain fractions were analyzed for residues of cloquintocet-mexyl using high pressure liquid chromatography with ultraviolet detector (HPLC/UV) method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The reported LOQ was 0.02 ppm for wheat grain and processed grain fractions. Samples were analyzed for residues of the metabolite CGA-153433



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using HPLC/UV method REM 138.10, the current enforcement method for residues of CGA-153433 in/on wheat commodities. The reported LOQ was 0.05 ppm for wheat grain and processed wheat commodities. These methods are adequate for data collection based on acceptable concurrent method recovery data.

The maximum storage intervals of processing study samples from harvest of wheat grain to analysis for cloquintocet-mexyl were 147 days (4.8 months) for wheat grain, 140 days (4.6 months) for aspirated grain fractions, and 153 days (5.0 months) for wheat processed commodities. The maximum storage intervals of processing study samples from harvest of grain to analysis for CGA-153433 were 159 days (5.2 months) for wheat grain, 161 days (5.3 months) for aspirated grain fractions and wheat processed fractions other than germ, and 158 days (5.2 months) for germ. The available storage stability data, submitted in conjunction with a previous cloquintocet-mexyl petition (PP#7E04920; DP Barcode D257181, 4/7/00, N. Dodd) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat grain stored at -18 °C for up to ~6 months. Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for 727 days (23.9 months). In addition, storage stability data submitted in conjunction with this submission (refer to the DER for MRID 46012917; 46012917.de2.wpd) indicate that residues of CGA-153433 are reasonably stable in/on fortified samples of wheat germ for up to 165 days (5.4 months) of frozen storage.

The available storage stability data are adequate to support the storage intervals and conditions of wheat grain samples but are not adequate to support the storage intervals and conditions of the aspirated grain fractions and processed commodities samples, with the exception of CGA-153433 in wheat germ. Supporting storage stability data are needed for all wheat commodities that were not analyzed within 30 days of collection or generation.

The reported processing factors do not exceed the theoretical concentration factors. According to Table 3 of OPPTS 860.1520, the theoretical concentration factors are 7.7x for wheat bran, 1.4x for wheat flour, and 8.3x for wheat shorts.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the wheat processing study residue data are classified as scientifically unacceptable but upgradable with the submission of supporting storage stability data. Storage stability data are needed demonstrating the stability of cloquintocet-mexyl residues in wheat germ, bran, shorts, middlings, flour, and aspirated grain fractions during up to 5 months of frozen storage, and data are needed demonstrating the stability of residues of CGA-153433 in wheat bran, shorts, middlings, flour, and aspirated grain fractions during up to 5.3 months of frozen storage.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D308470.



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COMPLIANCE:

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

A. BACKGROUND INFORMATION

Cloquintocet-mexyl is an herbicide safener contained in the formulation Discover™ Herbicide, which contains the herbicide clodinafop-propargyl (CGA-184927). Cloquintocet-mexyl is needed in the formulation to prevent damage to wheat due to phytotoxic effects of CGA-184927. Discover™ Herbicide was conditionally registered for use on wheat in June 2000 (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00). The petitioner has now submitted data to satisfy the conditions of full registration.

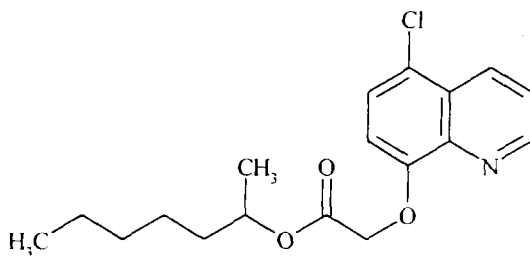
TABLE A.1. Test Compound Nomenclature.	
Chemical structure	
Common name	Cloquintocet-mexyl
Company experimental name	CGA-185072
IUPAC name	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
CAS name	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS registry number	99607-70-2
End-use product (EP)	Included as a safener in the clodinafop-propargyl products Discover Herbicide (EPA Reg. No. 100-907) and Discover NG Herbicide (EPA Reg. No. 100-1173)

TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Melting point/range	ca. 65-69.4 °C	ca.. 65 from physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html ; 69.4 °C is from experimental database for EPIWIN v3.12
pH	NA (not available)	—
Density	1.05 g/cm ³	physchem.ox.ac.uk/MSDS/CL/cloquintocet-mexyl.html ;
Water solubility (25 °C)	0.59 mg/L	Tomlin, C. (1997) according to EPIWIN v3.12
Solvent solubility (mg/L at °C)	NA	



