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

May 18, 1989

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mitigan Technical, EPA Reg. No. 11603-26  
Additional Product Chemistry Data in response to  
EPA letter of 1/14/87  
[MRID Nos. 402972-01, DEB No. 2881]

FROM: Susan V. Hummel, Chemist  
Special Registration Section II  
Dietary Exposure Branch  
Health Effects Division (H7509C) *Susan V. Hummel*

THRU: Francis B. Suhre, Acting Section Head  
Special Registration Section II  
Dietary Exposure Branch  
Health Effects Division (H7509C) *Francis B. Suhre*

TO: Dennis Edwards, PM#12  
Insecticide Rodenticide Branch  
Registration Division (H7505C)

Makhteshim-Agan (America) Inc., submits additional product chemistry data in response to our reviews of 11/12/86, 11/18/86, and 12/15/86 (S. Hummel, DEB Nos. 1570, 1435, and 1673). The results of our review were communicated to the registrant in EPA letter 1/14/87.

The dicofol PD4, which concluded the Special Review of dicofol (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 of DDTr in the technical. By 3/89, the registrants were required to reduce the amount of DDTr in their products to 0.1% of the amount of DDTr in their technical. Makhteshim-Agan submitted the required amendment to reduce the amount of DDTr in their technical to less than 2.5% in October, 1985, and additional data on later dates. This submission is the most recent data to support the reduction of DDTr to less than 2.5% of the technical product.

Deficiencies in the product chemistry data supporting the reduction of DDTr to 2.5% were:

1. Sufficient data are submitted to enable RCB to conclude that Mitigan Technical appears to contain less than 2.5% DDTr. However, additional data are needed.

2. The analyses reported in these submissions do not include analyses for all components of Mitigan Technical. Additionally, we note differences in the composition being reported since the original submission which reported the change in the manufacturing process to produce dicofol with less than 2.5% DDTr. 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.

3. Additional identification of the components of Mitigan Technical is needed. (See Confidential Appendix 62-1 of our 12/15/86 review for discussion.)

Since the current requirement, as of 3/89, is that dicofol technical products contain less than 0.1% DDTr, this submission will not be discussed in detail.

Makhteshim-Agan submitted six additional analyses (Section 62-1), along with means for each component; revised certified limits (Section 62-2); and a revised analytical method for dicofol and impurities. Details of additional attempts to identify additional impurities were included, along with proposed structures of some additional impurities. Calculations were also included. The manufacturing process and discussion of the formation of impurities were also resubmitted. The locations of the additional information in the registrant's submission (MRID No. 402972-01) are as follows:

62-1	pp 20-22 of 190
62-2	pp 6-7 of 190
62-3	pp 23-190

#### CONCLUSIONS

The additional data provided allow us to conclude that Makhteshim-Agan is capable of producing dicofol with less than 2.5% DDTr. However, this is now moot, since dicofol products are now required to contain less than 0.1% DDTr (based on the concentration DDTr in the technical product). If the registrant has not already done so, Product Chemistry data, demonstrating that the registrant can meet the requirement for less than 0.1% DDTr, are required.

RECOMMENDATION

We recommend that the registrant be informed that the data requirements for the 2.5% DDTr dicofol technical are now satisfied. The registrant should also be aware that the current requirement is that dicofol technical products contain less than 0.1% DDTr. Product Chemistry data demonstrating this are now required.

cc: R.F., Circu, S. Hummel, Dicofol S.F., Dicofol Reg. Std. F., PMSD/ISB, *R. Schmitt*.

RDI:FBS:05/18/89:EZ:05/18/89

H7509C:DEB:SVH:svh:RM810:CM#2:05/18/89

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