CONFIDENTIAL MEMORANDUM

SUBJECT: Dicofol - Request for Analyses
Quality Assurance Plan

FROM: Susan V. Hummel, Chemist
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THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (ST-769)

TO: Elizabeth Leovey
Quality Assurance Officer
Exposure Assessment Branch
Hazard Evaluation Division

and

Don Marlow, Chief
Chemical Operations Branch
Benefits and Use Division

RCB has requested that BUD analyze dicofol technicals from both registrants, Rohm and Haas and Makhteshim-Agan (memo of S. Hummel to L. Schnaubelt, 9/19/86). Subsequent to the original request, Kelthane Technical, manufactured by Rohm and Haas has been canceled. This memo defines the request for analyses and transmits the QA plan for the project.

TITLE: Analysis of Dicofol Technical

I. PURPOSE.

Analyses of Kelthane Technical and Mitigan Technical are being requested by Susan Hummel, RCB, to support the Special Review of dicofol. A requirement of the conclusion of the Special Review was that the registrants reduce the amount of DDT related impurities (DDTr) in their technicals to 2.5% immediately, and to 0.1% within 2 years. Recent data indicate that additional DDTr impurities have been identified, and that technicals from both registrants may contain greater than 2.5% DDTr.
The objectives of the project are fourfold.

A. Does Mitigan Technical contain unreported impurities?

B. Compare the composition of Kelthane and Mitigan Technicals. (presence/absence of peaks at a given retention time, relative peak heights)

C. Quantitate one sample of each technical.

D. Generate Ultra Violet and Mass Spectra of each DDTr impurity.

The data generated will be compared to the results obtained by the registrants, and may indicate that further action is required against Makhteshim-Agan. If BUD can ascertain and verify that Mitigan Technical contains greater than 2.5% DDTr, this information may be used for the cancellation of Mitigan Technical. RCB will use the spectra generated to attempt to identify each impurity in dicofol technicals.

II. SAMPLE DESCRIPTION

COB/BUD has already received samples submitted to the Agency by Rohm and Haas. These samples include the following.

Kelthane Technical, Batch 1255, 5 g.
Copy of Rohm and Haas analysis included.

COB/BUD has already received an enforcement sample of Mitigan Technical.

RD has requested that Makhteshim-Agan supply COB/BUD with standards of each impurity identified in Mitigan Technical.
III. CHAIN OF CUSTODY

COB/BUD should keep records of the chain of custody of the samples.

IV. METHODOLOGY

COB/BUD has received the three analytical methods to be used in this project. A brief description of these methods follows.

Rohm and Haas HPLC method

Makhteshim-Agan Method
V. QUALITY ASSURANCE

For Objectives A and B, duplicate injections of one solution of each technical should be made, with a solvent blank injected between each sample. Both methods should be used for each sample.

For objective C, five injections from one solution of each technical should be made.

For objective D, one sample of each technical should be analyzed by GC/MS with a solvent blank injected between the two technicals.
VI. SAFETY PRECAUTIONS
No unusual safety precautions are necessary for this project.

VII. FINAL REPORT

The final report should be routed to Susan V. Hummel, RCB. The report should include chromatograms generated for each sample or standard mixture, tabulations of each chromatogram including retention time, peak area, area %, and quantitation from standards (for Objective C). The composition of the technical should be expressed as % composition. The results from five samples of each technical should be summarized in a table, with the average, standard deviation, and relative standard deviation (precision) reported.

The report should also include the spectra generated for Objective D. Graphic format is preferable. Mass spectral peaks should be labeled with nominal masses. In addition to the graphic presentation of mass spectra, tabulation of the mass spectra would be helpful.

cc: R.F., S. Hummel, dicofol S.F., dicofol S.R.F., B. Kapner (SRB/RD), PMSD/ISB
RDI: EZ: 10/15/86; RDS: 10/15/86
TS-769: RCB: SVH; svh: RM810; CM#2: 10/20/86