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TABLE A.2. Physicochemical Properties of the Technical Grade Test Compound		
Parameter	Value	Reference
Vapour pressure at 20-25 °C	0.0025-0.005 mPa	Lowest is from a PDF Material Safety Data Sheet for HORIZON by Syngenta found doing a Google search on CAS No. and vapour pressure: highest is from experimental database for EPIWIN v3.12: converted from 4.00E-8 mm Hg at 25 °C
Dissociation constant (pK _a)	NA	
Octanol/water partition coefficient Log(K _{ow})	5.03	Tomlin, C. (1997) according to EPIWIN v3.12
UV/visible absorption spectrum	NA	

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

TABLE B.1.2. Study Use Pattern.							
Location (County, State; Year)	EP ¹	Application					Tank Mix Adjuvants
		Method: Timing	Vol (GPA ³)	Rate (lb safener/A) [g safener/A]	RTI ³ (days)	Total Rate (lb safener/A) [g safener/A]	
Spring wheat field trial							
Grand Forks, ND: 1998 (0W-HR-210- 98)	0.5 lb/gal EC	1: Postemergence foliar spray: Feekes 6-8	7.0	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
		1: Postemergence foliar spray: Feekes 6-8	7.0	0.078 [35.5]	NA	0.078 [35.5]	Score. 1.0% v/v
Winter wheat field trial							
Washita, OK: 1998-1999 (0S-HR-711- 98)	0.5 lb/gal EC	1: Postemergence foliar spray in the spring: Feekes 10.51	19	0.016 [7.1]	NA	0.016 [7.1]	Score. 1.0% v/v
		1: Postemergence foliar spray: Feekes 10.51	19	0.078 [35.5]	NA	0.078 [35.5]	Score. 1.0% v/v

¹ EP = End-use Product

² Treatment Plot 2 received a single postemergence application made early in the season at the Feekes Grow

³ GPA = Gallons per acre

³ RTI = Retreatment Interval

B.2. Sample Handling and Processing Procedures

Samples of wheat grain (RAC) were collected from the spring wheat trial at maturity, 61 days following treatment, and from the winter wheat trial at maturity, 59 days following treatment. The petitioner did not provide sampling procedures for wheat grain.

Samples of spring wheat grain were shipped at ambient temperatures one day after harvest, and samples of winter wheat grain were shipped frozen 7 days after harvest to the Food Protein Center of Texas A&M University. Samples were processed at Texas A&M, using simulated



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commercial processing procedures, to yield aspirated grain fractions, germ, bran, middlings, shorts, and flour. The petitioner included a flow chart of the processing procedures but did not include any additional information pertaining to processing. The storage conditions at the processing facility and the dates of processing were not provided. The petitioner stated that following processing, samples were shipped frozen to Syngenta Crop Protection, Inc. (Greensboro, NC), where samples were stored frozen (-20 °C) until extraction and analysis. Based on the dates that samples were shipped to the analytical facility, spring wheat grain samples were processed within 15 days of collection, and winter wheat grain samples were processed within 55 days of collection.

The petitioner should note for future submissions that the following information should be included in a submission of processing study data: a description of sample handling at the processing facility, a description of the processing procedures, material balance for processed commodities, and dates of sample processing.

B.3. Analytical Methodology

Samples of wheat grain and processed grain fractions, including aspirated grain fractions, were analyzed by Syngenta for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The limit of detection (LOD), as determined by the smallest standard injection, was 0.40 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.02 ppm for wheat grain and processed grain fractions. In addition, samples were analyzed for residues of the metabolite CGA-153433 using a modified version of HPLC/UV Method REM 138.10, which is the current enforcement method for residues of CGA-153433 in wheat commodities. The LOD, as determined by the smallest standard injection, was 0.125 ng, and the LOQ, as demonstrated by the smallest acceptable recovery level, was 0.05 ppm for wheat grain and processed grain fractions. Methods REM 138.01 and REM 138.10 were submitted and reviewed in conjunction with the previous cloquintocet-mexyl petition (PP#7E04920; DP Barcode D257181, 4/7/00, N. Dodd).

