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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 12 1983

MEMORANDUM

Subject: PP#2F2681. Lasso ME (encapsulating alachlor) on various crops. Amendment of 10/27/82.

From: John H. Onley, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Thru: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

To: Robert Taylor, Product Manager #25
Herbicide-Fungicide Branch
Registration Division (TS-769)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

This amendment (10/27/82) was submitted by Monsanto Company in response to the deficiencies outlined in our 9/9/82 review of PP#2F2681. Each deficiency is listed below and is followed by the petitioner's response and our comments/conclusions.

Deficiency No. 1

1). The added inert [redacted]

Petitioner's Response to Deficiency No. 1:

Upon reexamination of the product chemistry information submitted [redacted]

INERT INGREDIENT INFORMATION HAS BEEN DELETED.

Our Comments/Conclusions on the Petitioner's Response to Deficiency No. 1:

RCB concludes that deficiency No. 1 has been resolved.

Deficiency No. 2a:

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.

Petitioner's Response to Deficiency No. 2a:

The clearance sought [see TOX's (D.L. Ritter) memo of August 17, 1982] is as follows:

> Amend 40 CFR 180.10XX to exempt the crosslinked nylon type microencapsulating polymer, polymethylene polyphenylisocyanate (PAPI) with 1,6-hexamethylenediamine (HMDA) as the cross-linking reactant.

Our Comments/Conclusions on the Petitioner's Response to Deficiency No. 2a:

RCB concludes that deficiency no. 2a will be resolved if the present exemption (PP#2F2681) is granted.

Deficiency No. 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.

Petitioner's Response to Deficiency No. 2b:

The petitioner has discussed in this amendment how he intends to guarantee the uniformity of the encapsulating material from batch to batch; this discussion may be referred to, as needed.

Our Comments/Conclusions on the Petitioner's Response to Deficiency No. 2b:

The petitioner has adequately described quality control testing that will be used to insure consistent release characteristics of the formulation. We, therefore, conclude that deficiency no. 2b has been resolved.

Deficiency No. 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 treatment.

Petitioner's Response to Deficiency No. 3c:

The petitioner did not respond to deficiency no. 3c.

Our Comments/Conclusions on the Petitioner's Inaction to Deficiency No. 3c.

The petitioner will need to submit a revised Section B in which each segment of the label specify the number of treatments as stated above. Deficiency no. 3c has not been resolved.

Deficiency No. 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.

Petitioner's Response to Deficiency No. 6b:

We have reviewed the residue studies that were submitted to support registration of Lasso ME (alachlor) on corn. The study noted by the RCB did show abnormally high alachlor residues in corn forage and fodder, in both the treatment and control samples. Although this study was part of the data package submitted for alachlor/corn residues, we noted in the data summary (Volume 5, part 2, page 2) that this study was considered invalid because the untreated (control) and treated samples both contained residues. We believe that this contamination of the samples probably occurred through contact with the chemical after sampling. Furthermore, twelve other studies involving Lasso ME alone or in tank mix combinations did not show significant residue levels in corn forage.

Based on the other residue studies that were submitted, we request that the Agency accept the proposed use of Lasso ME on corn with the agreement that Monsanto will subsequently conduct another residue study in Iowa to confirm that the proposed use is acceptable in that state. The results of that study will be submitted to the Agency upon its completion.

The Agency's recent action to allow increased alachlor tolerances (from 0.2 ppm to 0.5 ppm,) on corn forage and fodder (PP No. OF2348; EPA Accession No. 99396) should adequately cover any residue from recommended treatment rates.

Our Comments/Conclusions on the Petitioner's Response to Deficiency No. 6b:

Corn forage grown at the Adel, Iowa location contained the following high residues:

	Rate	PHI	ppm range
Lasso ME (alone)	4 lbs.	64	6.61 - 7.53
Lasso ME (tank mix)	4 lbs.	64	3.30 - 3.77
Lasso ME (alone)	8 lbs.	64	2.84 - 4.37
Controls			0.99 - 1.01

In our review of PP#OF2348 (see our review of 10/23/80), we questioned the 1.42 ppm alachlor (Lasso®) residue value on corn forage grown in Hoytville, Ohio. In that case, the petitioner (also Monsanto) reported this experiment, and we concluded in our 11/30/82 review of amendment 11/16/82 to PP#OF2348 that a 0.5 ppm alachlor tolerance was adequate for corn forage and fodder.

