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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 22, 1997

MEMORANDUM

SUBJECT: Review of Acceptability of Reentry Study Submitted to Support the Reregistration of Carbofuran (MRID No. 434038-01); Dated August 31, 1994. (Case No. 0101; Chem. No. 090601) DP Barcode D213727

FROM: Jack Arthur, Environmental Health Scientist
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TO: Paul Lewis, Chemical Review Manager
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THRU: Susan Hummel, Branch Senior Scientist
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Susan Hummel

I. EXECUTIVE SUMMARY

- A. The study submitted to fulfill the requirements of Subdivision K Guideline Study §133-3 (Dermal passive dosimetry) is unacceptable.
- B. The Agency has conducted a surrogate analysis for reentry exposure and this analysis appears in the HED Chapter of the Carbofuran RED.
- C. The Agency agrees with the registrant's position in this submission that data call-in requirements for Subdivision K Guideline studies for §132-1(b) - Soil residue dissipation and §133-4 - Inhalation passive dosimetry are not necessary.

II. INTRODUCTION:

SRRD has requested that HED review the above referenced reentry exposure study for Subdivision K Guideline acceptability as required to support the reregistration of Carbofuran. Carbofuran is an insecticide and nematocide registered for a variety of food and non-food crops. This submission was made in response to a data call-in of March 9, 1992, which requested data from the following reentry guideline studies:

- §132-1(a) - Foliar residue dissipation;
- §132-1(b) - Soil residue dissipation;
- §133-3 - Dermal passive dosimetry; and,
- §133-4 - Inhalation passive dosimetry.

III. DETAILED CONSIDERATIONS:

In 1985 and 1986, registrant-sponsored studies were conducted to measure the dissipation of dislodgeable foliar residues (DFRs) on corn at three sites; Minnesota, Missouri and California. A 1991 HED review of those studies resulted in their rejection, for reasons that included lack of meteorological data, unexplained variations in DFRs, and certain other missing QA/QC data^{1,2}.

The 1992 data call-in for the four studies listed above, envisioned a new field study for 132-1(a), conducted in conformance with Agency guidelines, that would overcome the shortcomings of the previously performed studies, as well as new field studies to satisfy 132-1(b), 133-3 and 133-4.

Under a cover letter dated October 11, 1994, FMC submitted the document subject to this review to fulfill the data call-in requirement for the §133-3 dermal passive dosimetry study. The registrant relies on the data from the previously performed (Agency-rejected) DFR studies to satisfy requirements for 132-1(a), and rejects the need for 132-1(b) and 133-4, stating that carbofuran is not highly volatile, and reentry does not involve deliberate contact with the soil.

IV. CONCLUSIONS:

The submission made by the registrant to fulfill the data call-in requirement for §133-3 is not acceptable. The main reasons for its rejection is that the submission is not based on an actual concurrent reentry dermal dosimetry study conducted under Agency guidelines. Rather, the submission builds a surrogate reentry exposure scenario based on results from the original flawed DFR studies and on assumed activities and transfer factors. The Agency has performed a surrogate analyses of reentry exposure for the HED Chapter of the Carbofuran RED. The registrant has an opportunity to respond to the Agency's analysis in the reregistration process.

V. REFERENCES

1. EPA Memorandum from Peg Perreault (HED) to Lois Rossi (SRRD): In Depth Review of Postapplication/Reentry Data Submitted to Support the Reregistration of Carbofuran (HED Project #0-1053). Dated June 7, 1991.
2. Versar Final Report: Review of Carbofuran and 3-Hydroxy Carbofuran Dislodgeable Foliar Residue Studies. EPA Contract No. 68-D9-0166. Task No. 2-37. Submitted May 16, 1991.

cc: RDI:SVH:10/22/97
HED/CEB2/JA:811E:CM#2:305-4075
Jack Arthur,
Chemical File