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

MAR 3 1988

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCE

MEMORANDUM

SUBJECT: EPA Reg. No. 707-203
Rohm and Haas Kelthane Technical
Product Chemistry Data supporting
Amendment to reduce DDTr impurities to 0.1%
[MRID No. 405045-01, RCB No. 3388]

FROM: Susan V. Hummel, Chemist
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THRU: Edward Zager, Section Head
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Registration Division (TS-767)

This review is being EXPEDITED at the request of E. Tinsworth, Director, Registration Division. (See 2/17/88 memo from E. Tinsworth to A. Barton, Acting Director, Hazard Evaluation Division.) The expedited due dated is 3/4/88.

Rohm and Haas Company submits an amendment to their registration for Kelthane Technical, containing 91% dicofol [1,1-bis(chlorophenyl)-2,2,2-trichloroethanol], reducing the levels of DDTr impurities in Kelthane Technical to 0.1%. This amendment was required by be submitted and approved by 3/30/88 by the PD4/Notice of Intent to Cancel (51 FR 19508, 5/29/86), which concluded the Special Review of dicofol. A Special Review of dicofol was initiated in 1984 because of environmental concerns about DDT and related contaminants (collectively referred to as DDTr) in technical dicofol. A Registration Standard for dicofol was issued on 12/20/83. Product Chemistry data supporting the amendment were submitted. A revised label, increasing the percentage of active ingredient was also included.

Tolerances for dicofol [1,1-bis(p-chlorophenyl)-2,2,2- trichloroethanol] have been established (40 CFR 180.163) on a variety of crops. The tolerances are expressed in terms of dicofol, per se. No tolerances have been established on meat,

milk, poultry, or eggs. No food or feed additive tolerances have been established. A tolerance reassessment has not been completed because of outstanding metabolism data gaps from the dicofol Registration Standard.

CONCLUSIONS

1. Rohm and Haas has shown that they can produce dicofol technical containing less than 0.1% DDTr. Ad certified limit of 0.1% was established for DDTr.

2. Information on four starting materials is still needed (Section 61-2(a)). Clarification of the identification of one beginning material is needed (Section 61-2(a) and (b)). See Confidential Appendix Sections 61-2 (a) and)b) for further information. The registrant should note that the names and addresses of suppliers and the specifications of all beginning materials including solvents and catalysts must be submitted. This deficiency is minor. The amendment can be approved, contingent on the resolution of this deficiency.

3. Other Product Chemistry data are adequate at this time. Revised Product Chemistry data will be needed within 6 months after commercial production is begun. Any product chemistry data which have changed as a result of the change to commercial production, including physical and chemical properties, must be submitted at that time.

4. Generic residue chemistry data requirements for dicofol remain outstanding. Due dates for responses to residue chemistry data deficiencies are given in RD letter of 2/22/88).

RECOMMENDATIONS

We recommend for the proposed amendment, contingent on the resolution of the deficiency outlined in Conclusion 2. We recommend that the registrant be informed of our conclusions and advised to submit the required data, as outlined in Conclusion 2.

We recommend that the registrant be required to submit revised Product Chemistry data within 6 months of beginning commercial production, and be required to submit the required Residue Chemistry data within the time frames in Registration Division letter of 2/22/88.

DETAILED CONSIDERATIONS

Proposed Use

Kelthane technical is to be used for formulation into end use products intended for use on apples, pears, crabapples, quince, citrus, cotton, dry beans, succulent beans, cotton,mint, grapes, strawberries, walnuts, filberts, pecans, chestnuts, hickory nuts, tomatoes, peppers, hops, melons, cucumbers, squash, cantaloupes, watermelons, pumpkins, lawn and turf grasses, ornamental, flowers, nursery stock, shade trees, and around buildings.

RCB Comment

Rohm and Haas has not submitted residue data for filberts, chestnuts, hickory nuts, tomatoes, peppers, or hops. These uses should be removed from the label until valid residue data are submitted.

