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

MAR 2 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. Nos. 10182-173 and 10182-224. Phosmet.

Registration Standard Follow-up: ICI Americas Inc.
Response of 1/12/88 re Plant Metabolism Studies.

RCB Nos: 3331, 3332. MRID Nos: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

RMP

TO: George T. LaRocca, PM 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Background

See the attached memorandum (dated 7/21/87) entitled: "Corn and Potato Metabolism and Residue Studies Required by the Registration Standard" for a statement of RCB's position.

Based on that review, the registrant, ICI Americas Inc., was informed by the Agency (letter of 12/8/87) that there was no objection to the request to delete uses on corn and potatoes, but that two replacement metabolism studies would be required. Of the remaining crops with phosmet tolerances (40 CFR 180.261) alfalfa and grapes were recommended as the crops of choice for those metabolism studies.

The registrant has responded (letter of 1/12/88) as follows:

- o "We will comply with the Agency's request for metabolism data on two additional crops, namely, alfalfa (nongrass animal feed crop group) and grapes (small fruits and berries). These studies will be in addition to the on-going orchard tree fruit (cherry) study.
- o "...based upon the fact that three metabolism studies will be available, we propose to retain uses on corn and potatoes."

Discussion

RCB has no objection to the registrant's proposal to retain uses on corn and potatoes.

However, in view of this reversal on the registrant's part, we request that the two additional plant metabolism studies which the registrant has agreed to run be conducted on corn (grain and forage) and potatoes, as the Phosmet Registration Standard requests, rather than on the "substitutes", alfalfa and grapes. There is no longer any reason to accept substitute crops.

The registrant should be advised of our decision and informed that the requirements of the Phosmet Registration Standard re the need for corn and potato metabolism and residue studies are once again applicable, and must be complied with.

* * * *

CONCLUSIONS

1. The registrant now proposes to retain uses on corn and potatoes, and RCB has no objection to this.
2. The registrant indicates two additional plant metabolism studies (in addition to the on-going study on cherries) will be run; these will be on alfalfa and grapes.

RCB does not find this acceptable since uses are now to be retained on corn and potatoes. The two additional plant metabolism studies should be conducted on potatoes and corn (grain and forage), as specified in the Phosmet Registration Standard.

3. The requirements of the Phosmet Registration Standard re the need for corn and potato metabolism and residue studies are once again applicable, and must be complied with.

RECOMMENDATIONS

The PM should immediately notify ICI Americas Inc. of our Conclusions 1, 2, and 3.

Attachment: RCB memorandum of 7/21/87 entitled, "Corn and Potato Metabolism and Residue Studies Required by the [Phosmet] Registration Standard."

cc (with Attachment): RF, Circ, Reviewer (M. Nelson), Phosmet Registration Standard File, PMSD/ISB (Eldredge).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):3/1/88.

RDI:SectionHead:RSQuick:3/1/88:DeputyChief:RDSchmitt:3/1/88.

NOTE: In our previous review (7/21/87), the registrant of record for Imidan® 50-WP (EPA Reg. No. 476-1917) and 70-WP (EPA Reg. No. 476-2158) was Stauffer Chemical Company. This present amendment was submitted by ICI Americas Inc. and Imidan® 50-WP now has EPA Reg. No. 10182-173 and the 70-WP has EPA Reg. No. 10182-224.

Attachment



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

JUL 21 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 476-2178. Phosmet.
 Corn and Potato Metabolism and Residue Studies
 Required by the Registration Standard.
 RCB No.: 2376. MRID No.: None.

FROM: Maxie Jo Nelson, Chemist
 Tolerance Petition Section I
 Residue Chemistry Branch
 Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
 Tolerance Petition Section I
 Residue Chemistry Branch
 Hazard Evaluation Division (TS-769C) *RM*

TO: George T. LaRocca, PM 15
 Insecticide-Rodenticide Branch
 Registration Division (TS-767C)

By letter dated June 1, 1987, Stauffer Chemical Company, registrant of IMIDAN® (phosmet, active ingredient), has indicated that they no longer desire to maintain the registrations for the use of products containing phosmet on corn and potatoes.

Therefore, Stauffer indicates that uses on these crops will be deleted from the IMIDAN® 50-WP (EPA Reg. No. 476-1917, corn and potatoes) and IMIDAN® 70-WP (EPA Reg. No. 476-2158, potatoes) labels at reregistration.

Stauffer further states that:

"The Phosmet Reregistration Standard Guidance Document requested that metabolism studies on a tree fruit, potatoes and corn be conducted. In light of the above, the requirement to conduct metabolism studies in potatoes

and corn is no longer applicable. However, since we will retain the tree crop registrations, the tree crop (cherry) metabolism study will be conducted and has indeed been scheduled for initiation in the second quarter of 1987. We believe that the cotton metabolism data (MRID 112312) will support the continued registration of phosmet for use on cotton and other field crops (peas and alfalfa).

