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

PMSD/ISB
0190-E

JAN 21 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: 010501 Amendment - Mitigan Technical (Dicofol)
Reduction of DDTr
(Accession No. 259801, RCB No. 136)

FROM: Susan V. Hummel, Chemist
Special Review Section II
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Susan V. Hummel

THRU: Edward Zager, Section Head
Special Review Section II
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Hazard Evaluation Division (TS-769)

E. Zager

TO: Bruce Kapner, PM-70
Special Review Branch
Registration Division (TS-767)

and

Edward Allen and Jay Ellenberger PM#12
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Makhteshim-Agan (America), Inc. submits Product Chemistry Data for their product Mitigan Technical (EPA Reg. No. 11603-26) (formerly Acarin Technical), in response to the EPA Amended Notice of Preliminary Determination Concluding Special Review of Pesticide Products containing Dicofol (FR 50 pp 33007-33016, August 15, 1985). Mitigan Technical contains 88% dicofol [1,1-bis(chlorophenyl)-2,2,2-trichloroethanol].

Previously submitted product chemistry data have been reviewed in our memos of 6/18/84 (W. Boodee, Accession No. 253539) and 9/21/84 (W. Boodee, Accession No. 072724), 2/25/85 (S. Hummel, Accession No. 256070, RCB No. 500), 3/20/85 (S. Hummel, Accession No. 257035, RCB No. 727), and summarized in our memo of 4/9/85 (S. Hummel). Outstanding data gaps were 61-1, 61-2, 62-1, 62-2, 62-3, 63-8, and 63-9 (S. Hummel, 4/9/85).

\$61-1 Product Identity and Composition

See Confidential Appendix. No further information is required.

§61-2 Description of Beginning Materials and Manufacturing Process

See Confidential Appendix. Sources for beginning materials are given. The manufacturing process is the same as the one discussed in our review of 2/25/85 (S. Hummel), although the [REDACTED] have been identified. No further information is required.

§61-3 Discussion of the Formation of Impurities

See Confidential Appendix. No additional data are required for this section.

§62-1 Preliminary Analysis.

Analyses of five separate batches were submitted. The results of these analyses are found in the Confidential Appendix. The chromatograms submitted demonstrate that there are no unidentified peaks present at levels greater than 0.1%. The HPLC method used is discussed §62-3. The method used for the determination of one impurity was not submitted. Calculations were not included. A calibration curve including several levels of each standard should be submitted. This remains a data gap. The analytical method for the one impurity should be submitted. Calculations and a calibration curve should be submitted.

§62-2 Certification of Limits

See Confidential Appendix. Upper and lower certified limits for the active ingredient were submitted. An upper certified limit was submitted for total DDT-r impurities. This is acceptable, TOX and EAB considerations permitting. No further data are required.

§62-3 Analytical Methods to Verify Certified Limits

Two analytical methods were used [REDACTED]

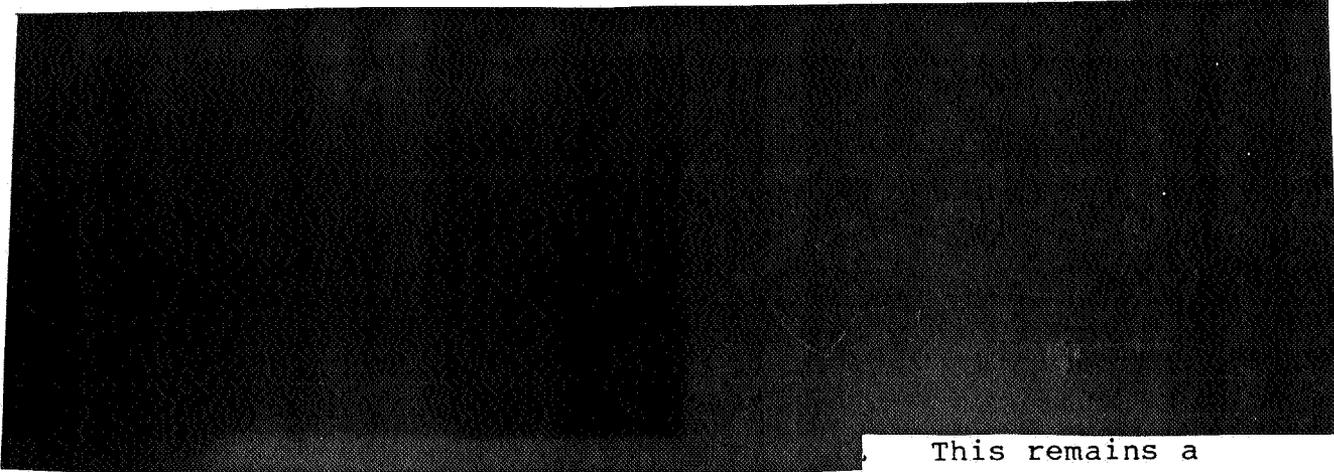
[REDACTED] This method was not submitted. A copy of this method is needed, including validation data.

