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

007178

MAY 17 1989

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: GX-071 - Company Response; Supplement to UDS Assay

TO: Michael Mendelson
Product Manager (17)
Registration Division (TS-767C)

FROM: Linda L. Taylor, Ph.D. Linda Lee Taylor 5/12/89
Toxicology Branch II, Section II
Health Effects Division (TS-769C)

THRU: K. Clark Swentzel K. Clark Swentzel 5/16/89
Acting Section II Head, Toxicology Branch II
Health Effects Division (TS-769C)

and

Marcia van Gemert, Ph.D. Marcia van Gemert 5/16/89
Acting Chief, Toxicology Branch/HFAS/HED (TS-769C)

Registrant: Griffin Corporation
Chemical: N-ethyl perfluorooctanesulfonamide
Synonyms: GX-071
Project: 9-1311
Caswell No.: 454E
Record No.: 243745
Identifying No.: 1812-327
Action Requested: Reconsider status of mutagenicity study.

Comment: The Registrant has submitted a response to the Agency's concerns regarding dose selection used in the unscheduled DNA synthesis assay.

In the original review by Dr. Irving Mauer (DER dated 2/8/89), this study was classified as UNACCEPTABLE, since the material was not tested to the limit of toxicity or solubility. Dr. Mauer has reviewed the supplemental data, and his review/comment is provided below.

GX-071 (Sulfuramide) — Additional data to UDS assay # HLA 10549-0-447, MRID # 408632-02, submitted under MRID # 410623-01 (4/11/89).

Additional data provided in this submission:

1) Data from preliminary tox. assay (for this study) -- No toxicity up to 1.00 ug/ml (83.5% survival relative to control); but at 2.51 — 14.1% survival and light precipitate; while at 5.01 -- 1.7% survival, precipitate, and many dead cells; and at 10 and above -- 0% survival (100% toxicity), precipitate, and all dead cells.

2) Standard protocol for the UDS assay.

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TOXICOLOGY CONCLUSIONS: If the assertion made by the author were true ["that a UDS response usually decreases below 80% survival"], then testing at increasingly toxic concentrations (from 1.00 to 5.01 ug/ml in at least a 5-step progression) should satisfy FIFRA testing guidelines (part 158), as well as resulting in a verifiable negative response.

Hence, the additional data submitted satisfies one of the deficiencies noted in our first review of this study ("preliminary range-finding data). However, no additional results of testing into the toxic range (2.51 and above) were submitted in this package. Therefore, the principal objection to validity of the results initially presented stands, namely, the test material was not assayed to the limits specified by out Testing Guidelines (FIFRA Part 158), and the study remains UNACCEPTABLE.

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