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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Soybean Hull Chromatograms and Storage Stability Data Submissions in Response to the Metolachlor Final Registration Standard and Tolerance Reassessment (FRSTR) follow-up (6/14/89). DP Barcode No. D166637. CBRS No. 8317. MRID Nos. 41506501 and 41425502.

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Ciba-Geigy Corporation has submitted soybean hull chromatograms (MRID #41506501) in response to a deficiency identified in the Metolachlor Final Registration Standard and Tolerance Reassessment (FRSTR) follow-up (6/14/89) and the final results of a two-year storage stability study conducted on peanut nutmeats, potatoes, corn grain, oil, and forage (MRID #41425502).

Soybean Hull Chromatograms (MRID #41506501)

The Metolachlor FRSTR follow-up (6/14/89) states in Recommendation No. 3 that "a decision regarding the need for a food additive tolerance for metolachlor residues in soybean hulls cannot be made without supporting chromatograms (ABR-88169; MRID 40980706)

depicting residues of metolachlor in or on hulls processed from soybean seeds treated at 1, 3, and 5x."

The registrant has submitted a complete set of chromatograms (MRID No. 41506501) depicting metolachlor residues in or on soybean hulls which were processed from soybean seeds as a result of soybean treatments at 1x, 3x, and 5x the maximum use rate. Chromatograms of standards, untreated controls and fortified untreated controls are provided as well.

The original study submitted by Ciba-Geigy Corporation concerning residues of metolachlor in or on soybean processed fractions (MRID #40980706) has already been reviewed in the Metolachlor FRSTR follow-up (6/14/89) and the method of analysis (Ciba-Geigy method AG-338) which was used to generate the data, has already been discussed in the Metolachlor FRSTR (1/16/87) and deemed adequate for the determinations of the combined residues of metolachlor and its metabolites, determined as the derivatives, CGA-37913 and CGA-49751. The Limits of Detection (LOD) are 0.03 ppm for CGA-37913 and 0.05 ppm for CGA-49751. Below is a summary of the residues and concentration factors of CGA-37913 and CGA-49751 (in metolachlor equivalents) in soybean seeds and processed fractions produced from seeds harvested 134 days posttreatment with metolachlor at the 1x, 3x, and 5x maximum registered rates.

		Residues in metolachlor equivalents (ppm)			
Substrate	Rate (x)	CGA-37913	CGA-49751	Combined	Conc. Factor
dry bean	1	0.04	<0.05	0.04	------
	3	0.06	<0.05	0.06	------
	5	0.09	<0.05	0.09	------
hulls	1	0.05	<0.05	0.05	1.25
	3	0.10	<0.05	0.10	1.7
	5	0.12	<0.05	0.12	1.3
meal	1	0.04	<0.05	0.04	------
	3	0.03	<0.05	0.03	------
	5	0.05	<0.05	0.05	------
crude oil	1,3,5	<0.03	<0.05	<0.08	------
refined oil	1,3,5	<0.03	<0.05	<0.08	------
soapstock	1,3,5	<0.03	<0.05	<0.08	------

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The Metolachlor FRSTR follow-up (6/14/89) concluded that residues of metolachlor concentrate up to 1.7x in soybean hulls. However, the registrant proposed that this apparent concentration was actually due to experimental variations.

The submitted soybean hull chromatograms support the assertion that residues of metolachlor concentrate up to 1.7x in soybean hulls. Experimental results, substantiated by the newly submitted chromatograms, depict a consistent, readily measurable increase in concentrations of CGA-37913 in processed soybean hulls (1.25x to 1.7x concentration factor) over a range of metolachlor application rates (1x to 5x the maximum use rate).

