UNDATED

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Study Type: Oncogenicity - Rats (National Cancer Institute Sponsored Study)

Accession No.:

MRID No.: 73372

Sponsor: National Cancer Institute

Testing Laboratory: Gulf South Breeze Research Institute (Study No. 79-1392).

Date: 1979

The test material was diazinon (see the review of the mouse oncogenicity study by NCI in this Registration Standard on page R-36 for a more complete description of the test material used).

The test animals used were Fischer F344 rats obtained from the NCI Frederick Cancer Research Center Frederick, MD. The rats were approximately 7 weeks of age at the start of the study. There were 25 males and 25 females in the matched control groups and 50 males and 50 females in each of two dosed groups which received either 400 or 800 ppm of diazinon in the diet. The dosing period was for 103 weeks which was followed by a 2-week observation period. Note: The dose levels used were selected following a subchronic range-finding study which showed toxicity (body weight loss) at 1600 ppm (in females) and some deaths at 3200 ppm.

Survival: There was no increase in deaths due to diazinon in the diet in either sex. In fact, there were more survivors in the male high-dose group. There were greater than 44 dosed rats per sex and 23 control rats per sex which survived 78 weeks of dosing, thus being at risk for late tumor development.

The clinical signs noted included that "tissue masses were observed at highest incidences in high dose males and low dose females, and tachypnea was observed at a higher incidences in dosed groups than in control groups." Other symptoms in the dosed rats were "hyperactivity, discolored urine (high-dose group), "bloating," "vaginal bleeding," and "vaginal discharge." None of these were quantitated or presented as frequency of occurrence or relative intensity. It is not possible to set NOEL's and LEL's from the available information.

There were no hematology, clinical chemistry, or urinalysis determinations made. There were no organ weight determinations made.

There was no summary table showing the gross necropsy findings and since individual animal pathology sheets were not presented, it could not be determined if gross necropsy observations were followed up microscopically.

The report conclusion for this study is "histopathologic examination provided no convincing evidence for carcinogenicity of diazinon in F344 rats under conditions of this bioassay." The data as presented appear to support this conclusion.

Conclusion:

This study is SUPPLEMENTARY. A second study will have to be provided by the sponsor to meet the requirement for oncogenicity testing in rats. The study as presented is lacking in sufficient detail to justify a CORE MINIMUM or higher rating.