

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAY 7 1992

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. Mark Lay (4/30/92)
Toxicology Branch II, Section II,
Health Effects Division (H7509C)

K. Clark Swentzel

THRU:

K. Clark Swentzel

Section II Head, Toxicology Branch II

Health Effects Division (H7509C)

and

Marcia van Gemert, Ph.D. Mkauened 5/6/92 Chief Toxicol 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.: Submission No.:

S416139 022081

195C

Case No.: 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 <u>via</u> 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 ongoing 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 <u>via</u> the drinking water, the dose levels appear reasonable.