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

MAR 17 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Kathon® 886F Microbicide: Two-Year Rat Chronic/ Carcinogenicity Study; Dose Level Selection

TO: Jim Wilson
Product Manager (31)
Registration Division (H7505C)

FROM: Linda L. Taylor, Ph.D. Linda L. Taylor 3/9/92
Toxicology Branch II, Section II,
Health Effects Division (H7509C)

THRU: K. Clark Swentzel K. Clark Swentzel 3/10/92
Section II Head, Toxicology Branch II
Health Effects Division (H7509C)

and

Marcia van Gemert, Ph.D. Marcia van Gemert 3/12/92
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
Project No.: 2-1308
Caswell No.: 195C
Record No.: none. Case 022081; Submission: S410641
DP Barcode: D173779
Identifying No.: 000707-00130
MRID No.: none
Action Requested: Please review letter.

Comment: The Registrant has submitted a letter (dated 11/8/91) informing the Agency of the basis for the dose levels used in an on-going 2-year rat chronic toxicity/carcinogenicity study.

The Registrant states that due to the dose-related intrinsic irritancy property of this biocide, the concentrations that can be tested are limited. From the information provided, increasing concentrations of the test material in the drinking water lead to decreases in intake of water; the higher the concentration in the water, the lower the water intake, which limits test material intake also. Based on this consideration, the dose selection

appears reasonable, However, it is not apparent to this reviewer why the test material is being administered via the drinking water, since gastric irritation is known to occur. Previously, TB II had suggested (TB II memo dated 10/5/90) that dosing via the diet might alleviate the irritative effects seen in the drinking water and gavage studies. The Registrant should provide justification for administering the test material via the drinking water and not via the diet.

CONCLUSION

The Registrant has submitted the criteria used to select dose levels for an ongoing (in progress for over 1 year) chronic toxicity/carcinogenicity study in rats for Agency review. Before a final determination regarding the adequacy of the dose levels can be made, justification for administering the test material via the drinking water should be provided.