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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 13-SEP-2002

SUBJECT: ID# 294475. **Review of Label Amendment for Clomazone (Command® 3ME Herbicide, EPA Registration #279-3158).** MRID# 455078-01. Barcode D278342. Chemical 125401. Case 294475. Submission S603452.

FROM: George F. Kramer, Ph.D., Chemist
Registration Action Branch 1 (RAB 1)
Health Effects Division (HED) (7509C)

THROUGH: G. Jeffrey Herndon, Branch Senior Scientist
RAB1/HED (7509C)

TO: Jim Tompkins, PM Team 23
Registration Division (RD) (7505C)

FMC is proposing an amendment of the Command® 3ME label by reducing the plantback interval (PBI) for wheat planted as a rotational crop from 9 to 4 months. Clomazone is a broad spectrum herbicide used to control annual grasses and broadleaf weeds. Permanent tolerances have been established under 40 CFR §180.425(a) for residues of clomazone *per se* in/on rice cotton, peas, peppers, pumpkins and soybeans, ranging from 0.02-0.1 ppm.

CONCLUSIONS/RECOMMENDATIONS

HED recommends in favor of the proposed label amendment for Command® 3ME label to reduce the PBI to 4 months for wheat planted as a rotational crop.

DETAILED CONSIDERATIONS

Currently, the rotational crop guidelines included on the Command® 3ME label state that the primary crops cotton, peas, peppers, pumpkins, soybeans and tobacco may be rotated at anytime. After 9 months, the following crops may be rotated:

Sorghum	Dry beans	Sweet potatoes
Corn	Peanuts	Tomatoes (transplanted)
- field	Potatoes	Cucurbits
- pop	Rice	Sugar beets
- seed	Snap beans	
- sweet		

After 12-16 months, all crops may be rotated. The label also includes the statement "do not graze or harvest for food or feed cover crops planted less than nine months after Command® 3ME treatment."

The minimum PBI, 9 months, has been approved by EFED (Memo Carolyn Offutt, 7/2/85). This restriction was based on low levels of organosoluble residues (<0.02 ppm) observed at the 10-month interval in the confined rotational crop study (Memo Samuel Creeger, 8/27/85).

Proposed Use: This amendment of the Command® 3ME label proposes to reduce the PBI for wheat to 4 months. FMC Corporation has submitted data (MRID 45507801) depicting the magnitude of clomazone residues in/on wheat matrices as a rotated crop (45507801.der.wpd). Six rotational field trials were conducted in Regions 4 (2 trials in AR, and 1 trial each in LA, MO, MS) and 6 (1 trial in TX). Residues of clomazone were below the LOQ (<0.05 ppm) in/on all samples of rotated wheat forage, hay, straw, and grain. As the limited rotational field trial data indicate that residues of clomazone are nonquantifiable (<0.05 ppm) in/on the matrices of wheat when planted as a rotational crop at a PBI of 4 months, HED has no objection to the proposed label amendment for Command® 3ME.

cc: G. Kramer (RAB1)
RDI: RAB1 Chemists (9/12/02)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1

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Health Effects Division (HED) (7509C)

G. Jeffrey Herndon, Branch Senior Scientist
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DP Barcode: D278342

Citation: MRID 45507801. Latorre, L. (2001) Field Accumulation Studies on Rotational Crops: Residues in/on Wheat Rotated After a Primary Crop Treated with Command® 3ME: Study Number: 164WHE99R1: Report Number: P-3481. Unpublished Study Prepared by FMC Corporation. 123 p.

Sponsor: FMC Corporation

Executive Summary

FMC Corporation has submitted data depicting the magnitude of clomazone residues in/on wheat matrices as a rotated crop. Six rotational field trials were conducted in Regions 4 (2 trials in AR, and 1 trial each in LA, MO, MS) and 6 (1 trial in TX).

