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

SEP 9 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#2F2681 Lasso ME on various crops. Evaluation of analytical methods and residue data.

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THRU: Charles L. Trichilo, Chief
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TO: Robert Taylor, Product Manager #25
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and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Monsanto Company requests an exemption from the requirements of a tolerance for residues of the cross-linked polyurea-type polymer formed by reacting polymethylene polyphenylisocyanate and hexamethylene diamine when used for encapsulating alachlor (2-chloro-N-(2,6-diethylphenyl)-N-(methoxymethyl) acetamide. Further, based on the Lasso ME crop data provided, Monsanto requests (see letter of 4/16/82-S.L. Kimball of Monsanto to Director of RD) that all crops presently registered (40 CFR 180.249) for treatment with alachlor (Lasso) also be accepted for treatments with Lasso ME; the various crops or fractions thereof with established tolerances are listed below:

3 parts per million in or on peanut forage and hay.
1.5 parts per million in or on peanut hulls.
0.75 part per million in or on soybean forage.
0.2 part per million (negligible residue) in or on corn fodder and forage,
corn grain, cotton forage, forage and hay of peas and beans, and soybeans.
0.1 part per million (negligible residue) in or

on field (dry) beans, green lima beans, peas with pods (determined on peas after removing any pod present when marketed), and potatoes.
0.05 part per million (negligible residue) in or on cottonseed, fresh corn including sweet corn (kernels plus cob with husk removed), and peanuts.

Further, Monsanto has requested that all proposed tank mix recommendations be accepted for Lasso ME based on the tank mix residue data provided and also on the Agency's new policy on waiver of tank mix residue data.

At the present time, PP#0F2348 (Alachlor use on corn) and EUP No. 524-EUP-UO (Lasso N on various commodities) are in a reject status. The name Lasso N has been changed to Lasso ME.

Conclusions

1). [redacted] is not cleared under 40 CFR 180.1001. This inert needs to be cleared or removed from the formulation.

2a). The polymer to be used for Lasso ME is formed from hexamethylenediamine and polymethylene polyphenylisocyanate; it is structurally different than the polyurea type polymer formed by reaction of toluene diisocyanate and polymethylene polyphenylisocyanate and exempted under 40 CFR 180.1039. We have concluded that an exemption from the requirement of a tolerance for the subject encapsulating material is not covered under 40 CFR 180.1039.

2b). For a permanent exemption for the subject encapsulating material, we need information to indicate what quality control checks will be used to guarantee the uniformity of the encapsulating material from batch to batch. In particular, we are concerned that uniformity of wall thickness and permeability be maintained so that the rate of release of the encapsulated pesticide would not differ widely due to batch variations.

3a). The proposed labeling includes post-emergence use for corn. Postemergence alachlor treatment on corn has not been approved (see PP#0F2348).

3b). The petitioner will need to review the approved Section B/label that was used for developing the "established" alachlor (Lasso) tolerance on corn (see PP#9F0740, take into consideration the PHI of 12 weeks, treatment rates, etc.) and then propose a label (revised Section B) that is in agreement; the proposed label in this petition is not supported by the residue data in this petition or PP#9F0740.

3c.) Residue data have been submitted that reflected one preplant or one preemergence treatment per year; certain segments of the label "as written" allow for more than one treatment. Each segment of the label should specify the number of treatments permitted.

3d.) Although the petitioner states that he wants all presently registered alachlor uses to be extended to include alachlor ME, we notice that a proposed use for Lasso ME on peanuts was not mentioned in Section B of the present petition or in the subject of the aforementioned letter of 4/16/82 (see introduction portion of this review). On 8/25/82, (Telecon between R. Quick (RCB) and Mr. Duncan of Monsanto), Mr. Duncan indicated that Monsanto did not want to include the use of Lasso ME on peanuts in their request at this time.

4). The nature of the alachlor residue in plants and animals is adequately understood.

5a.) Adequate alachlor methodology is available for regulatory purposes.

5b.) The Pesticide Analytical Manual contains regulatory procedures for those active ingredients that are tank-mixed with alachlor.

6a.) We reserve a conclusion on the adequacy of the established 0.2 ppm tolerance on corn grain until those deficiencies discussed in conclusions 2b, 3a, 3b, and 3c have been resolved.

6b.) The corn studies reflecting preemergence treatment in the present petition demonstrated that an alachlor tolerance of 8 ppm may be needed for corn forage. The petitioner should repeat the corn studies that were carried out in the state of Iowa.

7.) We reserve our conclusions on the adequacies of the established tolerances on soybeans, dry beans, peas, potatoes, and green lima beans until those deficiencies discussed above in conclusions 2b and 3c have been resolved.

