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

DEC 23 1992

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SUBJECT: Malaoxon: Chronic Toxicity/Oncogenicity Study in Rats

D185229
S430322
Chem. No. 057701
Tox. Chem. No. 535

FROM: Karen L. Hamernik, Ph.D.
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Toxicology Branch
Health Effects Division (H7509C)

K. Hamernik 12/17/92

TO: Joanne Edwards, PM Team #74
Reregistration Branch
Special Review and Registration Division (H7508W)

THRU: Karl Baetcke, Ph.D.
Chief, Toxicology Branch I
Health Effects Division (H7509C)

Karl H. Baetcke 12/22/92

Action Requested

Toxicology Branch I has been asked to concur on the proposed high dose for the Malaoxon rat two year chronic/oncogenicity study.

Response

Toxicology Branch has already commented on the dose levels proposed for this study including the high dose (see memo from Toxicology Branch I scientist, Dr. Brian Dementi to Joanne Edwards dated 10/9/92, D181671).

To reiterate: Toxicology Branch I has no objection to the proposed high dose of 2000 ppm or the other proposed doses of 0, 20, and 1000 ppm Malaoxon. The rationale put forth for dose level selection was judged to be reasonable. The onus is on the registrant to provide a study which adequately supports product registration and the acceptability of such a study can only be determined upon evaluation of the final study report.

Reregistration Branch will need to address the question of the due date for this study in light of the delay related to analytical method difficulties. From Toxicology Branch's standpoint, there are no outstanding issues that would delay study initiation.

1 Copy of correspondence from Jellinek, Schwartz and Connolly, Inc. attached.