The test substance used in the study was a microencapsulated (Mcap) formulation containing 3.0 lb ai/gal of herbicide. At each trial site, the test formulation was applied once to the primary crop, rice, either as a preplant incorporated or preemergence application at 0.60-0.62 lb ai/A (1X). The treated rice crop was harvested at its maturity. Wheat was then planted on the same plots 119 to 120 days after application of the test formulation. Wheat forage, hay, straw, and grain were collected following normal agricultural practices.

Samples of harvested wheat matrices were analyzed for clomazone residues by a gas chromatography method with mass selective detection (GC/MSD) entitled "*Residue Analytical Method for the Determination of Clomazone in/on Crop and Processed Part Matrices of Corn, Cottonseed, Soybean, and Tobacco.*" The method's limit of detection (LOD) ranged from 0.01 to 0.02 ppm depending on the linear calibration of each analysis set. The limit of quantitation (LOQ) was validated at 0.05 ppm. Based on concurrent method recovery data, the GC/MSD

method is adequate for data collection. Residues of clomazone were below the LOQ (<0.05 ppm) in/on all samples of rotated wheat forage, hay, straw, and grain.

The maximum storage intervals for rotational crop samples were 242 days (8.0 months) for wheat forage, 230 days (7.6 months) for wheat hay, 217 days (7.0 months) for wheat straw, and 175 days (5.8 months) for wheat grain. Storage stability data are available for field corn, rice and sugarcane which demonstrate that residues of clomazone are stable for up to 12 months (Memos, M. Perry, 1/29/98; D242601 and D. Vogel, 1/24/01; D272158). The available storage stability data thus support the storage conditions and intervals of the wheat rotational crop samples.

Under the conditions and parameters described in this Data Evaluation Record, the submitted study is adequate. The limited rotational field trial data indicate that residues of clomazone are nonquantifiable (<0.05 ppm) in/on the matrices of wheat when planted as a rotational crop at a plantback interval (PBI) of 119-120 days (4 months).

GLP Compliance

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

1. Materials and Methods

1.1. Test Substance

Active Ingredient

Common Name:	Clomazone
IUPAC Name:	2-(2-chlorobenzyl)-4,4-dimethylisoxazolidin-3-one
CAS Name:	2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone
CAS Number:	81777-89-1
Company Name:	None specified
Other Synonyms:	None specified

1.2. Trial Information

Table 1.2.1. Summary of Rotational Crop Trial Numbers and Geographic Location.

Wheat	Growing Region													Total Number of Trials
	1	2	3	4	5	6	7	8	9	10	11	12	13	
Submitted	-	-	-	5	-	1	-	-	-	-	-	-	-	6
Requested	-	-	-	-	-	-	-	-	-	-	-	-	-	2 [1]

[1] Two field trials for each rotated crop are required for a limited rotational crop study; location regions are not specified (OPPTS 860.1900).

Table 1.2.2. Rotational Crop Trial Information.

Location (County, State; Year)	EPA Region	Formulation	Total Application Rate (lb ai/A)/ Primary crop stage	Tank Mix Adjuvants	Rotated Crop; Variety	PBI (days)	Harvest Procedures	
							wheat matrix	DAP [2]
Wharton, TX; 1999-2000	6	3 lb/gal Mcap [1]	0.6 preemergence	None	Wheat; Mitt	119	forage	128
							hay	162 (8)
							straw and grain	184
St. Landry Parish, LA; 1999-2000	4	3 lb/gal Mcap	0.6 preplant incorporated	None	Wheat; Mason	120	forage	147
							hay	185 (3)
							straw and grain	237
Drew, AR; 1999-2000	4	3 lb/gal Mcap	0.6 delayed preemergence	Not specified (NS)	Wheat; TV8555	119	forage	173
							hay	222 (5)
							straw and grain	261
Jackson, AR; 1999-2000	4	3 lb/gal Mcap	0.6 preemergence	NS	Wheat; Shelby	120	forage	142
							hay	215 (4)
							straw and grain	244
Tunica, MS; 1999-2000	4	3 lb/gal Mcap	0.62 delayed preemergence	None	Wheat; Madison	120	forage	136
							hay	193 (3)
							straw and grain	230
Stoddard, MO 1999-2000	4	3 lb/gal Mcap	0.6 preemergence	None	Wheat; Pioneer 2580	120	forage	187
							hay	245 (5)
							straw and grain	273

[1] Mcap = microencapsulated; Command® 3ME (EPA Reg. No. 279-3158).
[2] Represents the number of days after planting (DAP) samples were harvested. For hay samples, the number in parentheses represents the number of days samples were dried.