8.) Data on the residue levels of the encapsulating material (polyurea-type polymer) will not be required since the proposed use involves application before edible parts are formed.

9.) The petitioner should be informed that we can extrapolate residue data from the soybean studies to dry beans, green lima beans, and peas; however, we can not extrapolate the residue data from the soybean studies to cotton. The petitioner will need to submit residue data reflecting the use of the encapsulating material-alachlor on cotton.

10.) Since residue data are available for alachlor on soybean hay, we suggest that the petitioner propose a tolerance for residues of alachlor in or on this commodity.

The product manager should advise the petitioner on the mechanics of such a proposal.

11.) Alachlor secondary residues in meat, milk, poultry, and eggs have been placed under category 2 of Section 180.6(a). We reserve our conclusion until a later date as to whether or not the established 0.02 ppm alachlor tolerance will be adequate for the propose use of Lasso ME. We want to alert the petitioner that a higher level cattle feeding study may be needed.

Recommendations

We recommend that the proposed exemptions not be established for the reasons given in conclusions 1, 2a, 2b, 3a, 3b, 3c, 6a, 6b, 7, 9, and 11.

The petitioner should be informed about conclusion 10.

Detailed Considerations

Manufacture and Formulation

The manufacturing process for alachlor is discussed in our review of PP#9F0776; no formation of nitrosamine during the manufacturing process has been reported.

The basic manufacturing process for the formulation [redacted]

At present, a polyurea type polymer formed by reaction of toluene diisocyanate and polymethylene polyphenylisocyanate is exempt from the requirement of a tolerance under 40 CFR 180.1039. [redacted]

Therefore, because of structural differences between the two polymers, we concluded in our review (7-7-80, L. Bradley) of EUP No. 524-EUP-UO that 40 CFR 180.1039 was not applicable and that a specific exemption for the present polymer in question was needed. Also, in our 7/7/80 review of EUP No. 524-EUP-UO, we concluded that adequate quality control procedures for insuring predictable release characteristics from the encapsulated material should be submitted; batch uniformity as regards to particle size, wall thickness, etc. were needed.

MANUFACTURING PROCESS INFORMATION HAS BEEN DELETED.

For a permanent exemption for the submit encapsulating material, we need information to indicate what quality control checks will be used to guarantee the uniformity of the encapsulating material from batch to batch. In particular, we are concerned that uniformity of wall thickness and permeability be maintained so that the rate of release of the encapsulated pesticide would not differ widely due to batch variations.

Proposed Uses

Corn (all types) (A.) Lasso ME, alone

: Preemergence Surface - Apply 2 to 4 lbs. a.i./A after planting before crop and weed emergence and within 5 days after last preplant tillage operation.

: Preplant Application - Apply 2.5 to 8 quarts (2.5 to 8 lbs. a.i./A).

(B.) Lasso ME plus Atrazine tank mix

: Preplant Application - Apply tank mixture (2 to 3 lbs alachlor plus 1.6 to 2.3 lb. atrazine a.i./A) within 7 days prior to planting.

: Preemergence Surface - Apply tank mixture (1.5-2.5 lbs. alachlor plus 1.3 to 2 lb. atrazine a.i./A) after planting, before crop and weed emergence and within 5 days after last preplant tillage operation.

: Postemergence Surface - Apply tank mixture (1.5 - 2.5 lbs. alachlor plus 1.3 to 2 lb. atrazine a.i./A after crop emergence until weeds reach the 2-leaf stage and the crop is no more than 5 inches tall.

Restrictions: Do not graze treated area or feed treated forage to livestock for 21 days following application of this tank mixture.

(C.) Lasso ME plus Banvel (tank mix)

: Preplant, Preemergence, and Postemergence Uses - Apply mixture of 2.5 lbs. a.i. (alachlor) and 0.5 quart Banvel/A. (The label does not indicate whether Banvel D or Banvel T is used).

(D.) Lasso ME plus Bladex 4L (tank mix)

: Preplant and Preemergence - Depending on the soil textures, etc., apply tank mixture containing 2-2.5 lbs. a.i. alachlor and 1.3 to 2.8 lbs a.i. (Bladex 4L (cyanazine)/A.

Field Corn or Silage Corn only (tank mixtures - preemergence)

(A.) Lasso ME (2.5 to 4 lbs. a.i./A) plus Roundup (0.75 to 3 lbs. a.i./A).

(B.) Lasso ME (2 to 3 lbs a.i./A) plus Atrazine (1.3 to 1.5 lb. a.i./A) plus Roundup (0.75 to 3 lbs. a.i./A).

