



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

331A
CASWELL FILE

009429

009707

APR 15 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: Addendum to the Review of B. Dementi on the 90-Day Subchronic Study with Didecyldimethylammonium Chloride in the Rat. EPA Identification No. 069149.

Project No.: 0-0376
Tox. Chem. No.: 331A
Record No.: 256551

FROM: Henry Spencer, Ph.D. *[Signature]* 3/10/92
Acting Section Head, Review Section III
Toxicology Branch 1
Health Effects Division (H7509C)

TO: Jim Wilson, PM #31
Antimicrobial Branch
Registration Division (H75005C)

THRU: Karl Baetcke, Ph.D.
Chief,
Toxicology Branch 1
Health Effects Division (H7509C)

Background: The 90 day study with the antimicrobial compound, didecyldimethylammonium chloride, was reviewed by B. Dementi, TBl, and was concluded to be core supplementary in classification based on possible effects on the lymph nodes in female test animals.

Conclusions: After further consultation with both regional consulting laboratory pathologists and the EPA contract consulting pathologist, this reviewer reports that this finding is usually not limited to females of this specie of test animal. In addition these lymph node aggregates are seen very often in control animals.



As a result of these consultations, Toxicology Branch does not consider the incidence of these effects to be treatment related. Therefore, further evaluation of the test animals by the registrant is not required.

The Toxicology Branch therefore can establish that the systemic toxicity NOEL is greater than 12mg/kg/day. The only apparent toxicity is that of dermal irritation with an LOEL of 2 mg/kg/day (LDT).

This study fulfills the guideline requirement of 82-3.