At six field trial locations in Regions 4 (AR, LA, MO, and MS) and 6 (TX), a single preplant incorporated or preemergence application of the 3 lb/gal Mcap formulation was made to the primary crop, rice, at 0.60-0.62 lb ai/A (1X). Applications were made in 13.7-15.7 gal/A of water using ground equipment (CO_2 backpack or tractor-mounted sprayer). The rotational crop, wheat, was planted 119-120 days following application.

A single untreated and duplicate treated samples of the rotational wheat crop were collected at normal maturity. Wheat forage (6-8 inches to stem elongation or jointing growth stage) was harvested 128-187 days after planting (DAP), mature wheat hay (early flower boot to soft dough growth stage) was harvested 162-245 DAP and dried in the field for 3-8 days, and mature wheat straw and grain were harvested 184-273 DAP. Sampling procedures were outlined for each trial. Approximate sample weights were 2-5 lbs each for wheat forage, hay, and straw and 2-4 lbs for wheat grain.

1.3. Post-harvest Procedures

Samples were frozen within 2.5 hours of harvest and were shipped frozen to FMC Corporation (Princeton, NJ), where the samples were ground and frozen (-18 C) until analysis. Samples were analyzed within 3 days of extraction.

Table 1.3.1. Summary of Storage Conditions at Analytical Facility

Matrix	RAC or Extract	Storage Temperature (°C)	Duration
Wheat	Forage	-18	224-242 days (7.4-8.0 months)
	Hay	-18	182-230 days (6.0-7.6 months)
	Straw	-18	164-217 days (5.4-7.1 months)
	Grain	-18	121-175 days (4.0-5.8 months)

1.4. Analytical Methods

Samples of rotated wheat commodities were analyzed for residues of clomazone using a GC/MSD method. Briefly, wheat samples were acid hydrolyzed by refluxing with 0.25 N HCl for approximately one hour. The extract was cooled, filtered under vacuum, and subjected to C_{18} solid phase extraction (SPE) under vacuum for residue cleanup. Residues were eluted with 5% ethyl acetate in hexane. The eluate was concentrated, reconstituted with hexane, and cleaned up further using SI SPE. Residues were sequentially eluted with hexane and 20% ethyl acetate in hexane. The eluate was concentrated, redissolved in hexane, and analyzed by GC/MSD. The estimated LOD ranged from 0.01 to 0.02 ppm depending on the linear calibration of each analysis set, and the validated LOQ was 0.05 ppm for the residues of clomazone in/on all rotated wheat commodities. A summary of concurrent analytical method validation is presented below in Table 2.1.

2. Results

Table 2.1. Summary of Concurrent Analytical Method Validation.

Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD
Wheat forage	0.05	83, 88, 95	89 ± 6.0
Wheat hay	0.05	83, 105	94
Wheat straw	0.05	74, 77, 105	85 ± 17.0
Wheat grain	0.05	82, 95, 105	94 ± 11.5

Table 2.2. Residue Data from Rotational Crop Trials with Clomazone.

