

10-13-95



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT 13 1995

MEMORANDUM

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Inhalation study on formulated Kathon products

TO: Marion Johnson
Product Manager (31)
SRRD (7508W)

FROM: Yung G. Yang, Ph.D. *Yung G. Yang 10/10/95*
Toxicology Branch II, Section II
Health Effect Division (7509C)

THRU: K. Clark Swentzel *K. Clark Swentzel 10/10/95*
Section Head, Section II
Toxicology Branch II, HED (7509C)

and

Karl P. Baetcke, Ph.D. *Karl P. Baetcke 10/11/95*
Acting Branch Chief
Toxicology Branch II, HED (7509C)

Chemical: 4,5-dichloro-2-n-octyl-3-(2H)-isothiazolone
Synonym: Kathon 287T
DP Barcode: D217277
Submission No.: S490284
Case: 192535
ID No.: 000707-00224
Caswell No.: 195C & 613C
Registrant: Rohm & Haas Company

Action requested: Review the possibility of citing a 90-day inhalation study conducted on a 30% product to satisfy the requirement for a 93-95% product (287T).

Background: The registrant submitted a 90-day inhalation study conducted on the C-9211M antifoulant, RH-287, (32.6%, a.i.) (MRID# 434875-01) and wished to use this study to satisfy the requirement for another product, 287T, (93-95%, a.i.).



Comment

The 90-day inhalation study (MRID# 434875-01), which was cited by the registrant and conducted on a 30% product (RH-287), estimated a NOEL of 0.00002 mg/l (0.02 mg/m³) and a LOEL of 0.00063 mg/l (0.63 mg/m³). The LOEL was based on histopathological changes seen in the nose and larynx (see attachment). The results suggested a severe respiratory toxicity was induced by the exposure of a 30% product. Assuming that a 93-95% product contains three times more active ingredient than a 30% product, a more severe toxicity will be expected during the exposure of a 93-95% product.

Conclusion

The 90-day inhalation study on a 30% product of Kathon **can not** be used to satisfy the requirement for a 93-95% product of Kathon. In addition, the TB II recommends the registrant to conduct an inhalation study on the technical material if it has not done so.