MEMORANDUM

TO: Richard Mountfort
PM-23
Registration Division (TS-767)

THRU: Christine F. Chaisson, Ph.D. C.F. Chaisson
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Review of Two Revised Protocols for "Chronic Toxicity and Oncogenicity Test(s) in Rats (and Mice) with Acrolein". Action #10707-9.

Action Requested:

Review of 2 revised protocols:

1) "Chronic Toxicity and Oncogenicity Test in Rats with Acrolein", and

2) "Chronic Toxicity and Oncogenicity Test in Mice with Acrolein".

Background:

Two revised protocols for "chronic/oncogenicity" studies were submitted by Magna Corporation for review. One study will be done using rats and one using mice.

The chemical being tested was identified as Magnacide H Herbicide. The protocols further identify the common/chemical names for this substance as arcolein; acrylic aldehyde; acraldehyde; and 2-propenal. The purity of the test substance to be tested is specified in the protocol to be "greater than 96%".

Protocol Review and Recommendation:

The protocols submitted for review by Magna Corporation have been revised according to my previous memo (Sandusky to Mountfort, 11/10/82) and are now consistent with the Agency's proposed testing guidelines for chronic/oncogenicity studies (FR, Vol. 43, No. 163, Section 163.83-1 and-2, chronic published 1978).
Furthermore, the sponsor is again advised, as per my previous memo (Sandusky to Mountfort, 11/10/82; item 6) to exercise care in the selection of doses to meet the "intent" of both chronic and oncogenicity testing.

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