Method REM 138.01: Briefly, homogenized wheat commodity samples were extracted with acetonitrile and filtered. The extract was cleaned up by partitioning with hexane (2x); the hexane phases were discarded. Saturated sodium chloride was added to the acetonitrile phase, which was then partitioned three times with hexane:diethyl ether (9:1; v:v). The combined organic phases were subjected to a second SPE on a silica cartridge, using hexane:acetone (8:2, v:v) to elute residues of cloquintocet-mexyl. The eluate was evaporated to dryness, residues were redissolved in hexane:ethanol (9:1, v:v), and the sample was analyzed by HPLC/UV using column switching.

Method REM 138.10: Briefly, homogenized samples were extracted with an acetone:citrate buffer (8:2, v:v) solution (pH 3) and filtered. The citrate solution was partitioned twice with hexane:diethyl ether (8:2, v:v). The combined aqueous phases were partitioned twice with ethyl acetate. The ethyl acetate layers were combined, evaporated to dryness, redissolved in phosphate



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buffer (pH 7), and cleaned up by SPE on a C-18 cartridge. Residues were eluted with methanol:buffer (50:50, v:v). The methanol:buffer solution was evaporated to dryness, redissolved in 0.005 M PIC Reagent A solution and CGA-153433 was determined by HPLC/UV using column switching. For selected samples the methanol:buffer solution was evaporated to dryness, redissolved in 0.1% acetic acid in water, and CGA-153433 was determined by HPLC/MS.

C. RESULTS AND DISCUSSION

Samples of spring and winter wheat grain (RAC) were harvested at maturity, 59-61 days following a single postemergence foliar spray application of the 0.5 lb/gal EC formulation at 0.016 or 0.078 lb safener/A (7.1 or 35.5 g safener/A; 1x or 5x the field trial application rate).

Concurrent method recovery data are presented in Table C.1. Samples of wheat grain, processed commodities, and aspirated grain fractions were analyzed for residues of cloquintocet-mexyl using HPLC/UV method REM 138.01, the current enforcement method for residues of cloquintocet-mexyl in wheat commodities. The reported LOQ was 0.05 ppm for wheat grain and processed grain fractions. Samples were analyzed for residues of the metabolite CGA-153433 using HPLC/UV method REM 138.10, the current enforcement method for residues of CGA-153433 in/on wheat commodities. The reported LOQ was 0.05 ppm for wheat grain and processed wheat commodities. We note that method recovery data were not provided at the stated LOQs for all wheat processed commodities; validation data at the LOQ were provided for grain, germ, middlings, and flour only. Apparent residues of cloquintocet-mexyl and its metabolite CGA-153433 were each less than the method LOQ (<0.02 ppm and <0.05 ppm) in two samples each of untreated wheat grain, two samples each of germ, bran, middlings, shorts, and aspirated grain fractions processed from untreated grain, and in one sample each of low grade flour, patent flour, and flour processed from untreated grain.

Sample storage intervals and conditions are summarized in Table C.2. Wheat grain and processed wheat commodities were stored frozen following processing until analysis. The maximum storage intervals of processing study samples from harvest of wheat grain to analysis for cloquintocet-mexyl were 147 days (4.8 months) for wheat grain, 140 days (4.6 months) for aspirated grain fractions, and 153 days (5.0 months) for wheat processed commodities. The maximum storage intervals of processing study samples from harvest of grain to analysis for CGA-153433 were 159 days (5.2 months) for wheat grain, 161 days (5.3 months) for aspirated grain fractions and wheat processed fractions other than germ, and 158 days (5.2 months) for germ.

The available storage stability data, submitted in conjunction with a previous cloquintocet-mexyl petition (PP#7E04920; DP Barcode D257181, N. Dodd, 4/7/00) demonstrate that residues of cloquintocet-mexyl are reasonably stable in wheat grain stored at -18 °C for up to ~6 months. Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for 727 days (23.9 months). In addition, storage stability data submitted in conjunction with this submission (46012917SS.der.wpd, W. Cutchin, in process)



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indicate that residues of CGA-153433 are reasonably stable in/on fortified samples of wheat germ for up to 165 days (5.4 months) of frozen storage.

The available storage stability data are adequate to support the storage intervals and conditions of wheat grain samples but are not adequate to support the storage intervals and conditions of the aspirated grain fractions and processed commodities samples, with the exception of CGA-153433 in wheat germ. Supporting storage stability data are needed for all wheat commodities that were not analyzed within 30 days of collection or generation. Therefore, storage stability data are needed demonstrating the stability of cloquintocet-mexyl residues in wheat germ, bran, shorts, middlings, flour, and aspirated grain fractions during up to 5 months of frozen storage, and data are needed demonstrating the stability of residues of CGA-153433 in wheat bran, shorts, middlings, flour, and aspirated grain fractions during up to 5.3 months of frozen storage.

