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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Alachlor (090501)
Response to Registration Standard Deficiencies
Response to Special Review DCI of 6/9/86
EPA Reg. No. 524-316
Monsanto Report Numbers:
MSL-6799 (Sunflower Seed Processing study)
[MRID No. 403146-01, RCB No. 2836]
MSL-6750 (Legume Cooking Study)
[MRID No. 403303-01, RCB No. 2839]
MSL-6832 (Dry Bean, updated report)
[MRID No. 403412-01, RCB No. 2833]
Progress Report - Special peanut processing study
[No MRID No. RCB No. 2834]

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Monsanto Company has submitted a response to the Special Review Data Call In Notice of June 9, 1986, consisting of a Legume Cooking Study and a progress report for the special peanut processing study for peanuts to be processed into dry roasted, oil roasted, and peanut butter. Monsanto also submitted an additional response to the Alachlor Registration Standard consisting of residue data for one additional lima bean sample location, and data on sunflower seed processed commodities (kernels, hulls, meal, oil, and soapstock). Alachlor [2-chloro-2',6'-diethyl-N-(methoxymethyl) acetanilide] is the active ingredient in LASSO Herbicide.

The Alachlor Registration Standard was issued 11/20/84. All residue data were due no later than 12/31/86. Alachlor was placed into Special Review in December, 1984. The Alachlor PD 2/3 was issued in September, 1986. The Alachlor PD4 is in preparation. The Special Review Data Call In Notice was issued June 9, 1986. The special cooking and processing data were due by June 9, 1987, for peanuts and legumes. The due date for the peanut data was extended until 9/88.

Tolerances have been established for the combined residues of alachlor and its metabolites in or on numerous commodities, ranging from 0.02 ppm (N) in animal commodities to 3 ppm in or on peanut forage. (40 CFR 180.249). These tolerances are tabulated below. No food or feed additive tolerances for residues of alachlor and its metabolites have been established.

This submission includes the Special Peanut Processing study progress report and the following studies:

"Determination of Alachlor Residues in Sunflower Fractions Following Preemergent Application of Lasso Herbicide to Sunflower Seeds," R. Lauer and M.L. Horner, July 21, 1987, Monsanto Report No. MSL-6799, Monsanto R.D. No. 808, MRID No. 403146-01, RCB No. 2836.

"Alachlor Metabolite Residues from Two Metabolite Classes in Dry Peas and Dry Lima, Navy, Pinto, and Red Kidney Beans," S. A. Adams, and P. Pijanowski, August 7, 1987, Monsanto Report No. MSL-6832, Monsanto R.D. No. 813, MRID No. 403412-01, RCB No. 2833.

"Alachlor Metabolite Residues from Two Metabolite Classes in Cooked and Processed Legume Vegetables," P. Pijanowski and S. A. Adams, August 12, 1987, Monsanto Report No. MSL-6750, Monsanto R. D. No. 811, MRID No. 403303-01, RCB No. 2839.

CONCLUSIONS

1. Peanut Progress report

The revised peanut processing protocol from Pert Labs is adequate.

2. Legume residue data

The one additional data point for lima beans does not satisfy this data requirement. Geographically representative residue data are still needed for each type of application (pre-plant incorporated and preemergence) at the maximum registered rate.

✓ Additional residue data are needed for each type of application (preplant incorporated and preemergent) to dry beans from ID, CO, and NE. Residue data for the preemergent application (including lima beans) are needed from MI, WI, IL, CA, ID, CO, and NE.

✓3. Legume cooking study

Concentration/reduction factors for cooking of dry beans could not be determined since residues in dry beans were non-detectable. However, concentration/reduction factors could be determined for succulent and dry peas, and ranged from 0.34 to 1.1. For the present time, until the dry bean special cooking and processing study is available, we will translate data from dry peas to dry beans, pending receipt of the cooking data for dry beans with detectable residues.

✓4. Sunflower seed processing study

The submitted sunflower seed processing data are adequate, pending receipt of the required storage stability data. The concentration/reduction factors reported will be used for tolerance setting and for special review residue estimates. Conclusion 12 b. of our memo of 11/3/87 has been resolved. However, feed additive tolerances will be needed for sunflower seed hulls and sunflower seed meal. This deficiency will be designated deficiency 2j.

