

IRB/TSS Precautionary Labeling Review

12/15/86

TO: PM-12

SUBJECT: 707-ENG  
Kelthane Technical  
Rohm and Haas Company  
Philadelphia, PA 19105

In TSS: 12-15-86 (Expedite)  
Record #: 186748  
Action #: 166

FORMULATION: Technical Kelthane.

Active Ingredient:  
Dicofol.....89%  
Inert Ingredients.....11%  
(Impurities in this technical dicofol contain [redacted])  
[redacted]

BACKGROUND: This is a follow-up review of Technical Kelthane registration application. Registrant has now adopted the Cite-All method of data support. The only other technical for dicofol is Mitigan Dicofol Technical (EPA Registration Number 11603-26), manufactured by Makhteshim-Agan (America) Inc. PM-12 wants to know if there is any reason why this registration should be granted.

COMMENTS:

- 1. A comparison<sup>not</sup> of the CSF of the two technicals, Technical Kelthane and Mitigan Dicofol Technical has indicated that the two products are quite similar in composition, in that the DDTr and non-DDTr impurities are largely the same. Sue Hummel of Residue Chemistry Branch is of the opinion that the [redacted] in Mitigan Dicofol Technical are also largely the same as some inerts in new Technical Kelthane.
- 2. Given the similarity in composition of the two technicals, the acute toxicity assessment of Kelthane Technical should be the same as Mitigan Dicofol Technical.
- 3. Precautionary labeling and signal word on proposed Kelthane Technical label should be revised to be consistent with Mitigan Dicofol Technical label.

INFORMATION WHICH MAY REVEAL FORMULATION IMPURITIES IS NOT INCLUDED

4. Note to PM: In the Mitigan Dicofol Technical jacket, there is no evidence of any acute toxicity data ever having been submitted or reviewed, so IRB/TSS cannot comment on appropriateness of signal word or precautionary labeling. We can only suggest that Kelthane Technical label should be similar to Mitigan label since registrant is using Cite-All method of data support and Mitigan is the only other registered technical dicofol product.

Rita Kumar  
IRB/TSS

*Rita Kumar*