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

OCT 19 1988

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Registrant Response - Update on SCE Assay

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

FROM: Linda L. Taylor, Ph.D. 10/5/88
Toxicology Branch II, Section II
Hazard Effects Division (TS-769C)

Thru: Marcia van Gemert, Ph.D. 10/5/88
Acting Section Head, Section II, TB II
Hazard Effects Division (TS-769C)

And

William Burnam, Ph.D. 10/18/88
Acting Chief, TB II, HED (TS-769C)

Registrant: Griffin Corporation
Chemical: GX-071; N-ethyl perfluorooctanesulfonamide
Project: 8-1273
Caswell No.: 454E
Record No.: 232150

Action Requested: Respond to Griffin's response to TB comments on Sister Chromatid Exchange assay on GX-071.

In the TB review of the studies submitted in support of the request for registration of GX-071, it was concluded that the Sister Chromatid Exchange assay (Project No. 86G-002) should be repeated using higher dose levels of GX-071 since the highest dose tested did not result in at least a 50% reduction in the second mitosis. In a letter dated September 20, 1988, from V.J. Piccirillo (NPC, Inc.) to S. Lovell (Griffin Corporation), it is stated that solubility information on GX-071 had not been available at the time Dr. Felkner and Ms. Worthy made their assessment of the data from this study. Based on solubility information from the testing laboratory (Toxikon; identified as Toxicon by Dr. Piccirillo), the limit of solubility of GX-071 is 500 ug/ml; the 1000 ug/ml level was described as partially soluble. Therefore, it is argued that the criteria for selection of the highest dose used in this assay comply with established criteria.

The Registrant should be requested to submit the data on the solubility of GX-071 being used to support their conclusion for TB review and as an addendum to the final report.

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