5. Other considerations

Numerous other deficiencies as discussed in our review of 11/3/87 remain outstanding.

RECOMMENDATIONS

We recommend that the registrant be informed of these deficiencies and advised to correct them, along with previously cited deficiencies (S. Hummel memo of 11/3/87). We recommend that our entire review be sent to the registrant.

DETAILED CONSIDERATIONS

REGISTERED USES

The registered uses for alachlor on beans are discussed below. Aerial applications were removed from all labels in connection with the Alachlor Registration Standard. The Alachlor PD 2/3 proposed allowing reinstatement of aerial applications based on applicator exposure data. Broadcast boom and banded

applications are registered. Center pivot application is also registered. The registrant should be informed that residue data from aerial applications must be submitted if aerial applications are to be reinstated on labels.

Dry Beans: The maximum Section 3 use for alachlor on dry beans is one preplant treatment at 3 lb ai/A west of the Mississippi, except in CA (Lasso Microtech) or Kern Co., CA (Lasso EC). Do not apply on dry beans after planting as crop injury may occur. Alachlor may be used on red kidney beans in IL, WI, and IN (Lasso EC only) for a 3 lb ai/A treatment preplant or preemergence. The label does not prohibit both preplant and preemergence treatments from being used. Older labels (Section B of PP#2G1176) contained this restriction. Both Lasso EC and Lasso Microtech may be used on dry beans. Alachlor may be used on navy beans in MI at 2 lb ai/A preplant incorporated (24(c) use in MI).

Lima Beans: The maximum Section 3 use for alachlor on lima beans is preplant or preemergence application of 3 lb ai/A in all states except CA. Both Lasso EC and Lasso Microtech may be used on Lima Beans. A 24(c) registration was obtained in MD for preplant incorporated or preemergence application at 2 lb ai/A. Section 3 and 24(c) labels do not prohibit the use of both applications. Older labels (Section B of PP#2G1176) contained this restriction.

REGISTRANT RESPONSES TO DEFICIENCIES

Deficiency 9e - Special Review Deficiency

Cooking and processing data for peanuts (oil roasted peanuts, dry roasted peanuts, and peanut butter) were required by the Special Review Data Call In Notice of June 9, 1986. Protocols were required, along with quarterly reports, and a final report by June, 1987. The due date for the final report was later extended to September, 1988, with quarterly progress reports.

Monsanto Response

Monsanto submitted the September, 1987 quarterly report. Peanuts were planted in GA, NC, and TX. Monsanto selected Pert Labs (Peanut Research and Testing Laboratories, a subsidiary of Seabrook Blanching Corporation) in Edenton, NC to process the peanuts to dry roasted peanuts, oil roasted peanuts, and peanut butter. Pert submitted a processing protocol to Monsanto which differs from the previously submitted Monsanto protocol and amendment. Monsanto intends the Pert Lab protocol to supersede any previous protocol or amendment. Copies of all previous protocols and amendments were included, as well. Samples will be

harvested according to normal agricultural practice and frozen prior to shipment to Monsanto and Pert Labs for processing.

Peanuts will be dried and shelled using commercial equipment. The peanuts will be buff blanching to remove the skins. Pert reports that commercial practice is to dry roast peanuts in 400 lb batches at 320F until the color is satisfactory. Pert intends to dry roast peanuts in a convection oven at 330-350F for 45-60 minutes. Peanuts are blanched after dry roasting.

For oil roasting, blanching is normally done first. Pert reports that commercial practice is to oil roast peanuts at 330-350F for 3 to 3-1/2 minutes until the peanuts reach a satisfactory color. Pert intends to oil roast peanuts in peanut oil at an unspecified temperature. The temperature and time for roasting will be reported.

For peanut butter, dry roasted, blanched peanuts are generally preground to a 300-400 micron blend. Pregrinding generates heat in the range of 135-142 F. The coarse ground peanut paste is then ground to 76 microns (temperature will reach 163-170F). Stabilizers are then melted and added. The peanut butter is cooled, placed in containers and allowed to crystallize at room temperature. For the quantities to be processed in this trial, the temperatures generated will not be as high, so the peanut butter will be heated to 150F to add 1% palm stearine as a peanut butter stabilizer.

