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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 17 1987

MEMORANDUM

SUBJECT: EPA File Symbol 707-ENG
Rohm and Haas Kelthane Technical
Additional Product Chemistry Data
supporting New Product Application
[No Accession No., RCB No. 1878]

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TO: Dennis Edwards, PM#12
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and

Bruce Kapner
Special Review Branch
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Rohm and Haas Company submits additional product chemistry data to support their application for new product registration for Kelthane Technical, containing 89% dicofol [1,1-bis(chlorophenyl)-2,2,2-trichloroethanol]. The Rohm and Haas original application was reviewed in our memo of 11/21/86 (S. Hummel). Several deficiencies were identified. These deficiencies were communicated to the registrant by EPA letter of 12/5/86. This submission is the registrant's response to the EPA letter of 12/5/86. The deficiency will be repeated, followed by the registrant response, and our conclusions.

Deficiency 2

Further identification of Kelthane Technical is needed. We defer to TOX, EAB, and EEB on the quantitation of Kelthane Technical.

Registrant Response

Rohm and Haas agrees to conduct studies to further identify some of the impurities, and submit the results within six months of December 5, 1986.

RCB Conclusion on Deficiency 2

This will be adequate. We await the submission of these data. This deficiency is still outstanding.

Deficiency 3

A melting point range should be reported for this product. (§63-5)

Registrant Response

Rohm and Haas states that Kelthane Technical at room temperature is an extremely viscous glass and not a solid crystalline material. It has an apparent melting point range of 50-57C within which Kelthane Technical converts from a glassy solid to a flowing liquid.

RCB Conclusion on Deficiency 3

The registrant response is adequate. This deficiency is resolved.

Deficiency 4

The discrepancy between the vapor pressure reported on the Material Safety Data Sheet and that referenced in Accession No. 253158 should be explained.

Registrant Response

Rohm and Haas reports that the correct vapor pressure for Kelthane is 3.9×10^{-7} mm Hg. The origin of the value on the Material Safety Data Sheet (MSDS) is unknown.

RCB Conclusion on Deficiency 4

This deficiency is resolved.

Deficiency 5

Samples of Kelthane Technical and each impurity present at >0.1% should be submitted to Beltsville when the product is registered. (§64-1)

Registrant Response

Rohm and Haas indicates that they have submitted analytical standards of the majority of impurities present in Technical Kelthane to Beltsville. They agree to submit a sample of Kelthane Technical and any impurities not already submitted immediately after registration is granted.

RCB Conclusion on Deficiency 5

This will be acceptable. This deficiency remains outstanding.

Deficiency 6

Generic residue chemistry data requirements for dicofol are listed in the Registration Standard Guidance Package are applicable to this product. These data are due in December, 1986, as indicated in the Registration Standard Guidance Package.

Registrant Response

This submission did not address the residue chemistry data requirements. However, some of the required residue chemistry data were submitted on December 30, 1986.

RCB Conclusion on Deficiency 6

The residue chemistry data submitted on December 30, 1986 are currently in review in RCB. The review of these data is being expedited and is due in four months. We do note, however, that residue data have not been submitted for all crops and have not been submitted for all processed commodities. This deficiency remains.

CONCLUSIONS

Deficiencies 3 and 4 have been resolved in this submission. The registrant indicates that they will resolve Deficiency 2 by June 5, 1987, and Deficiency 5 immediately after registration. Data for Deficiency 6 are currently in review. However, residue data have not been submitted for all crops and for all processed commodities. The PM should take appropriate action.

RECOMMENDATIONS

We have no objection to the registration of Kelthane Technical, provided that deficiencies 2 and 5 are resolved within the time frame indicated by the registrant. We recommend that the PM take appropriate action regarding the residue and processing data which were not submitted.

cc: R.F., Circu, dicofol S.F., S. Hummel, Dicofol Reg Std
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RDI:EZ:02/17/87:RDS:02/17/87
TS-769:RCB:SVH:svh:RM810:CM#2:02/17/87