(C.) Lasso ME (2 to 3 lbs a.i./A) plus Atrazine (1.3 to 1.5 lb. a.i./A) plus Paraquat (0.25 to 0.5 lb. a.i./A).

(D.) Lasso ME (2 to 3 lbs. a.i./A) plus Bladex (1.3 to 2.8 lbs. a.i./A) plus Roundup (0,75 to 3 lbs. a.i./A).

(E.) Lasso ME (2 to 3 lbs. a.i./A) plus Princep (1.3 to 2.8 lbs. a.i./A).

Soybeans

(A.) Lasso ME - Preplant application rates are 2.5 to 4 lbs. a.i./A Preemergence surface application rates are 2 to 4 lbs a.i./A.

(B.). Preplant application - Lasso ME (2.5 to 4 lbs. a.i./A) plus Amiben (2 lbs. a.i./A).

(C.) Preemergence surface application - Lasso ME (2 to 4 lbs. a.i./A) plus Amiben (2 lbs. a.i./A).

(D.) Preplant application - Lasso ME (2.5 to 3 lbs. a.i./A) plus Lexone or Sencor (0.4 to 0.5 lb. a.i./A).

(E.) Preemergence surface application - Lasso ME (2-2.5 lbs. a.i./A) plus Lexone or Sencor (0.4 to 0.5 lb. a.i./A).

(F.) Preemergence surface application - Lasso ME (1.5 to 3 lbs. a.i./A) plus Lorox (0.5 to 1.5 lb. a.i./A).

Soybeans (only)

(A.) Preemergence - Lasso ME (2.5 to 4 lbs./A).

(B.) Preemergence - Lasso ME (2.5 to 4 lbs. a.i./A) plus Lorox (0.5 to 1.5 lb. a.i./A).

(C.) Preemergence - Lasso ME (2-4 lbs. a.i./A) plus Lexone 4L or Sencor 4L (0.25 to 0.75 lb. a.i./A).

(D.) Preemergence - Lasso ME (2.5 to 4 lbs. a.i./A) plus Roundup (0.75 to 1.1 lb. a.i./A).

(E.) Preemergence - Lasso ME (2.5 to 4 lbs. a.i./A) plus Lorox (0.5 to 1.5 lb. a.i./A) plus paraquat (0.25 to 0.5 lb. a.i./A).

(F.) All preemergence treatments - The rates for each pesticide in the following mixtures are the same as above:

(1.) Lasso ME plus Lorox plus Roundup
(2.) Lasso ME Plus Lexone plus Roundup
(3.) Lasso ME plus Sencor plus Roundup

Dry Beans, Lima Beans (Green) and Green Peas

Depending on the crop, soil texture, geographical location, and the type of treatment (preplant or preemergence), Lasso ME alone (1.5 to 3 lbs a.i./A) or in tank mixtures Lasso ME (2.5 lbs. a.i./A) plus Treflan (0.5 lb. a.i./A) are proposed for the various treatments.

Potatoes

Depending on the soil texture, geographical location, and the type of treatment (pastplant or preemergence, Lasso ME alone (2.5 lbs. a.i./A) or in tank mixtures - Lasso ME (2 to 3 lbs a.i./A) plus Lexone or Sencor (0.4 to 0.8 lb. a.i./A) and Lasso (2-3 lbs. a.i./A) plus Lorox (0.75 to 1.25 lb. a.i./A) are proposed for the various treatments.

Cotton - Use only in Oklahoma and some Texas counties; preemergence treatment. Depending on the soil texture, one to two lbs of Lasso ME may be used.

Our Comments/Conclusions on the Proposed Label.

The petitioner will need to review the approved Section B/label that was used for developing the "established" alachlor (Lasso) tolerance on corn (see PP#9F0740, take into consideration the

PHI of 12 weeks, treatment rates, etc.) and then propose a label (revised Section B) that is in absolute agreement; the proposed label in this petition is not supported by the residue data in this petition or PP#9F0740.

Postemergence alachlor treatment on corn has not been approved (see PP#0F2348).

Residue data have been submitted that reflect one preplant or one preemergence treatment per year; certain segments of the label "as written" allow for more than one treatment. Each segment of the label should specify the number of treatments permitted.

We also noticed that a proposed use of Lasso ME on peanut crop was not mentioned in Section B of the present petition or in the subject of the aforementioned letter of 4/16/82 (see introduction portion of this review). On 8/25/82 (telecon between R. Quick (RCB) and Mr. Duncan of Monsanto) Mr. Duncan indicated that Monsanto did not want to include the use of Lasso ME on peanuts in their rquest at this time.

