

US EPA ARCHIVE DOCUMENT



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

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JUN 26 1990

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SULFLURAMID - REGISTRANT'S RESPONSE TO REQUEST
FOR ADDITIONAL DATA REGARDING THE DERMAL
SENSITIZATION STUDY IN GUINEA PIGS AND THE RAT
PRIMARY HEPATOCYTE UNSCHEDULED DNA SYNTHESIS ASSAY

TO: MICHAEL MENDEL SOHN
PRODUCT MANAGER (17)
REGISTRATION DIVISION (H75050)

FROM: LINDA L. TAYLOR, PH.D. *Linda Lee Sep 6/20/90*
TOXICOLOGY BRANCH II, SECTION II
HEALTH EFFECTS DIVISION (H7509C)

THRU: K. CLARK SWENTZEL *K. Clark Swentzel 6/20/90*
SECTION II HEAD, TOXICOLOGY BRANCH II
HEALTH EFFECTS DIVISION (H7509C)

AND

MARCIA VAN GEMERT, PH.D. *management 6/20/90*
CHIEF, TOXICOLOGY BRANCH/HFAS/HED (H7509C)
GRIFFIN CORPORATION

REGISTRANT: GRIFFIN CORPORATION
CHEMICAL: SULFLURAMID
SYNONYM: GX-071
PROJECT: 0-1414
CASWELL No.: 454E
RECORD No.: 265882
IDENTIFYING No.: 1812-327
MRID No.: 415051-01 & 415051-02
ACTION REQUESTED: PLEASE REVIEW COMPANY'S RESPONSE REGARDING THE DERMAL
SENSITIZATION AND UNSCHEDULED DNA ASSAY.

COMMENT: THE REGISTRANT HAS SUBMITTED INFORMATION REGARDING THE PROCEDURE
USED TO ADMINISTER THE TEST MATERIAL TO THE ANIMALS IN THE DERMAL
SENSITIZATION STUDY AND HAS PROVIDED THE REFERENCE FOR THE METHOD USED.
THIS INFORMATION IS ADEQUATE, AND THE STUDY MAY BE UPGRADED TO CORE MINIMUM.

INFORMATION ON THE PURITY OF THE TEST MATERIAL USED IN THE RAT HEPATOCYTE
UDS ASSAY WAS PROVIDED (99.6%; MRID # 415051-02). WITH REGARD TO THE
REQUEST FOR ANALYTICAL DATA TO VERIFY THE CONCENTRATIONS USED IN THE ASSAY,
TB II POINTS OUT THAT THE REASON FOR REQUESTING THE ANALYTICAL DATA WAS
THAT NO PURITY DATA WERE PROVIDED IN THE FINAL REPORT THAT WAS REVIEWED.
SINCE THE PURITY OF THE TEST MATERIAL HAS NOW BEEN PROVIDED, ANALYTICAL
DATA ARE NOT REQUIRED. THE STUDY MAY BE UPGRADED TO ACCEPTABLE, BASED
ON THE DATA NOW AVAILABLE.

CONCLUSION

1. (SULFLURAMID)-DERMAL SENSITIZATION TEST IN GUINEA PIGS; STUDY # 246722; MRID #'s 412510-01 & 415051-01; CORE: MINIMUM. THIS STUDY SATISFIES THE GUIDELINE REQUIREMENTS (81-6) FOR A DERMAL SENSITIZATION STUDY.
2. MUTAGENICITY - RAT PRIMARY HEPATOCYTE UNSCHEDULED DNA SYNTHESIS ASSAY; STUDY # 10549-1-447; MRID #'s 412510-02 & 415051-02; ACCEPTABLE. THIS STUDY SATISFIES THE GUIDELINE REQUIREMENTS (84-2c) FOR MUTAGENICITY- OTHER GENOTOXIC EFFECTS.