Residue data from the wheat processing study are reported in Table C.3. Residues of cloquintocet-mexyl and its metabolite CGA-153433 were each below the LOQ (<0.02 ppm for cloquintocet-mexyl and <0.05 ppm for CGA-153433) in/on wheat grain treated with the 0.5 lb ai/gal EC formulation at 0.016 or 0.078 lb ai/A. Residues of cloquintocet-mexyl were below the LOQ in all samples of spring and winter wheat aspirated grain fractions and processed commodities (germ, bran, middlings, shorts, low grade flour, patent flour, and flour). Residues of CGA-153433 were also below the LOQ (<0.05 ppm) in all samples of spring and winter wheat aspirated grain fractions and processed commodities.

The reported processing factors do not exceed the theoretical concentration factors. According to Table 3 of OPPTS 860.1520, the theoretical concentration factors are 7.7x for wheat brain, 1.4x for wheat flour, and 8.3x for wheat shorts.

We note that all results presented by the petitioner were corrected for concurrent method recovery (when recovery was <100%); uncorrected results were only found on the individual residue results sheets in the raw data. The petitioner should note that if corrected residue results are presented, the results should be **clearly** identified as corrected results, with an explanation of how the correction was made, and that uncorrected results should **also** be presented.

TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Processed Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Cloquintocet-mexyl; determined using Modified REM 138.01				
Wheat grain	0.02	1	104	104
Germ	0.02	2	83, 91	87
Bran	0.20	2	91, 93	92
Middlings	0.02	1	107	97
	0.20	1	86	
Shorts	0.50	2	115, 134	125
Low grade flour	0.02	1	126	126



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TABLE C.1. Summary of Concurrent Recoveries of Cloquintocet-Mexyl and its Metabolite CGA-153433 from Wheat Processed Commodities.				
Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean $\pm$ std dev
Patent flour	1.00	1	136	136
Flour	0.02	1	92	97
	0.10	1	101	
Aspirated grain fractions	0.10	2	107, 129	118
CGA-153433; determined using Modified REM 138.10				
Wheat grain	0.05	1	94	94
Germ	0.05	2	66, 68	67
Bran	0.20	2	64, 66	65
Middlings	0.05	2	62, 86	74
Shorts	0.50	2	58, 71	65
Low grade flour	0.05	2	60, 89	77 $\pm$ 15
	0.10	1	83	
Patent flour	1.00	1	67	67
Aspirated grain fractions	0.10	1	64	73 $\pm$ 15
	1.00	1	90	
	5.00	1	65	

TABLE C.2. Summary of Storage Conditions			
Matrix	Storage Temp. (°C)	Actual Storage Duration (days) ¹	Interval of Demonstrated Storage Stability ²
Cloquintocet-mexyl			
Wheat grain	-20	49-147	Residues of cloquintocet-mexyl are stable in/on wheat grain stored at -18 °C for ~6 months.
Germ		52-148	No supporting storage stability data provided.
Bran		48-148	
Middlings		51-153	
Shorts		51-141	
Low grade flour		50	
Patent flour		50	
Flour		147	
Aspirated grain fractions		49-140	



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TABLE C.2. Summary of Storage Conditions

Matrix	Storage Temp. (°C)	Actual Storage Duration (days) ¹	Interval of Demonstrated Storage Stability ²
CGA-153433			
Wheat grain	-20	62-159	Pending receipt of additional information, HED tentatively concluded that CGA-153433 is stable in wheat grain stored at -20 °C for up to 727 days.
Germ		63-158	Residues of CGA-153433 are stable in wheat germ for up to 165 days of frozen storage.
Bran		63-158	No supporting storage stability data provided.
Middlings		66-161	
Shorts		69-161	
Low grade flour		63, 64	
Patent flour		63, 64	
Flour		160	
Aspirated grain fractions		77-161	

¹ From collection of wheat grain until analysis of processed samples. Because the petitioner did not provide the dates of processing, the length of storage of processed samples as processed commodities could not be determined. Based on shipping dates, wheat grain samples were processed within 55 days of sample collection. Sample extracts were analyzed within 0-10 days of extraction.

² Refer to the 860.1380 DER (46012917SS.der.wpd, W. Cutchin, in process) and PP#7E04920: DP Barcode D257181. N. Dodd, 4/7/00.

