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

APR 27 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Avermectin; MK-244-Emamectin Semi-Synthetic Insecticide; Request for Waiver of Acute Inhalation Study; ID # 281972

Tox.Chem No.: 63AB
MRID No.: None
HED Project No.: 2-1586
Submission No.: S412606

TO: George LaRocca, PM #13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: William Dykstra, Ph.D., Toxicologist
Review Section 1
Toxicology Branch 1
Health Effects Division (H7509C)
William Dykstra 4/21/92

THRU: Roger Gardner, Section Head, Toxicologist
Review Section 1
Toxicology Branch 1
Health Effects Division (H7509C)
Roger Gardner 4-21-92
KB 4/24/92

ACTION REQUESTED: Merck has submitted a request to waive the required acute inhalation study in rats for its experimental avermectin derivative, MK-244. They are asking for a waiver because of the large particle size which would not be generally encountered in their manufacturing facilities. The Toxicology Branch (TB-I) has been requested to review and comment on the waiver application.

CONCLUSIONS: After consultation with TB-I inhalation experts, it is concluded that the waiver for the requirement of an acute inhalation study with technical MK-244 can not be granted unless the Registrant can provide information that this product is used in

a closed system.

The technical material is 95% dry and the justification provided by the Registrant does not give enough details to indicate that the workers in the manufacturing facilities will be adequately protected from exposure to the pesticide.

Review: Letter of February 7, 1992 from L.S. Grosso of Merck requesting waiver. No new toxicology data were submitted.