PRODUCT CHEMISTRY DATA

Product Chemistry data (Series 61 and 62) have been submitted for Kelthane Technical (Kelthane Technical B) from the pilot plant. Series 63 Product Chemistry data (Physical and Chemical Characteristics) were not submitted. Revised Product Chemistry data will be needed from samples from commercial production within 6 months after beginning commercial production, including any Series 63 Product Chemistry data required on the TGAI, which have changed as result of the revised manufacturing process.

61-1 Product Identity and Disclosure of Ingredients

A. Product Identity

Product Name: Kelthane Technical

Other Name: Kelthane Technical B

Generic Name: dicofol (p,p'-dicofol and o,p'-dicofol)

Empirical Formula: $C_{14}H_9Cl_5O$

Molecular Weight: 370.47

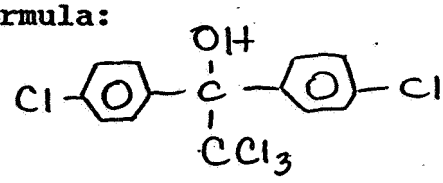
p,p'-dicofol:

Chemical Abstracts name: benzenemethanol, 4-chloro-α-(4-chlorophenyl)-α-(trichloromethyl)

Chemical Abstracts Number: 115-32-2

Other Chemical Names: 1,1-bis-(4-chlorophenyl)-2,2,2-trichloroethanol

Structural Formula:



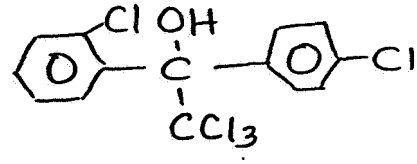
o,p'-dicofol:

Chemical Abstracts name: benzenemethanol, 2-chloro-α-(2-chlorophenyl)-α-(trichloromethyl)

Chemical Abstracts Number: 10606-46-9

Other Chemical Names: 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol

Structural Formula:



RCB Comment

The submitted information is adequate. No further information is required.

B. Confidential Statement of Formula

The typical composition of Kelthane Technical is presented in the Confidential Appendix (Section 61-1).

RCB Comment

A new confidential statement of formula, based on production runs will be needed for Kelthane Technical within 6 months after commercial production begins.

61-2 DESCRIPTION OF BEGINNING MATERIALS AND MANUFACTURING PROCESS

A. Beginning Materials

Information on the beginning materials is discussed in the Confidential Appendix, Section 61-2.

RCB Comment

Suppliers and specifications for [redacted] materials are needed. See the Confidential Appendix for more information.

B. Manufacturing Process

Information on the Manufacturing Process is discussed in the Confidential Appendix, Section 61-2.

RCB Comment

Verification of the identity of one beginning material is needed. See Confidential Appendix for more information.

61-3 THEORETICAL DISCUSSION OF FORMATION OF IMPURITIES

This discussion is found in the Confidential Appendix, Section 61-3. No further information is required.

62-1 PRELIMINARY ANALYSES

Five samples were analyzed. The results of these analyses is found in the Confidential Appendix, Section 62-3. The analytical method used is discussed in 62-3. Additional attempts to further identify and confirm the identity of impurities has been done.