TABLE C.3. Residue Data from Wheat Processing Study with Cloquintocet-Mexyl.

RAC	Processed Commodity	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Cloquintocet-mexyl		CGA-153433	
				Residues ¹ (ppm)	Processing Factor	Residues ¹ (ppm)	Processing Factor
Spring wheat grain ²	RAC	0.016 [7.1]	61	<0.02	--	<0.05	--
	Germ			<0.02	Not calculated (NC)	<0.05	NC
	Bran			<0.02	NC	<0.05	NC
	Middlings			<0.02	NC	<0.05	NC
	Shorts			<0.02	NC	<0.05	NC
	Low grade flour			<0.02	NC	<0.05	NC
	Patent flour			<0.02	NC	<0.05	NC
	Aspirated grain fractions			<0.02	NC	<0.05	NC



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TABLE C.3. Residue Data from Wheat Processing Study with Cloquintocet-Mexyl.							
RAC	Processed Commodity	Total Rate (lb safener/A) [g safener/A]	PHI (days)	Cloquintocet-mexyl		CGA-153433	
				Residues ¹ (ppm)	Processing Factor	Residues ¹ (ppm)	Processing Factor
Spring wheat grain ²	RAC	0.078 [35.5]	61	<0.02	--	<0.05	--
	Germ			<0.02	NC	<0.05	NC
	Bran			<0.02	NC	<0.05	NC
	Middlings			<0.02	NC	<0.05	NC
	Shorts			<0.02	NC	<0.05	NC
	Low grade flour			<0.02	NC	<0.05	NC
	Patent flour			<0.02	NC	<0.05	NC
	Aspirated grain fractions			<0.02	NC	<0.05	NC
Winter wheat grain	RAC	0.016 [7.1]	59	<0.02	--	<0.05	--
	Germ			<0.02	NC	<0.05	NC
	Bran			<0.02	NC	<0.05	NC
	Middlings			<0.02	NC	<0.05	NC
	Shorts			<0.02	NC	<0.05	NC
	Flour			<0.02	NC	<0.05	NC
	Aspirated grain fractions			<0.02	NC	<0.05	NC
Winter wheat grain	RAC	0.078 [35.5]	59	<0.02	--	<0.05	--
	Germ			<0.02	NC	<0.05	NC
	Bran			<0.02	NC	<0.05	NC
	Middlings			<0.02	NC	<0.05	NC
	Shorts			<0.02	NC	<0.05	NC
	Flour			<0.02	NC	<0.05	NC
	Aspirated grain fractions			<0.02	NC	<0.05 ³	NC

¹ The petitioner reported residue values corrected for method recovery. The uncorrected residues, reported in this table, were obtained by the study reviewer from the raw data.

² The results of the spring wheat processing study were reported previously (PP#7E04920, DP Barcode D257181, MRID 44755303, N. Dodd, 4/7/00).

³ We note that the corrected value presented by the petitioner for this sample was 0.06 ppm.

D. CONCLUSION

The wheat processing data indicate that residues of cloquintocet-mexyl were less than the method LOQ (<0.02 ppm) in wheat processed fractions (germ, bran, middlings, shorts, and flour), and aspirated grain fractions generated from wheat grain bearing nonquantifiable residues. Residues of CGA-153433 were also less than the method LOQ (<0.05 ppm) in all wheat processed fractions and aspirated grain fractions generated from wheat grain bearing nonquantifiable



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residues. Acceptable methods were used for the quantitation of residues in/on wheat grain, aspirated grain fractions, and wheat processed commodities.

E. REFERENCES

DP Barcode: D257181
Subject: PP#7E04920. Cloquintocet-mexyl (Safener) in/on Wheat. Review of Analytical Methods and Residue Data. First Food Use Review.
From: Nancy Dodd
To: Bipin Gandhi/Robert Forrest
Dated: 4/7/00
MRIDs: 44387454, 44387457-44387461, 44399207-44399211, 44399213, 44399216-44399231, 44568401, 44568402, 44755301-44755303

F. DOCUMENT TRACKING

RDI: W. Cutchin 7/28/05
Petition Number(s): PP#7E04920
DP Barcode(s): D308470
PC Code: 700099

Template Version September 2003



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Chemical: Acetic acid, {(5-chloro-8-quinolinyl)oxy}

PC Code: 700099

HED File Code 11000 Chemistry Reviews

Memo Date: 08/01/2005

File ID: DPD308470

Accession Number: 412-05-0099

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