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F. S. L. / J. S. B.
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Nos. 476-2217 and 476-2178 - Phosmet (Imidan[™]) Registration Standard - Stauffer Initiation of Data Requirements and Request for Time Extensions Dated December 4, 1986 and January 20, 1987 - No Accession Number - RCB Nos. 1919 and 1920

FROM: Martha J. Bradley, Chemist *M J Bradley*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

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

Stauffer Chemical Company has submitted specific comments on certain data requirements in the Phosmet Guidance Document and is requesting time extensions for the submission of the required data. This memorandum will only address the data requirements pertaining to Residue Chemistry Branch (RCB).

The registrant requests a 3-month time extension for the submission of all data to allow for joint data development negotiations with Zoecon.

Comment/Conclusion

No scientific issue is involved with this request and RCB defers to Registration Division (RD) on this general request.

1. PRODUCT CHEMISTRY

- A. Product Identity and Composition: 61-1, 61-2, 61-3
- B. Analysis and Certification of Product Ingredients: 62-1, 62-2, 62-3

Because Part B must be completed before Part A can be prepared and because suitable analytical methodology must be developed and validated, Stauffer requests that the time for submission of Part A be extended to coincide with the submission of Part B and requests a time extension to January 1988 for the submission date for all data in 1A and 1B above.

Comment/Conclusions

We concur that 1A cannot be prepared until 1B has been completed and have no objection to the requested time extension so that all data in 1A and 1B can be submitted at the same time.

2. RESIDUE CHEMISTRY 171-4A. Crop Residue Data

The registrant requests a time extension for all requested crop residue data to December 1990 to allow time for crop metabolism studies to be completed, submitted, and reviewed by the Agency before crop residue trials are initiated.

Comment/Conclusion

RCB has no objection to allowing time for the completion of crop metabolism studies before crop residue studies are conducted in accordance with PR Notice 85-5. However, it is not necessary or usual for the metabolism studies to be reviewed by the Agency before crop residue trials are conducted. It is Agency policy for all residue chemistry data to be submitted before scientific review is initiated.

B. Cranberry Tolerance

The registrant requests that the Agency not revoke the established tolerance for phosmet residues on cranberry. The specific revised use on cranberry will be included on the revised labeling to be submitted in response to the Guidance Document.

Comment/Conclusion

The Phosmet Registration Standard states that the available data support the cranberry tolerance and proposed use directions; therefore, we see no need to propose the revocation of the tolerance.

C. Cottonseed Processing Study

The Registration Standard requires a new cottonseed processing study because data for raw, unprocessed cottonseed are not available for the two studies submitted.

The registrant believes that another cottonseed processing study is not needed because the data for the raw, unprocessed cottonseed used in the two processing studies have been submitted. The study referenced as MRID No. 00067068 contains Reports FSDS Nos. A-25619 and A-25619-1 wherein data for the raw and processed products, respectively, are submitted. The study referenced as MRID No. 00112281 contains Reports FSDS Nos. A-10438-0 and A-10438-1 wherein data for the raw and processed products, respectively, are submitted. The registrant adds that additional information pertinent to the conduct of the above processing study (MRID No. 00067068) is available and will be submitted.

Comments/Conclusion

The above studies for raw and processed cottonseed have indeed been submitted: FSDS Nos. A-10438-0 and A-10438-1 were submitted as an amended registration and FSDS Nos. A-25619 and A-25619-1 were submitted in Pesticide Petition Nos. 9F2188 and 9H5211. However, the processing studies are conflicting, one study showing concentration of the residue in refined and crude oil, the other study showing no concentration of the residue. Our conclusion on the need for an additional processing study awaits the submission of the additional information pertinent to Reports FSDS Nos. A-25619 and A-25619-1.

D. Livestock Metabolism Studies (Ruminant, Oral; Poultry, Oral; Beef Cattle, Dermal; Swine, Dermal)

A time extension to December 1988 is requested to allow for the synthesis of necessary amounts of radiolabeled phosmet.

Comments/Conclusion

RCB has no objection to the requested time extension.

E. Crop Metabolism Studies

A time extension to September 1989 is requested to allow for seasonality considerations and to allow for the synthesis of necessary amounts of radiolabeled phosmet.

Comments/Conclusion

RCB has no objection to the requested time extension.

Conclusions/Recommendation

1. The 3-month time extension request to allow for joint data development negotiations does not involve scientific issues, therefore RCB defers to RD.
2. RCB has no objection to the requested time extensions for product and residue chemistry data requirements as they are in accordance with PR Notice 85-5. However, it is not necessary for the Agency to review crop metabolism studies before crop residue trials are initiated.
3. The registrant proposes to include the use of phosmet on cranberries in their revised labeling. The established tolerance for cranberries is supported by the available data (Registration Standard) and no need is seen for revoking this tolerance.
4. Residue data for the raw cottonseed used in two processing studies have been submitted and reviewed by RCB chemists. The decision on the need for an additional cottonseed processing study should await the additional information pertinent to one of the studies that the registrant intends to submit.

cc: M.Bradley, RF, circulate, Phosmet Reg. Std. F., PMSD/ISB
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