Location (City, State, Year)	Crop Variety	Formulation	Applic. Rate (lbs ai/A)	PBI (days)	Commodity	Residues (ppm)
Wharton, TX; 1999-2000	Wheat; Mitt	3 lb/gal Mcap	0.6	119	forage	ND [1], ND
					hay	ND, ND
					straw	ND, (0.01)
					grain	ND, ND
St. Landry Parish, LA; 1999-2000	Wheat; Mason	3 lb/gal Mcap	0.6	120	forage	ND, ND
					hay	ND, ND
					straw	(0.01), (0.02)
					grain	ND, ND
Drew, AR; 1999-2000	Wheat, TV8555	3 lb/gal Mcap	0.6	119	forage	ND, ND
					hay	ND, ND
					straw	(0.01), (0.01)
					grain	ND, ND
Jackson, AR; 1999-2000	Wheat, Shelby	3 lb/gal Mcap	0.6	120	forage	ND, ND
					hay	ND, ND
					straw	ND, ND
					grain	ND, ND
Tunica, MS; 1999-2000	Wheat; Madison	3 lb/gal Mcap	0.62	120	forage	ND, ND
					hay	ND, ND
					straw	ND, ND
					grain	ND, ND
Stoddard, MO; 1999-2000	Wheat; Pioneer 2580	3 lb/gal Mcap	0.6	120	forage	ND, ND
					hay	ND, ND
					straw	ND, ND
					grain	ND, ND

[1] ND = not detected; the method LOD was estimated at 0.01-0.02 ppm and the validated LOQ was 0.05 ppm.
Residue values in parentheses are estimates, as they are less than the LOQ (<0.05 ppm) but greater than the LOD.

Table 2.3. Summary of Residue Data from Rotational Crop Trials with Clomazone.

Commodity	Total Applic. Rate (lb ai/A)	PBI (days)	Residue Levels (ppm)			
			Maximum	HAFT	Mean [1]	Std. Dev. [1]
Wheat, forage	0.6-0.62	119-120	<0.05	<0.05	<0.05	0.0
Wheat, hay	0.6-0.62	119-120	<0.05	<0.05	<0.05	0.0
Wheat, straw	0.6-0.62	119-120	<0.05	<0.05	<0.05	0.0
Wheat, grain	0.6-0.62	119-120	<0.05	<0.05	<0.05	0.0

[1] Residues were calculated, by the study reviewer, using the LOQ value (0.05 ppm) for residues reported as ND or in parentheses (below the LOQ).

3. Discussion

3.1. Methods

At each field trial, a single preplant incorporated or preemergence application of the 3 lb/gal Mcap formulation was made to the primary crop, rice, at 0.6-0.62 lb ai/A. Applications were made in 13.7-15.7 gal/A of water using ground equipment. The rotational crop, wheat, was planted 119-120 days following application. Samples of wheat forage, hay (dried for 3-8 days), straw, and grain were harvested at normal maturity and analyzed for residues of clomazone using a GC/MSD method. Concurrent method recovery data included in this submission indicate that the method is adequate for data collection.

The maximum storage intervals for rotational crop samples from the submitted wheat rotational crop study were 242 days (8.0 months) for wheat forage, 230 days (7.6 months) for wheat hay, 217 days (7.0 months) for wheat straw, and 175 days (5.8 months) for wheat grain. Storage stability data are available for field corn, rice and sugarcane which demonstrate that residues of clomazone are stable for up to 12 months (Memos, M. Perry, 1/29/98; D242601 and D. Vogel, 1/24/01; D272158). The available storage stability data thus support the storage conditions and intervals of the wheat rotational crop samples.

3.2. Results

In wheat plants, planted 119-120 days following a single preplant incorporated or preemergence application of the 3 lb/gal Mcap formulation to the primary crop, rice, at 0.6-0.62 lb ai/A, residues of clomazone were below the LOQ (<0.05 ppm) in/on all samples of wheat forage, hay, straw, and grain.

The registrant reported that weather conditions throughout the growing season were normal except that: (i) conditions at the TX trial were cooler than normal in June and July, wetter than normal in July, and warmer/hotter and drier than normal in August through March; (ii) precipitation for the majority of the months was significantly below normal at the LA trial; (iii) conditions were considered hotter and drier than normal at the Drew, AR trial; (iv) rainfall was below normal from October to March for the MS trial; (v) rainfall patterns were variable at the MO trial. The soils at the test sites were fine sandy loam, silt clay loam, silt loam, and clay. The

weather conditions and soil types at the field trial sites did not have any major effects on the results of this field rotational crop study. Information was provided pertaining to the plot crop and pesticide history and maintenance chemicals.

4. Deficiencies

None.

5. References

None.

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