Nature of the Residue

No new metabolism studies were submitted with this petition. However, there are radiolabeled alachlor studies available for cotton, corn, soybean and peanut plants (PP#s 7F0622, 9F0740 and 9F0776). The major metabolites were reported as cationic in young plants and anionic in older plants. Even though the identification of all the metabolites was judged to be impractical, they contained the 2,6-diethylaniline moiety which is determined by the enforcement method. The metabolic routes were reported to be similar for all the plant metabolism studies.

The nature of the residue in animals was discussed in PP#9F0740.

We have concluded that the nature of the residue in plants and animals is adequately understood. Tolerances are established for the combined residues of the herbicide alachlor [2-chloro-2',6-diethyl-N-(methoxymethyl)acetanilide] and its metabolites (calculated as alachlor).

Analytical Method

The determinative step in the analytical procedure for alachlor will measure the parent compound alachlor and its metabolites which contain the 2,6-diethylaniline moiety. The corn forage and stover and soybean forage and hay samples are extracted with 10% 1N HCl/acetonitrile, and the corn and soybean grain, and potato samples are extracted with 10% water/acetonitrile. The extracted residue is digested first in acid to remove the

methoxymethyl group, then refluxed in base to liberate the 2,6-diethylaniline which is distilled and recovered in acid. The distillate is washed with hexane, made basic, and partitioned against hexane, which extracts the aniline. The aniline is further purified by passing through a Florisil column, and then quantitated by gas chromatography using a nitrogen specific detector. Residues are expressed as alachlor after appropriate calculation. The method provides a 0.02 ppm sensitivity for alachlor in grain and a 0.05 ppm sensitivity for alachlor in forage and stover.

The recovery values for alachlor on the various matrixes are given below:

Matrix	Fortification Level, ppm	% Recovered
Corn grain	0.02-1.0	51-82
" stover	0.05-1.0	50-78
" forage	0.05-4.0	46-71
Potatoes	0.02-0.25	55-61
Soybean grain	0.02-0.5	50-89
" forage	0.05-1.0	53-79
" hay	0.05-1.0	51-76

We conclude that adequate methodology for alachlor is available for regulatory purposes.

Methodology developed by the petitioner was used for tank mix data. However, the Pesticide Analytical Manual contains regulatory procedures for those active ingredients that are mixed with alachlor.

Residue Data

Corn. Residue data on Lasso ME (microencapsulated alachlor) resulted from one preemergence spray of the recommended rate of 4 lbs. a.i. (alachlor)/acre and at an exaggerated rate (2x) of 8 lbs. a.i./acre, using Lasso ME alone and in tank mixtures with Roundup, atrazine and cyanazine. Three tank mixes were tested: (1) A tank mix of 4 lbs. per acre a.i. Lasso ME + 1.5 lb per acre atrazine was applied at one location; (2) A tank mix of 4.5 pounds per acre a.i. Roundup® + 4.0 lbs a.i./A Lasso® ME + 3 lbs/A atrazine was applied at two locations; and (3) A tank mix of 4 lbs a.i./A Lasso® ME + 2.5 lbs/A atrazine + 2.5 lbs/A cyanazine + 4.5 lbs a.i./A Roundup® was applied at four locations. Plots for the overall study were located in the states of South Dakota, New York, California, Iowa, Michigan, Minnesota, and in the country of Canada.

Residue values for alachlor and its metabolites and for atrazine, cyanazine, and Roundup are given below:

Corn grain (PHI = 107-173 days)

alachlor : <0.02 ppm
checks : <0.02 ppm

atrazine : <0.05 ppm
checks : <0.05 ppm

cyanazine: <0.05 ppm
checks : <0.05 ppm

Corn stover (PHI = 107-173 days)

alachlor : <0.05-0.51 ppm
checks : <0.05-0.1 ppm

atrazine : <0.05
checks : <0.05

cyanazine: <0.05
checks : <0.05

Corn forage (PHI = 64-69 days)

alachlor : 0.12-7.53 ppm; highest value at 4 lb a.i./A
checks : <0.05-1.01 ppm

atrazine : <0.05
checks : <0.05
cyanazine : <0.05
checks : <0.05

Our Comments/Conclusions

We reserve our conclusion on the adequacy of the established 0.2 ppm tolerance on corn grain until those deficiencies discussed in conclusions 2b, 3a, 3b, and 3c (see conclusion section of this review) have been resolved.

The corn studies reflecting preemergence treatment in the present petition demonstrated that an alachlor tolerance of 8 ppm may be needed for corn forage. The petitioner should repeat the corn studies that were carried out in the state of Iowa.