The following samples will be collected and forwarded frozen to Monsanto:

- peanuts in shell before drying
- peanuts in shell after drying
- blanched peanuts
- skins from blanched peanuts
- hearts from blanched peanuts
- dry roasted peanuts
- peanut butter
- oil roasted peanuts
- oil before and after roasting

Photographs of the commercial equipment used for peanut processing were included in the progress report.

✓ RCB Comment

Since Pert Labs can do commercial peanut processing, their laboratory simulation of commercial processing will be considered adequate. Data should be received by 9/88, with quarterly reports until then.

LEGUMESDeficiency 11a

We previously concluded that the residue data on legumes would not be adequate if the protocol were followed, (See our review of the protocol for this study, M. Loftus, 4/18/86). We concluded that the proposed number of samples (1 from each geographical area) was inadequate. We concluded that the proposed geographical representation was inadequate. We stated that data for each type of application are needed from each geographical area.

Additional residue data for each type of application (pre plant incorporated and preemergent) to dry beans are needed from ID, CO, and NE. (Residue data are needed for each type of application to dry beans in ND, MI, WI, IL, CA, ID, CO, and NE at the maximum registered application rate.)

Monsanto Response

Monsanto submitted a revised report consisting of the same data previously submitted plus two additional lima bean samples (preplant incorporated at 2-3 lb ai/A) from one location in WI. Residues reported in this one lima bean sample were <0.026 ppm in the bean, and 0.32 ppm in the lima bean straw for the emulsifiable concentrate formulation; and <0.038 ppm in the bean and 0.56 ppm in the straw for the microencapsulated formulation. The samples were frozen within 2 hours of harvest. Dates of the analysis were not given. The samples could have been stored up to 8 months prior to analysis, based on the date of harvest and the date of the report.

RCB Comment

This study was previously reviewed in our memo of 6/15/87 (S. Hummel), and the raw data for the study were reviewed in our memo of 8/20/87. According to Agricultural Statistics (1985), lima beans for freezing are grown in the midwest and CA. Thus, lima bean samples from WI and CA would be adequate geographical representation (for lima beans). However, no residue data for lima bean samples given preemergent treatment were submitted.

The one additional data point for lima beans does not satisfy this data requirement for geographically representative residue data for each type of application (preplant incorporated and preemergence). No response was received for the balance of the data deficiency. Thus, this deficiency remains outstanding.

Additional residue data are needed for each type of application (preplant incorporated and preemergent) to dry beans from ID, CO, and NE. Residue data for the preemergent application (including lima beans) are needed from MI, WI, IL, CA, ID, CO, and NE.

Deficiency 11e Special Review Deficiency

Special cooking and processing (canning) data were required for dry beans and peas in the Special Review Data Call In Notice of June 9, 1986. These data were due in June, 1987.

Monsanto Response

Monsanto submitted revised protocols to grow additional legume samples to be treated with exaggerated rates on April 30, 1987, and the first quarterly progress report, which were reviewed in the S. Hummel memo of 8/20/87.

Monsanto submitted a final report on the samples which were processed from the 1986 field trials. In separate processing trials, raw succulent peas were boiled, washed, microwaved, and canned. The canned peas were analyzed with and without the water in the can. Dry peas were boiled. Red kidney beans were cooked. Results were reported as the average of duplicate samples and are presented below.

<u>Commodity</u>	<u>Residue</u> <u>(ppm alachlor equiv.)</u>	<u>Concentration/Reduction</u> <u>Factor</u>
Peas, raw, succ	0.032	1
Boiled	0.035	1.1
Washed	0.024	0.75
Microwaved	<0.020	<0.62
Canned (w/water)	<0.020	<0.62
Canned (w/o water)	<0.020	<0.62
Dry peas	0.12	1
boiled	0.041	0.34

All Red Kidney bean samples had non-detectable residues, thus, any reduction of residue on cooking could not be measured.

RCB Comment

The concentration/reduction factors presented here may be used to represent reduction of residue upon cooking for succulent and dry peas. For dry beans, Monsanto is conducting another processing study. However, for the present time, until the dry bean study is available, we will translate data from dry pea to dry beans. We will assume that alachlor residues in dry beans

will be reduced by a factor of 0.34, pending receipt of cooking data for dry beans with detectable residues. Special cooking and processing data from the 1987 field trials could be submitted to the Agency by 9/88.

