454 E
CASWELL FILE

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

JAN 12 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: GX-071 - 90-DAY DOG STUDY

TO: MICHAEL MENDELSON
PRODUCT MANAGER (17)
REGISTRATION DIVISION (H7505C)

FROM: LINDA L. TAYLOR, PH.D. 1/9/90
TOXICOLOGY BRANCH II, SECTION II
HEALTH EFFECTS DIVISION (H7509C)

THRU: K. CLARK SWENTZEL 1/10/90
SECTION II HEAD, TOXICOLOGY BRANCH II
HEALTH EFFECTS DIVISION (H7509C)

AND

MARCIA VAN GEMERT, PH.D. 1/11/90
CHIEF, TOXICOLOGY BRANCH/HFAS/HED (H7509C)

REGISTRANT: GRIFFIN CORPORATION
CHEMICAL: N-ETHYL PERFLUOROOCTANE SULFONAMID
SYNONYMS: GX-071; SULFLURAMID
PROJECT: 0-0432
CASWELL NO.: 454E
RECORD NO.: 257188
IDENTIFYING NO.: 1812-327
ACTION REQUESTED: CONFIRM TELEPHONE CONVERSATION AND REVIEW REVISED DOG STUDY PROTOCOL.

COMMENT: THE REGISTRANT HAS SUBMITTED THE REVISED (12/07/89) PROTOCOL FOR THE 90-DAY DOG STUDY TO BE PERFORMED ON GX-071. IT IS NOTED THAT DOSE LEVELS HAVE BEEN INCLUDED, WHICH WERE NOT PREVIOUSLY INCLUDED IN THE PROTOCOL (AS DISCUSSED IN TB II MEMO DATED SEPTEMBER 8, 1989). THE COVER LETTER FROM J.S. LOVELL PROVIDES A COPY OF A LETTER FROM DR. PICCIRILLO TO ME REGARDING THE AGE OF THE DOGS TO BE USED IN THE 90-DAY STUDY. THAT LETTER (UNDATED) FROM DR. PICCIRILLO IS ACCURATE WITH REGARD TO TB II CONCURRENCE WITH THE USE OF THE OLDER DOGS. HOWEVER, MR. LOVELL'S STATEMENT THAT TB II IS IN AGREEMENT WITH THE REVISED PROTOCOL IS NOT ACCRURATE, AS DISCUSSED BELOW.

THE PREVIOUS PROTOCOLS FOR THE 90-DAY DOG STUDY HAVE NOT INDICATED THE DOSE LEVELS THAT ARE TO BE TESTED NOR HAS ANY STATEMENT BEEN MADE THAT ADMINISTRATION BY CAPSULE MAY BE UTILIZED FOLLOWING A PALATIBILITY CHECK OF THE HIGH DOSE. CONCURRENCE FROM THE AGENCY WITH REGARD TO THIS PROPOSED STUDY HAS BEEN ON THE AGE OF THE DOGS AT STUDY INITIATION ONLY, NOT ON DOSE SELECTION. SINCE NO INFORMATION IS PROVIDED IN THE REVISED PROTOCOL AS TO HOW THE DOSES WERE CHOSEN, AND ASSUMING THAT THE STUDY IS CURRENTLY UNDERWAY, NO COMMENT (CONCURRENCE) ON THIS ASPECT IS APPROPRIATE BY TB II AT THIS TIME.

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