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

MAY 7 1992

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Kathon® 886F Microbicide: Two-Year Rat Chronic/ Carcinogenicity Study; Clarification of Why Test Material Incorporated into Drinking Water Rather than the Diet

TO: Jim Wilson
Product Manager (32)
John Lee/Valdis Goncarvos
Product Manager/PM Team Reviewer (31)
Registration Division (H7505C)

FROM: Linda L. Taylor, Ph.D. Linda Lee Taylor 4/30/92
Toxicology Branch II, Section II,
Health Effects Division (H7509C)

THRU: K. Clark Swentzel K. Clark Swentzel 5/6/92
Section II Head, Toxicology Branch II
Health Effects Division (H7509C)

and

Marcia van Gemert, Ph.D. Marcia van Gemert 5/6/92
Chief, Toxicology Branch II/HFAS/HED (H7509C)

Registrant: Rohm & Haas Company
Chemical: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one
Synonym: Kathon 886F Microbicide
Caswell No.: 195C
Submission No.: S416139
Case No.: 022081
DP Barcode: D177026
Identifying No.: 000707-00130
MRID No.: none
Action Requested: Please review letter of explanation. EXPEDITE

Comment: As requested (TB II memo dated 3/17/92), the Registrant has submitted a letter (dated 3/31/92) outlining the basis for the decision to perform the 2-year rat chronic toxicity/carcinogenicity study with the test material incorporated into the drinking water instead of the diet.

The Registrant stated that previous attempts to add the biocide to

animal feed resulted in poor and variable active ingredient recoveries, which is thought to be due to the binding of the active ingredients with, or their inactivation by, feed components. The decision not to gavage the animals was based on the irritant and corrosive properties of Kathon 886 F Microbicide. Additionally, the Registrant indicated that the active ingredients are stable and easily analyzed in drinking water, the desired dose levels can be administered, and the subchronic toxicity study, which was available for dose selection, incorporated the test material into the drinking water.

CONCLUSION

The Registrant has submitted justification for administering the test material via drinking water. The decision to incorporate the test material into the drinking water appears appropriate. Based on the criteria used to select the dose levels being used in the on-going rat chronic toxicity/carcinogenicity study (see TB II memo dated 3/17/92) and the justification (provided in the current submission) for administering the test material via the drinking water, the dose levels appear reasonable.