SUNFLOWERS

Deficiency 12b

Processing data are still needed for sunflower meal and hulls (separately). The registrant may want to submit data for refined sunflower oil since residues are likely to decrease with refining. The Registration Standard due date for this study was 12/86.

Monsanto Response

Monsanto submitted a processing study for sunflower seeds. Sunflower seeds which had been treated with Lasso EC or Lasso II were processed into hulls, kernels, presscake, defatted meal, crude oil, alkali refined oil, soapstock, bleached oil, and deodorized oil. The processing was completed in mid-March, 1987. DATA sheets were submitted for each sample. The processing was done within one day. Yields were given for each step of the process. Undated chromatograms were included in the report. The undated chromatograms appear to be from samples included in the report. Excerpts from Monsanto's standard operating procedures for sample handling, shipping, storage, and sample preparation were included. The data sheets for the field trials were included in this report, as well as in the report of the unprocessed samples.

The following concentration/reduction factors were reported. A concentration/reduction factor is the number which, when multiplied by the residue in the unprocessed raw agricultural commodity, gives the residue in the processed commodity.

Sunflower Seed Concentration/Reduction Factors

<u>Commodity</u>	<u>Range</u>	<u>Average</u>
sunflower seed	1	1
hulls	0.64 - 1.36	0.86
kernels	0.81 - 1.63	1.11
presscake	1.55 - 2.21	1.87
defatted meal	1.89 - 2.26	2.04
crude oil	0.05 - 0.27	0.12
alkali refined oil	0.04 - 0.12	0.07
soapstock	0.16 - 0.23	0.21
bleached oil	0.02 - 0.11	0.06
deodorized oil	0.02 - 0.11	0.06

RCB Comment

There are two types of sunflower seeds: oilseeds, which contain about 40% oil and non-oilseed varieties, which contain about 28% oil. The non-oilseed varieties are used as human and bird food.

Before pressing or extracting the oil from sunflower seeds, the seed is cooked by heating to 160F. The hulls may or may not be removed. The oil is generally screw-press extracted. The screw press does not remove all of the oil. Heat is generated in the process (about 200F). The remainder of the oil is then solvent extracted with hexane. The oil is then alkali refined, bleached and deodorized. The defatted meal can then be further processed into protein concentrates and isolates. However, protein concentrates and isolates are not used in the US for food (at least at the time the reference article was written in 1975)¹

The submitted processing data are adequate, pending receipt of the required storage stability data. The concentration-reduction factors reported will be used for tolerance setting and for special review residue estimates. Feed additive tolerances will be needed for sunflower seed hulls and sunflower seed meal.

SUMMARY OF RESIDUE ESTIMATES

Although a number of Registration Standard deficiencies remain, we are confident that the Special Review residue estimates accurately reflect the dietary exposure expected for alachlor and its metabolites. It is unlikely that additional residue data submitted to satisfy these deficiencies will demonstrate that our estimates need to be increased. However, if significant differences are found, we will inform SRB/RD of our revised residue estimates and request that the hazard associated with the dietary exposure to alachlor and its metabolites be re-evaluated.

Our current residue estimates for total alachlor (sum of, alachlor and its DEA and HEEA metabolites) are tabulated below. These estimates are substantially similar to our estimates in our most recent review (S. Hummel, 11/03/87). This update includes residue estimates from recently submitted residue and processing data for lima beans and sunflower seed, and the special cooking and processing data for legumes.

¹ "Use of Sunflower Seed in Food Products," J. A. Robertson, Critical Reviews in Food Science and Nutrition, Volume 6, Issue 2, CRC Press, Inc., July, 1975, p 201-240.

Current residue estimates are based on the maximum total alachlor residue found in field trials at the maximum typical application rate. Most of the alachlor residue data have not been completely validated, as discussed in our previous reviews (S. Hummel, 1/30/87, 6/13/87). Exceptions are sunflower seed, legumes, and sorghum data. Adequate validation data for these crops have been received and were discussed in our previous review (S. Hummel, 11/3/87).

The maximum typical application rate for alachlor is 4 lb ai/A for most crops. Some crops have Section 3 or Section 24(c) application rates in excess of 4 lb ai/A, e.g. (corn, 8 lb ai/A on high organic soils; peanuts, 8 lb ai/A in NC and VA only). However, these rates in excess of 4 lb ai/A are not typically used, and consequently were not considered in our Special Review estimates.

