#9000 Test group
#9000 Control group

PROTOCOL FOR

TWO-YEAR CARCINOGENICITY STUDY IN ALBINO RATS

I. Outline of Investigation

A. Type and Length: Two-Year Carcinogenicity

B. Animal Species Tested: Weanling Charles River Strain Albino Rats

C. Number of Animals: Two-Hundred (200)

D. Organization:

Group	Number of Animals Male	Female
Control	50	50
Test	50	50

E. Means of Administration: Voluntary oral ingestion; ad libitum feed of diets containing the selected concentration of test material.

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II. Parameters To Be Investigated

A. Mortality and Reactions

Checks for mortality and untoward behavioral reactions will be conducted daily. Each animal employed in the study will be examined weekly for signs of tumor formation.

B. Pathologic Studies

1. Gross

Complete gross pathologic examinations for tumor formation will be conducted upon all post mortem animals, all animals sacrificed in extremis, and upon all rats surviving 24 months of testing.

Representative tissues and organs will be taken and fixed from all rats that survive more than 18 months of testing and from any rat in which tumor formation was noted.

2. Microscopic

Microscopic examinations will be conducted upon tissues and organs from ten males and ten females from each group. The tissues and organs to be examined will include heart, liver, lung, pancreas, stomach (cardia, fundus and pylorus), small intestine (duodenum, jejunum and ileum), caecum, colon, spleen, lymph node, kidney, urinary bladder, testes, ovary, prostate, uterus, pituitary gland, adrenal gland, salivary gland (submaxillary), thyroid gland, parathyroid gland, skeletal muscle, bone marrow, peripheral nerve, trachea, spinal cord, eye, optic nerve and brain (cerebrum, cerebellum and pons).

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In addition, all tumors will be submitted for histopathologic examination and classification.

III. Reports

At the conclusion of the study, three copies of a final formal report will be submitted.

JP/kjl

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