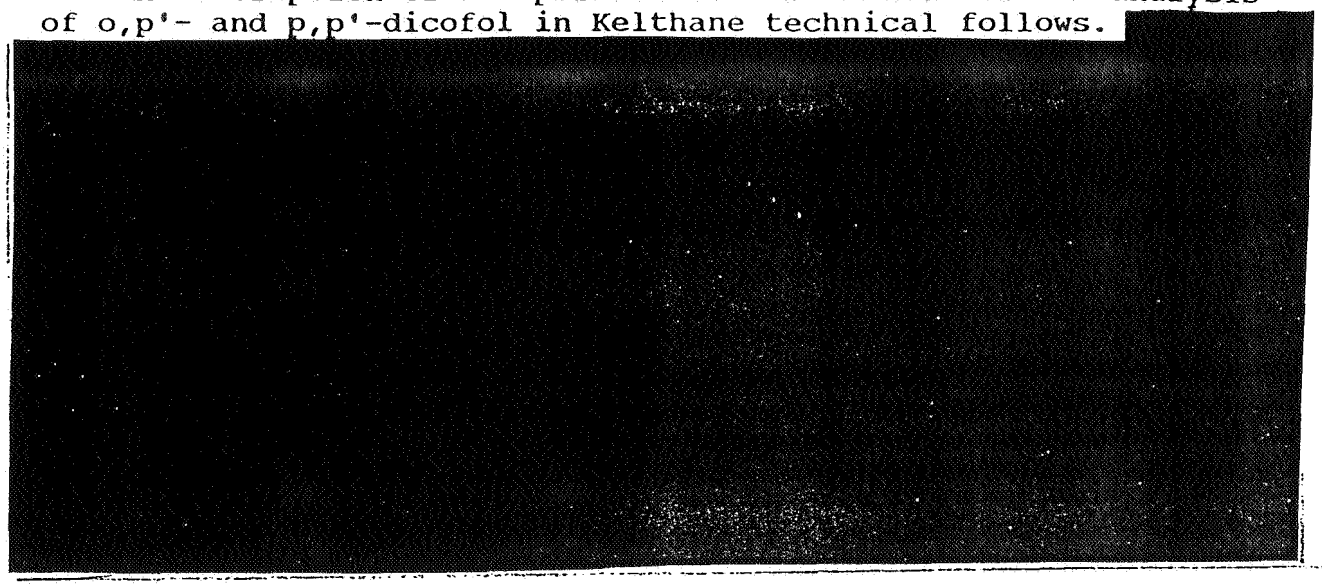
62-2 CERTIFIED LIMITS

Certified limits are found in the Confidential Appendix, Section 61-1. Rohm and Haas states that the certified limits are based on Rohm and Haas manufacturing experience in the manufacture of Kelthane Technical and the variability normally observed. Rohm and Haas has certified a limit of 0.1% for DDTr. No further information is required.

62-3 ANALYTICAL METHODS TO VERIFY CERTIFIED LIMITS

Four analytical methods were submitted for the analysis of Kelthane Technical. All four methods are required for the analysis of Kelthane Technical. The four methods involve the use of two different columns, four different mobile phases, and three different detectors.

A description of the portion of one method for the analysis of o,p'- and p,p'-dicofol in Kelthane technical follows.



Methodology for the analysis of specific impurities or groups of impurities are discussed in the Confidential Appendix Section 62-3.

RCB Comment

The methodology submitted is adequate, although one method for impurities is not completely described. (See Confidential Appendix Section 62-3).

63 PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical and chemical characteristics were not submitted with this amendment. Data for this section were submitted earlier and summarized in our memo of 11/21/86 (S. Hummel, RCB No. 1547). The melting point range for Kelthane Technical was given in our memo of 2/17/87 (S. Hummel, RCB No. 1878)

RCB Comment

New Product Chemistry data on physical and chemical characteristics are needed for the TGAI within 6 months after beginning commercial production, for any physical and chemical characteristics which changed as a result of the new manufacturing process.

RESIDUE CHEMISTRY DATA

No residue chemistry data were included in this submission. Numerous Residue Chemistry Registration Standard data gaps remain outstanding. A letter in 3(c)2(B) format was recently sent to the registrant (RD letter of 2/22/88). Refer to our memos of 5/27/87 (S. Hummel, RCB No. 1869) and 10/19/87 (S. Hummel, 2578) for further discussions of the dicofol Residue Chemistry data gaps. Due dates were given in RD letter of 2/22/88.

Attachment: Confidential Appendix (12pp): Attached to
copies to : PM#12, R.F., S. Hummel, Dicofol Reg Std file (W. Boodee), dicofol special review file (S. Hummel), L. Turner (EEB), TOX, PMSD/ISB

cc: R.F., Circu, dicofol S.F., S. Hummel, Dicofol Reg Std file (W. Boodee), dicofol special review file (S. Hummel), B. Kapner (SRB/RD), K. Barbehenn (SIS), R. Hitch (EAB) L. Turner (EEB), TOX, PMSD/ISB
RDI:EZ:03/02/88:RDS:03/02/88
TS-769:RCB:SVH:svh:RM810:CM#2:03/03/88