Two-Year Storage Stability Study Final Report (MRID #41425502)

Ciba-Geigy Corporation submitted two studies (MRIDs 40980702 and 40980703) concerning the stability of CGA-37913 and CGA-49751 residues in or on plant and animal substrates stored under frozen conditions which were reviewed in the Metolachlor FRSTR follow-up (6/14/89). The Metolachlor FRSTR follow-up (6/14/89) concluded that "the metabolites CGA-37913 and CGA-49751 are relatively stable in or on corn grain, corn forage, peanut nutmeats, potatoes, beef liver, milk and eggs stored at -15°C ± 5°C for ca. 1 year (371-394 days). Residues of CGA-37913 were stable in corn oil for 102 days and then decreased to ca. 54-58% of the initial fortification level after 193 days and to <10-50% after 377 days of storage. Residues of CGA-49751 remained stable in corn oil for the 377-day storage interval. Residues of CGA-37913 were stable in beef muscle for 52 days and then decreased to <10-36% of the initial fortification level after 109 days of storage; no additional decline was observed through the 376 days of storage. Residues of CGA-49751 remained stable in beef muscle for the 376-day storage interval."

CIBA-GEIGY Corporation has submitted a final storage stability report (MRID #41425502) of a two-year storage stability study which includes storage stability data for residues of metolachlor in or on peanut nutmeats, potatoes, corn grain, oil, and forage only. Samples were stored frozen (-15°C ± 5°C) at Tegeris Laboratories, Inc. of Temple Hills, Maryland during the first year of the study and in the second year samples were sent to Ciba-Geigy Corporation in Greensboro, North Carolina, where they were stored at -20.6°C to -17.8°C.

The only new data provided in this study are the final ca. 2-year (763-769 days) data points. All other data points were included in the original storage stability report (MRID #40980702) and reviewed in the Metolachlor FRSTR follow-up (6/14/91). On the following page is a summary of the entire two-year storage stability study conducted in/on peanut nutmeats, potatoes, corn grain, oil, and forage only.

Substrate	Storage Interval (days)	Percent Recovery CGA-37913	CGA-49751
Corn Grain	0	70, 82	96, 108
	31-32	72, 82	94, 96
	96	74, 100	98, 100
	188	72, 72	84, 118
	371	104, 104	98, 100
	767	66, 68	104, 104
Corn Oil	0	94, 106	90, 116
	43	102, 106	78, 118
	102	76, 102	108, 116
	193	54, 58	144, 144
	377	50, <10	90, 98
	763	46, 64	102, 98
Corn Forage	0	84, 106	116, 134
	32	94, 104	106, 108
	96	122, 122	90, 102
	186	70, 162	60, 66
	396	98, 122	98, 110
	764	76, 82	114, 124
Peanut Nutmeats	0	90, 98	88, 116
	31-34	82, 90	90, 100
	104	98, 102	106, 110
	215	62, 66	98, 106
	374	70, 98	74, 90
	763	76, 86	126, 112
Potato	0	106, 116	94, 96
	34	66, 70	76, 84
	104	82, 94	118, 130
	220	62, 72	102, 106
	374	98, 106	76, 76
	769	70, 72	96, 100

Note: Residue results were corrected for control values and procedural recoveries <100%.

Residues of CGA-37913 are stable in peanut nutmeats, potatoes, corn grain and corn forage for up to two years. Residues of CGA-49751 are stable in peanut nutmeats, potatoes, corn grain, corn forage, and corn oil for up to two years. Residues of CGA-37913 are stable in corn oil for up to 102 days and are unstable for periods exceeding 102 days when stored at -15°C ± 5°C.

Conclusions

1. Chromatograms provided in the new submission (MRID #41506501) concerning the soybean seed processing study which was previously reviewed in the Metolachlor FRSTR follow-up (6/14/89), substantiate the potential for residue concentrations up to 1.7x in/on soybean hulls. A food additive tolerance for metolachlor residues in soybean hulls should be set at 2x the tolerance limit established for soybeans (seeds).

2. Metolachlor residues in/on peanut nutmeats, potatoes, corn grain and corn forage are stable for up to two years when stored at -15°C ± 5°C. Residues of metolachlor are unstable in corn oil after 102 days of storage at -15°C ± 5°C.