In the present petition, we are considering a Lasso encapsulating material and, thus, must be sure that this material has residue patterns that are similar to the uncapsulated material. The above high residues on corn forage with a 64-day PHI and grown in a corn belt state had to be scrutinized. If the petitioner believed that contamination was a problem, then it should have been documented. We also noticed in the same study that the corn stover resulting from a 153 day PHI (4lbs./A treatment) had a high residue of 0.51 ppm which is slightly above the approved 0.5 ppm tolerance; we don't know what the residue level would had been on this same stover if it were harvested at the 9 - week PHI (PHI of 63 days) which has been approved for the use of uncapsulating Lasso® on field corn.

In order to arrive at a recommendation as to whether or not the 0.5 ppm alachlor tolerance on field corn forage and fodder is adequate, RCB must wait until it has reviewed the results from the repeated study in Iowa; the petitioner should submit these results as soon as possible or delete the proposed use of Lasso ME on corn until these results have been finalized. We conclude that deficiency no. 6b has not been resolved.

Deficiency No. 7:

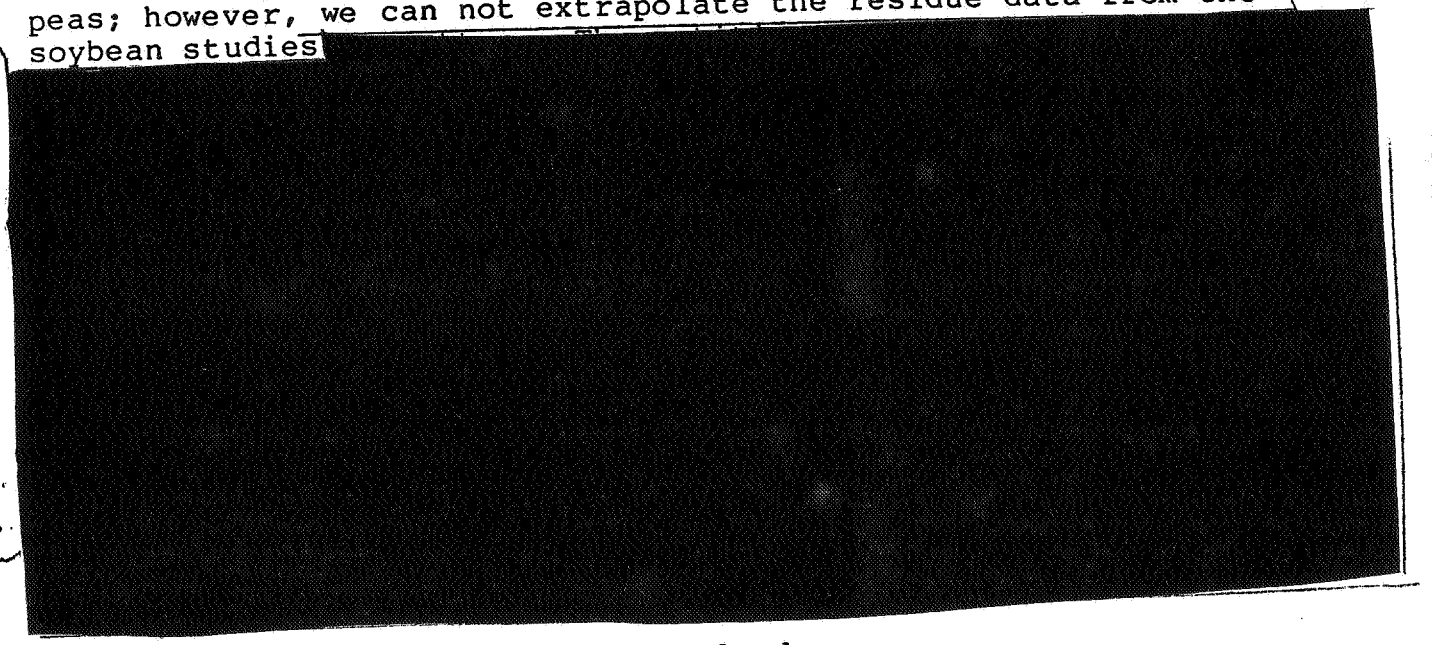
We reserve our conclusions on the adequacies of the established tolerances on soybeans, dry beans, peas, potatoes, and green lima beans until those deficiencies discussed above in conclusions 2b and 3c have been resolved.

Petitioner's Response to Deficiency No. 7/Our Comments on Deficiency No. 7:

The petitioner has resolved deficiency no. 2b above; however, deficiency no. 3c has not been addressed. We, therefore, still reserve our conclusions on the adequacies of the established tolerances on soybeans, dry beans, peas, potatoes, and green lima beans.

Deficiency No. 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



Deficiency No. 9 has not been resolved.