SUMMARY TABLE

TENTATIVE RESIDUE ESTIMATES (PPM ALACHLOR EQUIVALENTS)

<u>Crop</u>	Estimates based on Maximum Residue found in Field Trials at Maximum Use Pattern	Estimates based on Maximum Residue found in Field Trials at Typical Use	Estimate Adjusted for % Crop Treated
<u>Corn</u>			
grain	0.019	0.016	0.0056
K+CWHR	0.005	0.005	0.0018
forage	0.60	0.60	0.21
fodder&stover	0.20	0.20	0.07
meal	0.021	0.015	0.0052
(soapstock) ^{1/}	0.048	0.029	0.010
crude oil	0.076	0.042	0.015
refined oil	0.003	0.0019	0.0007
<u>Peanuts^{2/}</u>			
nuts	0.27	0.27	0.17
hulls	0.9	0.9	0.56
meal	0.49	0.37	0.23
soapstock	0.13	0.05	0.031
crude oil	0.23	0.10	0.062
refined oil	0.04	0.02	0.012
forage	3.4	3.4	2.1
vines	3.4	3.4	2.1
<u>Soybeans</u>			
grain	0.21	0.21	0.044
hulls	0.32	0.32	0.067
meal	0.36	0.26	0.055

SUMMARY TABLE, CONTINUEDTENTATIVE RESIDUE ESTIMATES (PPM ALACHLOR EQUIVALENTS)

<u>Crop</u>	<u>Estimates based on Maximum Residue found in Field Trials at Maximum Use Pattern</u>	<u>Estimates based on Maximum Residue found in Field Trials at Typical Use Pattern</u>	<u>Estimate Adjusted for % Crop Treated</u>
<u>Soybeans, cont.</u>			
refined oil ^{3/} protein	0.05	0.04	0.008
concentrates	0.08	0.07	0.015
protein isolates	0.05	0.04	0.008
soapstock	0.52	0.38	0.080
forage	2.6	2.6	0.55
hay	2.0	2.0	0.42
<u>Sorghum</u>			
grain	0.053	0.053	0.0042
grits	0.03	0.03	0.0024
bran	0.14	0.09	0.0072
germ	0.22	0.15	0.012
flour	0.15	0.13	0.010
forage	1.4	1.4	0.11
fodder&stover	0.65	0.65	0.052
<u>Legumes</u>			
bean/pea forage ^{4/}	2.6	2.6	0.39
bean/pea hay ^{4/}	4.6	4.6	0.97
pea seeds	0.03	0.03	0.0009
cooked pea seeds	0.03	0.03	0.0009
canned peas	<0.02	<0.02	<0.0006
lima bean seeds	0.03	0.03	0.0042
dry bean seeds	0.035	0.035	0.0052
dry beans, cooked	0.012	0.012	0.0018
dry pea seeds	0.12	0.12	0.0036
dry peas, cooked	0.041	0.041	0.0012
peas w/ pods ^{4/}	0.27	0.27	0.008
lima beans w/pods ^{4/}	0.21	0.21	0.029
<u>Sunflowers</u>			
sunflower seeds	0.85	0.85	0.016
meal w/hulls	1.19	1.09	0.021
hulls	1.16	0.73	0.015
meal	1.91	1.73	0.035
crude oil	0.23	0.10	0.0034
refined oil ^{5/}	0.094	0.051	0.0010
<u>Cotton</u>			
cottonseed	0.041	0.041	0.0004
refined oil ^{6/}	0.0005	0.0004	0.000004

- 1/ not regulated
 - 2/ If 8 lb ai/A single application for use on peanuts is to remain registered under Section 24(c), then maximum residues are tentatively estimated at 0.87 ppm in peanuts, 2.7 ppm in peanut hulls, 4.8 ppm in peanut hay, and 12 ppm in peanut vines
 - 3/ refined, deodorized oil for human consumption
 - 4/ estimated from earlier residue data where only DEA metabolites of alachlor were measured
 - 5/ refined, bleached, deodorized oil for human consumption
 - 6/ estimate based on sunflower seed and corn oil processing data
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cc: R. F., circu, S. Hummel, alachlor S.F., Alachlor S.R.F.,
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RDI:EZ:12/08/87:RDS:12/08/87
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