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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mitigan Technical, EPA Reg. No. 11603-26
Additional Product Chemistry Data in response
to PD4 and EPA letter of 3/14/86
[Accession No. 264826, RCB No. 1435]

FROM: Susan V. Hummel, Chemist
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Susan V. Hummel

THRU: Edward Zager, Section Head
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Residue Chemistry Branch
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TO: Dennis Edwards, PM#12
Insecticide Rodenticide Branch
Registration Division (TS-767)

and

Bruce Kapner
Special Review Branch
Registration Division (TS-767)

The dicofol PD4 (5/29/86) required that the registrants amend their dicofol product registrations, reducing the amount of DDT related impurities (DDTr) to 2.5% of the amount in the technical. Makhteshim-Agan submitted the required amendment in October, 1985. However, the product chemistry data needed to support the amendment were not complete (See S. Hummel review of 1/21/86, Accession No. 259801, RCB No. 136). The deficiencies in the submission were as follows.

1. The method used for the identification and quantification of one of the impurities must be submitted, along with validation data. Calculations and a calibration curve from the HPLC method [used for the analysis of the technical] should also be submitted. (§62-1, 62-2, 62-3)
2. The solubility of dicofol in solvents other than water must be submitted. (§63-8)

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The registrant was informed of these deficiencies by letter on 3/14/86, and given up to one year to respond to the deficiencies. The response to this letter (S. Hummel review of 1/26/86) is the subject of this review. However, more recent submissions are also pertinent. The revised analytical method and additional information on the composition of Mitigan Technical are discussed in the Confidential Appendix.

§63-8 Solubility

The solubility of p,p'-dicofol (98% pure) was determined in several organic solvents at 20C.

<u>Solvent</u>	<u>Solubility (g/100mL solvent)</u>
dichloromethane	260
methanol	275
xylene	135

The method for the determination of the solubility was given. No further information is needed. This data gap is filled.

CONCLUSIONS

1. The analytical method and calculations have been clarified. However, we note differences in the composition being reported in different submissions. Therefore, five additional analyses (§62-1) and revised certified limits (§62-2) are needed. The analytical method (§62-3) should be resubmitted, incorporating changes as used in more recent submissions. We request that complete calculations be included in all submissions. See Confidential Appendix for complete discussion.

2. The solubility of dicofol in solvents other than water is acceptable. This data gap is filled.

RECOMMENDATION

We recommend that the registrant be informed of our conclusions and advised to submit the data requested. Our entire review should be sent to the registrant. This review should be held until our review of Makhteshim-Agan's two more recent submissions are completed (still not formally submitted). Upon review of those submissions, our conclusions may be revised.

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

cc: R.F., Circu, S. Hummel, Dicofol S.F., Dicofol S.R.F, Dicofol Reg. Std. F., L. Turner (EEB), R. Hitch (EAB), TOX, PMSD/ISB
RDI:EZ:11/18/86:RDS:11/18/86
TS-769:RCB:SVH:svh:RM810:CM#2:11/18/86

Makhteshim-Agan responded to the EPA letter of 3/14/86 (S. Hummel review of 1/26/86) in their submission of 9/10/86 (Accession No. 264826). Subsequent to our review of 1/26/86, RCB became aware of the possibility of other DDT related impurities in technical dicofol which had not previously been reported by the registrants. Makhteshim-Agan was then required to perform additional analyses of Mitigan Technical to determine if any of these additional impurities were present (EPA letter of 9/26/86).

Additional submissions have been made in response to the EPA letter of 9/26/86. The registrant's initial submission to this letter was made 10/28/86 (Accession No. 265849, See S. Hummel review of 11/12/86). Subsequently, Maketeshim-Agan made an additional submission, on 11/7/86, not yet formally received for review in RCB. A third submission is expected this week. The last two submissions will be reviewed together in a separate memo.

The subject of this review, the Makhteshim-Agan submission of 9/10/86 (Accession No. 264826) includes a revised copy of

[REDACTED] The submission also includes a clarification of the calibration and calculation procedures. Additionally, the solubility of p,p'-dicofol is reported in three solvents other than water. (See non-confidential portion of this review.)

§62-1 Preliminary Analyses

No analyses are included in this submission. We previously questioned the calculation of the results included in this section. The calculations have been clarified (See §62-3). However, subsequent submissions have shown differing levels of the active ingredients (o,p'- and p,p'- dicofol), and the presence of additional impurities previously unreported (and not completely identified). Agan stated that this was due to differences between the pilot plant and full scale plant operation, rather than a change in the manufacturing process (Telecon, 11/12/86). Therefore, additional data are needed for this section. The analysis of an additional five batches are required. These batches should be representative of the variability of the composition of Mitigan Technical. Complete calculations should be included.

