MEMORANDUM

SUBJECT: Dicofol Confidential Statement of Formula and Revised Certified Limits
EPA Reg. No. 707-107 Kelthane Technical
(Accession No. 258054; RCB No. 1137)

FROM: Susan V. Hummel, Chemist
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Edward Allen, PM#12
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Rohm and Haas has submitted a revised Confidential Statement of Formula and revised Certified Limits for their product, EPA Reg. No. 707-107, Kelthane Technical (83.0% dicofol), containing <2.5% DDT-r. These new certified limits are listed in the Confidential Appendix.

The Certified Limits submitted are unacceptable. An average of 7.5% of the technical is reportedly unidentified, and the analytical method used is not identified, nor is it submitted. We reiterate that each component present at a level above 0.1% and each DDTr must be identified (S. Hummel, 4/9/85, 3/20/85, 3/15/85). Each of these components must have a certified limit. We reiterate that the analytical method used must be identified and submitted for review, along with raw data sheets and sample chromatograms (S. Hummel, 4/9/85, 3/20/85).

Product Chemistry data gaps for Kelthane Technical have been addressed in our memos of 4/9/85, 3/20/85, and 3/15/85 (S. Hummel). None of the other product chemistry data gaps are addressed in this submission. These data gaps (61-1, 61-2, 62-1, 62-2, and 62-3) are all still outstanding. Rohm and Haas has not responded to any of the deficiencies in our recent reviews (S. Hummel, 4/9/85, 3/20/85, 3/15/85).
Conclusions

The Certified Limits submitted are unacceptable. An average of 7.5% of the technical is reportedly unidentified, and the analytical method used is not identified, nor is it submitted. Each component present at a level above 0.1% and each DDTr must be identified. Each of these components must have a certified limit. The analytical method used must be identified and submitted for review, along with raw data sheets and sample chromatograms.

None of the other outstanding product chemistry data gaps are addressed in this submission. These data gaps (61-1, 61-2, 62-1, 62-2, and 62-3) are all still outstanding. Rohm and Haas has not responded to any of the deficiencies in our recent reviews.

Recommendations

Rohm and Haas should be advised to submit the required Product Chemistry data.


RD: EZ: 7/29/85; RDS: 7/29/85
The material not included contains the following type of information:

- Identity of product inert ingredients
- Identity of product impurities
- Description of the product manufacturing process
- Description of product quality control procedures
- Identity of the source of product ingredients
- Sales or other commercial/financial information
- A draft product label
- The product confidential statement of formula
- Information about a pending registration action
- FIPRA registration data
- The document is a duplicate of page(s) ________
- The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.