007202

TO: Judy Loranger

FROM: D. Ritter, TOX DRR 9-3-86

Subject: GUTHION Registration Standard.

In order to clarify the Oncogenic Effects portion of the RS for Toxicology I suggest that the following rewrite on p. 17 be included:

Para. II:

> "In an oncogenicity bioassay performed by the National Cancer Institute at Gulf Research Institute, azinphos-methyl was administered in the diet of Osborne-Mendel rats. Two groups of 50 male rats each received either 78 or 156 ppm for 80 weeks. Two groups of 50 females rats each received either 62.5 or 125 ppm for 80 weeks. Concurrent control groups consisted of 10 animals per sex each. All animals were observed for an additional 34 - 35 weeks. Neoplasms of the thyroid gland and of the pancreas suggested, but did not provide sufficient evidence to conclude, that azinphos methyl is oncogenic to male Osborne-Mendel rats. This study was judged to be inadequate for statistical evaluation of risk because only 10 concurrent control animals per sex were used".

Note:

In response to the question, "why were 10 control animals in this study not acceptable whereas 10 control animals was acceptable in the mouse study?":

The rat study showed evidence of potential oncogenicity and was subjected to Risk Analysis. Statistical techniques for this require that the numbers of control animals be at least similar to those in the treated group, which they were not. Hence, we asked for a new rat study.

The mouse study was clean for oncogenic effects; hence no Risk Analysis was needed. In any event, we consider that the mouse requirement is fulfilled.

CC:
Dr. Farber
Dr. Zendzian
Dr. Engler
Mr. Burnam
Mr. Jaeger

1-24

AZINPHOS-METHYL

Page_____ is not included in this copy.

Pages 2 through 4 are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

X REGISTRATION STANDARD CHANGES BASED ON EPA'S OGC INPUT AND DELIBERATION

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.