Potatoes. Residue data on Lasso ME resulted from one preemergence spray of the recommended rate of 3 lbs. a.i. (alachlor)/acre and at an exaggerated rate (2x) of 6 lbs. a.i./acre. Residues of alachlor in potato tubers ranged from less than 0.02 ppm to 0.05 ppm at the 3 lbs./acre rate and <0.2 to 0.13 ppm at the 6 lbs./acre rate.

The potatoes were grown in the states of Idaho, Minnesota, Wisconsin and in the country of Canada; PHI's ranged from 101 to 145 days.

Our Comments/Conclusions

We reserve our conclusion on the adequacy of the established tolerance on potatoes until those deficiencies discussed above in conclusions 2b and 3c have been resolved.

Soybeans. Residue data on Lasso ME resulted from one preemergent applicaiton at the recommended rate of 4 lbs. a.i. alachlor/A and at an exaggerated rate (2x) of 8 lbs. a.i./acre, using Lasso ME alone or in tank mix combinations. The following 3 tank mixes were tested: (1) Tank-mix of 4 lbs. a.i. of Lasso ME plus 0.75 or 0.5 lb a.i. of metribuzin per acre; (2) 4 lbs. Lasso ME (a.i.) plus 1.5 lb. of linuron per acre; and (3) 4 lbs. Lasso ME (a.i.) plus 4.5 lbs. a.i. of Roundup plus 0.5 lbs. a.i. of metribuzin per acre. The studies were carried out in the states of Kansas, Illinois, Maryland, Louisiana, Indiana, Iowa and the country of Canada.

Residues of alachlor and its metabolites were non-detectable in soybean grain (<0.02 ppm, method sensitivity) at all locations, and in all tank-mix treatments. Alachlor residues in soybean hay ranged from less than 0.05 ppm (method sensitivity) to 0.66 ppm at the recommended application rate of 4 pounds per acre, and <0.05 to 0.92 ppm at the exaggerated application rate of 8 lbs/A. In soybean forage, alachlor residues ranged from <0.06 to 0.42 ppm at the recommended application rate of 4 lbs. a.i./acre and 0.1 to 0.44 ppm at the exaggerated application rate of 8 lbs. a.i./A.

In soybean grain, residues of linuron ranged from <0.05 to 0.17 ppm, in hay from 0.16 to 0.26 ppm, and in forage from <0.05 to 0.38 ppm.

In soybean grain and hay no detectable residues of metribuzin (including the DA, DADK and DK metabolites) were found with the exception of a single 0.09 ppm residue of DADK metabolite in hay. Residues of metribuzin (including the DA and DK metabolites) in soybean forage were non-detectable. Residues of the DADK metabolite of metribuzin in soybean forage ranged from <0.05 to 1.2 ppm.

Our Comments/Conclusions.

We reserve our conclusions on the adequacies of the established tolerances on soybeans, dry beans, peas, and green lima beans until those deficiences discussed above in conclusions 2b and 3c have been resolved.

Also, since residue data are available for alachlor on soybean hay, we suggest that the petitioner propose a tolerance for residues of alachor in or on this commodity. The product manager should advise the petitioner on the mechanics of such a proposal.

The petitioner should be informed that we can extrapolate residue data from the soybean studies to dry beans, green lima beans, and peas; however, we can not extrapolate the residue data from the soybean studies to cotton and peanuts. The petitioner will need to submit residue data reflecting the use of the encapsulating material on cotton. The use of Lasso ME on peanuts is not being considered at this time.

Meat, Milk, Poultry and Eggs

No new feeding study using the encapsulating material was submitted. RCB has determined previously that alachlor residues are likely to occur in milk, livestock meat, fat, meat by-product, poultry and eggs (see our reviews of PP#s 9F0776 and OF2348); these residues were, thus, placed under category 2 of Section 180.6 (a). It was also previously concluded that residues that were likely to occur in milk, livestock meat, fat, meat by-product, poultry and eggs would be adequately covered by the established 0.02 ppm alachlor tolerance. However, in the present petition, higher residue values (as much as 7.53 ppm) have been reported on corn forage (see the Residue Data section of this review). Therefore, we now reserve our conclusion until a later data as to whether or not secondary residues in meat, milk, poultry and eggs would be adequately covered by the established 0.02 ppm alachlor tolerance. We want to alert the petitioner that a higher level cattle feeding study may be needed for alachlor.

TS-769:RCB:HOnley:vg:CM#2:Rm810X77377:9/7/82
cc: RF, Circ., Onley, Thompson, FDA, TOX, EEB, EFB, PP#2F2681
RDI: Quick, 9/2/82; Schmitt 9/2/82