"The Phosmet Reregistration Standard Guidance Document also outlines additional magnitude of residue data requirements for both potatoes (field residue studies, processing study) and corn (processing study). However, as with the metabolism studies, the requirement to conduct the corn and potato residue studies is no longer applicable.

"In summary, since phosmet registrations on corn and potatoes will be cancelled, the Reregistration Standard metabolism and residue data requirements are no longer applicable. The existing cotton metabolism data and scheduled tree crop metabolism study will be adequate to support the continued registration of all other phosmet agricultural uses."

Background

The Residue Chemistry science support Chapter (dated 3/26/86) to the Phosmet Registration Standard contains the following statements relevant to this review:

"The metabolism of phosmet in plants is not adequately understood due to the lack of sufficient data. The following data are required:

- "° The uptake, distribution, and metabolism of ¹⁴C-carbonyl or ring-labeled phosmet in representative mature crops, preferably [emphasis added] an orchard tree fruit, potatoes, and corn (grain and forage) following foliar applications. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC and/or mass spectrometry. Data must also be presented that reflect the extraction efficiency of the solvent(s) used to remove residues following application of phosmet to living plants.

"Note: Representative samples from the above-described tests must also be analyzed by accepted enforcement methods to ascertain that these methods are capable of determining all metabolites of concern." [page 2]

* * *

"We conclude that the available plant metabolism data are not adequate because: (i) metabolites of phosmet have not been completely quantified or identified, (ii) metabolism studies exist for only one crop (cotton), and (iii) no data regarding the efficiency of extraction of ¹⁴C-residues from crops bearing weathered residues were submitted. Therefore, additional data must be submitted which delineate the metabolism of phosmet and its metabolites in three [emphasis added] representative mature crops." [page 4]

* * *

"The nature of the residues in plants has not been adequately elucidated for the following reasons: (i) the relative proportions of those terminal residues that have been identified have not been determined, and (ii) the metabolism of phosmet has been only partially examined in one crop (cotton) [emphasis added]." [page 8]

Discussion

Stauffer indicates that they no longer intend to support the registration of products containing phosmet on corn and potatoes. On that basis, we concur that the requirements to conduct phosmet metabolism and residue studies in potatoes and corn are no longer applicable to Stauffer.

RD should notify the other end-product formulators of phosmet of Stauffer's decision not to support the continued registration of phosmet-containing products on corn and potatoes.

Those formulators will need either to delete the uses on corn and potatoes from their labels, or to supply the residue data on corn and potatoes required by the Phosmet Registration Standard.

The Residue Chemistry science support Chapter clearly indicates that "...additional data must be submitted which delineate the metabolism of phosmet and its metabolites in three representative mature crops." [Page 4]

Thus, in addition to the tree crop (cherry) metabolism study which Stauffer indicates they intend to conduct, metabolism studies will also be needed on two other representative [mature] crops.

After examining a list of the remaining crops for which phosmet tolerances are established [40 CFR 180.261], we suggest alfalfa [non-grass animal feed crop group] and grapes [small fruits and berries crop group] as the crops of choice.

Conclusions

1. Since Stauffer indicates they no longer desire to maintain the registrations for the use of Stauffer products containing phosmet on corn and potatoes, the requirements of the Phosmet Registration Standard to conduct corn and potato metabolism and residue studies are no longer applicable to Stauffer.
2. Stauffer should be advised that phosmet metabolism studies on three representative mature crops are still required by the Phosmet Registration Standard. These should consist of an orchard tree fruit (Stauffer indicates a cherry metabolism study is to be conducted) and crops from two other crop groups. Based on the remaining crops with phosmet tolerances [40 CFR 180.261], we consider alfalfa [non-grass animal feed crop group] and grapes [small fruits and berries crop group] to be the crops of choice.
3. RD should notify other end-product formulators of phosmet of Stauffer's decision not to support the continued registration of phosmet-containing products on corn and potatoes, and of the need either to delete uses on corn and potatoes, or to supply the residue data required on these crops by the Phosmet Registration Standard.
4. RD should ensure that the uses on corn and potatoes are deleted from all applicable labels of phosmet-containing products at the time of reregistration.

Recommendations

The PM should notify Stauffer Chemical Co. of Conclusions 1 and 2.

The PM should notify other end-product formulators of phosmet products of Conclusion 3.

The PM should note Conclusion 4 for appropriate RD action.

cc: RF, Circ, Reviewer (M. Nelson), PM#15, Phosmet Registration Standard file, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):7/20/87.
RDI:SectionHead:RSQuick:7/20/87:DeputyChief:RDSchmitt:7/20/87.

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