Residues of CGA-37913 were stable in corn oil for 102 days and then decreased to ca. 54-58% of the initial fortification level after 193 days, to <10-50% after 377 days, and to 46-64% after 763 days. Residues of CGA-49751 remain stable in corn oil for up to two years (763 days).

3. Due to the unstable nature of metolachlor residues in corn oil when stored frozen at -15°C ± 5°C for more than 102 days, the registrant must submit details of the handling/processing/storage of the wet and dry milled corn oil processed fractions submitted in MRID #40980705 and reviewed in the Metolachlor FRSTR follow-up (6/14/89).

Ciba-Geigy submitted a study (MRID #40980705) concerning residues of metolachlor in corn processed fractions (dry and wet milling) which included broken kernels, small grits, meal, flour, hulls, germ, presscake and crude oil expeller, presscake, and crude oil solvent extracted, refined oil, soapstock, refined bleached oil, and refined bleached & deodorized oil by dry milling; and by wet milling into broken kernels, steepwater concentrate and distillates, dried germ, hulls, gluten, starch, coarse gluten starch, process water, presscake, and crude oil expeller, presscake, crude oil solvent extracted, refined oil, and soapstock. Mature corn was harvested (10/13/87) 158 days posttreatment (5/8/87), frozen and shipped to the Food Protein Center at Texas A & M for commercial processing. Samples were received by Ciba-Geigy Corporation between 7/27/88 and 10/26/88 and extracted between 8/88 and 11/88.

The exact handling/processing/storage of the mature corn and processed fractions between the sample date (10/13/87) and the date of receipt from the processing center (as late as 10/26/88) must be provided in order to ensure that low metolachlor residues in processed corn oil samples were not a result of degradation due to conditions and/or length of sample storage.

4. The storage stability data in the current submission (MRID No. 41425502) do not necessarily address the storage stability data requirements which were specified in the Metolachlor FRSTR (1/16/87) and which indicated a need for storage stability data conducted for periods of storage longer than 13 months and at temperatures other than -15°C. The registrant must still submit information/data concerning the storage intervals and storage conditions of samples used to support all established tolerances for residues of metolachlor. These data must be accompanied by storage stability data depicting the percent decline of residues of metolachlor which approximate the same conditions and time intervals of the actual storage conditions and time intervals of the treated samples used to determine the magnitude of the residue in/on these commodities.

Recommendations

CBRS recommends that a food additive tolerance for metolachlor residues in soybean hulls be set at 2x the tolerance limit established for soybeans (seeds).

Due to the unstable nature of metolachlor residues in corn oil the registrant must submit sufficient information to substantiate a previous submission (MRID #40980705) concerning corn processed fractions. The exact handling/processing/storage of mature corn and processed corn fraction samples between the sample date (10/13/87) and the date of receipt from the processing center (as late as 10/26/88) must be provided in order to ensure that low metolachlor residues in processed corn oil samples was not a result of degradation due to conditions and/or length of storage.

The registrant should be made aware that the storage stability data in the current submission (MRID No. 41425502) does not necessarily address the storage stability data requirements which were specified in the Metolachlor FRSTR (1/16/87). The registrant must submit information/data concerning the storage intervals and storage conditions of samples used to support all established tolerances for residues of metolachlor. These data must be accompanied by storage stability data depicting the percent decline of residues of metolachlor which approximate the same conditions and time intervals of the actual storage conditions and time intervals of the treated samples used to determine the magnitude of the residue in/on these commodities. On receipt of these data, the adequacy of the affected tolerances will be reevaluated.

cc: BLCKohlligian (CBRS), Metolachlor SF, RF, Metolachlor Reg. Std. File, List A Update file, Circulate (7).

RDI: WJHazel:2/21/92 EZager:4/10/92

H7509C:CBRS:BLCKohlligian:CM#2:Rm 803:703-305-7462:10/11/91.