CONFIDENTIAL APPENDIX 1435
to RCB Science Review No.

(Contains FIFRA Trade Secret/CBI Information)

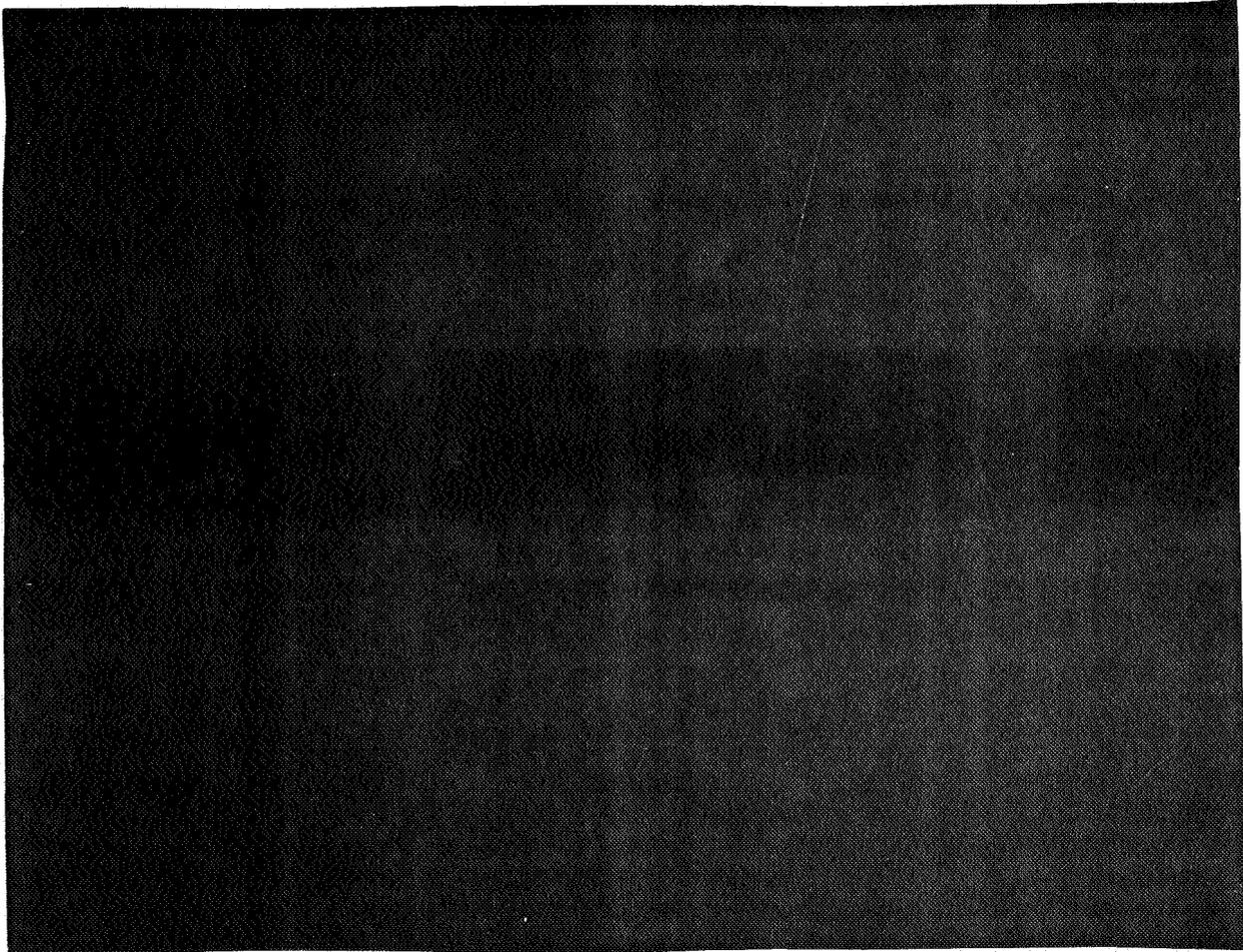
INFORMATION WHICH MAY REVEAL QUALITY CONTROL PROCEDURES IS NOT INCLUDED

§62-2 Certified Limits

Revised Certified Limits are needed for the reasons discussed above in §62-1.

§62-3 Analytical Method to Verify Certified Limits

The analytical method has not changed. However, the description of the analytical method has been clarified. A complete description follows.



The analytical method should be resubmitted with the appropriate changes. We request that complete calculations be included in all future submissions.

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