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

SEP 29 1980

OFFICE OF TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: ~~EPA Reg.#524-308~~; Glyphosate; 3-Month Mouse Feeding Study
CASWELL#661A Accession#242799

FROM: William Dykstra
Toxicology Branch, HED (TS-769) WHD 9/19/80

TO: Robert Taylor (25)
Registration Division (TS-767) WHD

Recommendation:

1) The three-month mouse feeding study is acceptable as supplementary data. The NOEL for the parameters studied is 10,000 ppm.

Review:

1) A 3-Month Mouse Feeding Study of Glyphosate in Mice (Biodynamics Project No. 77-2111, Dec. 31, 1979)

Test Material: Glyphosate, 98.7 A.I.; fine white powder; LOT#XHJ-64

Glyphosate technical was fed ad libitum for three months to four groups of 15 male and 15 female Charles River CD-1 albino mice at dietary concentrations of 0, 5000, 10,000, and 50,000 ppm. The animals were observed twice daily for mortality and toxic signs. Once a week, animals were given a detailed physical examination, weighed, and food consumption was measured. Test substance intake, expressed as mg test material per kg body weight per day, was calculated weekly. Complete gross necropsies were performed at the end of the study when animals were sacrificed. At that time, the following organs were removed from each animal and their weights recorded: brain, gonads, heart, spleen, kidneys and liver. Histopathological examinations were conducted on adrenal, bone, bone marrow, brain, esophagus, eye, optic nerve, gall bladder, ovary, testis, epididymis, heart, cecum, colon, duodenum, ileum, jejunum, kidney, liver, lung, mesenteric lymph node, mandibular salivary gland, sciatic nerve, pancreas, pituitary, skeletal muscle, spinal cord, spleen, stomach, thymus, thyroid, parathyroid, urinary bladder, uterus, prostate and any additional grossly observed alterations or tissue masses from 10 animals of each sex from the control and high dose groups (50,000 ppm).

Results:

One control male and one 10,000 ppm female died during the study. The death of the treated female was not considered related to compound administration. No unusual behavioral reactions or toxicologic signs related to treatment were observed throughout the study.

Mean food consumption values for males from the three treated groups were slightly to significantly greater than the control values throughout most of the test period. However, there were no consistent dose-related trends in these elevations. Mean food consumption for treated females was comparable to that for the controls during most of the study. Body weight gains of the 50,000 ppm group males and females were about 24% and 18% lower, respectively than that of the control animals at study termination. Body weight gains of both sexes of the 5,000 ppm and 10,000 ppm group animals were comparable to those of the controls.

The organ weights, organ/body weight ratios and organ/brain/weight ratios were either considered comparable between treated and control animals or were judged to be of no biological significance.

Gross necropsy examinations and histopathologic evaluations did not reveal any evidence of effects related to compound administration.

Conclusion:

The NOEL for the study is 10,000 ppm. The LEL is 50,000 ppm and the effect consisted of reduced weight gain in both sexes.

Classification: Supplementary Data

a) Clinical Chemistries and hematologies not performed.

TS-769:TOX/HED:th:LCHITLIK:8-19-80