"Determination of dicofol and impurities by high pressure liquid chromatography", Accession no. 259801.

[REDACTED]

INFORMATION WHICH MAY REVEAL QUALITY CONTROL PROCEDURES IS NOT INCLUDED

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This remains a

data gap.

Physical and Chemical Characteristics

Much of the data submitted on physical and chemical characteristics of dicofol is repeated from earlier submissions. Only additional data will be discussed in this review.

§63-8 Solubility

The solubility of dicofol in water was reported to be 0.8 ug/mL. This value came from a published report in which purified dicofol from Rohm and Haas was analyzed [P. R. Walsh and R. A. Hites, "Dicofol Solubility and Hydrolysis in Water," Bull. Environm. Contamin. Toxic., 22, 305-311 (1979)]

The solubility of dicofol in other solvents (n-hexanol, xylene, dichloromethane, methanol, acetone, and ethyl acetate) was reported as "greater than 100 g / 100 g solvent." The actual solubility should be determined. This data gap is still outstanding.

§63-9 Vapor Pressure

The vapor pressure of p,p'-dicofol and p,p'-Cl-DDT were determined by method CG-1600 and CS-1600 (Gas Saturation Method). A description of the method and sample chromatograms are included.

The vapor pressures were reported as follows:

	<u>Pa x 10⁻⁵</u>	<u>mm Hg x 10⁻⁷</u>
p,p'-dicofol @25°C	18.24	13.68
@34°C	40.61	30.46
p,p'-Cl-DDT @25°C	19.25	14.44
@34°C	85.50	64.13

No further information is required.

Conclusions

1. The following Product Chemistry data gaps for Acarin Technical are still outstanding.

§62-1 Preliminary Analysis. The method used for identification and quantification of the one impurity must be submitted, along with validation data. Calculations and a calibration curve from the HPLC method should also be submitted.

§62-2 Certification of Limits. An upper certified limit was submitted for total DDT-r. This is acceptable, TOX and EAB considerations permitting.

§62-3 Analytical Methods to Verify Certified Limits. A copy of [REDACTED] including validation data, should be submitted. Calculations and a calibration curve from the HPLC method should also be submitted.

§63-8 Solubility. The solubility of dicofol in solvents other than water must be submitted. ("Greater than 100g/100g solvent" is not acceptable.)

2. No residue chemistry data have been received. These data gaps are still outstanding.

Recommendations

The data gap tables should be revised in accordance with our conclusions. This information should be made a part of the registration standard. Makhteshim-Agan should be informed of our conclusions, and advised to submit the data to fill the data gaps.

Attachment 1: Confidential Appendix: attached to copies to S. Hummel, W. Boodee (Reg Std. File) dicofol S.R.F., PMSD/ISB

cc: R. F., circo, S. Hummel, dicofol S.F., dicofol S.R.F., W. Boodee (Reg. Std. File) B. Kapner (SRB), PMSD/ISB

RDI:EZ:1/16/86:RDS:1/16/86

TS-769:RCB:SVH:svh:RM810:CM# 2:x73043:1/16/86

INFORMATION WHICH MAY REVEAL QUALITY CONTROL PROCEDURES IS NOT INCLUDED

Dicofol residue chemistry reviews

Page _____ is not included in this copy.

Pages 5 through 8 are not included in this copy.

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
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
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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.