Conclusion No. 10:

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

Petitioner's Response to Conclusion No. 10 (EPA letter, item 9):

The petitioner has requested that a 1.0 ppm alachlor tolerance be established on soybean hay.

Our Comments on the Petitioner's Response to Conclusion No. 10:

We conclude that a 1.0 ppm alachlor tolerance on soybean hay should be adequate.

Deficiency No. 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 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.

Petitioner's Response to Deficiency No. 11:

No response was made.

Our Comments/Conclusions on the Petitioner's Inaction to Deficiency No. 11:

At the present time, the residue data on corn (deficiency no. 6b), clarification on the number of treatments (deficiency no. 3a), and a need for cottonseed residue data (deficiency no. 9) prevent us from arriving at a conclusion on the adequacy of the established 0.02 ppm alachlor tolerance on animal commodities. If the usages of Lasso ME on corn and cottonseed were deleted from the proposed label, then RCB would conclude at this time that the established 0.02 ppm alachlor tolerance on meat, milk, poultry, and egg commodities would be adequate. However, the petitioner should be informed again that new feeding studies, conducted at higher feeding levels, will probably be needed in the future.

Recommendations

RCB recommends that the proposed exemptions not be established for the reasons given in Our Comments/Conclusions on the Petitioner's Responses or Inactions to Deficiencies Nos. 3c, 6b, 7, 9, and 11.

TS-769:RCB:JOnley:vg:CM#2:RM810:X77377:1/11/83
cc: RF, Circ., Onley, Thompson, FDA, TOX, EEB, EFB, PP#2F2681
RDI: Quick, 1/7/83; Schmitt, 1/7/83

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

MEMORANDUM AUG 17 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: D. Dickson, PM #25
Herbicides/Fungicides Branch
Registration Division (TS-769)

and

Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: R. Jaeger, Section Head
Review Section #1
Toxicology Branch/HED (TS-769)

SUBJECT: Proposal to exempt an Inert Ingredient from the requirement of a tolerance.

Reg. No.: 524-EUP-49; 524-GUU/PP #2F2681

Caswell #: [redacted]

Moiety: Cross-linked polyurea-type encapsulating material.

Clearance Sought: Amend 40 CFR 180.10XX to exempt the cross-linked nylon type microencapsulating polymer, polymethylene polphenylsiocyanate (PAPI) with 1,6-hexamethylenediamine (HMDA) as the cross-linking reactant.

Restrictions: Limited to application to soil before the edible portion of the crop forms and to use only with formulations containing the herbicide alachlor.

Sponsor: Monsanto Co.
Washington, D.C.

Conclusion:

RCB considerations permitting, Toxicology Branch has no objection to exempting this encapsulating polymer with the above restrictions.

Bases for the Conclusion:

1. The close structural similarity of the proposed polymer to two presently cleared polymers, PAPI with toluene diisocyanate as the cross-linking reactant (cleared under 180.1039, a Stauffer product), and PAPI mixed with sebacoyl chloride and a mixture of ethylenediamine and diethylenetriamine (cleared under 180.1028, a Pennwalt product), permits the conclusion that there is likewise no expectation of significant toxicity that could be associated with the proposed encapsulating polymer.

2. RCB considerations permitting, there will be no residues (<0.002 ppm as determined by ^{14}C-radio-labeled studies) of the polymer in primary crops or in follow-up rotational crops.

Discussion:

Monsanto proposes using this encapsulating polymer with the herbicide, Alachlor [2-chloro-2',6'-N-(methoxymethyl) acetamide].

Tolerances for residues of alachlor in racs have been established pursuant to 40 CFR 180.249 (Lasso™ Herbicide; EPA Reg. #524-314).

The proposed new product (Lasso ME, EPA Reg. #524-GUU) will be used only on those crops for which tolerances have been established, and no changes in these are contemplated.

The application is to be limited to "before formation of edible portions of the crop".

The sponsor argues that the use of the cross-linking agent, HMDA, using PAPI as the basic homopolymer, will not result in a polymer that is more toxic than the presently exempted Stauffer and Pennwalt polymers.

The available evidence strongly suggests that nylon-type polymer capsules in general are not absorbed across the gut wall. [redacted]

Sponsor contends that no residues (<0.002 ppm in racs as demonstrated by ^{14}C-radiotracer studies) are expected. This will require RCB's confirmation.

Deferals:

1. We defer to RCB as to whether the submitted residue data in fact reflect no resides (<0.002 ppm) in racs when the product is used as proposed.

8/10/82

David L. Ritter, Adjuvants Toxicologist
Review Section #1
Toxicology Branch/HED (TS-769)

8/15/82

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