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

JUL 12 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Malathion Rat Chronic/Oncogenicity Study - Change of Dosage Level for the Low Dose Group

Tox Chem No.: 535
Submission No.: S440408
DP Barcode No.: D191078
ID No.: 057701

FROM: Brian Dementi, Ph.D., D.A.B.T.
Review Section III
Toxicology Branch I
Health Effects Division (H7509C)

Brian Dementi 6/15/93

TO: Peg Perreault
Review Manager, PM 73
Reregistration Branch
Special Review and Reregistration Divison (H7508W)

THRU: Karen Hamernik, Ph.D.
Section Head, Review Section III
Toxicology Branch I
Health Effects Divison (H7509C)

Karen Hamernik 6/30/93

Ms. Diane Allemang of Jellinek, Schwartz and Connolly, Inc. in her letter of April 27, 1993 to Ms. Losi Rossi seeks to confirm a conversation between myself and Dr. Judith Hauswirth regarding changing the low dose level for the ongoing malathion 24-month chronic toxicity/oncogenicity study in rats. Ms. Allemang advises that Dr. Hauswirth contacted Dr. Dementi at EPA on April 14, 1993, to discuss changing the low dose in the study from 100 ppm to 60 ppm due to continuing inhibition of rbc cholinesterase in female rats of the 100 ppm dose group. Ms. Allemang indicates that Dr. Dementi concurred that this seemed to be a reasonable approach.

I should like to confirm the phone call in question from Dr. Hauswirth in which she advised me of the continuing rbc cholinesterase inhibition in females at the low dose level in the chronic/oncogenicity study. Dr. Hauswirth indicated that a decision had been made by the Registrant to lower the dosage level of the low dose group as mentioned. I acknowledged the

information and asked if she were seeking Agency concurrence on the change. She said the decision was the Registrant's and that she was not seeking concurrence. Dr. Hauswirth said she would follow up on our conversation with a letter to the Agency advising of the dosage change.

I thanked her for the call and indicated I would pass the information along.

I should note that while I did not actually recommend or endorse the dosage change, I likely would have upon further consideration of the matter. In this case the Registrant had already rendered the decision.

DP BARCODE: D191078 REREG CASE # 02

CASE: 519951 DATA PACKAGE RECORD DATE: 05/07/
SUBMISSION: S410408 BEAN SHEET Page 1 OF

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 629 GENERAL CORR - REREGIS
CHEMICAL: 057701 Malathion 100.00

ID#: 057701
COMPANY:
PRODUCT MANAGER: 73 LINDA PROPST (703) 308-8200 ROOM: CS1 3L5
PM TEAM REVIEWER: PEG PERREAULT (703) 308-8200 ROOM: CS1 3L5
RECEIVED DATE: 04/30/93 DUE OUT DATE: 07/29/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 191078 EXPEDITE: N DATE SENT: 05/07/93 DATE RET.: / /
CHEMICAL: 057701 Malathion
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 07/21/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV.: HED	/ /	/ /
BRAN: TB-1	/ /	/ /
SECT:	/ /	/ /
REVR:	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

MALATHION - ATTN: KAREN HAMMERNICK/BRIAN DEMENTI

83-5 Rat Chronic/Onco. Study - change in the low dose level from 100 ppm to 50 ppm. Please concur on the letter from Dell Lusk.

Thanks, Peg

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

3