May 18, 1989

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
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THRU:  Francis B. Suhre, Acting Section Head
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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 dicofo1 PD4, which concluded the Special Review of
dicofo1 (5/29/86), required that the registrants amend their
dicofo1 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.

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